Research Handbooks in Intellectual Property

Patent Law and Theory

A Handbook of Contemporary Research

Edited by **Toshiko Takenaka**

PATENT LAW AND THEORY

RESEARCH HANDBOOKS IN INTELLECTUAL PROPERTY

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Toshiko Takenaka

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Preface and acknowledgement

This book grew out of discussions with Dr. Rainer Moufang, my long-time friend from the Max Planck Institute for German and International Intellectual Property (The institute has been renamed as the Max Planck Institute for Intellectual Property, Competition and Tax Law). On a cold, quiet afternoon in Munich in 2006, we sat in his office discussing the need for a comprehensive review of fundamental and contemporary patent issues as they relate to the protection of both traditional and new technologies. We envisioned a book that would appeal to both academics and practitioners, and we selected experts from three major patent jurisdictions – the United States, Europe and Japan – who could write on each topic. Although we granted these authors complete freedom with regard to writing style, we strongly encouraged them to analyze their topics from the comparative law perspective.

Given the opportunity to edit such a book, the first person I would wish to work with is Dr. Moufang, and we originally planned to divide responsibility for the topics while jointly editing the chapters. Unfortunately Dr. Moufang's busy work schedule, along with his family responsibilities, made it impossible for him to participate. Nonetheless, I owe him a huge debt for his insightful topic suggestions and his recommendations of experts from the European Patent Office.

I would also like to thank Professor Jeremy Phillips for giving me the opportunity to edit this book, one of the volumes in a series for which he serves as the general editor. Professor Phillips not only agreed to contribute a chapter but also suggested additional authors from the UK, thereby giving the book an approach to patent protection from a common law tradition that is different from the common law tradition that the USA follows.

I also would like to thank my assistant, Ms Ruth Beardsley for providing prompt secretarial support and my former research assistants, particularly Ms Juri Yoshida, who oversaw the entire editing process, communicating with authors and managing deadlines. Finally, I would like to thank my husband, Hisato, for his forbearance and continuous support of my work.

Toshiko Takenaka

PART 1

FOUNDATIONS

1 On the economics of patent law and policy

F. Scott Kieff [1]

1 Introduction

Although important literatures explore patent systems from various perspectives, such as morality, gender, race, etc., most patent systems in most industrialized nations are heavily influenced by some version of a utilitarian law and economics perspective.[2] These law and economics approaches generally are in agreement in seeing the patent system as a tool for achieving some particular goals; but generally disagree on the goals, as well as whether patents are effective in achieving those goals.

This chapter explores some of the major law and economic approaches to patents. In particular, it examines the different policy goals these approaches advance and the major areas of significant conflict in contemporary policy debates about patents. The basic theme is that enforcing patents as property rights can improve the socially constructive coordination that facilitates the complex process of commercializing innovation thereby improving both access and competition. By contrast, avoiding property treatment can facilitate the socially destructive coordination among large players employing a 'keiretsu' strategy of anticompetitive collusion.[3]

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[1] F. Scott Kieff runs the Hoover Project on Commercializing Innovation, which studies the law, economics, and politics of innovation, and is available at www.innovation.hoover.org. Comments are welcome at fskieff.91@alum.mit.edu.

[2] *See, e.g.*, Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988). For a discussion of the intellectual history of patents with a focus on the U.S. patent system *see, e.g.*, Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. Rev. 689 (2007); Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent 'Privilege' in Historical Context*, 92 CORNELL L. REV. 953 (2007); Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History*, 52 HASTINGS L.J. 1255 (2001).

[3] The ideas discussed in this chapter are explored in more depth in earlier work by the present author including F. Scott Kieff, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 YALE L.J. POCKET PART 101 (Supp. 2007); F. Scott Kieff, *Coordination, Property & Intellectual Property: An Unconventional Approach to Anticompetitive Effects & Downstream Access*, 56 EMORY L.J. 327 (2006); F. Scott Kieff, *The Case for*

2 Some background economics applied to patents

This chapter offers a systems-based,[4] comparative institutional analysis using the set of analytical tools from the field generally called Law and Economics or New Institutional Economics, which is often associated with the work on institutions, transaction costs, agency costs, the theory of the firm, and the theory of property.[5] Several of the basic economic concepts that are discussed throughout this economic literature in general are featured prominently in the patent literature in particular, and so are reviewed below.

Absent patents, those wishing to negotiate over an intellectual asset like an invention face a number of problems including one generally known as the Arrow Information Paradox, after Kenneth Arrow, who wrote that the 'funda-

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Registering Patents and the Law and Economics of Present Patent-Obtaining Rules, 45 B.C. L. REV. 55 (2003); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai & Eisenberg*, 95 NW. U. L. REV. 691 (2001); and F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001).

[4] *See* Lynn M. LoPucki, *The Systems Approach to Law*, 82 CORNELL L. REV. 479 (1997).

[5] Some examples of this literature that are accessible to a broad audience include the works by Robert Fogel and Douglass North, as discussed in Press Release, The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 1993 (Oct. 12, 1983), *available at* http://www.nobel.se/economics/laureates/1993, and the work by Ronald Coase, as discussed in Press Release, The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 1991, *available at* http://www.nobel.se/economics/laureates/1991. For more detailed discussion *see, e.g.*, OLIVER E. WILLIAMSON, MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS: A STUDY IN THE ECONOMICS OF INTERNAL ORGANIZATION 1 (1975); Ronald Coase, *The New Institutional Economics*, 88 AM. ECON. REV. 72 (1998). For a discussion of the relationship between the terms 'New Institutional Economics', 'Law and Economics', and 'Neoclassical Economics', *see, e.g.*, Richard A. Posner, *The New Institutional Economics Meets Law and Economics*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 73 (1993); Ronald H. Coase, *Coase on Posner on Coase*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 96 (1993); Oliver E. Williamson, *Transaction Costs Economics Meets Posnerian Law and Economics*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 99 (1993); and Richard A. Posner, *Reply*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 119 (1993). For examples of recent work applying these ideas to the study of intellectual property *see, e.g.*, Robert P. Merges, *Intellectual Property Rights and the New Institutional Economics*, 53 VAND. L. REV. 1857 (2000); Dan L. Burk, *Intellectual Property and the Firm*, 71 U. CHI. L. REV. 3 (2004), Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004); John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37 (2004); Oren Bar-Gill and Gideon Parchomovsky, *Intellectual Property Law and the Boundaries of the Firm* (U. of Pa. Inst. for L. and Econ. Res., Paper No. 04-19; Harv. L. & Econ., Discussion Paper No. 480), *available at* http://ssrn.com/abstract=559195; Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465 (2004).

mental paradox' of information is that 'its value for the purchaser is not known until he has the information, but then he has in effect acquired it without cost'.[6] While parties can mitigate this problem using contracts, property rights in patents help in a number of ways. As Robert Merges explains, property rights provide several options for enforcement that contract law cannot: suits before contract liability attaches, suits against third parties, a longer statute of limitations, increased damages, and injunctions.[7]

But the additional enforcement characteristics that patents can enjoy over contracts are not inherent in every patent and contract system. It is well recognized that different legal systems employ different enforcement characteristics for entitlements. The literature generally categorizes enforcement characteristics into one of two prototypical bundles: the one that includes remedies such as injunctions and enhanced damages is generally known as a property rule, while one that is limited to only an objective measure of actual damages is generally known as a liability rule.[8] Although many view patents as generally enforced by a property rule and contracts as generally enforced by a liability rule, any entitlement could be enforced by either type of rule.

Recent high profile cases like the patent litigation threatening to shut down the Blackberry service[9] have drawn sharp criticism in the business community as being prime examples of the pernicious impact of protecting patents with

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[6] KENNETH J. ARROW, ESSAYS IN THE THEORY OF RISK-BEARING 152 (1971).

[7] Robert P. Merges, *A Transactional View of Property Rights*, 20 BERKELEY TECH. L.J. 1477, 1505 n.76 (2005).

[8] The label 'property rule' is used here as it is used in the classic Calabresi-Melamed framework under which an entitlement is said to enjoy the protection of a property rule if the law condones its surrender only through voluntary exchange. The holder of such an entitlement is allowed to enjoin infringement. An entitlement is said to have the lesser protection of a liability rule if it can be lost lawfully to anyone willing to pay some court-determined compensation. The holder of such an entitlement is only entitled to damages caused by infringement. *See* Guido Calabresi and A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972). *But see* Jules L. Coleman and Jody Kraus, *Rethinking the Theory of Legal Rights*, 95 YALE L.J. 1335, 1340, 1342 (1986) (offering a 'reinterpretation of the Calabresi-Melamed framework' under which property rules and liability rules merely represent two pieces of a broader 'transaction structure' in that they are two different approaches for setting forth 'conditions of legitimate transfer').

[9] *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005), *cert denied*, 126 S. Ct. 1174 (2006). A similar case that also has attracted great attention involves the eBay service, in which the Supreme Court reaffirmed that a trial court is not writing entirely on a clean slate in view of past practices when the court is applying the ordinary four-factor test for permanent injunctions to determine whether a patentee may get a permanent injunction once patent validity and infringement have been adjudicated. *eBay, Inc. v. MercExchange*, L.L.C., 126 S. Ct. 1837 (2006).

property rules.[10] In response to concerns of this type many commentators suggest that the enforcement characteristics of patents should be shifted from being more like a property rule towards being more like a liability rule. For example, Ian Ayres and Paul Klemperer advocate a patent litigation system characterized by uncertainty and delay, which they show could serve as a form of compulsory license, or liability rule.[11] Others advocate various exemptions to infringement, such as treating certain uses as fair use.[12] The arguments raised today are similar to those raised throughout most of the past century and target all three branches of government – legislature, executive agencies, and courts.[13]

Most of the arguments in favor of enforcing patents only with liability rules are designed to avoid the many problems known to be associated with property rules. As discussed more fully below, while each of these problems is real, each may be mitigated to varying degrees and most can arise under both property rules and liability rules. In addition, many of these problems may be implicated more seriously by liability rules than by property rules.

When any entitlement is made available to a community there is a risk that the problem of rent dissipation will arise. Rent is a term for the benefit gained from an activity. Private rents are those accruing to the individual. Public rents are those accruing to society as a whole. Private and public rents may differ from each other in ways that may cause private incentives to engage in a given rent-generating activity to be either above or below a socially optimal level. Where the availability of private rents provides overly strong incentives for an individual to try to gain those private rents, the individual's efforts may ulti-

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10 *See, e.g.*, *Patently Absurd*, WALL ST. J., Mar. 1, 2006, at A14 (criticizing a set of cases including *NTP*); Bruce Sewell, *Troll Call*, WALL ST. J., Mar. 6, 2006, at A14 (criticizing both the *NTP* and *eBay* cases).

11 *See* Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985 (1999) (arguing that sufficient incentive to invent can be provided without the monopoly power associated with a property right).

12 *See, e.g.*, Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (offering a fair use exception in response to what are argued to be excessive transaction costs causing too many market failures surrounding patents that are enforced as property).

13 Representative examples from different times throughout the past century include Name of Resolution, the effort by Congress to create the Temporary National Economic Committee (TNEC), S.J. Res. 300, 75th Cong., 52 Stat. 705 (1938); THE PRESIDENT'S COMM'N ON THE PATENT SYSTEM, REPORT TO PROMOTE THE USEFUL ARTS IN AN AGE OF EXPLODING TECHNOLOGY (1966); and the year-long set of hearings jointly held in 2001 by the Federal Trade Commission and the Justice Department's Antitrust Division (Notice of Public Hearings, Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, 66 Fed. Reg. 58, 146–7 (Nov. 20, 2001)).

mately dissipate the social rents.[14] This is the problem of rent dissipation, and includes both overinvestment in the race to obtain the rent as well as investment in socially undesirable techniques to win that race.

Terry Anderson and Peter Hill have shown that rent dissipation problems associated with the creation of property rights can be mitigated if the potential owners of the rights can tailor them at the time of creation.[15] The intuition underlying this result is that this approach allows the owners to shape the right at creation based on the best available information about its value (e.g., the precise contours of the property right). The greater the gap (both in time and in the individuals participating in relevant decisions) between the definition of the right and its actual creation, the greater the chance there will be a mismatch against actual needs. Anderson and Hill point out that the two central problems will contribute to the size of this mismatch. A simple 'land-grab' approach will lead to overinvestment in racing to grab and thus over-grabbing actual parcels because the opportunity to claim later will be forgone.[16] In this regard, nobody is able to claim the residual that would be left behind by waiting until an actual need were developed – in other words, there is no 'residual claimant'.[17] In addition, once government actors see the private interest in obtaining the rights, the bureaucracy will have an incentive to withhold the

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[14] For example, an inventor may develop something only slightly better than available options in a way that turns out to cause waste overall. Avinash K. Dixit and Joseph E. Stiglitz, *Monopolistic Competition and Optimum Product Diversity*, 67 AM. ECON. REV. 297 (1977) (showing how it may be profitable for one firm to come to market to get customers, but total industry profits may decline by more than consumer welfare increases). *See also*, Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348 (1968) (showing how overinvestment can lead to invention occurring too early); Glenn C. Loury, *Market Structure and Innovation*, 93 Q.J. ECON. 395 (1979) (model showing overinvestment under certain conditions); Partha Dasgupta & Joseph Stiglitz, *Industrial Structure and the Nature of Innovative Activity*, 90 ECON. J. 266 (1980) (same). It also may be possible for the private rents to be too small compared to the social rents. For example, what an inventor gets for herself often is less than what her invention generates for society. *See* Steven Shavell and Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights* (Nat'l Bureau of Econ. Research, Working Paper No. 6956, 1999), *available at* http://www.nber.org/papers/w6956 (suggesting a system of government-sponsored cash rewards instead of, or in addition to, a system of patents to improve the match between the private and public rents associated with an invention).

[15] Terry L. Anderson & Peter J. Hill, *Privatizing the Commons: An Improvement?*, 50 S. ECON. J. 438, 441, 447 (1983).

[16] *Id.* at 441.

[17] Anderson and Hill attribute the term 'residual claimant' to work by Armen Alchian and Harold Demsetz on the theory of the firm. *Id.* at 439 (citing Armen A. Alchian and Harold Demsetz, *Production, Information Costs, and Economic Organization*, 62 AM. ECON. REV. 777 (1972)).

rights unless they determine a particular claimant is 'worthy', which will in turn provide a convenient excuse for the bureaucracy to amass the resources that it claims are needed to judge 'worthiness'.[18]

All other things being equal, the more the regime allows those who ultimately hold the rights to craft the rights at the time of creation, the more likely it is that rent dissipation effects will be mitigated. Even a quick comparison of different intellectual property regimes reveals a stark difference in this regard. For example, patent applicants generally shape their own property rights through the drafting of their claim. Similarly, the contours of the rights staked out by trademarks are largely set by the rights holders themselves through actual use. In contrast, the contours of a copyright typically are set as immutable rules (not even default rules) through the central regime rather than by the individual claimants.

Entitlements that are intended to be traded or shared raise the problem of transaction costs because to work well, they must be able to be sold and licensed to those who value them most at any given time. The term 'transaction cost' generally refers to all the costs associated with contracting among individuals, including the hassle those parties experience in finding and dealing with each other, the costs of lawyers and other professionals to arrange the deals, and the bargaining process itself. Transaction costs also can be thought of as including information costs because information must be gathered and processed before those individuals decide to interact with each other.[19] The term encompasses the costs of successful transactions (such as time and money), as well as the costs of failed transactions (such as lost opportunities) to the extent those failed transactions are good things that would have occurred but for the costs of transacting.

Although transactions impose costs, they also have benefits. First, transactions are associated with specialization and division of labor, which are both generally thought to be good things.[20] The availability of transactions to

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[18] Anderson and Hill, *supra* note 15, at 443.

[19] *See* Armen A. Alchian, *Information Costs, Pricing, and Resource Unemployment*, 7 W. ECON. J. 109 (1969); *see also* George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 213 (1961) (noting that acquiring and processing information about potential exchange opportunities is costly).

[20] John Joseph Wallis and Douglass C. North, *Measuring the Transaction Sector in the American Economy, 1870–1970*, in LONG-TERM FACTORS IN AMERICAN ECONOMIC GROWTH 95–161 (Stanley L. Engerman and Robert E. Gallmann eds., 1986). Adam Smith previously articulated the connection between division of labor and transaction costs, including the inevitable limit that transaction costs places on the extent of the division of labor. *See* Harold Demsetz, *The Cost of Transacting*, 82 Q.J. ECON. 33, 35 (1968) (summarizing empirical evidence of transaction costs in the market of the New York Stock Exchange and quoting Adam Smith: 'As it is the power of exchang-

obtain from others the goods and services beyond those that an individual is most interested in or most adept at providing facilitates each individual's ability to have and to hone those specialized skills and tastes, as well as to bear individualized distributions. The link between specialization and transactions allows even large numbers of individuals to achieve complex tasks by coordinating with each other directly or indirectly. Second, transactions are associated with the privately beneficial exchanges among individuals that are essential for achieving mutual gains from trade.[21] Third, transactions are associated with the publicly beneficial socialization that occurs when individuals come to interact with each other.[22] This socialization effect occurs because for transactions to achieve mutual gains from trade, individuals must learn enough about each other's diverse resources and preferences to exploit them. This process of learning about each other's values is part of socialization. Fourth, the bargaining process – for both consummated transactions and failed ones – inherently elicits important information about not only the particular transaction being negotiated, including intensity of preferences and budget

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ing that gives occasion to the division of labour, so the extent of this division must always be limited by the extent of that power, or, in other words, by the extent of the market.').

[21] *See* ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES 184 (1991) (pointing out that societies tend to develop institutions – such as norms in the case he is studying – that 'minimize the members' objective sum of (1) transaction costs and (2) deadweight losses arising from failures to exploit potential gains from trade'); *see also* R.H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 10 (1960) (noting that the principal condition that must be satisfied for individuals to maximize wealth by engaging in an exchange is that the transaction costs of the exchange must not exceed the gains from trade); Terry L. Anderson and Donald R. Leal, *Free Market Environmentalism: Hindsight and Foresight*, 8 CORNELL J.L. & PUB. POL'Y 111, 113 (1998).

> [H]umans interact to capture potential gains from trade – the knowledge for this interaction is bounded by transaction costs. The gains from trade (a positive-sum game) result because people place different values on goods and services and because people have different abilities to produce those goods and services. Because of these differences, trade has the potential to make the parties exchanging goods and services – of lower value to each respectively – better off.

Id.

[22] *See, e.g.*, Milton Friedman, *Value Judgments in Economics*, *in* THE ESSENCE OF FRIEDMAN 3, 5–8 (Kurt R. Leube ed., 1987) (discussing the 'role of the market as a device for the voluntary cooperation of many individuals in the establishment of common values' and concluding that '[i]n many ways, this is the basic role of the free market in both goods and ideas – to enable mankind to cooperate in this process of searching for and developing values').

constraints, but also relative values compared to other available transactions. Thus, transactions can mitigate information costs.

Of course, it would be desirable to increase the benefits and decrease the costs of transactions. But to the extent that efforts to minimize the transaction costs cause direct exchanges between individuals in the market to be replaced by court or agency mandated and mediated exchanges (replacing property rules with liability rules), some of the benefits of having those transactions occur directly between individuals would be lost. For example, the availability of court or agency mandated exchange may decrease the incentives, opportunities, and abilities for individuals to directly interact with each other. Moreover, the likelihood and extent of the harmful impact of most transaction costs is recognized generally to be worse in political markets than in economic markets.[23] The intuition behind this view is that for political markets, the assets being traded – such as promises to vote a certain way – are both harder to evaluate and harder to enforce because they are less certain at the time of negotiation, less predictable, less fungible, less dividable, and less bundleable.[24]

Both the likelihood and extent of the harmful impact of many types of transaction costs generally are worse in thinner markets than in thicker markets, where 'thinner' and 'thicker' refer to the amount and diversity of resources and participants, including their diverse evaluative techniques and preferences.[25] There are two basic intuitions behind this lesson: First, thickness increases the chance that some individual in the market will find it profitable to arbitrage what otherwise would be a gap in information flow by finding and acting on that information to offer an attractive option for what otherwise might be a holdup problem. Second, the increase in bargaining associated with a thicker market mitigates information costs.

The transaction cost effects of patents in the field of basic biotechnology research are instructive. While there is some pernicious impact of the trans-

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[23] For an in-depth treatment of the topic, see Douglass C. North, *A Transaction Cost Theory of Politics*, 2 J. THEORETICAL POL. 355 (1990).

[24] *Id.*; *see also* Douglass C. North, *Institutions and Credible Commitment*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 18 (1993) ('Political markets are far more prone to inefficiency').

[25] The so-called efficient market hypothesis is based on the view that in a perfectly thick market, assets will be perfectly priced. Paul Samuelson and Benoit Mandelbrot laid the basic theoretical foundation for the EMH. *See* Paul A. Samuelson, *Proof that Properly Anticipated Prices Fluctuate Randomly*, 6 INDUS. MGMT. REV. 41, 48 (1965); Benoit Mandelbrot, *Forecasts of Future Prices, Unbiased Markets, and* Martingale *Models*, 39 J. BUS. 242, 248 (1966). Eugene Fama added empirical support. *See* Eugene Fama, *Efficient Capital Markets: A Review of Theory and Empirical Work*, 25 J. FIN. 383, 392 (1970).

action costs associated with patents, the degree of that impact must be compared with the similar problems that arise without patents. The addition of patents to what otherwise was a market characterized only by academic kudos should make the market thicker rather than thinner and thereby decrease overall transaction costs.

While it may seem difficult for a scientist to gain access to a patented technology without spending the time and money to hire a team of expensive lawyers, this is not the case. In fact, remarkably low transaction cost business models have been devised and implemented. For example, in the 'freezer program' business model, the patent is assigned or licensed to a business that arranges for the patented biological material to regularly be brought fresh and frozen directly to the scientist's university department or lab. The business only charges the scientist's research account for the quantities actually used.[26] The transaction costs associated with freezer programs are even less than the costs associated with buying a can of soda from a soda machine. While the freezer program involves direct billing, the typical soda machine requires the buyer to use coins or low denomination bills – a higher transaction cost that is nonetheless well tolerated by society. Indeed, the freezer programs may provide a host of additional benefits. They save the scientist from having to spend the time and other resources needed to obtain the material herself, and they help the scientific community at large by providing a more homogenous source of inputs that decreases variability across scientific experiments.

In a related point, transaction costs are borne, at least in part, by both the party wanting to buy or license and the party wanting to sell or license – that is, both the infringer and the owner. This helps explain why many property owners elect not to aggressively enforce their property rights against certain users by granting broad licenses rather than suing to exclude. Indeed, recent empirical data shows that far from being subject to endless holdups and blockades, in both industry and universities, researchers have beaten whatever problems patents in this area might have imposed by adopting strategies of 'licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges and simply using the

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[26] An online shopping guide for basic scientists provides this description: 'Vendor Freezer and Cabinet programs offer a freezer or cabinet with a customized inventory of the products you use. Companies may provide a complimentary cabinet, freezer, or refrigerator, stock it, and often apply discounts to the host lab.' The Biocompare Buyer's Guide for Life Scientists, http://www.biocompare.com/freezer.asp (listing details of several companies' programs and providing web links); *see also* Virginia Commonwealth University, Applied Biosystems PCR-Sequencing Reagent Freezer Program, http://www.narf.vcu.edu/abi.html.

technology without a license (i.e., infringement)' to achieve their particular goals.[27]

And the law correctly ensures that property owners cannot avoid their share of these transaction costs. When property owners are not willing to incur the transaction costs associated with policing their own rights, the law exposes them to the risk of varying degrees of forfeiture. For example, if a patentee sits back for too long while letting others infringe, later actions for infringement may be barred by laches.[28] If the patentee actually leads the infringer to infringe, an action for infringement may be barred by equitable estoppel.[29] Importantly, however, neither laches nor estoppel fundamentally threatens the patent system because each leaves it within the power of the patent owner to avoid the loss.

What is more, certain features inherent in the commercial law system impose much higher costs on property owners than might be apparent at first. Put differently, in the real world perfectly strong property rule protection for intellectual property is not possible in the context of the existing system of commercial law for several reasons. First, as Ayres and Klemperer point out, uncertainty in how the rights will be enforced in court functions the same as enforcing those rights with liability rules.[30] Largely because of pressure from patent skeptics, there is substantial and increasing uncertainty over the rules for obtaining intellectual property rights, transacting over intellectual property rights, and enforcing intellectual property rights. Second, the ability for an infringer to be kept effectively judgment proof through corporate and bankruptcy laws may also operate as a form of liability rule gloss on the present property rule regime. Third, otherwise infringing uses that are by or for the

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[27] John P. Walsh et al., *Working through the Patent Problem*, 299 SCIENCE 1021 (2003); *see also* John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005) (reporting empirical results that demonstrate that 'access to patents on knowledge inputs rarely imposes a significant burden on academic biomedical research'); Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091 (2006) (reviewing literature).

[28] *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992) (en banc) (discussing laches). The patentee is not required to go after every infringer right away. The laches effect may be put on hold with respect to some infringers where the patentee is kept busy tracking down others and bringing lawsuits against them. *Accuscan, Inc. v. Xerox Corp.*, 1998 WL 273074 (S.D.N.Y. May 27, 1998) (presumption of laches rebutted where patentee delayed filing infringement suit in order to avoid the burden of conducting two simultaneous infringement suits and to attempt to negotiate a license agreement with the defendant).

[29] *Wang Labs. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1582 (Fed. Cir. 1997) (discussing equitable estoppel).

[30] *See* Ayres & Klemperer, *supra* note 11.

federal government enjoy sovereign immunity protection that effectively results in a compulsory licensing regime. Therefore, total restriction of access under a property rule always can be avoided to some extent because at least some liability rule treatment is always available for patents.

Related to the problem of transaction costs is the problem of 'behavioral[ism]', which refers to all of the ways in which human beings are not perfectly rational in making decisions. Humans are only boundedly rational due to cognitive biases, framing effects, and reliance on heuristics.[31] Some scholars, such as Richard Posner, have suggested that decision making under conditions of behavioralism is the same as perfectly rational decision making in a world of positive information costs.[32] Other scholars, such as Oliver Williamson, suggest that behavioralism really refers to something more complex,[33] including (1) situations that simply are impossible to think through;[34] (2) the problems of misconception, like short-sightedness and incorrectly assessing probabilities; (3) the problems of being rushed to make decisions;[35] and (4) the limitations of language.[36] According to Williamson,

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[31] For recent reviews of the behavioralism literature, *see, e.g.*, Russell Korobkin, *Bounded Rationality, Standard Form Contracts, and Unconscionability*, 70 U. CHI. L. REV. 1203 (2003) (collecting sources); Troy A. Paredes, *Blinded by the Light: Information Overload and its Consequences for Securities Regulation*, 81 WASH. U. L.Q. 417 (2003); BEHAVIORAL LAW & ECONOMICS (Cass R. Sunstein ed., 2000); Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471 (1995).

[32] Posner, *The New Institutional Economics Meets Law and Economics*, *supra* note 5, at 80. This view of behavioralism is consistent with a view that sees information costs associated with obtaining and processing information, which traces its routes back to the work of Herbert Simon. *See, e.g.*, Herbert A. Simon, *A Behavioral Model of Rational Choice*, 69 Q.J. ECON. 99, 99 (1955) ('[T]he task is to replace the global rationality of economic man with a kind of rational behavior that is compatible with the access to information and computational capacities that are actually possessed by . . . man.'); *see also* Press Release, The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 1978 (Oct. 16, 1978), *available at* http://www.nobel.se/economics/laureates/1978/press.html.

[33] OLIVER E. WILLIAMSON, MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS: A STUDY IN THE ECONOMICS OF INTERNAL ORGANIZATION 109–10 (1975).

[34] *Id*. at 109 (citing Herbert Simon, *Theories of Bounded Rationality*, *in* DECISION AND ORGANIZATION 161 (C.B. McGuire & R. Radner eds., 1972)).

[35] *Id*. at 109–10 (citing Oliver E. Williamson, *Calculativeness, Trust, and Economic Organization*, 36 J. L. & ECON. 453 (1992) (problems of being rushed to make decisions)).

[36] *Id*. at 110 (citing MICHAEL POLANYI, PERSONAL KNOWLEDGE: TOWARD A POST-CRITICAL PHILOSOPHY (1962)).

an especially productive way to conceptualize the set of problems associated with behavioralism is the 'idea of the mind as a scarce resource'.[37]

Regardless of precise etiology, the problems of behavioralism have a number of manifestations. Decision-making processes reveal strategies that, using the terminology of Herbert Simon, seek to 'satisfice' rather than 'optimize'; or in the more modern parlance, employ 'heuristics', as explored more recently in the work by Amos Tversky, Daniel Kahneman, and Paul Slovic.[38] Other manifestations include risk and loss aversions[39] and various cognitive biases such as primacy and recency,[40] framing,[41] anchoring,[42] as well as overoptimism, overconfidence, and egocentricism.[43] Another

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[37] *Id*. (citing Herbert Simon, *Rationality as Process and Product of Thought*, 68 AM. ECON. REV. 1, 12 (1978)).

[38] Paredes, *supra* note 31, at 436 (citing Herbert A. Simon, *A Behavioral Model of Rational Choice*, 69 Q.J. ECON. 99, 262–4 (1955); JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES (Daniel Kahneman et al. eds., 1982); JOHN W. PAYNE ET AL., THE ADAPTIVE DECISION MAKER 1–2 (1993); HERBERT A. SIMON, MODELS OF BOUNDED RATIONALITY: ECONOMIC ANALYSIS AND PUBLIC POLICY (1982)); *see also* Press Release, The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 2002 (Oct. 9, 2002), *available at* http://www.nobel.se/economics/laureates/2002/press.html.

[39] For the basic exploration of methods for measuring risk aversion, see KENNETH J. ARROW, ASPECTS OF THE THEORY OF RISK-BEARING (1965); John W. Pratt, *Risk Aversion in the Small and in the Large*, 32 ECONOMETRICA 122 (1964).

[40] Jeffrey J. Rachlinski, *The Uncertain Psychological Case for Paternalism*, 97 NW. U. L. REV. 1165, 1169–70 (2003) ('psychologists have found that when individuals are asked to memorize a long sequence of words, they are more likely to remember the first few words (the "primacy" effect) and the last few words (the "recency" effect) much better than the words in the middle of the list' (citing EUGENE B. ZECHMEISTER AND STANLEY E. NYBERG, HUMAN MEMORY: AN INTRODUCTION TO RESEARCH AND THEORY 60–71 (1982)).

[41] For empirical evidence of framing effects, *see, e.g.*, Daniel Kahneman and Amos Tversky, *Choices, Values, and Frames*, 39 AM. PSYCHOL. 341 (1984) (framing effects observed in decisions involving lotteries and other risky monetary payoffs); Amos Tversky and Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 SCIENCE 453 (1981) (same).

[42] Rachlinski, *supra* note 40, at 1171 ('When making numeric estimates, individuals will tend to rely heavily on reference points and then adjust from these reference points.') (citing Tversky and Kahneman, *supra* note 41, at 1128–30 (explaining anchoring and the related process of adjustment)).

[43] Tversky and Kahneman, *supra* note 41, at 1172 (defining 'overoptimism, which consists of overestimating one's capabilities; overconfidence, which consists of overestimating one's ability to predict outcomes; and egocentricism, which consists of overstating the role that one has played in events in which one has participated'); *see also* Paredes, *supra* note 31, at 481 ('Some of the most well-known sources of these deviations from rationality include loss aversion, framing, the representativeness heuristic, the availability heuristic, overoptimism, and overconfidence.').

component of the behavioralism problem is the problem known as 'groupthink'.[44]

While the behavioralism literature does add a great deal to our understanding, some of the policy prescriptions that might at first blush seem to follow from it may not be so prudent. Consider, for example, switching to liability rule treatment as a strategy for avoiding irrational holdups. Several countervailing concerns must be addressed: First, if the ability to avoid the property rule treatment hinged upon the failure of a deal getting done, then there would be a markedly increased incentive for those wanting to obtain use through court-ordered terms to resist striking licensing deals. A legal test that rewards a failure to cooperate would lead to a decrease, rather than an increase, in cooperation. Second, the legislators, administrators, or judges who would be asked to determine when this should take place are themselves individuals who also face their own behavioralism limitations. Third, because they are government actors, they would trigger the public choice concerns discussed later in this chapter.

Also related to the general problem of transaction costs is the particular problem that some think is triggered by multiple patents covering a single good or service, which is the problem Michael Heller termed the 'anticommons'[45] and others have termed a 'patent thicket'.[46] But there is no serious patent thicket or anticommons problem with a system in which patents are designed and treated like predictable property. If anything, the flexibility of approaches based on governance and liability rules raises the problem more seriously, as Richard Epstein noted in his work on 'permit thickets'[47] and as the political economy literature notes when discussing 'License Raj' in India.[48]

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[44] *See* Troy A. Paredes, *Too Much Pay, Too Much Deference: Is CEO Overconfidence the Product of Corporate Governance?* 60 n.227 (Wash. Univ. Sch. of Law, Working Paper No. 04-08-02, 2004), *available at* http://ssrn.com/abstract=587162 (discussing groupthink in the context of corporate governance and as a contributing factor to CEO overconfidence) (citing IRVING L. JANIS, GROUPTHINK (2d ed. 1982), and Marleen O'Connor, *The Enron Board: The Perils of Groupthink*, 71 U. CIN. L. REV. 1233 (2003)).

[45] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).

[46] *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 NBER INNOVATION POLICY AND THE ECONOMY 119, 119 (Adam B. Jaffe et al. eds., 2001) (treating a 'patent thicket' to occur when many patents relate to a single product); James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies* (Research on Innovation and Boston Univ. Sch. of Law, Working Paper, 2003), *available at* http://www.researchoninnovation.org/thicket.pdf.

[47] Richard. A. Epstein, *The Permit Power Meets the Constitution*, 81 IOWA L. REV. 407 (1995).

[48] Sunita Parikh and Barry R. Weingast, *A Comparative Theory of Federalism:*

Michael Heller's important initial work on the anticommons problem sought to explain why so many storefronts in the postsocialist economies were left unused. Heller found that a large number of bureaucrats were able to deny permission for the space to be used and called the resulting underuse an 'anti-commons'.[49] More recent work claiming an anticommons problem for patents mistakenly stresses this fragmentation of interest – that is, how many different people have a say over an asset's use – as the key to the anticommons effect.[50]

More important than the number of people who have a say, however, is the type of people with a say and the type of say they have. By focusing on the number of patent permissions needed to use a technology, patent critics have ginned up arguments that the patent system creates an anticommons.

The U.S. patent system is fundamentally different from the unused storefronts of the postsocialist economy. As Epstein and Bruce Kuhlik have pointed out, where the permission of postsocialist bureaucrats was required, efforts by the bureaucrats to openly trade their permission for personal gain were likely to trigger various forms of legal liability for graft, bribery, public corruption, and the like.[51] Patent rights are different, because a U.S. patent owner has incentives to engage in, not avoid, open transactions. Transactions over patents are not only allowable; they are important to monetizing the value of any asset like a patent that is constantly declining in value due to its limited statutory term and the threat of new competing technologies, especially given the limited ways to extract value from an asset that confers only a right to exclude and not a right to use. Patentees have a strong incentive to encourage use, not to block it. Furthermore, transactions over patents are also different

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India, 83 VA. L. REV. 1593, 1608 (1997) ('This system, known in India as License Raj, means that the center retains control over the distribution of permits and licenses for new areas of economic development through the relevant central ministry').

[49] Heller, *supra* note 45; *see also id*. at 624 (arguing that '[w]hen there are too many owners holding rights of exclusion [in a resource], the resource is prone to underuse').

[50] *See, e.g*., Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1174-5 (1999) (describing how 'the proliferation of intellectual property rights in upstream research may be stifling life-saving innovations further downstream in the course of research and product development'); Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998) (emphasizing fragmentation and arguing that it creates an anticommons).

[51] Richard A. Epstein and Bruce N. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman* 4 (Univ. of Chicago Law Sch. John M. Olin Program in Law & Econ. Working Paper No. 209 (2d ser.), 2004), *available at* http://ssrn.com/abstract=536322 ('But the state bureaucrat is not the owner of any asset whose value will remain unlocked unless he brings it to market.').

from transactions with postsocialist bureaucrats in the way the law enforces patent-related transactions. Unlike the bureaucratic permissions of the postsocialist state over which transactions so often failed, patents are more clear and certain, and their owner can be easily discovered for free on the Internet.[52] In addition, courts readily enforce whatever licenses or assignments are sold by the patentee against her and those with whom she is in privity.

One could imagine that the number of patent permissions needed to get business done could lead to high prices and difficulties structuring the needed transactions. But even a quick scan of the Internet shows that this problem is not real. The typical laptop computer represents a bundle of thousands of patent and other IP permissions, yet the negotiation to buy one takes only a few clicks of a mouse and costs as little as $1,000, if not less. Indeed, recent empirical work by Ronald Mann has found that even in the controversial area of business method patents, there is not any serious 'patent thicket' problem.[53]

A relative of the anticommons problem for patents is the problem some call 'patent trolls'.[54] The argument seems to be that 'patent trolls' hold their patents neither for development nor for prospective licensing, but solely to hold up others who accidentally stumble onto their path.[55] To the extent the concern about trolls reflects anxiety about the uncertainty of the scope and validity of patents, as well as the high cost of patent litigation – both of which would provide potential opportunities for 'trolls' to exploit even weak- or low-value patents – then the problem can be best addressed using various tools for policing bad patents such as decreasing the statutory presumption of validity as a tool for achieving symmetry in fee shifting between patentees and infringers.

But the pernicious impact of the troll is limited to a large extent by very practical economic factors. First, all patents are wasting assets in that they have a life capped at less than 20 years, and are subject to defenses based on laches and estoppel. Second, a decision to lie in wait causes the troll to lose income that would have to be recouped in the future; but just as in the context

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[52] *See* U.S. Patent and Trademark Office, Assignment Search Page, http://assignments.uspto.gov/assignments/q?db=pat (free searching of property interests in patents by several fields including patent number); U.S. Patent and Trademark Office, Full Text and Image Database Search Page, http://patft.uspto.gov/netahtml/PTO/search-adv.htm (free searching to yield relevant patents).

[53] Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 999–1009 (2005).

[54] *See* Brenda Sandburg, *Trolling for Dollars*, RECORDER (S.F., Cal.), July 30, 2001, at 1 (attributing the origin of the term to Peter Detkin, who at the time was counsel at Intel).

[55] *See id.*

of predatory pricing, the promise of that future gain is risky.[56] Indeed, just as a fallow plot of land may attract offers for development, a patent posted on the patent office web page and searchable for free provides sufficient information to attract anyone seriously interested in practicing the covered technology. A patentee who is not looking to sell or license is not beyond the reach of those who wish to buy or license. Those sets of economic forces acting on both parties help explain why, once the court made clear an injunction was imminent, even the infamously bitter litigation over the Blackberry service settled before any disruption of service took place. What is more, the settlement price in that case is significantly below independent estimates that reflect the hold-out risk and even more significantly below the licensee's reserves of cash and cash equivalents.[57]

Indeed, the raw numbers suggest that one underappreciated element of the delay in settlement in the Blackberry case may have been restrictions on the market for corporate control, not the problems of anticommons, patent thickets, or patent trolls. The actual settlement price suggests that the infringer either was acting rationally in holding out because of the uncertainty that there was going to be an injunction (in keeping with the view that property rules can encourage deals and liability rules can frustrate them), or it was acting irrationally in not closing a deal sooner (so as to avoid losing customer goodwill among those in fear of being left without service) at such an attractive price – a price in line with market estimates and lower than its own private estimates as evidenced by the size of its reserves of cash and cash equivalents. If the market for corporate control were working better, there might have been enough gains to be had by settling the case sooner that a raider would have done a takeover, fired the leadership, and struck a deal with the patentee.[58]

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[56] *See Matsushita Elec. Indus Co. v. Zenith Radio Corp*., 475 U.S. 574, 588–94 (1986) (discussing perils of predatory pricing).

[57] *See* Mark Heinzl and Amol Sharma, *Getting the Message: RIM to Pay NTP $612.5 Million to Settle Blackberry Patent Suit*, WALL ST. J., Mar. 4, 2006, at A1 (noting that settlement estimates ranged to above $1 billion and that infringer's reserves of cash and cash equivalents were about $1.8 billion).

[58] A quick calculation is instructive. The infringer in that case, RIM, is a publicly traded company whose stock price fluctuated over the year from a low of about $52, to a typical price around $63, and to a high of about $88, which RIM almost immediately regained by the next business day after the settlement. The majority of the outstanding shares (191 million) were in the public float (141 million). If the entire public float were purchased in a takeover by offering a $10 premium over the prevailing price of $63, it would require about $1.4 billion over that price. This new controlling shareholder could then fire management and settle the case. If the settlement were at the estimated high level of $1 billion, then that takeover investor would have invested a total of $2.4 billion over the prevailing price, plus perhaps another $100

Earlier settlement also would have saved more goodwill for the infringer, RIM, maker of Blackberry, which now has more competition.

Just as the putative problems of anticommons and trolls often turn out to have more to do with name calling than with the economics of patents, the term monopoly also is often attached to patents without sufficient attention to the actual economic harm of monopolies. The problem of monopoly effects is often misunderstood in the patent literature in at least two important ways: The first is to overlook the distinction between ex ante and ex post, or the distinction between dynamic and static efficiency. The second is to overlook the precise nature of the *inefficiency* (in contrast with what some see as the *unfairness*) associated with monopolies.

A dynamic approach to efficiency stands in contrast to more static approaches to efficiency, which may see resource distributions at any point in time as suboptimal. For example, a promise to make my car available to you at a particular time may create conditions in which the car is not in use by anyone. In the static sense, at that moment in time, it may indeed look as though the car is being allowed to go to waste, which would be inefficient.[59] Yet, if I am allowed to deploy the car to other uses to avoid the risk that it might go unused, then your expectation that it will be available will be dashed. Moreover, if you know this ex ante, then you may not even be willing to enter into the contract to reserve the car at all, or you may be willing to pay for the car, but only at a lesser amount. Thus, in the dynamic sense, the expected future abrogation of the contract to provide the car that presumably would make both you and me better off because we each would elect to enter into it

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million in professional fees and other costs for a total investment of $2.5 billion. If the price then jumped back to its year high after the settlement – which did occur – then this investor would see an increase in book value of about $3.5 billion, leaving a net gain of about $1 billion. If the deal were done as a leverage buyout using the shares themselves as collateral for a loan, then the return on investment would hinge on the valuation used to support the loan, which would determine the size of the loan. If the valuation were set at the generally prevailing price then the return on investment would be measured as a $1 billion gain over an investment of $2.5 billion, which yields the attractive floor for the rate of return at about 40%. If the valuation were set higher, then the rate of return also would be higher. Of course, Wall Street's regular raiders likely did the same math. The point here is that the reasons they may have elected not to dive in likely included anti-takeover provisions in the corporate documents themselves, as well as various regulatory restrictions on the market for corporate control that are designed to decrease takeovers.

[59] This gives rise to the approach termed 'efficient breach' in some contract cases. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 117–19 (4th ed. 1992) (discussing efficient breach approach); *see also* OLIVER WENDELL HOLMES, JR., THE COMMON LAW 301 (1881) (originating the approach). *But see* Daniel Friedmann, *The Efficient Breach Fallacy*, 18 J. LEGAL STUD. 1 (1989) (criticizing the approach).

in the first instance may make the contract one that is less likely for us to consummate ex ante. As a result, over time we cannot engage in as many productive exchanges as otherwise. Put differently, there would be dynamic inefficiency.[60]

It is recognized that recent work by Ian Ayers and Eric Talley and by Jason Scott Johnston shows how uncertainty in enforcement may in some cases improve the ability to negotiate over property rights and contracts by decreasing holdout problems through a feedback mechanism in which uncertainty makes the threat of ex post infringement or breach more credible, which in turn may cycle back to decrease the incentive for the rights holder to hold out ex ante.[61] Nevertheless, other recent empirical work by Rachel Croson and Johnston shows that in other cases, uncertainty degrades the ability to reach dynamic efficiency.[62] Indeed, other work by Ayres and Robert Gertner highlights the importance of at least some certainty through the use of what they term 'penalty default' rules because they will have the impact of bringing to light information about potential negotiations and help avoid opportunism by one party attempting 'to get a larger piece of the smaller contractual pie'.[63] At bottom, in many cases private bargaining over property rights can be more efficient if the right is clearly defined ex ante according to a predictable rule, rather than made ex post by a judge applying a standard.[64]

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[60] *See generally* David D. Haddock et al., *An Ordinary Economic Rationale for Extraordinary Legal Sanctions*, 78 CAL. L. REV. 1, 16–19 (1990) (showing how uncertainty in enforcement discourages investment ex ante).

[61] *See* Ian Ayres and Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement to Facilitate Coasean Trade*, 104 YALE L.J. 1027 (1995); Jason Scott Johnston, *Bargaining Under Rules Versus Standards*, 11 J.L. ECON. & ORG. 256, 257 (1995).

[62] Rachel Croson and Jason Scott Johnston, *Experimental Results on Bargaining Under Alternative Property Rights Regimes*, 16 J.L. ECON. & ORG. 50, 67–70 (2000).

[63] Ian Ayres and Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 127 (1989).

[64] ROBERT COOTER AND THOMAS ULEN, LAW AND ECONOMICS 100–01 (1988). *See generally* MARK KELMAN, A GUIDE TO CRITICAL LEGAL STUDIES 15–63 (1987) (for a discussion of the broader debate between legal systems based on rules and those based on standards; and describing the basic framework of the debate and collecting sources); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992) (exploring the costs implicated by the choice between rules and standards, and showing: (1) rules are typically more costly than standards to create, (2) standards are typically more costly for individuals to interpret (both by individuals deciding how to act under them and by government decision makers deciding how to apply them), and (3) individuals are more likely to act in accordance with the goals of rules so long as those individuals can determine how they will be applied); Russell B. Korobkin, *Behavioral Analysis and Legal Form: Rules vs. Standards Revisited*, 79 OR. L. REV. 23 (2000) (reviewing more recent literature and collecting sources).

To the extent that change is desirable in and of itself, the difference between dynamic and static efficiency also matters beyond the narrow setting of individual transactions discussed above. For example, as resources such as fossil fuels become depleted, we must change to make use of alternative energy sources. Innovation that occurs over time can improve the size of the pie for everyone by making more options available.[65] Put simply, the distinction between dynamic and static efficiency is particularly important for patents because patents are focused on innovation over time.

The nature of the problem actually associated with monopolies also must be kept in mind. The central inefficiency associated with monopolies is the creation of deadweight loss by the monopolist's ability to set price above marginal cost or to have power over price.[66] But there are several reasons why the extent of this inefficiency may not be the same in practice as it is in theory.

First, monopoly is a term that relates to a market rather than to any particular good or service sold in that market.[67] Often there is a difference between a product or service market and an IP asset. For example, consumers often buy computers that essentially involve the licensing of hundreds of licensed IP rights – for hard drive, processors, DRAM, and other chips – without acting as direct customers with respect to any of the IP owners.

While every property right can be thought of as a monopoly, only those that convey effective control over an entire market can have the troubling economic inefficiencies associated with monopolies. For example, the owner of a hypothetical piece of real estate can exclude use of that particular parcel, but must compete with other parcels of land in the market for land generally. Indeed, while the amount of real estate in the world actually is limited by the surface area of the planet, there is no reason to think that for patents, the long-run monopoly impact of a given property right is likely to be any worse than

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65 Einer Elhauge, *Defining Better Monopolization Standards*, 56 STAN. L. REV. 253, 275 (2003) (criticizing forms of antitrust enforcement that are motivated by concerns for static efficiency but that may negatively impact innovation collecting sources); *see also* Christopher S. Yoo, *Rethinking the Commitment to Free, Local Television*, 52 EMORY L.J. 1579 (2003) (reviewing tension between static and dynamic efficiency within the context of public goods and monopolistic competition).

66 This deadweight loss represents a collective loss of societal wealth, in that it is not merely wealth that has been shifted from consumers to producers, but rather wealth that is altogether lost from producers and consumers collectively.

67 *See Illinois Tool Works, Inc. v. Independent Ink, Inc.*, 126 S. Ct. 1281, 1284 (2006) (patent does not give rise to presumption that patentee has market power); *see also* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 249–50 (1994) ('[T]he right to exclude another from "manufacture, use, and sale" may give no significant market power, even when the patent covers a product that is sold in the market.').

for real property. Instead, it is likely to be much less. Nevertheless, in the short run for at least some goods or services, the broad scope of some patent rights may convey what at least some would see as market power with respect to consumers having a particularly dire need (such as medical patients in immediate need of a patented drug).

Second, the economic inefficiency that is associated with a monopolist's power over price is not inevitable. More specifically, the inefficiency is tied to the potential for a decrease in quantity (not an increase in price) compared to the perfectly competitive model. If the monopolist is able to engage in perfect price discrimination, then the quantity produced will be the same as if there were competition. Moreover, while the price charged for at least some consumers will be higher, there will be no deadweight loss inefficiency. While perfect price discrimination is not possible in the real world, the extent to which the monopolist can engage in price discrimination may mitigate the practical extent of the theoretical static inefficiency associated with monopoly deadweight loss.[68]

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[68] *See, e.g.*, JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 133–68 (1988) (providing a basic overview of the economics of price discrimination). It also is recognized that in certain cases efforts to engage in price discrimination may lead to a decrease in efficiency. For example, recent work by Wendy Gordon, Glynn Lunney, and Michael Meurer has shown that while price discrimination by intellectual property owners might lead to more use in certain instances in theory, in practice some price discrimination strategies can result in less output than if such price discrimination were prohibited, depending, in part, on the licensing arrangements employed to discriminate among users). Wendy J. Gordon, *Intellectual Property as Price Discrimination: Implications for Contract*, 73 CHI.-KENT L. REV. 1367 (1998); Glynn S. Lunney, Jr., *Copyright and the Supposed Efficiency of First-Degree Price Discrimination* (Working Paper Series 2002), *available at* http://papers.ssrn.com/sol3/papers.cfm ?abstract_id=293904; Michael J. Meurer, *Copyright Law and Price Discrimination*, 23 CARDOZO L. REV. 55 (2001). However, as summarized by Richard Posner,

> Perfect price discrimination would bring about the same output as under competition, because no customer willing to pay the seller's marginal cost would be turned away. But perfect price discrimination is infeasible, and imperfect price discrimination can result in a lower or higher output than under competition, or the same output.

Richard A. Posner, *Antitrust in the New Economy*, 68 ANTITRUST L.J. 925, 932–3 n.10 (2001) (citing F.M. SCHERER & DAVID ROSS, MARKET STRUCTURE AND INDUSTRIAL PERFORMANCE 494–6 (3d ed. 1990); PAUL A. SAMUELSON, FOUNDATIONS OF ECONOMIC ANALYSIS 42–5 (1947); JOAN ROBINSON, THE ECONOMICS OF IMPERFECT COMPETITION 188–95 (1933)). 'Many economists believe that even crude discrimination is more likely to expand than to reduce output.' *Id.* (citing Robinson, *supra*, at 201; Scherer and Ross, *supra*, at 494–6; Peter O. Steiner, Book Review, 44 U. CHI. L. REV. 873, 882

An additional problem that often is discussed in the economic literature of patents is the problem of externalities, which often is used as a justification for patents (rather than as a problem caused by patents). The conventional view of property rights in the literatures of both law and economics follows the 1967 work by Harold Demsetz, which views property rights as tools for internalizing externalities.[69] Demsetz built on the 1960 work on externalities by Ronald Coase,[70] which itself was a response to work on externalities from the beginning of the 1900s by A.C. Pigou.[71]

Although this lineage likely is familiar to those versed in property literature, a review is useful in highlighting some important questions that it left open, which relate to the issue of coordination. What is more, as discussed later in this chapter, the majority view of patent rights is premised on the same externalities focus as this literature, but seems to follow only its beginnings relating to Pigouvian taxes and subsidies, while overlooking its refinements relating to property rights.

The term 'externality' typically is used to refer to some cost or benefit that is external to a given economic decision-making system in that it is not factored into the decisions made by that system.[72] But, the term can be somewhat

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(1977)). However, 'there does not appear to be a firm basis for this belief'. *Id.* (citing Hal R. Varian, *Price Discrimination*, *in* HANDBOOK OF INDUSTRIAL ORGANIZATION 597, 629–33 (Richard Schmalensee & Robert D. Willig eds., 1989)).

69 *See*, Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. (PAPERS & PROC.) 347, 356 (1967) (arguing that property rights emerge when the benefits of internalization that they achieve outweigh the transaction costs of recognizing them) [hereinafter *Toward a Theory of Property Rights I*]. For Demsetz's more recent focus on coordination see Harold Demsetz, *Toward a Theory of Property Rights II: The Competition Between Private and Collective Ownership*, 31 J. LEGAL STUD. S653, S657, S664–5 (2002) [hereinafter *Toward a Theory of Property Rights II*].

70 *See* Coase, *supra* note 21 (pointing out how a fully defined set of property rights can allow for externalities to be internalized).

71 Pigou saw factory chimney soot as a problem of externalities imposed on others in the environment around the factory and argued that the proper use of taxes or subsidies could be used by the government to encourage such factories to account properly for the benefits and harms they project on those around them. According to Pigou, 'resources devoted to the prevention of smoke from factory chimneys' provide an 'uncompensated service', or what some would call a positive externality, while smoke 'inflicts a heavy uncharged loss on the community', or provides what some would call a negative externality. *See generall*y ARTHUR C. PIGOU, THE ECONOMICS OF WELFARE 160–1, 166–8 (1920); *see also* A.C. PIGOU, WEALTH AND WELFARE (1912).

72 Some definitions in the literature seem to define the term in relation to individuals, in that an externality is seen as something external to the decision making of an individual. *See, e.g.*, HAL R. VARIAN, MICROECONOMIC ANALYSIS 423 (3d ed. 1992) ('When the actions of one agent directly affect the environment of another agent, we say that there is an *externality*.'). Other definitions in the literature see the term as referring to something external to the decision-making process of the entire market. ROBERT

misleading because if the decision-making process is working perfectly, then nothing will be completely external to the individual or the market.[73] Because decision making in the real world is not perfect, Coase's work points out two other and more important implications about externalities: (1) the problem of externalities is entirely reciprocal;[74] and (2) the tough questions facing any

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S. PINDYCK & DANIEL L. RUBINFELD, MICROECONOMICS 297, 617 (1989) ('Such costs or benefits are called *externalities* because they are "external" to the market. . . . In this chapter we study externalities – the effects of production and consumption activities not directly reflected in the market.').

[73] This is one of the insights of the work by Coase that was labeled by Stigler as the Coase Theorem. *See supra* note 5 (discussing Nobel Prize to Coase); *see also* RONALD COASE, THE FIRM, THE MARKET, AND THE LAW 157 (1988) ('I did not originate the phrase, the "Coase Theorem," nor its precise formulation, both of which we owe to Stigler.'); GEORGE J. STIGLER, THE THEORY OF PRICE 113 (3d ed. 1966) (coining the term '[t]he Coase [T]heorem' and writing that it 'asserts that under perfect competition private and social costs will be equal').

[74] *See* Coase, *supra* note 21, at 2, 13 ('If we are to discuss the problem in terms of causation, both parties cause the damage.'); *see also* Terry L. Anderson, *Donning Coase-Colored Glasses: A Property Rights View of Natural Resource Economics*, 48 AUSTL. J. OF AGRIC. & RESOURCE ECON. 445, 448 (2004) ('Coase emphasized that because one use precludes the other, the costs are reciprocal.'); A.W. Brian Simpson, *Coase v. Pigou Reexamined*, 25 J. LEGAL STUD. 53, 60 (1996) (describing one of the core ideas presented by Coase to be that 'the problem of social cost [or externalities] is, at least to an economist, a reciprocal problem'). Even a leading scholar, who is often seen as a critic of Coase, has agreed that this lesson is not merely a question of ideology. *See* Guido Calabresi, *Neologisms Revisited*, 64 MD. L. REV. 736, 738 (2005) (citing Guido Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499, 506 n.24 (1961)). In the case of the externality of soot, for example, the factory's neighbor would see a potential interference with the right to use the air as a reservoir free from emissions while the factory would see a potential interference with the right to use the air as a reservoir in which to place the emissions. In this sense, there is no such thing as '*an* externality' in the singular because externalities only come in pairs. What this means for the externality analysis is that it must be studied from both angles, with the understanding that otherwise the attractiveness of different institutional responses may likely turn on the angle from which the problem is viewed rather than on the proposed solution's overall ability to ensure that resources are used best over time. Put differently, the questions facing society as a whole in this hypothetical case concern both how free the air should be from emissions and how full the air should be of emissions. This is because both parties to the problem are to at least some extent connected to both sides of the problem. For example, as long as the factory has constituencies of owners, workers, and customers having some preference for air that is free of emissions, the factory must consider both its own direct interest in dumping and its indirect interest (through these affected constituencies) in avoiding dumping. Similarly, as long as those constituencies want the investment opportunities, jobs, and products that are associated with a factory having some need to use air as a reservoir into which it can dump, they must consider both their direct interest in avoiding dumping and their indirect interest through their tie to the factory in having dumping.

real decision-making process about how best to allocate rights among reciprocal claimants requires determining what truly is the best allocation in every given case and how best to insure its implementation.[75]

Coase pointed out that under appropriate conditions, such as zero transaction costs, a well-defined allocation of property rights among those impacted would ensure that these individuals traded with each other to achieve the same perfect result sought by Pigou.[76] A central benefit of Coase's property rights alternative is that it would not require an ex ante determination of what truly is the best allocation in every given case because the impacted parties themselves would gather information and make trades to ensure the resource is put to its highest and best use at any given time. Coase continued by pointing out that of course the world is not perfect and therefore not all potential exchanges will occur due to the presence of transaction costs and other imperfections.[77] As a result, he urged that there be consideration of overall net costs and benefits associated with the alternative initial allocations, including the costs of any subsequent transactions that might be needed, with an eye towards ensuring that the entitlement to the resource be allocated in such a way that the resource itself would most likely end up at its highest and best use.[78] The essential policy implication from this point is to carefully compare real costs and benefits of available institutional arrangements, such as different entitlement allocations, enforcement rules, and taxes and subsidies.[79]

This focus by Coase on the comparative costs of institutions laid an important part of the foundation for the later work by Demsetz on the emergence of property rights as a tool for internalizing the positive externalities[80] that often

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[75] *See generally* Coase, *supra* note 73, at 157–86 (responding to a number of common misperceptions regarding the Coase Theorem).

[76] *See* Coase, *supra* note 21, at 6–8. In the case of the soot, this would be either a right to emit it or a right to be free from it.

[77] *Id*. at 16 (noting that because of transaction costs, 'the initial delimitation of legal rights does have an effect on the efficiency with which the economic system operates').

[78] *Id*. at 27 (arguing that we should ask 'whether the gain from preventing the harm is greater than the loss which would be suffered elsewhere as a result of stopping the action which produced the harm').

[79] Anderson, *supra* note 74, at 452 ('Following Coase's lead, we need to carefully examine the institutions . . . .'). As a qualitative example, consider that the costs of using a government tax or subsidy approach include public choice costs and administration costs, while the costs of using an entitlement delimitation approach include transaction costs and enforcement costs.

[80] *See Toward a Theory of Property Rights I*, *supra* note 69, at 356 (explaining the emergence of property rights in land among Labradorian Indians as a response to overhunting: 'an owner, by virtue of his power to exclude others, can generally count on realizing the rewards associated with husbanding the game and increasing fertility of his land').

are shared among those facing what Garrett Hardin soon thereafter termed a 'tragedy of the commons'.[81] What is so tragic about a commons is that its resources tend to be either overused or underused because of what some call a free rider problem or a public goods problem.[82]

Demsetz argued that property rights emerge when the benefits of internalization outweigh its costs, that is, when the good of concentrating benefits and costs on owners so they deploy resources more efficiently outweighs the bad of the transaction costs associated with recognizing those rights.[83] According to Demsetz, property rights emerged among the historical native North American population he was studying because without property rights, the underuse of animal husbanding and land management resources (skills and labor) led to near exhaustion (or overuse) of animal resources (food and clothing), while the presence of property rights provided incentives for individuals

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[81] Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968) (elucidating how unrestricted sharing of limited resources can lead to their overuse and depletion); *see also* THE COMMONS, ITS TRAGEDIES AND OTHER FOLLIES xii (Tibor R. Machan ed., 2001) (providing a critical review of literature on the 'tragedy of the commons'). For more on the role of property rights in avoiding the tragedy of the commons, see Armen A. Alchian & Harold Demsetz, *The Property Rights Paradigm*, 33 J. ECON. HIST. 16, 23–4 (1973) (providing the example of a community in which food caught in a hunt for animals may be shared by all and the resulting diminished incentive for individuals in that community to elect to hunt, or in their words 'shirk', absent other inducements such as a state order to hunt or a cultural indoctrination to hunt), and Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 675 (1998) (providing the example of a hypothetical community Poach Pond in which underfishing of the pond may occur if the rule were that any community member could appropriate fish until the moment of consumption because people might prefer to wait on shore and poach others' catches rather than invest in fishing itself).

[82] Public goods are distinct from private goods in being both nonrival (i.e., inexhaustible) and nonexclusive. A good is considered to be nonrival if consumption by one individual does not leave any less of the good to be consumed by others. Put differently, a good is considered to be nonrival if for any given level of production, the marginal cost of providing it to an additional consumer is zero. A good is nonexclusive if people cannot be excluded from consuming it. National defense, television signals, and police protection are generally considered to be examples of public goods. For a more detailed discussion of public goods and the market failures associated with them, see BRIAN R. BINGER AND ELIZABETH HOFFMAN, MICROECONOMICS WITH CALCULUS 99–102, 556–85 (1988); Cooter and Ulen, *supra* note 64, at 46–9, 108–18, 134–41 (1988); PINDYCK AND RUBINFELD, *supra* note 72, at 617–41.

[83] *Toward a Theory of Property Rights I*, *supra* note 69, at 353 (noting that property rights did not emerge among those living on the southwest plains because the benefits would have been less since there were no animals of commercial importance comparable to the furry animals of the north whose pelts were tradable and because the costs would have been more since the animals that were there tended to wander more).

to make more use of the one set of resources in order not to waste, and indeed to replenish, the other.

But, this left open questions about the mechanism by which property rights operate to achieve this internalization benefit. As academic work within the field of patents began to suggest the role of property rights as focal points in facilitating coordination among complementary users of an invention, Demsetz also began to highlight this coordination function of property rights when discussing the increased specialization of labor that has occurred over time:

> Difficulties in stipulating and enforcing agreements so as to encourage and facilitate productivity-increasing cooperation between different owners come into play here.
> . . . .
> . . . The legal institutions that define private ownership and guide exchange arrangements must become operative if the complexity that is inherent in specialization is to be productive . . . .[84]

More specifically, Demsetz disavowed the extent of his earlier focus on internalizing externalities:

> In retrospect, it now seems to me that the theory of property rights implicit in this explanation places too much weight on externalities (where, in the case discussed, the externality is the neglected impact of hunting today on the cost of hunting tomorrow). The 'Toward' that begins the essay's title, therefore, should be taken seriously. Externality here refers to an effect on the production transformation opportunities facing others, such effect being a result of actions taken by someone who does not bear the value consequences of this effect. Hunting today causes a change in the production opportunities facing hunters tomorrow. As circumstances make the externality more costly to bear, private rights adjust to reduce the seriousness of the externality. This is an important pattern of property right development. Nonetheless, private-ownership arrangements would exist even if there were no externality problems of the type being discussed.[85]

Under Demsetz's new view, the key is 'coordination in the sense of bringing forth control decisions that are consistent with each other but that emanate from different persons'.[86] This is consistent with the approach that is more fully elaborated later in this chapter, which shows how coordination is achieved by property through two effects. Property brings parties together (the beacon effect) and it helps them interact with each other once brought together

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84 *Toward a Theory of Property Rights II*, *supra* note 69, at S657, S664–5.
85 *Id*. at S656.
86 *Id*. at S664.

(the bargain effect). Both of these effects have been confirmed very recently in the independent works of others. Part of the beacon effect is discussed in recent work by the team of Antoine Bureth, Rachel Lévy, Julien Pénin, and Sandrine Wolff, which shows that firms elect to use patents as tools for coordinating with each other.[87] The work of that team confirms this chapter's focus by showing empirical data about the ways patentees can and actually do use patents as tools for facilitating coordination.

A final problem that too often is overlooked in the patent literature stems from the recognition that any government action, whether it is to create, modify, or eliminate an entitlement, is premised on some underlying decision to act. The study of such decisions within the government setting is known generally as 'public choice' or 'collective choice'.[88] As noted by Richard Epstein, '[M]odern public choice literature postulates self-interest to all political players, and asks how they respond to the incentives created by the rules of the political game'.[89]

Public choice problems begin with the particular difficulties government actors – executives, legislators, regulators, and judges – have in determining exactly what the public really wants the government to do and in achieving those goals.[90] While some see the proper role of government to be limited to

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[87] Julien Penin, *Patents Versus Ex Post Rewards: A New Look*, 34 RES. POL'Y 641 (2005); Antoine Bureth et al., *Patenting Practices Within the Upper-Rhine Biovalley Network: Exclusion and Coordination Rationales* (Working paper presented at the Workshop on the Law and Economics of Intellectual Property and Information Technology at Università Carlo Cattaneo Castellanza LIUC on July 22–3, 2005), *available at* http://www.liuc.it/ricerca/istitutoeconomia/laweconomicsjuly2005/papers/Bureth_et_al_LIUCpaper.pdf; Antoine Bureth et al., *The Ambivalence of the Local Practices of Patenting within the BioValley Network*, 58 CHIMIA 796 (2004).

[88] For an excellent review of the field, *see, e.g.*, PERSPECTIVES ON PUBLIC CHOICE: A HANDBOOK (Dennis C. Mueller ed., 1997); Maxwell L. Stearns, PUBLIC CHOICE AND PUBLIC LAW: READING AND COMMENTARY (1997); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and 'Empirical' Practice of the Public Choice Movement*, 74 VA. L. REV. 199 (1988); Jonathan R. Macey, *Transaction Costs and the Normative Elements of the Public Choice Model: An Application to Constitutional Theory*, 74 VA. L. REV. 471 (1988).

[89] Richard A. Epstein, *The Perils of Posnerian Pragmatism*, 71 U. CHI. L. REV. 639, 652 (2004).

[90] While the focus of this literature was initially on understanding the behavior of legislatures and agencies, it now also focuses on courts. *See, e.g.*, McNollgast, *The Political Economy of Law: Decision-Making by Judicial, Legislative, Executive and Administrative Agencies* 109–25 (Stanford Inst. for Econ. Pol'y Res., Working Paper No. 04-25, 2005), *available at* http://siepr.stanford.edu/papers/pdf/04-35.pdf (reviewing field and collecting sources). The term 'public choice' is used in this chapter in its broad sense, which encompasses the impact on legislatures, as well as on agencies and courts.

providing services the market would fail to provide efficiently because of some market failure,[91] others argue that the government also does (and should) provide tools for achieving important distributive social justice goals.[92] But regardless of your preferred theory about what government should achieve, government has both strengths and weaknesses. Each of the problems explored above as a type of market failure (such as information costs, transaction costs, behavioralism, etc.) can manifest itself as a type of government failure. For example, just as the transaction costs of the market include the costs of bargaining over property rights and striking and enforcing contracts, including the costs of lawyers and accountants to help with these processes, the transaction costs of the political process include the costs of striking and enforcing political deals, including the costs of lobbyists and political parties to help with these processes.[93] In addition, it often is overlooked that the transaction costs of government also include the costs of administering particular government processes.[94] As another example, while behavioralism problems can plague those negotiating over property rights and contracts, they can also plague legislators, administrators, and judges.[95] As a third example, similar to the market, government must bear the costs of

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[91] *See, e.g.*, ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 26 (1974) (setting forth classical libertarian exposition of the role of the minimalist state as 'limited to the functions of protecting all its citizens against violence, theft, and fraud, and to the enforcement of contracts'). For later refinement of the issue, see ROBERT NOZICK, THE EXAMINED LIFE: PHILOSOPHICAL MEDITATIONS 286–7 (1989) ('The libertarian position I once propounded now seems to me seriously inadequate . . . .'); *see also* MILTON FRIEDMAN, CAPITALISM AND FREEDOM 25–32 (1962) (emphasizing that the role of the government can be justified not as a tool for protecting rights in and of themselves but as a tool for protecting rights as a method for solving collective action problems).

[92] *See generally* JOHN RAWLS, A THEORY OF JUSTICE (1971) (expounding a view that justifies a more expansive role of government to protect the disadvantaged). *See also*, AMARTYA K. SEN, COLLECTIVE CHOICE AND SOCIAL WELFARE (1970) (suggesting methods for aggregating values across different individuals and improving welfare distributions through social choice).

[93] *See generally* EIRIK G. FURUBOTN AND RUDOLF RICHTER, INSTITUTIONS AND ECONOMIC THEORY: THE CONTRIBUTION OF THE NEW INSTITUTIONAL ECONOMICS 55–7 (2005) (summarizing political transaction costs) (citing MANCUR OLSON, JR., THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 46 (1965)).

[94] These costs include the costs of obtaining the information needed to carry out government processes, the costs of behavioralism by those charged with carrying out these processes, as well as the costs of transactions that occur when the government attempts to carry them out. In addition, just as transaction costs of the market include the costs of transactions that are efficient but that fail, the transaction costs of government administration include the costs of failed processes that should have been successful.

[95] Paredes, *supra* note 31.

obtaining and processing the information needed to make decisions and the agency costs of ensuring its decisions are carried out.

But the information and transaction cost problems facing individuals in government may be even greater than those facing individuals in the market.[96] As Douglass North points out, in government it is 'extraordinarily difficult to measure what is being exchanged – promises for votes'.[97] Government also faces a problem in obtaining the information needed to make a decision in the first instance. As David Haddock points out, 'One crippling bureaucratic disadvantage is that many external costs and benefits are subjective and thus knowable only to the demander or supplier, while [for government] the links from production to consumption skirt formal markets where objective proxies might be observed.'[98] Although the government can simply ask individuals what they want and feel, in the hope they will reveal such subjective information accurately, Haddock notes: '[S]urvey respondents do not put their money where their mouths are, and often return either zero or unrealistically high valuations with little variation across a wide range of amenities, in addition to cross-amenity comparisons that are inconsistent, intransitive, or sensitive to query order and wording'.[99]

Two initial problems involve the general difficulties in assessing the information content of votes due to their limited ability to fully reflect intensity of preferences and relative preferences. Concerning intensity of preferences, while the mechanism of price provides a finely grained medium for expressing intensity of preferences in a market, votes in a political system do not convey similarly fine-tuned expressions of intensity of preferences. In the United States, for example, when an individual casts a vote in a national election, the individual can only elect for each ballot item whether to cast a single vote. The individual cannot cast a smaller or larger vote. Indeed, this is why

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96 Furubotn and Richter, *supra* note 93, at 26 ('[T]ransaction costs associated with political markets are high, and for this reason institutional inefficiency tends to persist.') (citing DOUGLASS C. NORTH, INSTITUTIONS, INSTITUTIONAL CHANGE, AND ECONOMIC PERFORMANCE 52 (1990)).

97 Douglass C. North, *Institutions and Credible Commitment*, 149 J. INSTITUTIONAL & THEORETICAL ECON. 18 (1993) (referring to the information costs needed to engage in exchanges); *see also* North, *supra* note 96, at 51 ('[Efficient] markets are scarce enough in the economic world and even scarcer in the political world.').

98 David D. Haddock, *Irrelevant Internalities, Irrelevant Externalities, and Irrelevant Anxieties* 9–10 (Nw. L. & Econ. Research Paper No. 03-16, 2003), *available at* http://papers.ssrn.com/abstract=437221 (citing Friedrich A. von Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 529 (1945)).

99 *Id*. at 10 n.11 (citing Matthew D. Adler and Eric A. Posner, *Implementing Cost-Benefit Analysis When Preferences Are Distorted*, 29 J. LEGAL STUD. 1105 (2000)).

the technique of cumulative voting is offered as an alternative voting system mitigating this effect.[100] Concerning relative preferences, while the fungibility of money and many other resources in the market allows them potentially to be spent on various competing uses, votes within the political system can only be spent on the few items on the ballot at any given time, and efforts to make them more fungible, for example, by offering them for sale, are strongly discouraged.[101] The increased fungibility of price over voting helps price develop greater information about a wider range of relative preferences.[102]

Even when it might be known or surmised what the public in general would like, the public choice literature has elucidated at least two additional problems facing the processing of voter input – interest group politics[103] and agency capture.[104] Where minorities care a great deal about an issue but the majority cares little, George Stigler points out that such 'small minorities achieve their effectiveness primarily because it is uneconomic for the majority to oppose them'.[105] When a minority interest group consistently targets one

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[100] LANI GUINIER, THE TYRANNY OF THE MAJORITY: FUNDAMENTAL FAIRNESS IN REPRESENTATIVE DEMOCRACY 14–15 (1994) (describing cumulative voting).

[101] Kathleen M. Sullivan, *Political Money and Freedom of Speech*, 30 U.C. DAVIS L. REV. 663, 671 (1997) (comparing vote markets to price markets).

[102] Price is not a perfect vehicle for information. For example, one shortcoming of price is that marginal consumers can have a disproportionate impact on decision making, and Michael Spence has shown that on issues like quality, the preferences of those within the margin may be ignored. *See* A. Michael Spence, *Monopoly, Quality, and Regulation*, 6 BELL J. ECON. 417 (1975) (noting the benefits of rate of return regulation to concerns about quality).

[103] For more on interest group politics, see Gary S. Becker, *Public Policies, Pressure Groups, and Deadweight Costs*, *in* THE ESSENCE OF BECKER 608 (Ramon Febero & Pedro S. Schwartz eds., 1995) at 544 (presenting a model of competition among interest groups and showing that '[a]n increase in the deadweight cost of taxation encourages pressure by taxpayers, while an increase in the deadweight costs of subsidies discourages pressure by recipients').

[104] For more on agency capture, see Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1050–52 (1997).

[105] George J. Stigler, *Economic Competition and Political Competition*, *in* THE ESSENCE OF STIGLER 117, 125 (Kurt R. Leube and Thomas Gale Moore eds., 1986) (citing George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971)); Press Release, The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel 1982 (Oct. 20, 1982), *available at* http://nobelprize.org/nobel_prizes/economics/laureates/1982/press.html [hereinafter *Nobel Prize in Economics – 1982*]; *see also* David B. Spence & Frank Cross, *A Public Choice Case for the Administrative State*, 89 GEO. L.J. 97, 105 n.37 (2000) (collecting sources and describing two variants of capture: one they attribute to the formation of 'subgovernments' along the lines outlined by Stigler and another that is slightly different in which the general public is seen to lose 'interest in agency policymaking, leaving only regulated interest groups to participate in the process').

particular part of the government, it can effectively capture that part of the government.

The agency capture problem is exacerbated by the rent-seeking impulses that are triggered within those seeking such government benefits, which leads to further rent dissipation. This link between lobbying and rent dissipation was first elaborated by James Buchanan and Gordon Tullock.[106] The basic concept is that the 'competition for government favors . . . involves a wastage of resources in (unproductive) lobbying activities, bribes, legal fees, and so on'.[107]

The agency capture problem is worsened when the government actors themselves realize they also can benefit from being captured. Fred McChesney and Hernando de Soto explore problems created when the beneficiaries include the government actors themselves, who might enjoy enhanced political contributions or political power. The problem can be seen as one form of the principal–agent problem in which the official is the agent of the public but is pursuing personal goals instead of those of the public.[108] Under this view, 'The problem, then, is how principals in the form of . . . taxpayers can protect themselves against opportunistic behavior on the part of their agents (the policy authorities)'.[109]

The situation further worsens when government actors compete to extract this benefit, giving rise to what the team of Simeon Djankov, Rafael La Porta, Florencio Lopez-De-Silanes, and Andrei Shleifer call the 'tollbooth' problem.[110] The tollbooth problem is itself worsened by a mission creep problem, where other government actors shift towards the operating tollbooths and also erect their own. That is, even when those within an agency experience periods of underuse, there will be a tendency for the agency to take on additional

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106 *See, e.g.*, JAMES M. BUCHANAN AND GORDON TULLOCK, THE CALCULUS OF CONSENT: LOGICAL FOUNDATIONS OF CONSTITUTIONAL DEMOCRACY (1962); TOWARD A THEORY OF THE RENT-SEEKING SOCIETY (James M. Buchanan et al. eds., 1980); *see also Nobel Prize in Economics – 1982*, *supra* note 105.

107 Furubotn and Richter, *supra* note 93, at 551.

108 *See* Fred S. McChesney, *Rent Extraction and Rent Creation in the Economic Theory of Regulation*, 16 J. LEGAL STUD. 101 (1987) (arguing that politicians and bureaucrats use legislation, regulation, and the threat of both to create rents and to extract them through campaign contributions, votes, political favors, or even bribes); *see also* FRED S. MCCHESNEY, MONEY FOR NOTHING: POLITICIANS, RENT EXTRACTION, AND POLITICAL EXTORTION (1997) (same and collecting sources); HERNANDO DE SOTO, THE OTHER PATH: THE INVISIBLE REVOLUTION IN THE THIRD WORLD (1989) (same).

109 Furubotn and Richter, *supra* note 93, at 28.

110 Simeon Djankov et al., *The Regulation of Entry*, 117 Q.J. ECON. 1 (2002) (empirical data showing existence and extent of the tollbooth problem).

missions in the same area as the successful tollbooths.[111] Recent empirical study by this team of entry regulation in 85 countries, including the United States, confirms both the extent and nature of the capture and tollbooth problems. Concluding their report of the data showing decreased public benefits, competition, and increased corruption, they note that '[t]his evidence is difficult to reconcile with public interest theories of regulation but supports the public choice approach, especially the tollbooth theory that emphasizes rent extraction by politicians'.[112] Such rent extraction implicates both the cost of rent seeking caused by the option of a particular legal result,[113] as well as any improper restrictions on freedom of contract and exchange imposed by such a law.[114]

At bottom, the public choice literature sets out numerous parameters that limit the ability for government to achieve the goals of the governed: (1) the information content of votes compared to price; (2) the general dominance of narrow interest groups compared to the broad public; (3) the ways in which that effect gets particularly targeted to certain parts of the government, leaving them captured; (4) the way groups will dissipate rents associated with capture when competing to achieve; and (5) the way different parts of the government will erect tollbooths in an effort to be captured. These effects are seen within the context of legislatures and agencies through models of these actors being able to extract some very tangible benefit, such as votes and money. But these same effects also impact judges. Even judges with lifetime tenure act strategically within some institutional constraints – including formal affirmances and reversals, critiques by academia, the bar, and the media, and informal social pressure at all levels – and they do so in response to their own individualized preferences for, among other things, procedural and substantive policies, prestige, fame, standing out, or fitting in. The objects of these preferences in the judicial setting still drive actual behavior, even though they are less tangible than the votes and money that are emblematic of the legislative and agency models. For all of these reasons, the greater discretion that is given to judicial actors, which leaves them greater room to act, the greater their

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111 MILTON FRIEDMAN, *Why Government is the Problem*, *in* ESSAYS ON PUBLIC POLICY 1, 9 (1993) ('If the initial reason for undertaking the activity disappears, [that part of the government has] a strong incentive to find another justification for its continued existence.').

112 Djankov et al., *supra* note 110, at 35 (citation omitted).

113 James M. Buchanan, *Rent Seeking and Profit Seeking*, *in* TOWARD A THEORY OF THE RENT-SEEKING SOCIETY, *supra* note 106, at 359–67 (exploring rent-seeking effects).

114 JAMES D. GWARTNEY ET AL., ECONOMIC FREEDOM OF THE WORLD: 1975–1995 (1996) (comparative study of the effects of reduced economic freedom).

opportunity will be to exhibit public choice problems. These problems, in turn, leave the government most exposed to being co-opted by large, entrenched interests to the detriment of market entrants and to the detriment of increased commercialization and resulting access that these new business models would have generated.

Although property does trigger a number of problems, the above discussion explains many of the techniques for their mitigation that have been well explored in the literature. The problems of rent dissipation and information cost can be mitigated by having the contours of the property rights staked out by claimants at the time of creation instead of being set immutably by statute. The problems of asset specificity and opportunism can be mitigated by ensuring that the creation of these rights does not frustrate reasonable investment-backed expectations of others. The problem of transaction costs can be mitigated by ensuring that once in existence the rights give clear and predictable notice about what they cover. The problems of monopoly effects and anticommons effects can be mitigated by keeping the ownership of these rights in the hands of a residual claimant who is openly identifiable through some form of registry, such as the patent office, and who as an individual market actor can negotiate over the rights and extract value – the residual claim – by electing to give permission via a license or title via an assignment, and who is given broad flexibility to divide these rights and aggregate them. In addition, liability rules may be more likely to trigger many of these problems in more significant ways than property rules.

While the actual net impact of property rights in patents remains an open empirical question, the economics reviewed here do provide important insights for both the theory and practice of patent systems. The discussion that follows applies these insights to the debates about patent theory.

3 Competing economic theories about the purpose of patents

Most conventional patent theories are focused either on providing direct incentives as a tool for increasing access or on controlling rent dissipation. But, both of these approaches fail to explain the positive law rules for obtaining patents. In addition, following these approaches when shaping the detailed institutional framework of the positive law regimes would not facilitate the good coordination that is effective in increasing access, but instead would facilitate the bad coordination that is effective in increasing monopoly effects.

The majority view in the conventional law and economics literature on patent regimes sees the role of the government as providing targeted incentives to specific creative individuals in order to solve the public goods problem associated with intellectual works while at the same time endeavoring to increase access by mitigating the monopoly and transaction costs associated

with the right to exclude.[115] The concern driving this perspective is that the subject matter protected by patents will be underproduced because it is characterized by the Arrow Information Paradox (i.e., it has public good qualities or positive externalities). Under this view, incentives to produce are provided through specific rewards for specific creative work. For example, patents are offered as incentives to invent and copyrights are offered as incentives to generate creative expression. Importantly, the literature does not see rewards merely as some kind of ancillary effect of patents. Instead, the literature sees reward as patents' central goal. What is more, under this view, the reward and its recipient must be regulated carefully to mitigate monopoly effects and transaction costs.[116] For example, as summarized by J. Hirshleifer and John Riley, 'The central problem considered by modern analysts has been the conflict between the social goals of *achieving efficient use of information once produced* versus *providing ideal motivation for production of information*'.[117] Glynn Lunney has called this conflict, or balance, between incentive and access the 'incentives-access paradigm'.[118]

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115 *See, e.g.*, Long, *supra* note 5, at 466 ('The conventional theory of intellectual property rights posits that such rights exist to stimulate the creation and distribution of intellectual goods.') (citing Mark A. Lemley, *The Economics of Improvement in Intellectual Property*, 75 TEX. L. REV. 989, 993 (1997) ('Intellectual property [rights are] fundamentally about incentives to invent and create.')). Although there are a number of incentive-based theories for patents that are mentioned in the literature – including 'incentive to invent', 'incentive to disclose' or 'teach', 'incentive to innovate', and 'incentive to design around' – there are essentially three dominant theories today: (1) some version of the 'incentive to invent' and 'disclose' theories treated together under the rubric of 'reward', (2) the 'prospect' theory, and (3) the commercialization theory. For a recent review of the patent literature on incentive theories and a collection of sources, see Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, at 1024–46 (1989); A. Samuel Oddi, *Un-Unified Economic Theories of Patents – The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996).

116 *See, e.g.*, Stanley M. Besen and Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSP. 3, 8 (1991) ('The patent offers the incentive of the statutory right to exclude as a means for inducing creative activity.'). Several types of regulatory responses to patent rights are said to be justified by this concern, including liability rule treatment, misuse, and fair use.

117 J. Hirshleifer and John G. Riley, *The Analytics of Uncertainty and Information – An Expository Survey*, 17 J. ECON. LIT. 1375, 1404 (1979) (citing Kenneth Arrow, *Economic Welfare and the Allocation of Resources of Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609 (Nat'l Bureau Comm. for Econ. Res. eds., 1962); Fritz Machlup, *Patents*, *in* 11 INTERNATIONAL ENCYCLOPEDIA OF THE SOCIAL SCIENCES 461 (David L. Sills ed., 1968)).

118 Glynn S. Lunney, Jr., *Reexamining Copyright's Incentives-Access Paradigm*, 49 VAND. L. REV. 483 (1996) (reviewing the incentive access-paradigm and highlight-

Although the reward literature contributes much to our understanding of patents, it has a number of serious limitations. One perspective is to see these theories as focusing on the role of government in providing both subsidy and regulation rather than less-invasive forms of intervention, such as setting rules and resolving disputes. That is, the government is seen as needed on the one hand to prop up potential patent holders and on the other to keep those patent holders in check. Another perspective is to see the reward literature as paying too much attention to direct incentives for creators, monopoly power, and transaction costs, all in only some settings, while paying remarkably little attention to these same issues in other settings, as well as overlooking a host of other important issues, including coordination problems and public choice problems. Simply put, both sides of the incentive-access paradigm are inapt: the incentive side because designing a patent system to provide direct incentives is imprudent, and the access side because property rights facilitate access.

One problem with the incentive side of the paradigm is that direct incentives are very sloppy in their effect; they achieve some beneficial effect, but at a high cost. Focusing on providing direct incentives with rewards has limited need, limited effectiveness, cannot be targeted, and has bad side effects. Rewards have limited need because much of the desired activity may occur without added incentive of the reward.[119] Rewards have limited effectiveness

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ing an additional cost of patents to be the opportunity cost of deploying resources toward patents that could instead have been deployed elsewhere).

[119] For example, individuals may be driven by self-satisfaction, a search for knowledge, reputation, etc. Indeed, although the positive shift in 1980 to allow patents in basic biotechnology did lead to some increase in the amount of inventive activity being done in the field, the amount before that time was still quite substantial. This is not surprising given that, in a field with a large number of people having sufficient creative ability working to solve a problem, it is likely the solution will be found. *See* JACOB SCHMOOKLER, INVENTION AND ECONOMIC GROWTH 215 (1966); *see also* Robert K. Merton, *The Role of Genius in Scientific Advance*, NEW SCIENTIST, Nov. 2, 1961, at 306 (providing more on the norms of science and the incentive they provide toward discovery).

In the real world, many externalities turn out to be irrelevant to efficient allocation of resources. *See* Haddock, *supra* note 98, at 1–2 (providing examples and models, and referencing James M. Buchanan and William Craig Stubblebine, *Externality*, 29 ECONOMICA 371 (1962)). For example, in the case of positive externalities, such as the pleasure many persons get when they see a visually aesthetic garden even though they likely did not contribute to the garden's upkeep, the keeper of the garden has managed to fund its creation and maintenance without reaping specific contributions from those passers-by. *See, e.g.*, Jeffrey I. Bernstein and M. Ishaq Nadiri, *Interindustry R&D Spillovers, Rates of Return, and Production in High-Tech Industries*, 78 AM. ECON. REV. 429 (1988) (giving other examples of such irrelevant positive externalities and finding that, in recent years, social rates of return significantly exceeded private rates

because much of the desired activity is not responsive to additional incentive.[120] Even to the extent that rewards have a beneficial effect, it is very hard to correlate the amount of reward and the merit of the awarded activity, especially in a way that is predictable to all players ex ante.[121] Most importantly, efforts to achieve even such sloppy reward effects have serious costs. One that is well recognized in the literature is that the social costs of investments made

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of return in five high-tech industries). The positive externalities the passers-by enjoy have not prevented the good from being produced. In economic terminology, these uses are said to be 'inframarginal', as opposed to 'marginal'. Haddock, *supra* note 98, at 17 ('Transaction cost for collective goods – even those demonstrably enjoyed by millions – are chronically overestimated in policy discussions. Only one or a few strong demands often determine both actual and ideal provision, and even two million demands are irrelevant if inframarginal.'). While the possibility of capturing some benefit from these users of a garden may be a factor that a garden planner might consider when making decisions about how to fund the garden creation and maintenance processes, those gains would have to be weighed against the costs of such metering techniques. Indeed, many such externalities are found in the real world effectively to be irrelevant to decision making because a sufficiently small number of individuals having sufficiently great interest in the externalities are able to engage in sufficient private ordering for the appropriate amount of the desired activity to take place. *Id*. at 1–2 (citing Buchanan and Stubblebine, *supra*). This means that in many cases things that generate positive externalities would be made anyway, regardless of whether that positive externality is fully internalized to the producer.

[120] This may be because the activity is only responsive to alternative inducements, such as self-satisfaction, search for knowledge, and reputation. *See, e.g.*, Besen & Raskind, *supra* note 116, at 6.

> Another critical element in deciding how to strike the balance between encouraging creativity and dissemination is the extent to which creative activity responds to economic rewards. The less that innovation depends on the resources invested and the potential economic rewards, the more limited is the case for granting substantial rights to creators.

Id.

[121] On the one hand, for example, empirical works by Steven Shavell and Tanguy van Ypersele and by Michael Kremer have shown that, at least for patents, the patentee often does not receive the full social surplus created by the patented invention. *See, e.g.*, Shavell and van Ypersele, *supra* note 14, at 1–8; MICHAEL KREMER, PATENT BUY-OUTS: A MECHANISM FOR ENCOURAGING INNOVATION 1–5 (Nat'l Bureau of Econ. Res., Working Paper No. 6304, 1997), *available at* http://www.nber.org/papers/w6304. Social surplus is the amount of total social welfare generated by the invention minus the costs of making the invention, such as research by the inventor and the inventor's competitors. Social welfare is the aggregate value of all utility that individuals obtain from the invention. On the other hand, for example, there are important difficulties in developing a theory of just deserts as a basis for government to allocate any reward among potential claimants, whether the reward is a patent or cash.

to get rewards may be greater than the social value of the activity rewarded.[122] Indeed, this has spawned the minority view in the conventional law and economics literature on patent regimes, which focuses on rent dissipation, as discussed below.

But one cost of rewards that is underappreciated in the literature is tied to the importance of understanding the relationship between the reward and the activity being rewarded. This matters because it would inform determinations about how to set the reward in practice. If set too low, then there may be insufficient positive response. If too great, the marginal excess may generate too little marginal positive response or may generate too many negative side effects.[123] While simple metrics such as too big or too small may turn out not to matter, at least some dimension of the reward will matter, and yet the reward theories offer no guidance as to how to set the reward along that dimension. This problem can be thought of as 'screening' and its resolution is one of the strengths of a patent theory focused on commercialization and coordination, which turns out to have great explanatory power for the positive law rules governing when valid patent rights are available.[124]

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[122] This may be because the social costs may trigger rent dissipation – a related concern over the opportunity cost associated with the efforts made towards winning the reward. *See* Lunney, *supra* note 118 (discussing the role of opportunity costs).

[123] For example, too little positive response might occur because those responding to the rewards might have decreasing marginal desire or ability to respond. Similarly, too many negative side effects might occur if the opportunity costs of the resources being spent responding are too high or their rent-seeking costs are too great.

[124] As Merges has pointed out, a related limitation of reward theories is that they seem to view an intellectual property right as somehow having a one-to-one correlation with a good or service that is sold in a market. *See* Merges, *supra* note 5, at 1859–60 (criticizing a common view in the literature as assuming a one-to-one correlation). As a result, while on the one hand seeing the transaction costs of property rights as an obstacle to the cumulative nature of intellectual endeavors, the reward theories overlook that this very cumulative nature makes it remarkably difficult to allocate merit among various contributors to an intellectual endeavor. For example, in the model offered by Shavell and van Ypersele, the reward is determined by looking to market demand. *See* Shavell and van Ypersele, *supra* note 14. Yet, the authors do not suggest how to disaggregate demand for licenses to intermittent windshield wiper technology used in cars, for example, from the demand for cars. Put differently, every market having large demand would generate droves of reward claimants each asserting to have made some contribution. What is more, no market participant would have an adequate incentive to provide the government with information relating to the validity of the reward. Only in the rare cases of two individuals claiming to have invented the same exact thing does one individual have an incentive to challenge the claim of the other. When a patent is the focus of a reward, the reward provider must determine how to allocate the reward, and it is likely there will be excessive claimants. When patent rights instead are protected by property rules, the allocation is made among those hold-

Some of the reward theorists suggest techniques for solving some of the problems of determining the reward while at the same time mitigating the monopoly power and transaction costs problems associated with the property right in a patent by suggesting various forms of cash reward, prize, buyout, or subsidy as alternatives to patents.[125] These reward or prize proposals are each more ingenious than the other in developing methods for finding, at least on average and in theory, the 'right' price for rewards. And while Michael Abamowicz provides extensive analyses of many of their shortcomings, he also provides potential solutions for several of them.[126]

But there are at least two central problems with these reward proposals: First, they trigger their own high transaction costs. While their strength is in using market forces to generate better information with fewer public choice problems than the simple Pigouvian subsidies that were the target of criticism in the treatment by Coase and Demsetz of the externality problem, their weakness is in relying on their own extensive government-mediated collateral markets for patent auctions and buybacks which themselves will be costly to operate. Second, even the best case for these proposals sees them only as adjuncts to the patent system, not as complete replacements, precisely because they are all premised on the patent acting first as a coordination tool to some extent.[127]

Therefore, the most serious cost of rewards, which is almost totally overlooked in the literature, is that rewards themselves fail to facilitate coordination of the type needed to increase downstream development and access.

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ing the various patent rights through whatever contracts they entered into so as to obtain commercialization. What is more, in contrast to the difficulties in setting appropriate reward, the positive law rules for obtaining patent rights can serve as remarkably inexpensive screening tools for determining who will even get such a right.

125 *See* Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003) (for an excellent review of these proposals, including in-depth critiques). For convenience, these proposals can be summarized in very brief form as follows: (1) patents are bought out by the government with prices informed by test marketing (Robert C. Guell and Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK Q. 213 (1995)), (2) awards are given in the place of patents with the amount of reward set by later developed data from actual demand (Shavell & van Ypersele, *supra* note 14), (3) patents are bought out with prices informed by probabilistic auctions (Kremer, *supra* note 121), (4) subsidizing purchases of subject matter covered by patents as a tool for improving effectiveness of price discrimination by patentees (Douglas Gary Lichtman, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 HARV. J.L. & TECH. 123 (1997)), and (5) the use of retrospective prizes in exchange for efforts to decrease monopoly effects of patents (Abramowicz, *supra*).

126 *See* Abramowicz, *supra* note 125, at 211–36.

127 *See, e.g.*, *id.* at 115 (ultimately concluding that its proposal 'would complement rather than replace the patent system').

Reward systems assume, but do nothing to facilitate, this type of coordination and commercialization.

What is more, the reliance of even reward systems on some initial coordination is instructive because it highlights the reason why the access side of the incentive-access paradigm is similarly inapt. The access problems associated with property can be mitigated more effectively than the access problems associated with avoiding property.

The reward literature places great emphasis on the risk that the right to exclude will lead to insufficient access to the subject matter protected by a patent because of the potential monopoly distortion and transaction costs associated with the patent right to exclude. But, as explored below in the discussion of the commercialization theory and its implications for these and other social costs in the context of patents, the reward theories' concerns about these costs are in a sense both overstated in that the costs are not as great as feared and understated in that property rights can be essential for mitigating them. In addition, any approach that avoids property rights, whether or not such an approach includes rewards, triggers its own access problems that are tied to a lack of coordination and commercialization.

The minority view in the conventional law and economics literature on patent regimes, which focuses on rent dissipation, also fails to facilitate access while potentially increasing anticompetitive effect. The rent dissipation view of patents is premised on the concern about excessive and improper rent seeking on the part of those seeking a government-provided benefit like a patent. The theory was first explored by Edmund Kitch in his 1977 piece on what he called the 'prospect theory' of the patent system, which builds upon work by Yoram Barzel and others and argues that the use of property rights in patents could avoid or mitigate the rent dissipating effect otherwise associated with those rewards.[128] A similar view called the 'rent dissipation theory' was offered by Mark Grady and Jay Alexander in 1992, which focused on harnessing the patent owner's control power over downstream users to coordinate what otherwise would be competing efforts.[129] The thrust of the prospect (or rent dissipation) approach is that property rights can facilitate coordination among competing users of a target asset so as to avoid overuse of other assets

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[128] Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 265–7 (1977) (citing Barzel, *supra* note 14).

[129] Mark F. Grady and Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 305–10, 316–22 (1992) (building upon the prospect theory by suggesting that the particular contours of the positive law rules for obtaining and enforcing patents are and should be adapted to minimize rent dissipation both pre- and post- patent).

in the race to obtain the target.[130] Kitch suggests that patents operate similarly as a tool to decrease both pre- and post-patent rent seeking.[131] The prospect and rent dissipation theories of patents make important contributions by elucidating the ways that property rights can facilitate coordination among competing users of an asset so as to avoid overuse of other resources. It seems from the literature that patents may indeed have this net beneficial impact in the real world to some extent.

Nevertheless, there are several serious shortcomings of the prospect and rent dissipation approaches to patents.[132] By way of summary these include: (1) that a number of factors mitigate rent dissipation effects in practice and (2) that rent seeking for prizes has countervailing positive effects in the case of innovation because there is not a single prize or even a practically limited number of total prizes. But most importantly, the prospect and rent dissipation theories fail to provide a way to use the social cost lessons of prospecting to design legal rules for obtaining patents that can operate ex ante to mitigate the social costs of prospecting. This final problem is so important because ex ante predictability is essential both for facilitating the private ordering of the property owner and those with whom it contracts and for mitigating the information costs of third parties.[133] In addition, leaving these decisions to ex post determination within the broad discretion of government agencies or courts will inevitably favor the large established players over market entrants.

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130 Kitch, *supra* note 128, at 265, 278–9 (citing Barzel, *supra* note 14); *see also* Grady and Alexander, *supra* note 129, at 316–22.

131 *See generally* Kitch, *supra* note 128, at 276–9; *see also* Grady and Alexander, *supra* note 129, at 316–22.

132 See Michael Abramowicz, *Copyright Redundancy*, 10–18 (George Mason Univ. Sch. of Law, Law & Econ. Working Paper No. 03-03, 2003), *available at* http://ssrn.com/abstract=374580 (collecting sources and showing how each of these factors may operate to mitigate rent dissipation effects).

133 In addition, as Henry Smith has pointed out, property rights can be and should be structured so that they impose sufficiently modest information-processing costs on third parties who must evaluate and understand them enough to respect them by avoiding infringement. Henry E. Smith, *The Language of Property: Form, Context, and Audience*, 55 STAN. L. REV. 1105, 1108 (2003) ('If everyone in the world is expected to respect an owner's right to Blackacre, the content of that right cannot be too complicated or idiosyncratic without placing a large burden on many third parties.').

> [T]he correlation between extensiveness of the audience and mandated unintensiveness of legally significant communication holds in a variety of areas beyond land law, including patent law, copyright law, and innovative forms of intellectual property such as that suggested by the approach of the Supreme Court in *International News Service v. Associated Press*.

Id. at 1114–15.

Although the capture problem is tied to agencies, a related problem arises before courts where the outcome of such a broad discretionary inquiry so often, as it has in the past for intellectual property, leads simply to most victories being won by the large established players who are better able to finance protected litigation than market entrants. Finally, as explored earlier, an effective way to avoid rent dissipation effects is to allow the residual claimants of a property right to define it when staking it out, a technique that at least the present patent and trademark systems presently follow.

In contrast to both the reward and rent dissipation theories of patents, the commercialization theory sees property rights in patents as important for both increasing access and competition. The commercialization theory of patents views patents, backed by property rules, as important tools for facilitating the downstream commercialization of the subject matter that is protected by the patent rights. As emphasized in the registration component of the commercialization theory, the positive law rules for determining when a valid patent right may be obtained work to protect reasonable investment-backed expectations of both patentees and the public, thereby decreasing the risk of asset-specific investments and opportunism. The prior art rules operate to make sure a patent right to exclude does not block activities in which individuals are otherwise engaging. And the disclosure rules operate to make sure potential infringers can largely avoid making investments in patented territories inadvertently. Moreover, these positive law patent validity rules can achieve these results with relatively low administrative and public choice costs. In this regard, the commercialization and registration theories are essentially two components of the coordination view explored here.

Enforcing patents with property rules provides significant incentives for parties to collaborate, helping to solve a key problem that would otherwise frustrate the socially constructive coordination that facilitates commercialization of innovation. Bringing an invention to market requires coordination among its many complementary users, including developers, managers, laborers, other technologists, financiers, manufacturers, marketers, and distributors. This socially constructive coordination depends in at least two fundamental ways on the expectation that patents will be enforced with strong property protection.

First, the credible threat of exclusion associated with a published patent acts like a beacon in the dark, drawing to itself all those interested in the patented subject matter. This beacon effect motivates these diverse actors to interact with each other and with the patentee, starting conversations among the relevant parties. Providing a focal point, or beacon, the publicly recorded patent right helps each of these individuals to find each other.[134]

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134 *Compare* Richard A. Epstein, *Notice and Freedom of Contract in the Law of*

Although so many on the so-called 'pro-patent side' of the patent literature, like Joseph Schumpeter and Edmund Kitch, maintain that the patent owner should be able to control uses,[135] we should be agnostic about who should control the ensuing negotiations. Because we cannot know ex ante who will be best for that role, we should leave this determination to the particular facts of each negotiation. As the beacon effect highlights, facilitating coordination among interested parties is a less aggressive goal than assigning control to a particular party like the patent owner.

Second, the widespread expectation that the patent will be enforced motivates each of these parties to reach agreement with one another over the use and deployment of the technology. This bargaining effect falls apart if the parties are unsure the patent will be enforced because, in that case, there is significantly less need to reach agreement ex ante. The fear of weak enforcement creates a disincentive for the necessary parties to work together at the outset.

The patent literature has not devoted much focus to the mechanism by which this breakdown occurs. While Merges focuses on how property rules give patent owners access to more remedies than liability rules, which in turn gives them greater control,[136] it is important to see how property rule treatment improves incentives for everyone in the bargaining process, not just the patent owner. Henry Smith, Merges, and Epstein have all examined the information cost advantages of property rules in their scholarship,[137] and work by Louis Kaplow and Steven Shavell has explored the risk that liability rules will lead to undercompensation of property owners because of multiple takings.[138] But none of these scholars focuses on how adopting liability rather than property rules can impede coordination among takers and dissipate the incentives that parties other than the patent owner have to consummate a deal.

Knowing there is a good chance that a court employing a liability rule approach will set a lower price than the patent owner would accept, some

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Servitudes, 55 S. CAL. L. REV. 1353, 1354 (1982) (proposing 'that under a unified theory of servitudes, the only need for public regulation, either judicial or legislative, is to provide notice by recordation of the interests privately created').

135 JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY (3d ed. 1950); Kitch, *supra* note 128.

136 Merges, *supra* note 7.

137 Richard A. Epstein, *A Clear View of the Cathedral: The Dominance of Property Rules*, 106 YALE L.J. 2091 (1997); Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 COLUM. L. REV. 2655 (1994); Henry E. Smith, *The Language of Property: Form, Context, and Audience*, 55 STAN. L. REV. 1005 (2003).

138 Louis Kaplow and Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 HARV. L. REV. 713 (1996); *see also id.* at 732–3 n.61.

potential infringers may first try for a low damage award from the court, rather than consummate a deal up front with the patent owner, and then make a deal later if the court award is too high. The prospect that infringement may be an attractive option to some can decrease the incentives for all others to attempt or consummate a deal ex ante, thereby weakening both the beacon effect and the bargain effect.

In addition, while liability rules focus on price, deals involving patents often hinge on complex terms other than price, especially early in the process of commercializing new technologies. These terms often involve assets that are difficult to hedge, diversify, or insure, such as a particular individual's unique skills, time, and relationships, as well as specialized technical support, field-of-use or territory limitations, grant-backs, cross-licenses, payment schedules, and most-favored-nation provisions.

The problem is that a court-imposed damage award, which is emblematic of liability rule treatment, is nearly always reduced to a simple monetary amount. The promise of some share of a possible damages award does little to mitigate risk of loss of these other relatively unique assets for either the patent owner or the other parties involved.

For this reason, the helpful strategies explored by Ian Ayres for achieving similar or even superior results through liability rules[139] hinge on whether those impacted are portfolio players. That is, Ayres's strategies favor those large, portfolio players who can more easily hedge, diversify, and insure the assets they are considering investing in these deals over smaller players making unique investments. For these smaller players and others relying on unique assets, though, property rules are more likely to protect their interests, thus helping them to coordinate.

What is perhaps most disturbing about the conventional literature on patents is that it seems to get the anticommons, anticompetitive effects, and public choice concerns backwards. That is, through public choice problems, the government responses generated by liability rule treatment and regulation are themselves likely to generate true problems of anticommons and anticompetitive effects. Indeed, the anticompetitive effects are achieved because the undesirable type of coordination is facilitated (that is, coordination among existing players rather than coordination among those interested in forming market entrants). Public choice problems have, at least until recently, almost entirely escaped attention in the patent literature.[140] Nevertheless, public

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139 IAN AYRES, OPTIONAL LAW: THE STRUCTURE OF LEGAL ENTITLEMENTS (2005).

140 The recent recognition of public choice problems in the body of intellectual property literature discussing copyright term extensions only scratches the surface. The literature often discusses the recent Copyright Term Extension Act ('CTEA') as an example of public choice pressure from the entertainment industry. While this may be

choice problems do matter and should be considered because they are linked inextricably to government action, and so must be weighed as countervailing considerations to the extent regulation is offered as an alternative to patents.

To begin the public choice analysis of patents, it may help to start with the legislative origins of the present positive law intellectual property regimes, which at least hint at reasons to think the public choice problems may be greater in some areas than in others. Through what may have been mere historical happenstance,[141] the basic framework of the present patent and trademark regimes both grew out of a concerted effort at about the same time (the 1940s) by the same bar association (the New York Patent Law Association).[142] Focused not on any particular set of clients, owners or infringers (because the drafters typically represented both), but rather on crafting a coherent system, these efforts produced institutional frameworks that generally cohere and as a result generally are effective and efficient at achieving their core goal: commercialization.[143]

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so, it gravely underestimates the public choice problems in intellectual property generally and patents in particular. For examples of the public choice view of the CTEA, *see, e.g.*, *Free Mickey Mouse: Lawrence Lessig Wants Less Copyright Protection, Including for Disney's Famous Rodent*, ECONOMIST, Oct. 12, 2002, at 67; Michael H. Davis, *Extending Copyright and the Constitution: 'Have I Stayed Too Long?'*, 52 FLA. L. REV. 989, 1005 (2000) (arguing that the CTEA provided 'not an incentive, but a gift or windfall'); William Patry, *The Failure of the American Copyright System: Protecting the Idle Rich*, 72 NOTRE DAME L. REV. 907, 932 (1997) ('The real impetus for term extension comes from a very small group: children and grandchildren of famous composers whose works are beginning to fall into the public domain, thereby threatening trust funds.'); Richard A. Epstein, *The Dubious Constitutionality of the Copyright Term Extension Act*, 36 LOY. L.A. L. REV. 123, 128 (2002) (the CTEA 'pads the wealth of the widows and children of the original copyright holders', seemingly creating a 'massive giveaway of public domain resources'); Dennis S. Karjala, *Judicial Review of Copyright Term Extension Legislation*, 36 LOY. L.A. L. REV. 199, 232–6 (2002) (setting forth a basic public choice view of CTEA). Larry Lessig has gone so far as to refer to the statute itself as the 'Mickey Mouse Protection Act' in reference to perceived public choice pressure brought by Disney. Doug Bedell, *Professor Says Disney, Other Firms Typify What's Wrong with Copyrights*, DALLAS MORNING NEWS, Mar. 14, 2002, at 3D.

[141] Heady with success in implementing the Lanham Trademark Act, the present U.S. trademark system, a few years earlier, in 1948, the New York Patent Law Association enlisted Giles Rich to draft for introduction in Congress a bill that eventually became the 1952 Patent Act, the present U.S. patent system.

[142] The organization is presently called the New York Intellectual Property Law Association. *See* GREGORY J. BATTERSBY ET AL., A SEVENTY-FIVE YEAR HISTORY OF NYIPLA, *available at* http://www.nyipla.org/public/01_history.html.

[143] The point here is not that these statutes are perfect. The drafters of these statutes, like all human beings, are characterized by human foibles, including behavioralism. Rather, the point here is that because of the way the drafters were organized

This seeming purity in the drafting of these regimes has not persisted. For example, the overhaul to the statutory regime governing the interaction between patent law and Food and Drug law called the Hatch-Waxman Act[144] was very much a collective bargaining process that raises a host of public choice, administrative, and market power problems.[145]

Similarly, the basic statutory scheme for the present copyright regime grew out of a classic public choice bargain among large interest groups. These groups have regularly returned to the legislative process to reshape the framework and reach new compromises each time technology or other factors sufficiently have changed the interests of those groups.[146] While such an approach does a reasonable job of integrating into the statute many of the collective preferences of those present in the negotiations at that time, it does less well at integrating the concerns of others or even the concerns of the same parties at later times.[147]

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during the drafting process, the individual incentives they each faced happened to be more consistent with their efforts being directed toward drafting a statute that coherently achieved the coordination function to which they had subscribed than with their efforts being directed toward helping any one class of client. At a minimum, they were largely isolated from public choice pressures.

144 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000) and 35 U.S.C. §§ 156, 271 (2000)).

145 *See, e.g.*, FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (describing problems with the Hatch-Waxman Act and collecting sources). While getting interested constituencies together to negotiate a statute sounds attractive, as the basic economics of the drafting constituencies' businesses changes over time due to changing technologies and norms, it should not be surprising that each iteration of the legislative bargain often will be too intensely focused on responding to prior allocations. That is, there is a lag between the change in technology and the change in economics and a subsequent lag between the change in economics and efforts to renegotiate the legislative bargain.

146 *See generally* JESSICA LITMAN, DIGITAL COPYRIGHT 23, 35–63 (2001) (reviewing the legislative history of copyright and explaining how since 1909 frequent revisions to copyright law can be attributed to collective bargaining among some of the impacted industries); *see also* Niels Schaumann, *Copyright, Containers, and the Court: A Reply to Professor Leaffer*, 30 WM. MITCHELL L. REV. 1617, 1619 n.8 (citing the same two exceptions). Even these two revisions that putatively did not emerge directly from interest group pressures may themselves have been driven by concerns for interest groups. For example, I thank Mike Meurer for pointing out the interest Congress may have had in appearing to be sensitive to the needs of small restaurants and coffee shops when passing The Fairness in Music Licensing Act of 1998. *See* David Nimmer, *Codifying Copyright Comprehensibly*, 51 UCLA L. REV. 1233, 1281 (2004) (arguing that the statute 'smacks of special interest legislation for the benefit of a defined class').

147 In part this is a 'race-to-the-bottom' story and so does not argue that such a process will always yield this bad result. Rather, it explains how one contributing factor may have played a role in this case.

The copyright regime, having been drafted and regularly redrafted with an eye towards balance among politically powerful constituents, has ended up featuring more flexible governance. By contrast, the patent system promulgated through the 1952 Act, having been drafted with an eye towards coherence, ended up employing more predictable exclusion. While further research might compare the operative legislative histories of these different regimes to determine the reasons why they seemed to have taken such different approaches and led to such different results, the results themselves are unsurprising. It also is no surprise that even the governance regime of copyright is not always flexible. For example, in promulgating immutable, rather than default, rules for what constitutes fair use, preemption, and misuse, the copyright system protects established industries by leaving potential market entrants unclear as to what coordinating deals can be struck – if not certain that important deals cannot be struck.

Taking seriously the notion that more is not always better, patent scholars should pay more attention to how the entitlements are structured rather than simply how many there are. Entitlements generally become easier for diverse market actors to use and tend to encourage economic growth and competition the more that those entitlements have attributes that facilitate predictable enforcement, ease of trade, bundling, and dividing, and the more that they force users of those entitlements to deal with private individuals. In contrast, when entitlements have attributes that can only be created or changed at the discretion of government actors and otherwise have fixed owners and contours, users of those entitlements have to deal more with government, which tends to concentrate wealth and power in political actors like regulators and influential constituents.

Consider also current patent reform efforts that are designed to make it easier for government decision makers to reject patents, usually on the basis of what is technically known as 'prior art' – that is, whether the claimed invention was previously known. Such changes shift more discretion to government decision makers to decide what the prior art teaches. For example, under these proposals, Patent Office examiners would be able to block patents on the basis of their own assertions about what the state of the art was at a particular time in history, without having to rely on the factual proof that has long been required, such as documents and sample products.

This is perhaps where flexibility most starkly shows its Achilles' heel. Allowing a government decision maker to determine what she thinks the state of the art was at a particular time in history gives her great discretion. Because large firms have fatter lobbying and litigation budgets than smaller innovators, such discretion converts the patent system into a tool for suppressing competition by making it much easier for big firms to tie up any patent owned by a small innovator. In contrast, the Federal Rules of Civil Procedure, which have

been carefully developed to give the fairest process we have to offer, contain the tools of joinder, compulsory counterclaims, and preclusion, so as to avoid abusive and repetitive process, as well as summary judgment, to avoid long trials where there is no genuine issue of material fact.[148]

A related public choice problem with intellectual property – and indeed with the creation of any types of property rights or other benefits available from the government – is the rent dissipation problem that can come when each particular right is created.[149] This problem can be mitigated if the potential owners of the rights are able to tailor them at the time of creation.

But the public choice problems in patents have extended beyond the legislatures to the agencies and the courts. For example, when decisional frameworks relating to patents have been left open to *sui generis* determination, as opposed to being guided by applicable statutory framework, courts and agencies have acted swiftly to eviscerate patents.[150] Even if any of the problems of market power, transaction costs, anticommons, or behavioralism is a concern that ought to drive regulation of patents, the central problem that public choice adds to the mix (and one which is often overlooked by the literature) is that too often these concerns have been invoked in particular cases to restructure particular arrangements ex post for the benefit of one particular constituency or set of constituencies.[151] For example, the recent trend by the Federal Trade Commission and Department of Justice Antitrust Division to pursue actions

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148 *See* FED. R. CIV. P. 19 (joinder); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) (discussing res judicata and collateral estoppel); Fed. R. Civ. P. 56 (summary judgment).

149 *See* Anderson and Hill, *supra* note 15, at 443 (showing how less centralization in the definition and enforcement of property rights helps to improve efficiency by avoiding rent dissipation).

150 Examples in the patent context include the agency and court decisions to prohibit patents in software and modern biotechnology (finally reversed by later court decisions). *See Diamond v. Diehr*, 450 U.S. 175, 187 (1981) ('[A] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.'); *Diamond v. Chakrabarty*, 447 U.S. 303, 309–18 (1980) (holding that living organisms are not *per se* unpatentable).

151 For at least the computer software example, the public choice story has been infamously demonstrated on two occasions: first, in *Gottschalk v. Benson*, 409 U.S. 63 (1972) (holding software to be ineligible for patent protection), and, second, in *In re Alappat*, 33 F.3d 1526 (1994) (en banc) (reversing Patent Office decision to reconstitute its internal Board of Appeals to hold a rehearing before a specially packed Board designed to reject the patent on a type of software). Some suggest that the problems of agency capture and improper political influence may be playing out in the most recent iteration of the Blackberry dispute – the reexamination of the patents in that suit. *See, e.g., NTP Charges Misconduct in PTO's Review of Patents in Blackberry Dispute*, 72 Pat. Trademark & Copyright J. (BNA) No. 1770, at 52 (May 19, 2006).

against patentees on so-called 'upstream' technologies in the name of mitigating problems of market power, transaction costs, and anticommons problems may be evidence of agency capture that both frustrates market entry and upsets private ordering overall, as all players in the market realize over time that terms like 'upstream' and 'downstream' are so relative that they simply may be synonyms for 'things to be bought' and 'things to be sold' by any private party able to gain the agency's attention.[152] These types of public choice problems and their negative impact on ex ante incentives and private ordering potentially would likely be mitigated only if the government actions called for in the literature were to eliminate patents or to regulate them through revisions to statutory or regulatory decisional frameworks that were sufficiently predictable.

If in any given case a party may invoke concerns about market power, transaction costs, anticommons, or behavioralism as a justification for avoiding patents, then we should not be surprised to see many cases in which parties make precisely such charges. These concerns can be used to inform a set of positive law rules for determining validity that can operate in a relatively predictable manner based on facts knowable to both plaintiffs and defendants ex ante, thereby facilitating private ordering. But the rub is that having used those concerns to shape the positive law regimes that guide decisions going forward, they should not then be available for use on a one-off basis to rework decisions ex post.

What is most troubling about the concerns expressed in the literature about market power, transaction costs, anticommons, and behavioralism is that no attempt is made to suggest a decisional framework for determining ex ante when these concerns will be enough to trigger government action. This leaves open the possibility of a return to the time when the decisional framework by courts was either so obtuse that no patent could satisfy them[153] or so unable to

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[152] *See* Stanley M. Gorinson et al., *Federal Antitrust Enforcers Focus on Intellectual Property Abuses*, INTELLECTUAL PROPERTY TODAY, Aug. 2003, at 38 (Aug. 2003) (providing an excellent and easily accessible review of recent FTC activities and discussing the *Rambus* and *Unocal* cases).

[153] For example, the test for patentability has at different times become so rigid for some courts that no patents were held valid within their jurisdiction. By the early 1940s, the standard had become so vague and yet so difficult to satisfy throughout the U.S. that Justice Jackson remarked, '[T]he only patent that is valid is one which this court has not been able to get its hands on'. *Jungersen v. Ostby & Barton Co*., 335 U.S. 560, 572 (1949) (Frankfurter & Burton, JJ., dissenting). Even after the statute was amended in response to these cases, the problem persisted in the Second Circuit as late as the 1960s. *See* Gerald J. Mossinghoff, *Side Bar: The Creation of the Federal Circuit*, in PRINCIPLES OF PATENT LAW 30, 31–32 (F. Scott Kieff, Pauline Newman, Herbert F.

be predictably satisfied that the effective value of all impacted patent rights simply collapsed towards zero.[154]

What may be worse than effective elimination of patents[155] is that the nature of patents may be changed through this public choice mechanism to be more focused on liability rules and governance in a way that strongly favors established big players in the industry who are able to best bring public choice pressure while, at the same time, actually hindering competition and market entry. There is at least some evidence this is already happening.

Consider what might be called a *keiretsu* strategy for dealing with patents. The term '*keiretsu*' refers to the large conglomerates in Japan,[156] where the patent system is well known to be replete with large numbers of essentially weak patents and devoid of strong patents.[157] Despite the fears about transactions costs of litigation and conflict that some might expect would dominate, the *keiretsu* might actually prefer to have a system like this exactly because it makes it easy to have large numbers of skirmish battles while avoiding the threat of death blows. While large numbers of skirmish battles do have high transaction costs, they also buy a great deal.

First, they allow the battling *keiretsu* to communicate with each other in a way that may be more forthright than a direct conversation (i.e., they mitigate a trust problem). Seeing where an opponent will spend resources to fight can communicate more than a direct conversation about what territory is most coveted. In the meantime, the extensive exchanges of documents and sworn

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Schwartz and Henry E. Smith, eds., 4th ed. 2008) (former Patent Office Commissioner Mossinghoff recounting that during the confirmation hearings for then-Second Circuit Judge Thurgood Marshall's nomination to the Supreme Court, Judge Marshall responded to a question about patents by saying, 'I haven't given patents much thought, Senator, because I'm from the Second Circuit and as you know we don't uphold patents in the Second Circuit').

154 This is in effect the 'permit thicket', 'License Raj', or true anticommons problem discussed earlier.

155 Elimination of patents may not even be bad; in fact, the commercialization theory would embrace a decision to eliminate patents if it turned out that the commercialization benefits were outweighed by the costs of the system. The analysis offered here suggests reasons why that is not expected to be the case. The ultimate question, however, is an empirical one and is not answered here.

156 *See* Ronald J. Gilson and Mark J. Roe, *Understanding the Japanese Keiretsu: Overlaps Between Corporate Governance and Industrial Organization*, 102 YALE L.J. 871, 872 (1993).

157 The terms 'weak' and 'strong' are somewhat vague but the general idea is that the patents are either given very narrow scope and so are easily avoided or they are enforced with what amounts to liability rule treatment. *See* Toshiko Takenaka, *The Role of the Japanese Patent System in Japanese Industry*, 13 UCLA PAC. BASIN L.J. 25 (1994) (providing a general overview of the Japanese patent system and collecting sources).

deposition testimonies that are so infamously ingrained in litigation, especially in the U.S. system, further help those playing the *keiretsu* strategy to communicate vast quantities of more detailed information.

Second, they allow the battling *keiretsu* to communicate with each other in a way that may be more protected from antitrust review than a direct conversation (thus they mitigate an antitrust problem). The taking of one territory while yielding up another through a set of court battles will more easily escape antitrust scrutiny – and also will more easily mitigate the damages awarded if any antitrust action were brought and won – than would a direct conversation to divide these territories. Ensuring that each deal is struck in front of a federal judge helps decrease both the likelihood of scrutiny by antitrust enforcers and the chance that a later judge or jury will side with those enforcers and determine that the conduct was so egregious as to merit a particularly harsh civil or criminal penalty.

Third, having large numbers of patents can be a simple tool for extracting a higher price after regulatory interventions because in the large antitrust actions brought against large patentees, such as the well-known IBM litigation,[158] the amount the regulators allow the companies to charge is often based in part on the simple total of the number of patents in its portfolio. But what is essential to this *keiretsu* model is that only weak patents be available.

Large players are particularly likely to succeed in this *keiretsu* strategy if they can be assured that only weak patents are available, because patents with strong property protection could become the slingshots by which the Davids take down the Goliaths.[159] Conveniently for such large established firms, they typically have the strong lobbying budgets and contacts to ensure, through the public choice process, that weak patents predominate. The government legislators, regulators, and judges may be particularly responsive to the desires of those able to offer significant political or financial capital.

This *keiretsu* strategy is at least consistent with the recent explosion of antitrust regulation for patents. In October 2003, after conducting a year of joint hearings with the Department of Justice's (DOJ's) Antitrust Division 'to develop a better understanding of how to manage the issues that arise at the intersection of antitrust and intellectual property law and policy',[160] the

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158 *See IBM Ordered to Offer its Machines for Sale and Open Some Patents to Others in Antitrust Suit Settlement*, WALL ST. J., Jan. 26, 1956, at 3.

159 *See Picard v. United Aircraft Corp.*, 128 F.2d 632, 643–4 (2d Cir. 1942) (Frank, J., dissenting).

160 *See* Press Release, Federal Trade Commission, Muris Announces Plans for Intellectual Property Hearings (Nov. 15, 2001), *available at* http://www.ftc.gov/opa/2001/11/iprelease.htm (collecting sources, including links to Federal Register Notice and to speech by Chairman Timothy Muris, and questioning these and other

Federal Trade Commission (FTC) issued a report of over 300 pages that appears to represent only the patent portion of its own (not the DOJ's) conclusions and recommendations.[161] Many of the important recommendations of the report would make it so that the present U.S. patent system would only have weak patents.[162] Interestingly, the recommendations in the FTC Report closely correlate with data recently gathered and reported by Iain M. Cockburn and Rebecca Henderson.[163] This information was gathered from a 2002 survey of a group of senior intellectual property managers at large companies, which was sponsored by the Intellectual Property Owners Association. The close correlation between the recommendations in the FTC Report and the results of the survey is consistent with the view, espoused by some leaders in the field, that the agency 'got it right'. However, this data does not indicate whether the agency 'got it right' about the views of the same people at a different time, or other people situated differently, such as those who work in small- and medium-sized businesses or those endeavoring to approach the issue without a specific client or with a specific agenda in mind. Indeed, the

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aspects of the patent system); *see also* Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, 66 Fed. Reg. 58,146 (Nov. 20, 2001) (announcing joint hearings and explaining the reasons for them).

161 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; *see* Constance K. Robinson et al., *IP and Antitrust: US Antitrust Enforcement Agency Proposes Changes to US Patent Law*, COMPETITION LAW INSIGHT, Dec. 2003/Jan. 2004, at 23 (for an excellent and easily accessible brief review of the report and its main recommendations).

162 For example, the proposed changes on nonobviousness, utility, subject matter, economic impact, more involved examination, and deference would expose small- and medium-sized patentees to the concentrated public choice pressures that have repeatedly injected these pernicious judge- and agency-made laws into our system over the past 100 years. For more on the FTC report, see FED. TRADE COMM'N, *supra* note 161, at 10–17 (Recommendations 3–6, 8–10). Similarly, the proposed changes on increased funding would at worst raise the same objections and at best simply lead to waste because the information needed to determine validity over the prior art is more inexpensively provided by private parties in litigation. *Id*. at 74–98. The proposed change to give prior user rights for parties who infringe claims that are disclosed in a published application but not actually added to the claims portion of a patent application until after publication should be avoided because they would totally pervert the nuanced and smooth interaction between patent law's disclosure rules and the notice function of patents. Lastly, the proposed requirement for written notice or deliberate copying before a patentee could win enhanced damages for willful infringement should be avoided because they would make the patent right more like a liability rule and less like a property rule in ways that particularly favor bigger parties.

163 The author is grateful to Iain and Rebecca for generously sharing the results of their data. Interview with Iain M. Cockburn, Professor of Finance and Economics, Boston University School of Management, in Boston, Mass. (Nov. 11, 2003).

close correlation between the views of large patent holders and the FTC Report is consistent with a public choice agency capture story. This supports the perception that the FTC Report recommendations will lead to a more *keiretsu*-like approach for the U.S. patent system than ever before. That is, following the FTC recommendations may lead to a system under which large players could regularly trade large numbers of weak patents with each other while at the same time frustrating market entry.[164]

Public choice problems are an important countervailing consideration to the regulatory proposals suggested throughout the reward literature in response to concerns about property rights in patents, including concerns relating to power over price, transaction costs, anticommons, and behavioralism. In a comparative institutional analysis, the question is not merely whether a particular problem can be fixed, but rather if the general state of affairs would be improved by following a specific prescription for fixing a particular problem.

What is perhaps most striking about the commercialization theory, given that it is neither the majority nor the minority view within the conventional literature on the law and economics of intellectual property, is that it was the central motivation behind the framing of at least the present patent system, the 1952 Patent Act, and served as part of the motivation behind the present trademark system, the 1946 Lanham Act.[165] Moreover, while the commercialization

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[164] For a more extensive discussion of the many ways corporations can wield influence over legislatures and regulatory agencies, see Jill E. Fisch, *How Do Corporations Play Politics?: The FedEx Story*, 58 VAND. L. REV. 1495 (2005) (exploring in detail, through a case study of one corporation over the past 40 years, the numerous mechanisms by which corporations influence government actions, other than by directly buying political favors with campaign contributions, such as lobbying, maintaining general popularity and fame, and doing favors for government officials and organizations).

[165] *See, e.g.*, Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC'Y 159 (1942). The article was printed as a series: 24 J. PAT. OFF. SOC'Y 85 (Feb., 1942), 24 J. PAT. OFF. SOC'Y 159 (Mar., 1942), 24 J. PAT. OFF. SOC'Y 241 (Apr., 1942), 24 J. PAT. OFF. SOC'Y 328 (May, 1942), and 24 J. PAT. OFF. SOC'Y 422 (Jun., 1942). The central framer of the present U.S. patent system specifically focused on commercialization:

> The third aspect of inducement is by far the greatest in practical importance. It applies to the inventor but not solely to him, unless he is his own capitalist. It might be called inducement to *risk an attempt to commercialize the invention*. It is the 'business' aspect of the matter which is responsible for the actual delivery of the invention into the hands of the public.

Rich, 24 J. PAT. OFF. SOC'Y 159, 177 (Mar., 1942) (emphasis added).

theory is discussed by the conventional literature, it is often misperceived in at least two ways: First, the theory is often misperceived on its own terms. Second, the solutions it offers for many of the problems generally identified with patent rights often are overlooked. Both types of misperception are discussed below.

The focus of the commercialization theory is on the incentives for diffuse individuals to decide individually to act in a way that facilitates coordination. While rewards may provide an incentive for the individual reward recipient to act, rewards do little, as compared with property rights, to bring that individual together with all other complementary users to engage successfully in the complex commercialization process.[166] Regrettably, this simple mechanism of the commercialization theory's coordination function is often misunderstood in the literature in several respects.

First, the link is often confused between the commercialization theory and the prospect or rent dissipation theories.[167] Put simply, while the *commercialization* theory focuses on the ability for intellectual property to coordinate efforts among *complementary* users of an asset to *increase* (or avoid insufficient) use of resources, *prospect* theory focuses on the ability of intellectual property to coordinate efforts among *competing* users of an asset to *decrease* (or avoid excessive) use of resources.[168] Therefore, efforts to respond to the

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166 Compare the focus on providing direct incentives to the holder of the patent rights under the reward theories. *See, e.g.*, Lemley, *supra* note 5, at 130 (discussing the role of intellectual property as an '[incentive] the right gives its owner').

167 *See, e.g.*, Lemley, *supra* note 5, at 141 n.42 (referring to commercialization theory as an 'elaboration' on 'prospect' theory). In addition, unlike the prospect and reward theories, the commercialization theory, and its companion registration theory, has explanatory power for the positive law rules of the patent legal institutions.

168 For game theory examples of the formal link between the role property rights can have in these two different settings, described in that article as racing games and mating games, see Dale T. Mortensen, *Property Rights and Efficiency in Mating, Racing, and Related Games*, 72 AM. ECON. REV. 968 (1982). One additional point about rent dissipation that bears mentioning is that it also teaches something about the coordination theory of property. More specifically, what is often overlooked in viewing property rights as tools for internalizing externalities is that the free rider, tragedy of the commons, and positive externalities problems each can be thought of essentially as an inverse of the problem of rent dissipation. The problems of free riding, commons, and positive externalities refer to cases in which individuals within a group decide not to invest in a given activity for fear that others will benefit but not compensate. As a result, too little of the activity is produced. The problem of rent dissipation refers to a case in which individuals within a group decide to invest in a given activity for fear that others will do the same and win the race for the common prize. In this instance, too much of the activity is produced. In both cases, the failure to coordinate leads to inappropriate amounts of the given activity being conducted.

prospect and rent dissipation theories' concerns about overuse are inapposite to commercialization theory.

Second, the link between the commercialization theory for patents and the theory of property rights is generally overlooked. That is, much of the conventional literature overlooks the coordination function in its entirety, simply lumping the property rights aspects of the prospect theory by Kitch with the property rights aspects of Demsetz's work on internalizing externalities.[169] However, as discussed earlier in this chapter, property acts as a tool for facilitating coordination among complementary users of assets protected by patents in a way that is not explored in the early Demsetz work or in the work by Kitch.

Third, the commercialization theory has also been erroneously confused with the work of Schumpeter in being focused on the patent holder's assertion of control.[170] While the commercialization theory is focused on who will have both the incentive and the ability to negotiate with whom, it is agnostic as to who will end up controlling those negotiations. In fact, determining who will control is ultimately a function of a great many factors other than who owns the patent. For example, factors such as the parties' relative wealth effects, bargaining positions, negotiating skills, other resources, holdout prices, and alternative options will each impact the bottom line issue of control. In a world in which each market player may bring their own skill set, patent set, technology set, and other assets and opportunities to bear on the development of a

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[169] *See, e.g.*, Julie E. Cohen, *Lochner in Cyberspace: The New Economic Orthodoxy of 'Rights Management'*, 97 MICH. L. REV. 462, 497 n.121 (1998) (citing work by Demsetz and noting '[s]imilar reasoning underlies Edmund Kitch's proposed "prospect" approach to patents'); Eisenberg, *supra* note 115, at 1040 (citing work by Kitch and Demsetz and noting, 'The prospect theory offers a justification for patents that is in keeping with broader theories of property rights elaborated by Harold Demsetz . . . .'); Neil Weinstock Netanel, *Copyright and a Democratic Civil Society*, 106 YALE L.J. 283, 309 n.108 (1996) (citing work by Kitch and Demsetz and noting, 'For neoclassicists, therefore, intellectual property is less about creating an artificial scarcity in intellectual creations than about managing the real scarcity in the other resources that may be employed in using, developing, and marketing intellectual creations.'); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 121 n.236 (1999) (citing Kitch, *supra* note 128, at 276; *Toward a Theory of Property Rights I*, *supra* note 69).

[170] *See, e.g.*, Lemley, *supra* note 5, at 139 n.35 (discussing the role of patentee as coordinator due to the control exerted through the patent and citing Kieff, *Commercializing Inventions*, *supra* note 14; Schumpeter, *supra* note 78, at 100–02); *see also* Lemley, *supra* note 11, at 139–40 (suggesting that when the government assigns the intellectual property right, it effectively selects who will have 'control over an area of research and development rather than trusting the market to pick the best researcher').

particular patented subject matter, the end result of who controls the subsequent development and use of that subject matter is unclear. Indeed the issue of control is often left to the market and private bargains.

For this reason, the concern raised by Robert Merges and Richard Nelson regarding owners of patents exercising excessive control is overstated.[171] The mere fact that a particular patent right is broad does not mean that its owner will control negotiations with others in that same technology. In this regard, the coordination function of patents is distinct from the two extremes of open competition and control. The patent right facilitates coordination among both competing and complementary users of the asset without determining who will control in any given case, and the commercialization view of patents focuses on the importance of a patent backed by a property right as a tool for facilitating such a division of labor and other forms of specialization.

Fourth, the importance the commercialization theory places on the distinction between ex ante and ex post may be confused by the different use of those terms recently by Mark Lemley.[172] Under the commercialization theory, for patents to serve the commercialization function, the rules about how patents can be obtained and enforced must be knowable to all market actors ex ante, in advance of their decisions about whether to act. This means that regulation and liability rule treatment may be suspect, at least to the extent that they have the effect of rewriting agreements or changing rules ex post. When used in this context, the terms 'ex ante' and 'ex post' are used in their general sense, which is different from their use in the recent work by Lemley.[173]

Lemley uses the term 'ex ante' in a special narrow sense to refer to the time period before any specific creative work is made.[174] Similarly, he uses the term 'ex post' in a special narrow sense to refer to a time period after any specific creative work is made.[175] The commercialization theory relies on the term 'ex ante' in the more general sense to refer to a time period before any given act occurs, with a focus on the importance of predictability. For example, this view of ex ante focuses on the period before the textured contracting needed to facilitate commercialization takes place. Similarly, it relies on the term 'ex post' in the more general sense to refer to a time period after any given act occurs, again with a focus on predictability. This view of ex post focuses on the period after the contracting has taken place. As these terms are

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171 *See* Robert P. Merges and Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990) (studying the problem of a single firm controlling development of a particular technology).

172 *See* Lemley, *supra* note 5.

173 *Id*.

174 *Id*. at 130.

175 *Id*.

used for purposes of the commercialization theory, the focus is on the ability of private actors to predict a legal result before deciding whether, or in what way, to act on any specific issue. Under the commercialization view, predictability ex ante is essential in facilitating private ordering.

Fifth, some have suggested that 'if patent law's concern is to ensure commercialization of inventions, then it is both overinclusive and underinclusive'.[176] The point is well taken as far as it goes, but it may not account for the full reach of the commercialization theory. On the question of overinclusiveness, Abramowicz points out that 'sometimes first-mover advantages will outweigh second-mover advantages'.[177] This is correct, but only where a sufficient number of the complementary users of the asset believe that this is the case ex ante – and believe so with sufficient conviction to take on the coordinating role – will coordination so easily take place without the property right. This can, and likely does, happen. However, the point of the commercialization theory is that patent rights can make it easier for this to happen in many more settings. On the question of underinclusiveness, Abramowicz further points out the need for commercialization of subject matter that does not meet the positive law rules for patent protection.[178] But the point of the registration component of the commercialization theory of patents is that the positive law rules for obtaining patents are normatively important for protecting the reasonable investment-backed expectations of potential commercialization efforts by third parties. Put simply, these positive law rules about patent validity are essential for making the patent system work well. The extent to which they leave behind some subject matter is a reason to explore the use of other tools to help coordination in those areas, such as perhaps the firm, or maybe the government. Patents do not solve all problems and are offered merely as an additional tool for helping to solve some.

The commercialization theory also provides several overlooked solutions for the underlying problems often associated with patents. These include the problems of transaction costs, anticompetitive effects, and access.

The commercialization theory sees the patent right backed by the credible threat of an injunction as playing an essential coordinating role for all the players in the commercialization process.[179] Those wishing to buy title to or

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176 Abramowicz, *supra* note 263, at 174.

177 *Id*.

178 *Id*. at 174–5 ('Patent law is underinclusive because commercializers of unpatentable inventions also face the prospect of copying.').

179 By focusing on the right to exclude, the commercialization theory of intellectual property differs in important ways from the general theory of property in land and goods, which typically consider more than the right to exclude. Adam Mossoff provides an excellent historical account of property theories that emphasizes the fail-

permission under the patent right must negotiate with the patent holder. As long as the existence of the patent right and the identity of the patent holder are readily discernible, each of the putative participants in the commercialization process will have an individual incentive to seek out and negotiate with that person, and through that person, with each of the others.

While the reward literature has emphasized the concerns about output restrictions, or problems of access, the discussion below points out why such concerns are significantly less severe than perceived, and why in some cases property rights may be essential for mitigating them. It also shows both why the concerns about government and public choice must not be overlooked, as well as the ways in which these problems can be either magnified or mitigated by particular aspects of positive law patent regimes. As a result, it shows several aspects of the present positive law regimes that are candidates for change because they only exacerbate the problems of anticompetitive effect and access.

As discussed above in the context of reward theories, much of the literature on patents is consumed with concerns about limiting the potential monopoly power associated with property rights. Yet, actual empirical data is inconclusive, for example, as to whether patents have been used to facilitate cartel behavior.[180] Although a dominant concern of the reward is that patents can confer power over price of the type generally associated with monopolies, the connection this literature draws between patents and monopolies is backwards in several respects. As discussed below, patents often do not confer monopoly power; yet they can be essential antimonopoly weapons, and their availability can serve as an effective antimonopoly vaccine for a market.

In large part, patent rights often do not confer monopoly power because there is rarely a one-to-one correlation between any particular patent asset and a market. In addition, patents face competition from alternative technologies, both extant and potential. For example, even a patent on a better mousetrap faces competition from existing spring and glue traps, the threat of future traps, and, of course, from cats.

Moreover, patents can facilitate market entry, at least so long as they are backed by property rules. As a result, they can be powerful antimonopoly

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ure of approaches that focus only on the right to exclude. *See* Adam Mossoff, *What is Property? Putting the Pieces Back Together*, 45 ARIZ. L. REV. 371, 376 (2003) ('The concept of property is explained best as an integrated unity of the exclusive rights to acquisition, use and disposal; in other words, property is explained best by the integrated theory of property.'). *But see, e.g.*, Thomas W. Merrill, *Property and the Right to Exclude*, 77 NEB. L. REV. 730, 747–8 (1998) (suggesting the right to exclude is a central feature of property).

[180] *See* Christopher D. Hall, *Patents, Licensing, and Antitrust*, 8 RES. L. & ECON. 59 (1986).

weapons. For example, the commercialization theory suggests that if meaningful patent rights had been available in the computer software industry in the 1970s and 1980s, by the time of the Microsoft antitrust suit, the industry likely would have been characterized by a medium number of medium-sized players rather than a single large player.

As another example, consider the impact on competition of the 1980 shift in positive patent law: Only in the United States and only since 1980 have patents been available in modern biotechnology. While the United States, Europe, and Japan each had large biotechnology companies, often collectively called 'Big Pharma',[181] before 1980, and still had them after 1980, only in the United States and only since 1980 has the biotechnology industry also included a steady pool of roughly 1,400 small- and medium-sized companies that is consistently turning over.[182]

In addition, the gains that patent rights offer for competition and market entry across markets at any one time, as well as across time, offset the potential for individual deadweight loss in cases where a patent right truly conveys a monopoly at some point in time for some market. In part, this point is tied to the distinction between dynamic and static efficiency, which is to say that the static inefficiency associated with monopoly deadweight loss may be outweighed by the dynamic efficiency gains associated with innovation and entry.

What is more, patents can and often do operate to facilitate price discrimination, which can mitigate the deadweight loss efficiency considerations of monopolies. That is, the use of property rights in patents is also consistent with another basic work by Demsetz in which he demonstrated that (1) private producers can produce public goods efficiently given the ability to exclude nonpurchasers, and (2) price discrimination is consistent with competitive equilibrium for such public goods.[183] Indeed, because of the doctrines of indirect infringement, patent rights facilitate price discrimination through tying in

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[181] *NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 108th Cong. 49 (2003), *available at* http://energycommerce.house.gov/108/action/108-38.pdf (statement of Phyllis Gardner, Senior Associate Dean for Education and Student Affairs, Stanford University) (detailing the differences between the biotechnology industry and the pharmaceutical industry).

[182] *Id*. at 47. At the same time, both Europe and Japan have demonstrated technological capacities in this industry that are comparable to the United States. In addition, both Europe and Japan have comparably developed capital markets. Even if they did not, businesses could operate in Europe and Japan while still having access to the capital markets in the United States.

[183] Harold Demsetz, *The Private Production of Public Goods*, 13 J.L. & ECON. 293 (1970).

a great many more cases than otherwise. (Including, for example, where tying is not facilitated by technological constraints.)[184]

While patent rights do give some power over price, and therefore are associated, in theory, with some deadweight loss, the actual monopoly effects of patents often are overstated and the antimonopoly benefits of patents often are overlooked. In the real world, the benefits of this type of market power for capital formation and dynamic competition must be weighed against its theoretical cost in the form of static deadweight loss. Indeed, there are many reasons why it may be prudent to avoid letting antimonopoly concerns drive us to respond too aggressively to every occasion of power over price. In this sense, the reward literature's concern over mitigating monopoly effects of patents can be seen as unduly exalting static efficiency over dynamic efficiency.[185]

While the commercialization theory sees the nature of a patent to be essential to the ability for patents to facilitate coordination, it recognizes that this coordination requires transactions. One of the central focuses of the reward theories is on the transaction costs associated with patents compared to a commons. Thus, it is appropriate to compare the transaction costs of

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[184] There are several aspects of the positive law intellectual property regimes that facilitate complex contracting of the type that can both facilitate coordination and decrease output distortions of a property right. For example, the work-for-hire doctrine in copyright law helps concentrate ownership in a work that results from a complex production process. Further, the provisions of Section 271 of the Patent Act insulate patentees from fear of liability for misuse. This allows patentees to elect to sue or to license anyone who would otherwise be liable for direct infringement, induced infringement, or contributory infringement. *See* 35 U.S.C. § 271(a)–(d). Before the 1952 Act, courts used the misuse doctrine to erode the ability of intellectual property owners to engage in price discrimination or restrictive licensing. Section 271(d) expressly states that such conduct shall not be misuse. *See Dawson Chem. Co. v. Rohm & Haas Co*., 448 U.S. 176 (1980) (recognizing impact of Section 271(d) and its reason for inclusion in the 1952 Patent Act). To be certain this was clear, Congress acted again in 1988 by adding subparts 4 and 5 to Section 271(d) of the Patent Act to expressly provide that neither a refusal to license nor a tying arrangement in the absence of market power is patent misuse. § 271(d)(4)–(5) (added by Pub. L. No. 100–703, § 201, 102 Stat. 4674 (1988)). The trademark regime allows similar contracting, but because the need to make commercial use of the subject matter protected by trademarks is less compelling than for patents – since functionality is a bar to trademark protection – the impact of any remaining distortion caused by market power is less severe. That is, there is still the potential for static economic deadweight loss, but the alternative moral claims about output effects are mitigated.

[185] *See, e.g.*, STAN J. LIEBOWITZ and STEPHEN E. MARGOLIS, WINNERS, LOSERS & MICROSOFT: COMPETITION AND ANTITRUST IN HIGH TECHNOLOGY [pincite] (1999) (showing that truly inefficient outcomes are extremely rare, and instead, that even situations of serial monopoly may be the best available in reality).

exchanges over property rights in patents against the transaction costs of exchanges over what otherwise would be the subject matter of patents, but instead were within a realistic commons, such as the putative commons of basic academic knowledge.[186] But even this so-called 'commons' is riddled with its own form of less commercial but nonetheless important property rights known informally as 'kudos', which include more personal and less fungible assets generally associated with academic and public sectors such as reputational benefits, fame, promotions, awards, and titles. A comparative institutional analysis reveals why, for exchanges in that setting of a putative commons as compared with the same setting having added patent rights, the transaction costs of exchanges are likely to be worse without patents than with patents because patents bring increased wealth and diversity to that market.

As discussed earlier in this chapter when exploring transaction costs generally, transaction costs are likely to be more pernicious in thinner markets than in thicker markets, and the use of patents thickens the market. In addition, recent work by Buchanan and Yoon adds to this analysis by pointing out that exchanges in such a commons also are more likely to fail because of what they call the 'non-economic motivations' associated with such assets.[187] There are reasons to think that transaction costs are likely to be higher for a commons as compared to patents. Indeed, recent empirical work by John Walsh, Charlene Cho, and Wesley Cohen did not find transaction costs problems associated with patents in basic science, essentially because potential infringers engaging in low value uses were simply being allowed to infringe with approval, albeit tacit, from patentees.[188]

It is recognized that enforcement mechanisms within norm communities like academic science do have important benefits over those within formal legal systems by courts. The work by Lisa Bernstein on relational contracting within homogeneous communities shows how enforcement within norm communities can trigger lower administrative costs than with formal legal institutions because it relies on informal institutions for enforcement and dispute resolution such as norms and reputation.[189] Similarly, recent work by

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[186] *See, e.g.*, Rai, *supra* note 169 (arguing that intellectual property rights impose greater transaction costs than the basic scientific norms in the open 'commons' of academics); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987) (exploring the potential negative impact of patent rights on scientific norms in the field of basic biological research).

[187] James M. Buchanan and Yong J. Yoon, *Symmetric Tragedies: Commons and Anticommons*, 43 J.L. & ECON. 1, 12 (2000).

[188] John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005).

[189] *See, e.g.*, Lisa Bernstein, *Opting out of the Legal System: Extralegal Contractual Relations in the Diamond Industry*, 21 J. LEGAL STUD. 115 (1992) (show-

Barak Richman comes closer to the theory of the firm literature and focuses on the importance of the private enforcement and dispute resolution techniques as means for ensuring not just lower administrative costs, but also better contractual enforcement and enhanced transaction certainty.[190]

While Barak Richman has shown that private enforcement mechanisms may, under appropriate conditions such as small and homogenous communities, also provide even more transactional security at a lower administrative cost than public enforcement,[191] the option of public enforcement benefits

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ing how some communities opt for informal private enforcement mechanisms for contractual relationships instead of formal legal approaches because the administrative costs can be lower); *see also* Lisa Bernstein, *Private Commercial Law in the Cotton Industry: Creating Cooperation Through Rules, Norms, and Institutions*, 99 MICH. L. REV. 1724 (2001). Bernstein's use of the term 'private governance' to refer to private enforcement is consistent with the use by Williamson, which is narrower than the use in this chapter, which encompasses all private interactions voluntarily entered. *See also* Steven L. Schwarcz, *Private Ordering*, 97 NW. U. L. REV. 319 (2002) (also using the term 'private ordering' to refer to private enforcement or regulation). This chapter's view of property rights differs from both of these perspectives by seeing private ordering in a more general sense than simply private enforcement. Instead, private ordering is seen as the set of interactions among individuals that are more reliable because they are enforced in some way, whether by private informal institutions, such as norms, or by formal legal institutions, such as the coercive power of the state. This view is consistent with traditional liberal views of the rule of law and role of government as the monopoly over the coercive powers, such as force, to back property rights and contractual arrangements. Such backing enhances the overall market economy by enhancing individual liberty to deploy one's resources in whatever way best suits that individual. *See, e.g.*, North, *supra* note 96 (elucidating the importance to economic growth of the reliable enforcement of property rights and contracts by formal public legal institutions); DOUGLASS C. NORTH AND ROBERT PAUL THOMAS, THE RISE OF THE WESTERN WORLD: A NEW ECONOMIC HISTORY (1973) (putting property rights at the center of the explanation of economic performance); Avner Greif & Eugene Kandel, *Contract Enforcement Institutions: Historical Perspective and Current Status in Russia*, *in* ECONOMIC TRANSITION IN EASTERN EUROPE AND RUSSIA: REALITIES OF REFORM 291 (Edward P. Lazear ed., 1995) (same); *see also* Friedrich August von Hayek, *The Principles of a Liberal Social Order*, *in* THE ESSENCE OF HAYEK 363 (Chiaki Nishiyama & Kurt R. Leube eds., 1984) (providing general discussion of the theory of liberal government including its use of coercive powers to enforce law).

[190] Barak D. Richman, *Firms, Courts, and Reputation Mechanisms: Towards a Positive Theory of Private Ordering*, 104 COLUM. L. REV. 2328, 2332 (2004) ('This Essay argues that concerns over transactional assurance and contractual enforcement, not . . . administrative costs, drive merchant communities to private ordering (and to vertical integration as well).').

[191] *But see* Barak D. Richman, *Community Enforcement of Informal Contracts: Jewish Diamond Merchants in New York* 24 (John M. Olin Ctr. for L., Econ. & Bus., Discussion Paper No. 384, 2002), *available at* http://www.law.harvard.edu/programs/olin_center/papers/pdf/384.pdf (contrasting benefits and costs of, *inter alia*, private and public enforcement mechanisms under different conditions).

those under other more generalized or diverse conditions. As Troy Paredes explains within the context of corporate and securities laws: '[W]hen laws are in place, parties can rely less on personal and family relationships when transacting, allowing them to engage in transactions with strangers'.[192] Put differently, the benefits of improved enforcement characteristics of close-knit norm communities are contingent on the community being closed to outsiders.

Keeping transactions entirely within a particular organization like a firm or norm community also raises the disadvantages that Stephen Haber calls the problems of 'crony capitalism'.[193] The enforcement benefits within closed organizations are due to the specificity of investments the community's members must make in them, which bring along the inevitable concerns about opportunism. What is more, the attributes that underlie the unique connection to the community, such as family, religious, or ethnic affiliation, or a close relationship with the community leadership, are typically nonfungible in that they cannot easily be traded, divided, or bundled.

The development of software like Linux within a community that adheres to an open source philosophy can be seen as one example of a coordinated activity that occurred within a norm community around a coordinating device akin to fame rather than around more formal property, like patents. Under this view, the fame of Linus Torvalds allows him to control development of the Linux kernel to ensure that it occurs in a coordinated fashion. The ability for fame or other focal points to achieve coordination is consistent with the beacon view of property.[194]

While open participation would seem to be a touchstone promise of open source, several empirical studies of several different open source software projects have shown that this openness is not experienced in reality. Changes to the actual projects in these cases are limited to a very small number of individuals in different, cohesive control groups for each case studied.[195] While it

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[192] Troy A. Paredes, *A Systems Approach to Corporate Governance Reform: Why Importing U.S. Corporate Law Isn't the Answer*, 45 WM. & MARY L. REV. 1055, 1064 (2004) (noting that '[s]trong legal protections for shareholders expand the available pool of capital for businesses and entrepreneurs and facilitate contracting by shoring up shareholder rights').

[193] STEPHEN HABER, CRONY CAPITALISM AND ECONOMIC GROWTH IN LATIN AMERICA: THEORY AND EVIDENCE (2002).

[194] *See also* Randall L. Calvert, *The Rational Choice Theory of Social Institutions: Cooperation, Coordination, and Communication*, in MODERN POLITICAL ECONOMY: OLD TOPICS, NEW DIRECTIONS 216, 244 (J.S. Banks and Eric A. Hanushek eds., 1995) ('Recognizing or creating focal points is one important way in which the players can successfully coordinate.').

[195] *See* Jai Asundi et al., *Examining Change Contributions in an OSS Project: The Case of the Apache Web Server Project* (2005) (unpublished manuscript, on file

makes sense as a practical matter to have a small group for information processing needs,[196] this stark difference from the rhetoric of the legend matters a great deal. Unlike the formal property rights in patents, the fame that is the key to the open source type of centralized coordination is less easily transferred, divided, or bundled. It also is specific to that community. In addition, fame can be more difficult to obtain in general than property. And its exclusivity makes it more difficult for diverse individuals to obtain. At bottom, the element that allows control by the leader within a norm community, whether it be fame or some other special community attribute, is only available to those who are insiders – in the case of Linux, that includes only Torvalds and his chief lieutenants. Simply put, the above discussion elucidates some reasons why relying on norm communities, like open source projects, to the exclusion of property would have the effect of generally biasing against new entrants and in favor of those who are members of the establishment.

4 Conclusion

Although many different useful perspectives have been offered in the literature about the goals society should have in mind before deciding to create property rights in general and patent rights in particular, a too often overlooked goal is coordination. This chapter suggests that coordination of the type needed to facilitate commercialization is a goal that can be achieved by property rights in general and patent rights in particular. Coordination of this type is useful in helping diverse members of society remain diverse from each other in terms of skills, assets, and preferences, while at the same time interacting with each other as complementary users of assets in a way that helps bring those assets to market. Focus on coordination is offered as an alternative to focus on other goals that have been suggested in the literature, including internalizing externalities, avoiding rent dissipation, and providing direct incen-

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with author) (providing data for the Apache project and discussing numerous examples of empirical studies of other projects).

[196] The smaller the control group, the more intense can be the information content of the communications among them. As Henry Smith has pointed out there is a fundamental informational tradeoff:

> As audience size increases, the marginal benefits of intensive communication are likely to decrease and the marginal costs are likely to increase. Thus, to minimize the sum of communication costs, any communication system faces a tradeoff between information intensiveness on the one hand and information extensiveness on the other.

Henry E. Smith, *The Language of Property: Form, Context, and Audience*, 55 STAN. L. REV. 1105, 1111 (2003).

tives. Further, property rights are offered as an alternative tool for achieving this goal, in contrast to other institutions and organizations, including norm communities like open source projects, firms, and government. Recognizing that each institution and organization will have benefits and costs, the chapter also highlights strategies for helping to ensure that the benefits of property rights are enhanced while the costs of property rights are mitigated or otherwise structured so as to be more easily borne. Taking seriously the recognition that any effect, including coordination, can have both good and bad forms, the chapter further explores often-overlooked ways in which the various prescriptions that dominate the literature can have the counterproductive effect of facilitating the bad type of coordination that frustrates competition. The chapter elucidates why institutional choices for patent regimes that have been motivated by conventional approaches toward patents, which focus on rewards, and that have not focused on coordination, have turned out to be both less effective and less efficient in improving access and competition than suggested by their proponents.

2 Patents and policies for innovations and entrepreneurship[1]

Ove Granstrand

1 Introduction

While few observers nowadays question the emergence of an ever more knowledge-based economy, the expression 'the new economy' can be questioned. What is 'new' is the fact that the economy has come to be dominated by intellectual capital in different forms (human, relational, intellectual property (IP) etc.) – together defined as non-physical, non-financial capital, which is related mainly to long-run accumulation of valuable knowledge – technical knowledge (i.e. technology) in particular (e.g. information and communication technologies), knowledge which is embedded in innovations launched by entrepreneurs, especially corporate entrepreneurs. At the same time, traditional capitalistic institutions have not only survived but become strengthened and globalized after the downfall of the Soviet empire. Intellectual property (IP) and legal rights to it ('IPRs') have consequently become much more important, and a new IP regime, including a 'pro-patent era', has developed since the 1980s, originating in the US. Its effects are pervasive at various levels, not least internationally. Countries and companies arm themselves with strengthened IP rights as competitive means, at present with the USA and Japan in the lead. Patent and IP issues, once obscure secondary questions for specialists, have thereby become strategic and risen to high levels of political and industrial management. On the other hand, there are difficulties in integrating these issues with other economic policies and company strategies – although these difficulties appear by and large to be temporary. A trend toward a more aggressive patenting policy can be expected in countries such as China, Taiwan and Korea, which are thus further increasing their technology-based

[1] The chapter is to a large extent based on research in connection with a Swedish governmental investigation of economic policy issues related to patenting and economic growth in Sweden and abroad. The full report is in Swedish, authored by O. Granstrand, with reference: SOU (2006:80), *Patents and Innovations for Growth and Welfare* (*Patent och innovationer för tillväxt och välfärd*) (Stockholm: Fritzes Publishing Co., 2006).

competitive power and are likely to catch up and forge ahead, similar to the case of Japan.[2]

Numerous inquiries, policy studies and reforms have been carried out in the patent and IP area after the advent of the pro-patent era. The studies and work on many policy issues in Europe, regarding, for example, the proposal for a community patent, common policies for patent dispute resolution, proposals to reduce the number of translations, and common policies for computer-related inventions, have made little progress, whereas strong measures have been introduced in countries such as Japan and Korea. Thus, Japan, for example, has introduced a new basic law on IP and created an interministerial 'Strategic Council on IP' directly under the Prime Minister in order, among other things, to transform Japan into an 'IP-based nation'. A concerted patent reform effort began in the USA in 2000 and has been ongoing ever since, via continual implementation of a series of small changes. The shape of the reforms in the USA is still emerging and somewhat unknown as the reforms ultimately involve the competing interests of major economic players (notably the electronics and software industry versus the chemical and pharmaceutical industry). National economic aspects play a great role in all this reform work. The situation in China and India is less clear, although both countries are increasingly pro-patent and have experienced substantial increases in domestic patent filings. IP questions, especially in China, have been raised to the highest political level – largely because of America's international activism against pirate copying, but also due to Chinese actors' growing self-interest in patenting.

2 Patents, innovation, entrepreneurship and economic growth – a brief review

The economics of patents and innovation must be seen from both the micro and macro perspectives of business and society. Basic concepts are inventions and innovations of different kinds (technical, organizational, financial, product and process innovations, etc.) and size (large/small or radical/incremental), launched by entrepreneurs of various kinds (autonomous, corporate, state, university, etc.) generating diffusion of innovations among buyers and sellers, during which imitation usually occurs to some extent, for example, partial imitation of a new technology. Basic models include the product life-cycle model and interactive innovation-activity models. Generic strategies for

[2] There is by now an abundance of academic as well as popular literature on these developments. For further readings, see Granstrand (2000, 2003, 2004, 2005, 2006, forthcoming 2009), SOU (2006: 80) Guellec and van Pottelsberghe (2007), Jaffe (2000), Jaffe and Lerner (2004), Landes and Posner (2003), Merrill et al. (2004), Scotchmer (2004) and Takenaka and Nakayama (2004). Classic writings on catch-up dynamics are Abramovitz (1986, 1991).

investment in new technologies and their exploitation in a business economic perspective include in-house R&D, production and marketing; acquisitions and spin-offs; different types of collaborations, joint ventures and external partnering; in- and out-licensing; divestment and finally residual types of in- and outflows of technical information and knowledge (i.e. technology). These strategies are becoming ever more common and have important effects on growth and financing.[3] There are also several generic forms of financing (internal/external, public/private, loan/equity etc.).

The patent system's structure and processes are designed to stimulate invention, innovation and diffusion by giving the inventor/innovator a sufficiently strong and long-lived competitive advantage against imitation in return for public disclosure of information about the invention. The patent system has advantages and disadvantages on diverse levels and there are several theories underlying the system. In this connection, much traditional as well as new criticism of the patent system's drawbacks has been voiced. The customary criticism of the patent system concerns its costs for society in the form of static limitations on competition and monopolistic pricing, administrative costs and transaction costs, including high costs of disputes, distorting effects, and opportunities for abuse. This is reinforced by the more recent criticism that too many patents, also of poor quality, are granted in too many sectors where they hinder progress more than promoting it, for example, in the electronics and telecommunications domain, especially the software sector. Further, critics argue that there is unfair treatment of small companies, and of developing countries which are becoming too dependent on the technology of large companies and developed countries. In addition, the system as it has evolved during the pro-patent era is criticized for paying excessive attention to big industry's interests in the developed world, notably in the USA. Society's interest in, for example, open access to R&D results has been deferred in this respect. In sum, the recent criticism implies that not only static competition, but also dynamic competition, is restricted by an overly strong patent system, which thereby counteracts its fundamental aim of promoting dynamic competition – that is, innovation-based competition – partly at the expense of static competition. Of course, these critics acknowledge that each individual patent right expires completely after 20 years, and, therefore, focus their criticisms on the active 20-year period.

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[3] Note that these strategies represent different degrees of organizational integration or conversely 'openness' (with the current notion of 'open innovation' as a special case). The more open strategies for technology exploitation are usually associated with lower company growth compared to in-house production and marketing, everything else being equal.

Growth studies of different kinds (empirical, theoretical) have rather unambiguously indicated the decisive role of technological and organizational development for economic growth on the macro level, in the form of different kinds of innovations. Here, the patent system has traditionally been fairly weak and has played a secondary role, with certain important exceptions (e.g. in chemicals and pharmaceuticals). By and large the patent system has historically been neither necessary nor sufficient for either economic or technological development, which is somewhat surprising given its purpose to stimulate technological development and the decisive role of new technologies for economic growth. The inherent tendency of markets with fully free competition to fail to generate valuable but costly innovations that are cheaply imitable is mitigated by a number of government incentivizing policies and company appropriation strategies, however.

On the micro level, the links are more varied and unclear. It can be demonstrated theoretically that innovations of different kinds usually contribute to companies' growth – but not always, and especially not for process innovations even if these have perfect patent protection or secrecy protection. Neither do inventions theoretically necessarily contribute to welfare although they could usually be expected to.[4] (Empirically, military innovations are a case in point.)

Empirically, no general results exist that point to a single size group of companies or type of entrepreneurs as being most important for growth. Rather, the synergies between companies and their strategies in an innovation system are of great importance. Studies during recent years have shown, for instance, the significance of technology diversification, generic technologies and convergent technologies, and 'creative accumulation' for technology-based companies' growth – companies which thus become multi-technological. Structural changes in the form of company acquisitions and spin-offs also have high growth potential.[5]

Thus our state of knowledge about the role of patenting in company growth and development is generally somewhat vague. This fact is connected with a formerly weak patent system and a low interest among economists in patent issues, which traditionally have been handled by lawyers and licensing executives. However, foreign as well as Swedish studies have revealed certain positive links, although weak, between patenting and corporate growth. These studies have also revealed a related 'patenting paradox' – the fact that companies,

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[4] See Granstrand (forthcoming 2009) for proof of the former statement and Baumol (2002) for proof of the latter.

[5] See Granstrand and Sjölander (1990a, 1990b) and Granstrand et al. (1997), and Oskarsson (1993) and Lindholm (1994).

especially in chemistry and pharmaceuticals, nonetheless do considerable patenting despite uncertainty about the economic value of any given patent. That growth generates R&D, which in turn generates patents, has been shown more clearly across industries, albeit again with variations. Thus, growth generates patents while the opposite relationship is weaker and less clear.[6]

Still, the state of knowledge will very probably be strengthened in the future, just as the links between patenting and economic development have probably been strengthened by the pro-patent era's emergence. At the same time, the fact remains that the variations in economic importance between different patents are very large, and this hinders or sometimes totally frustrates making statistical inferences with reasonable confidence.

As for Sweden, a major study conducted by the Royal Swedish Academy of Engineering Sciences ('IVA') and the Swedish Patent Office ('PRV') during the early 1990s pointed to a Swedish 'growth paradox' of strong R&D development and weak growth development. At the same time, the development of Swedish patenting was quite weak, especially in comparison with Japan, which exhibited strong growth of R&D, industrial production and patenting in the 1980s. Further, the study identified a number of weaknesses regarding exploitation of technology in the Swedish system of innovation and entrepreneurship.[7]

3 Economic theories of the patent system[8]

3.1 Overview

Classical economic theories of the patent system build on old notions that in the absence of patents underinvestment in R&D and innovation would occur and/or that too much secrecy would occur. Thus an extra incentive to invent, disclose and innovate would be needed and a patent right would help fill this need.

However, a strong patent right tailored as a reward to an inventor who is first in some sense with an invention may also lead to excessive races with overinvestment and uncoordinated exploitation of new technologies as a result. Then it has been argued that a patent right should be tailored as a

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6 See especially the works by Mansfield, Scherer, Griliches and Cohen. For example, Mansfield (1986), Scherer (1983, 1984, 1999), Griliches (1984, 1990), and Cohen et al. (2003).

7 See further IVA (2003) and Granstrand (2000).

8 For a classic qualitative review of theories of the pros and cons of patents, see Machlup (1958) and for a current review (with similar classification of theories) from an economic perspective, see Mazzoleni and Nelson (1998), and from a legal perspective Gutterman (1997).

prospect right giving an exclusive right to the rights holder to further exploration in a wider area, the right being handed out at an early stage of the exploitation process as in mineral extraction. In this way further exploitation of new technological areas could presumably be better coordinated or governed.[9]

These received theories focus on different parts or stages of the compound invention/innovation/diffusion process and on the different but related roles of IPRs as incentivizing and coordinating mechanisms. Thus the received theories together contain the elements of what could be said to constitute two newer integrated and complementary perspectives. One views patents as joint incentives to both exploration and exploitation through integrated innovation and diffusion processes. The other perspective views patents (and more generally IPRs) as a mode of coordination or governance similar (but not equivalent) to the role of property rights in tangibles.

Table 2.1 gives a summary of both the received economic rationales for a patent system and the newer economic perspectives on patents. Viewing patents as a joint innovation/diffusion incentive integrates received incentive-oriented rationales (treating disclosure as diffusion of information) and in doing so also focuses on the interdependence and dynamics over time of the processes involved. Hereby dynamic (Schumpeterian) competition is more clearly articulated and contrasted with static competition.

3.1.1 The property approach viewed in a governance perspective A general controversy (or set of controversies) concerns the use of a property approach with its pros and cons not only for incentivizing innovators compared to alternative approaches (tax-based subsidies, procurement contracts etc.) but also for handling coordination or governance problems in innovation and diffusion. The property approach has then been criticized for creating rather than solving coordination problems, for example, in the common context of sequential or cumulative innovation or in the contexts of 'open science' or complex technologies, then creating anti-commons problems or problems with assembling different necessary IPRs for productive use of resources.

However, information and knowledge are uncertain and highly heterogeneous entities and so are the conditions under which they are produced and

[9] This so-called prospect theory was introduced by Kitch (1977), building partly on Barzel (1968) and earlier works by Scherer, and has been highly cited but also subjected to severe critique, e.g. that a prospect right does not solve the coordination problem but merely pushes uncoordinated overinvestment tendencies to earlier stages in the innovation race, besides the difficulty of identifying early on the few inventions that are generic enough to justify a prospect right.

Table 2.1 Economic rationales for a patent system

Received economic theories	Newer economic perspectives on patents
Incentive-to-Invent theory Focus: Impact on invention and R&D Concerns: • Distortion of R&D (e.g. too many substitutes/too few complements, too little basic/too much applied, too much patentable/too little unpatentable) • Barriers to competition • Heterogeneity of industries/firms/inventors	**Patents as a joint incentive to innovate and diffuse** Focus: Impact on dynamic competition through 'continuous' and entangled (interdependent) innovation and diffusion processes Concerns: • As for incentive-to-innovate • Efficiency/distortion of diffusion • Interdependence of inventions and innovations over time (e.g. in sequential innovation) • Dynamic interaction between innovation and diffusion processes
Incentive-to-Disclose theory Focus: Impact on secrecy Concerns: • Quality/quantity of disclosure • Impact on R&D (e.g. stimulation, coordination) • Impact on diffusion (e.g. on technology markets)	**Patent rights and patent information as a governance mechanism** Focus: Property rights allocation and disclosure as a mode of incentivizing and organizing for decentralized governance through management hierarchies and markets and hybrids of these two governance modes. Concerns: • Allocation and transfer of rights • Cumulation and dispersion of rights • Interdependence of rights • Scope and duration of rights
Incentive-to-Innovate theory Focus: Impact on innovation and competition Concerns: • Incentives ex ante and ex post invention • Impact on complementary investments	

- Transaction costs
- Invention/innovation distinction
- Patent scope and duration

Prospect theory

Focus: Resource exploitation efficiency

Concerns:
- Coordination and duplication of R&D
- Exploration
- Improvement
- Firm strategies
- Enforcement of rights
- Governance efficiencies, e.g. in terms of coordination and communication costs, e.g. market efficiencies, e.g. in terms of transaction costs
- Optimal decentralized ‘tariffs’ or ‘taxation’ (through prices or damages)
- Role of governance bodies and institutions (legislators, courts, patent offices, patent management, patent pools, clearing houses, anti-trust authorities etc.)
- Alternative governance mechanisms

diffused, justifying a combined variety of approaches to fostering suitable conditions. Thus, using the property approach means decentralizing decision-making about scarce resources to agents with unique access to localized information for proper decisions, and incentivizing them to exercise their capabilities by providing them with access to a share of the extra surpluses they then generate. The latter is done by allowing the property holder to charge prices higher than marginal cost in order to help cover fixed investment costs.

Such monopolistic pricing is a drawback of the property approach, as it incurs a certain loss of consumer surplus apart from a shift of some surplus from consumers to the producer. However, in order to assess the property approach, this drawback (cost) has to be compared with the corresponding drawbacks of other approaches. If the right to exercise certain monopolistic pricing is seen as a decentralized right to tax consumers, it corresponds to the right to impose a targeted sales tax administered by private agents. The administrative cost could then be fairly low in comparison with public forms of taxation, be they targeted (selective) or general.[10] Of course, taxes could be more than minimally distorting and over-taxation could occur, as it could with any form of tax. (Few people seem to disagree on this.) One real virtue as well as a drawback of the property approach is its amenability to flexible decentralization which then could easily lead to over-decentralization in the sense that too many costly agent interdependencies will arise, resulting in too high transaction costs, eventually high enough to outweigh incentive effects and other efficiency gains. In addition, recentralization is usually more difficult (costly) than decentralization.

Thus, using a property approach is largely a matter of how far decentralization should go and along what organizational principles, in order not to let transaction costs and administrative expenses outweigh innovative and efficiency gains by handing out too many small interdependent property rights.

This does not imply that a proper trade-off along the centralization–decentralization continuum makes the property approach the single best solution. For this, all costs and benefits of a property approach relative to other approaches have to be weighed up, and particularly for an intellectual property approach, these costs and benefits are far from well understood. An IPR system is likely to be more costly to run than a physical property right ('PPR')

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[10] Just to mention one comparable alternative, consider the popular use of R&D tax credits or tax deductions for stimulating innovation, based on the idea of subsidizing R&D inputs through targeted cuts in general taxes. This tax arrangement has significant limitations and hardly qualifies as a minimally distorting tax arrangement (see Mansfield 1982). It could be modified of course, for example, to cover commercial activities as well, not just R&D, but it will still be inherently limited (see Granstrand 1998b).

system, although its benefits might have increased as technological innovations have become more highly valued (see Landes and Posner 2003).

3.1.2 Patent rights and disclosures as a governance mechanism Viewing patents as a governance mechanism incorporates coordination aspects besides incentive aspects (and thereby has a focus related to the prospect theory). To some extent the governance perspective on patents and IPRs more generally is similar to a governance perspective on PPRs. However, in a fundamental way IPRs differ from PPRs and the difference actually strengthens the justification for viewing IPRs in a governance perspective. The difference relates to the simple (but important) fact that, in contrast to an exchange of a physical object (resource, artifact) between two agents, an economically motivated exchange of proprietary information new to one of the agents leaves both agents in possession of the information. As dispossession of human embodied information is impossible and information does not wear out through usage, there is a long-term need to coordinate or control the agents in their use of the symmetrically possessed but asymmetrically owned information. This could be done (more or less imperfectly) through explicit or implicit contracting, for example, through a license contract or an employment contract with a non-disclosure agreement. Thus, exploiting IPRs tends to create longer post-exchange contractual relations than for PPRs (for which exhaustion of the seller's rights occur when selling a physical object – warranties, product liabilities, etc. aside).

Different forms of licensing (in a broad sense) and other forms of contracting on markets for IPRs then become essential for transfer and assembly of resources via markets in the economy.

Finally, a strong motive historically for handing out patent-like privileges was to disclose and diffuse secrets, for example, those held by skilled artisans and guilds.[11] Disclosure would thereby stimulate and coordinate the R&D of others, speed up differentiation and cumulation of results, speed up exploration of new, promising areas, help to avoid duplication, and provide for more efficient technology markets.[12]

The idea of disclosure as the inventor's payment (apart from fees) for patent rights has thus been central to the patent system from early on. Despite this apparently important role of patents, there is not much systematic

[11] Note that the dual functions of patents as incentives and disclosures do not need to be integrated, that is, a patent system could in principle be designed to offer incentives without requiring disclosure and disclosure could be achieved in other ways.

[12] There is also a dilemma of growing importance when R&D information protected by patents is used by others in their R&D in a way considered as infringement.

evidence of its functioning and value. Recent studies have pointed to the value of patent information for companies in managing their R&D as well as for countries in disseminating new technologies, for example, in Japan (Ordover 1991, Granstrand 2000, Cohen et al. 2003).

4 Methodology

4.1 The directive for the Swedish study

The Swedish Government decided in 2004 to appoint a special investigator to survey the economic aspects of patenting for corporate growth and development. The directive stated that patent protection was of great importance for entrepreneurship and growth. The directive further specified that the investigation should include an analysis of how Swedish companies deal with patenting as a means of competition, especially in comparison with companies in other European countries but also in comparison with the rest of the world. Here, the latest developments in the EU region were to be considered. The study was also tasked with including a Nordic comparison and identifying problems and opportunities in the Nordic patent market.

According to the directive, the commission's remit was more specifically to:

1. lead to proposals that could create understanding and insight, particularly in small knowledge-intensive firms, about the economic profits – and costs – of patenting;
2. lead to proposals of how knowledge-intensive firms could be stimulated to patent their innovations to a greater extent;
3. illuminate the relationship between patenting and economic growth;
4. contain an analysis of the decline in patenting frequency in Sweden and the most important causes of this trend.

Finally, an evidence-based approach for policy design should be sought; that is, a policy analysis should be based, as far as possible within given resource limits, on empirical and theoretical evidence (rather than on different interest groups' opinions).[13]

[13] The evidence-based approach must, however, be adapted to the state of knowledge and access to resources, including time. A good time margin in policy research is advantageous here. Such a margin has not existed regarding economic aspects of patenting, that is, within patent economics, due among other things to the rapid developments in the patent field and to economists' traditional lack of interest in patent issues.

4.2 Analytical framework and study design

A frame of reference for the investigation, in the form of a so-called 'patent/growth spiral', was developed in several steps for the studies of the various links between patenting and growth (see Figure 2.1). Intermediate variables related to R&D and innovations were introduced, and the mutual influence between different companies was taken into account. The frame of reference was deepened with more intermediate variables and also broadened with a model of a national system of innovation and entrepreneurship as a whole as illustrated in Figure 2.2. This model was not nation-specific but had been used in earlier cross-national studies of innovation and entrepreneurship. It was also important to use a methodological design that enabled current as well as future cross-national comparisons.[14] As seen in the figure, three types of entrepreneurship are identified – autonomous (essentially small firm), corporate and state (publicly owned). At a higher level of resolution, the model also identifies university (academic) entrepreneurship which could be of the corporate or state type depending on ownership. Obviously various mixes of the types arise due to inter-organizational collaborations.

A relatively large number of substudies were then designed with different levels and units of analysis (countries, sectors, companies, innovations, technologies and patents), with different methods of data collection (e.g. interviews, case studies, questionnaires, and/or statistics). For reasons of time and space, a basic sampling principle was to choose units of analysis which, in some sense, represented high growth levels or high patenting and R&D levels.

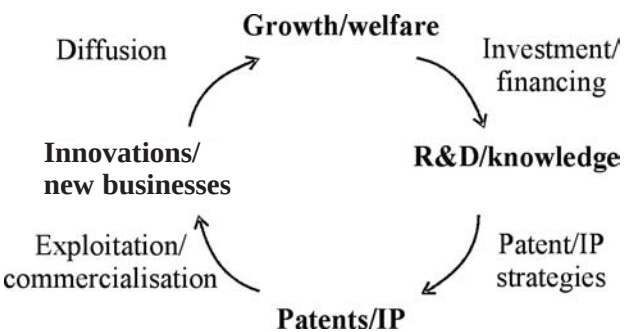
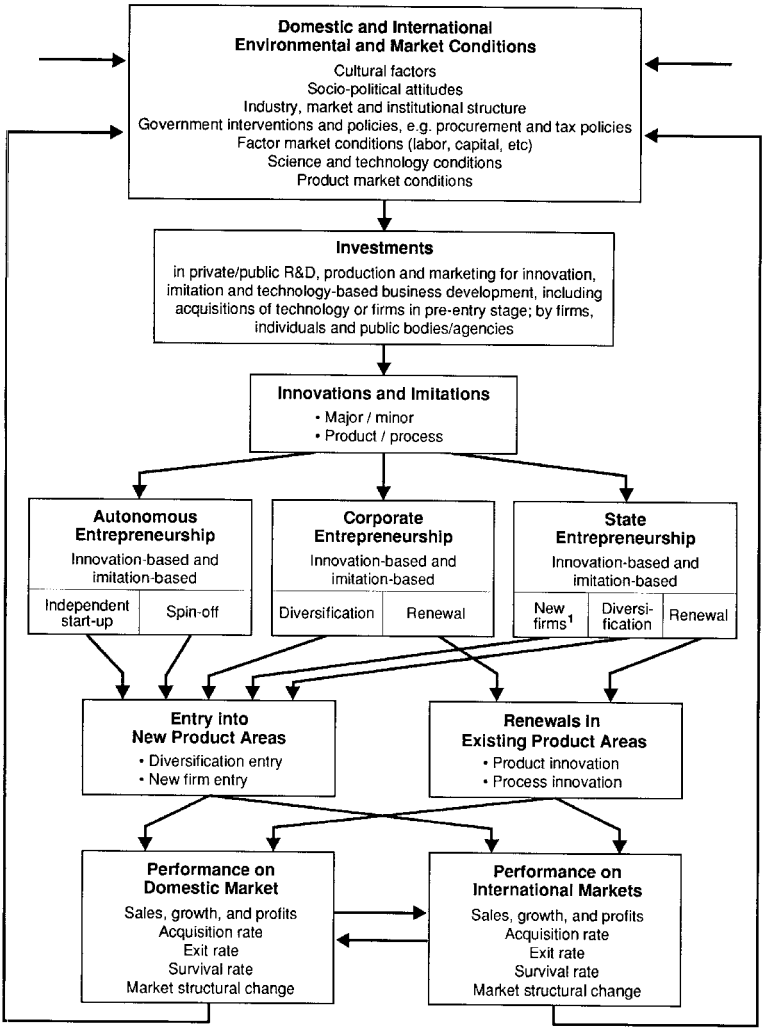


Figure 2.1 The patent/growth spiral with intermediate variables

[14] The European Community Innovation Survey (CIS) was considered too general for probing various patent issues, however, although some of its questionnaire questions were used. Detailed econometric studies of causal links between patenting and growth were also ruled out early on due to insufficient data availability.



Notes:

[1] This category of state entrepreneurship refers to cases where the state directly performs entrepreneurial events during the early phases of a new firm start-up process (e.g. by selecting product, market and technology). When the new firm reaches the state of a going concern, an independent entrepreneur may take over full responsibility.

[2] The types of entrepreneurship depend on ownership (private/public) and size of firm (small/large). Independent innovators fall into the autonomous category. University entrepreneurship could fall into the corporate or state category depending upon ownership.

Figure 2.2 A general model of a national system of innovation and entrepreneurship[2]

Several substudies with relatively small samples were preferred to a few with large samples. A questionnaire study of large companies was fairly large, however, with 50 companies in the sample. The substudies were fundamental to the investigation, in accordance with an evidence-based approach for policy design. In total, around 75 persons were visited for long interviews, in addition there were a large number of short telephone interviews and conversations, and around 200 companies were approached with survey questionnaires. The overall methodological design and breakdown into different substudies are shown in Table 2.2. The most important research results are presented in summary below. The emphasis in this chapter is on the results in terms of policy recommendations, however.

5 The investigation's empirical results

5.1 Patents, innovations and growth in Sweden – a description and analysis

The many substudies in the inquiry were performed in order to illuminate the often complex connections between R&D, patents, innovations and growth in Sweden. The results shed light on many disparate connections that do not readily lend themselves to summarization. A substudy of the principal Swedish innovations pointed to several structural problems in the Swedish innovation and entrepreneur system. These were the low overall frequency and proportion of innovations in small and medium-sized firms ('SMFs'), large companies' low frequency of radical innovations in new business areas, and the rapidly increasing foreign ownership of innovative Swedish companies, especially in the pharmaceutical industry. The interplay between large and small companies, as well as that between companies and universities was important in the processes of innovation and diffusion, while the growth rate and the speed to international markets did not differ much between large and small companies. Another substudy, of how exploitation has occurred for important Swedish patents, indicated once again the dominance of already large companies and how seldom small companies grow large, even small companies that have good patent protection. Here, too, foreign ownership of important Swedish patentees had increased markedly.

Fast-growing small companies in general grow for many different reasons, and patents could not be proved to play any role in this group of companies. However, their patent awareness was strikingly low and the sample very small, with a large share of service companies. This result suggests further investigation of the role of patenting for fast-growing companies in general. On the other hand, and not surprisingly, patents had a clearer connection with growth in fast-growing small technology firms, which were also patent-aware even if their patent know-how was low. In these firms, patents also had great

Table 2.2 Overall methodological design of the empirical investigation

Levels and units of analysis	Sub-study	Data collection method
International (Europe, Asia, USA)	INT	Public statistics, literature, conferences
National (Sweden)	SWE	Public statistics, literature, interviews
	IPE	Interviews, statistics, documents
Industry sectors	TBS	Interviews, statistics
– Services (finance, medicine, telecoms, energy, universities, military)		
– Other industries (especially biomedical technology and infocom technology)	TBI	Interviews, statistics
Companies		
– Large firms	PEX4-L	Survey questionnaire (mail, e-mail)
– SMFs	PEX4-SMF	Survey questionnaire (mail, e-mail)
	GAZ	Interviews
	HIT	Interviews, survey questionnaire
	IPM	Interviews
	GGVV	Interviews
	IT-SMF	Survey questionnaire
– IP consultancy firms	PEX4-PB	Survey questionnaire, interviews
– Patent office (PRV)	PEX4-PRV	Patent statistics, interviews
Innovations	SSI	Survey questionnaire, interviews, case studies
Technology systems	BIO-M	Interviews, case studies, statistics

Table 2.2 Continued

Levels and units of analysis	Sub-study	Data collection method
Patents	PEST	Questionnaire, interviews, statistics
	PPP chemistry	Examination of patent information
	Cases (Losec, Nokia etc.)	Interviews, statistics, patent information, public and private documentation

Notes: INT = international, SWE = Sweden, IPE = study of availability of IP education in Sweden, TBS = study of technology-based service industry, TBI = study of technology-based manufacturing industry, PEX4-L = study of large companies, PEX4-SMF = study of small- and medium-sized companies (SMFs), PEX4-PB = study of patent consulting bureaus, PEX4-PRV = study of PRV's patent statistics, GAZ = study of fast-growing 'Gazsell' companies (based on the newspaper Dagens Industri's selection), HIT = study of high-tech companies (based on the newspaper Ny Teknik's selection), IPM = study of IP management, GGVV = study of the Gnosjö region, IT-SMF = study of SMFs in the IT sector, SSI = study of Sweden's largest innovations, BIO-M = study of bio-material, PEST = study of exploitation strategies for important patents, PPP chemistry = study of product- and process patents in the chemistry area.

significance for attracting risk capital. The study of small companies in the IT sector, including software companies, demonstrated the great importance of product innovations for software companies' growth, although patenting was less important for growth. The proportion of IT companies that engage in license trading was comparatively high. A major part of the software companies believed that legal patent protection should be extended to pure software, as did nearly all the patent bureaus questioned in a separate substudy. A number of short case descriptions provided more situation-specific clarifications. Further, one should remember that several of the substudies' sample sizes were relatively small, which calls for caution in their interpretation.

A large questionnaire survey of 50 large companies in Sweden, of which 38 answered, showed in sum how important patents and patenting possibilities were for their R&D, innovations and growth.

The companies' product development rate was high in a Nordic comparison. Much of the companies' sales, and most of their inventions in both products and processes, were protected by patents. Patenting in order to delay or prevent competition by imitations was also the most important commercialization strategy for new products, and was now considered more important in big Swedish companies than previously, as well as by comparison to companies in the USA.

The relative strength (elasticity) of different variable relationships in the companies' patent/growth spirals was also clearly and consistently positive.

The companies' own R&D also often grow through other companies' patenting, which causes extra work in order to circumvent the blocking of patents. At the same time, although much less often, companies' own R&D is reduced through others' patents and patent information, since duplicate work is avoided but companies' own R&D may also be obstructed so much that it is discontinued.

Finally, the patent system itself has great influence on large companies' inventions, new products and R&D efforts, which would be reduced by roughly one third – and product sales by a fourth – if the possibilities of patenting were to disappear.

The study of large companies also examined reasons for the decline in patent applications to the PRV, i.e., the Swedish P. This part of the study of large companies is reported more in detail below.

A survey of the IP education offered in Sweden indicated, among other things, that fewer than 10 per cent of graduate Master's students in technology, economics, and law had taken any course in IP; that almost no qualified education existed in IP economics; that qualified advice was scarce throughout the IP sector's range of competence, despite the abundance of actors in the area of innovations and entrepreneurship; and that business managers in Swedish technology-based companies did not receive any substantial education in IP issues. Moreover, there was a great shortage of certified patent specialists in Sweden. These conditions were far from consistent with the dominance of intellectual capital in an ever more knowledge-based and IP-oriented economy.

5.2 Had patenting declined, and if so, why?

As one of the inquiry's four main tasks, a description and analysis was made of changes in Swedish companies' patenting frequency and in numbers of patent applications received by the Swedish PRV, especially priority application filings. Patenting frequency as a concept can then refer to both patent-application frequency and patent-granting frequency, where as a rule 'frequency' refers to number per year. Various factors lie behind companies' patenting frequency and patenting propensity – that is, the propensity to patent a given patentable invention – as well as the frequency of filing patent applications at PRV. When counting patent applications, it is important at least to separate the four main paths by which a first filing can be submitted: as a national application in Sweden or in some foreign country, and as a European Patent Office (EPO) or a Patent Cooperation Treaty (PCT) application. These paths can then be combined in several ways, for example, a patentee could co-file an application with the EPO and the UK Patent Office, with the intention of receiving an early search report from the UK Patent Office to show to investors or others but with the intention of ultimately protecting the invention via the EPO.

Large multinational companies such as Nokia, with large and internationalized R&D and large patent portfolios, are to an increasing extent internationalizing their patenting work and their application procedures. This leads, all things being equal, to a decline in the number of patent applications received by the national patent offices of small countries that have many large multinational companies, such as Sweden. But this does not necessarily mean a decline in the number of EPO applications designating Sweden, for example, since the application will be received by the EPO and not the PRV. The statistics also showed that a decline occurred for national filings in Sweden, Norway and Finland during the last five years, simultaneously with a steady rise on the whole throughout the pro-patent era in filings in the USA, Japan and the PCT. The decline in Sweden was attributable mainly to Swedish applicants and, to a greater extent, to large companies' patenting. The percentage decline, though, was roughly similar for the two groups of patent-seeking companies and individual inventors, which were of about the same size in 1998. The turnover in the population of applicants was moreover very high. Of the applicants who, at least in some year during the seven-year period 1998–2004, submitted a first filing to PRV, only around 5 per cent had submitted further first filings during each of four or more of the seven years – that is, around 95 per cent of the applicants submitted first filings less often than every other year. The flow of patentable inventions for an actor is thus of great significance to consider. This flow's size depends mainly on R&D resources and patenting resources.

The decline in Sweden also varied a good deal according to the area of technology in question, with a striking drop in the electrical and electronics sector from 2000 until 2004. The large companies in this sector – Ericsson, ABB and TeliaSonera – dominated the decline both in this sector and among the 20 companies which were largest in terms of numbers of first filings to PRV during the period 1998–2000. This indicates that the decline owed much to a business recession within the IT and telecom sector, although not exclusively so in view of other specific problems, chiefly at Ericsson and ABB.

To simplify, one can say that the IT bubble burst and, with it, a patent bubble. At the same time, companies sensitive to business cycles within the mechanical engineering sector, such as Volvo, Scania, Sandvik, Electrolux and Atlas Copco, increased their patent-application frequency. If Ericsson and ABB are counted out, the increase among these companies roughly compensated for the decline among other companies on the top-20 list of most frequent patentees at PRV.

A questionnaire study among the largest R&D-intensive companies, with a control group among SMFs, then showed that changes in R&D resources and patenting resources are important factors behind both upward and downward changes in patenting frequency for both large and small companies, in line with previous studies. Besides these factors, a major explanation given for a

decline in patenting frequency is a decline in patent propensity, in the form of a more selective and quality-oriented patent strategy which, in several companies, followed a period of quantity-oriented patenting during the 1990s. This view was generally confirmed by a questionnaire study among the 14 largest patent bureaus in Sweden. (The turnover in the patent bureau business did not decrease during 2001–2004, however.) Further, for SMFs, patents played a much smaller role in financing after the IT bubble burst, when access to risk capital as a whole decreased sharply in Sweden.

The quality and cost-efficiency of PRV services were considered satisfactory by most of the large companies, even though a substantial potential for improvement of customer satisfaction could be noted. The PRV's share of the Swedish large companies' first filings was also generally constant during the period 1998–2004, while the US Patent and Trademark Office (USPTO)'s share of Swedish large company priority filings dropped greatly, according to the study. The share of PCT applications has also grown among large companies during the period, and most of these applications went to the PRV as the international receiving office. However, the PRV's share of PCT applications as international receiving office declined on the whole. More Swedish applicants are also electing either the EPO or the World Intellectual Property Organization (WIPO) International Bureau as their international receiving office.

Swedish large companies did not, on average, decrease their patenting in the USA to any substantial extent during the period 1998–2004 in absolute terms, although they did so in relative terms. Sweden had also, on the whole since 1994, retained its tenth place on the top-20 list of most frequent patentees in the USA. On the other hand, several countries in Asia climbed up this list – Taiwan, Korea, China and Singapore – and dominated, together with Japan and Hong Kong, over the European countries on the list, in terms of numbers of patents in the USA.

6 The investigation's policy recommendations

6.1 General recommendations

The inquiry's general recommendations are largely concerned with the wider context of patenting – R&D, innovations, business development and growth, and the mutual relationship between patenting and growth. The more specific recommendations address the inquiry's first two tasks – to increase understanding and insight in patent economics and to increase companies' patenting. Since patenting, in turn, tends to increase when growth increases, the general and specific recommendations are intimately related to each other. The following is a summary of general recommendations.

An economy that increasingly evolves in the direction of being ever more knowledge-based, IP-oriented and globalized creates greater and different

opportunities, but also problems of control. These in turn require changes of roles for, and interplay between, the state and the business sector in order to achieve high goals of growth and welfare.

Sweden's economy has several good possibilities for developing favorably toward an increasingly knowledge-based economy through good knowledge resources in the form of good education and high R&D intensity, highly diversified and internationalized industry, and so on – but also through good access to natural resources per capita, which is lacking in economies such as those of Japan and Korea. To take better advantage of these possibilities, for example in the form of synergies between knowledge resources and natural resources, a national culture for IP and business development, including entrepreneurship, should be built up and strengthened in various ways. Here, focusing on patent and IP issues is no end in itself. On the other hand, such a focus is instrumental for creating more economically efficient innovative activity in business and government, similarly to how focusing on quality issues and lead times was previously instrumental for the broader aims in the business sector's vitalization and transformation.

The Swedish entrepreneur system, including the Swedish innovation system, should be strengthened by reinforcing both state (public) and private entrepreneurship. That the state directly acts as an entrepreneur, and does not just indirectly promote entrepreneurship, illustrates a changed role in a changed economy. This role is especially strong in a small country with a large and important technology-based service sector, which to a great extent is public. This sector is heterogeneous and involves the university and college sectors, the telecom and energy sectors, the financial sector, the defense and security sector, the medical and health sector, and others. These technology-based service sectors have considerable innovation potential and business opportunities. Their patent and IP orientation is in general weakly developed, however.

Private entrepreneurship should be strengthened in various ways. Innovation-based entrepreneurship in small- and medium-sized companies needs to be made stronger, as does the will and ability of Swedish large companies to create new business areas and radical innovations – activities beyond merely renewing their existing business areas, which has historically been a strength for these companies. Further, collaboration between innovation activities in Swedish large and small companies needs to be maintained and strengthened. A divergence between technology-based new firms and large firms is to be feared, for instance, as well as a thinning in other respects of the domestic network of buyer/seller relations. Moreover, regional entrepreneurship should be strengthened by taking better advantage of the growth opportunities in already strong, entrepreneurial regions and along geographical axes of growth.

Economic competence should be raised in the Swedish entrepreneur system, just as the Swedish appropriation of growth should be increased. For example, growth is created in the R&D sector (which is a service sector) at the same time as technology sales of licenses and shares in R&D companies to foreign buyers and manufacturing abroad does not generate domestic growth to a sufficiently great extent. It is not credible that a knowledge-based economy in international competition can be based merely on a dominant R&D service sector.

A number of general recommendations for the IP sector can then be formulated, such as continuing to work for (a) Nordic collaboration; (b) English as the language for business, patents and IP; (c) further implementation and development of the international patent system in differing old and new respects, for example, regarding international harmonization and rationalization, development of the PCT system and the enforcement system – as well as changes in patentability criteria, mainly in the form of raising the requirement for inventiveness and reformulating the requirement of technical character; and (d) offensive transformation of the PRV toward greater internationalization, diversification and rationalization. In this context, a change of law was proposed so that patent applications to PRV could be allowed to be written in English without requiring later translation (in other words, accepting the London Protocol without requiring its full ratification throughout Europe). The PRV should also test the issuing of non-binding examinations of validity and infringement, according to the British model.

A final recommendation, due to the future importance and generic character of these questions, is the creation of an interministerial Strategy Council for IP and innovations, directly under the Prime Minister's office. Active, clear support from leaders in the business sector and in government is of decisive significance for implementation of the above recommendations.

6.2 Summary of special recommendations for increasing patent awareness, insight and propensity to patent

A package of specific recommendations was designed, partly in order to increase companies' understanding and insight in patent economics, and partly to increase their possibilities and will to patent. Greater understanding of patent economics can be assumed to increase patenting propensity, which in turn increases patenting frequency, all things being equal. Patenting frequency, however, is influenced by a number of additional factors within and beyond both the companies' and the state's control, factors which also have been basic to structuring the recommendations.

Understanding patent economics involves some fundamental difficulties. Patent issues are complex and interdisciplinary, with many interwoven economic, legal and technical aspects. Costs and earnings are long-term and

therefore of investment character, while patent costs are much clearer than patent earnings. In addition, patent earnings have such a highly skewed distribution that the simple counting of patents is often misleading. A number of primary deficiencies in the patenting competence of Swedish companies were also reported, such as deficient competence in business strategy and business economics, with consequent deficiencies of integration and interplay between business strategies and IP strategies in companies. Additionally, there is a widespread lack of basic patent awareness within the business sector, especially in SMFs, as well as in the academic and the political spheres.

The problems of raising awareness and understanding of patents and patent economics are neither new nor solely Swedish, but have been accentuated by the pro-patent trend, which has led to efforts of different kinds in different countries. Experience indicates that patent disputes, large awards of damages, and aggressive patent behavior by competitors have great importance for raising patent awareness and patent understanding – as do good examples of new business opportunities and national studies with competitor comparisons ('benchmarking' studies). State and/or state-supported programs and efforts to provide advice and support can play a great role here, for example, to reduce expensive learning within companies.

A number of state-supported programs and measures, partly to increase patent awareness and patent advice, and partly to increase patent understanding, were proposed. These programs should be coupled with programs and efforts for business development, innovations and entrepreneurship in general but their specifics have to be omitted here. Two concentrated educational efforts should be carried out as soon as possible: One to cover an educational need for IP advisers, and one to educate patent specialists for certification as European Patent Attorneys. All of these educational efforts should be quality-assured, and a certification system for IP specialists should be developed in addition to certification of European Patent Attorneys.

The direct measures proposed to increase companies' possibilities and will to patent comprise, besides the above measures, also giving special state support for investments in patents and patent education coupled with other state support for R&D; giving special stimulation to employment of internal patent and IP specialists; supplementing companies' own stimulation measures with special reward systems; supporting the design of guidelines for company boards' and business managers' handling of patents and IP; and a number of specially directed efforts, particularly to technology-based service sectors with a large public part. Special inquiries into issues of business development and IP within the military and medical sectors should be carried out, for instance to assess the potential and forms of technology procurement and technology trade.

For those measures above which can be coupled with other current state

measures for supporting and increasing R&D resources in the Swedish R&D system, ear-marking should be done in the form of a 4 per cent goal for costs of patent and IPR work as a share of R&D costs, with variations of ±1 per cent depending on the sector and type of company.

Also proposed are better financing opportunities for investments in patents in SMFs, especially in the early phases, where leverage can be obtained for financing via private risk capital. For this purpose, the proposals are special patent loans with advantageous conditions, reduced fees for first- and second-time priority applications to PRV, the possibility of faster, prioritized handling by PRV, and stronger advisory assistance, including language assistance. This requires a change in the PRV's rules and operating directives.

In other respects, methods for IP evaluation need to be improved and quality-assured, not least in connection with the utilization of new accounting rules for immaterial assets, that is, IP. At the same time, there is a need to increase Swedish damages for patent and IP infringement and to improve the grounds for calculating damages. A review of these matters together with tax issues that bear upon patents and the licensing trade should be made. Likewise, a review of the patent system's regulations, including rules for the area of patentable inventions, needs to be performed and coordinated with corresponding work in the EU.

A reformulation of the requirement of a technical character should also be undertaken in order to take better account of the need to balance and coordinate investments in innovation in general, and thereby also investments in innovation within the service sector. Regardless of how this requirement is formulated, a raising of the requirement for inventiveness should take place. A review of the patentability of surgical, therapeutic and diagnostic methods should also be undertaken. These three issues will be investigated further below.

Finally, it is proposed that there be an increased use of patent information and patent analyses for design of patent policies and their coupling with policies of R&D, innovation and growth. Examples of important areas in this respect are nanotechnology and biohealth technology.

6.3 Patentability criteria

With regard to judgment of patentability, there are a number of long-standing issues, and many proposals in different countries have been formulated during different periods. A complete survey of these issues was outside the scope of the investigation. The proposals advanced below are such that both a coupling with growth and a basis for position-taking exist. At the same time, it is worth remembering that the prospects of essential and one-sided changes in legislation or practice in Sweden are limited in the short term by international undertakings and conventions. Moreover, the possibilities of making isolated

changes in the patent system itself are limited by its close connections within a whole in which different parts' functions depend on each other. This must not hinder long-term work for improvements, but the work must be based on a holistic view of the entire patent system – with all its requirements for patentability and the coupling between these, and the system's economic functionality with positive and negative side-effects.

6.3.1 Raise the inventive step (non-obviousness) requirement A requirement of inventiveness for patentability of an invention is economically justified and has a long history. Yet, among all the requirements for patentability, it is the hardest one to establish, both in economic theory and in practical examination with the help of guidelines and tests for examiners, courts and patent lawyers. International calibration between different patent offices is rendered more difficult thereby, even though the patent laws are often not very distinct from each other. Patent offices have different resources and processes for examination work. Small resources, both in absolute terms and relative to many patent applicants' resources, together with incentives in the form of patent fees and weak sanctions against wrong decisions such as inappropriate approval, easily result in a tendency to lower the requirement of inventiveness. This tendency is strengthened in new fields of technology[15] where good reference material has not, for obvious reasons, yet been developed. The 'bar' is then set too low from the beginning. In addition, early inventions in new areas are often of more generic character, that is, they have broad applications, at the same time as a suitable patent scope is difficult to establish because of general uncertainty about a new technology. On the whole, this easily leads to a situation which, to simplify, can be described as an excess of patents, frequently also with excessive scope, which in turn leads to high transaction costs. These may be so great that growth in an area is impeded or lacking, due to delayed or prevented business transactions. The area becomes a jungle of patents divided among many competing patent-right holders which are costly and hard to negotiate with, not least for small companies and new entrants. This can be compared to a situation where farmland is divided into too many small holdings for efficient agriculture.

The inventive step requirement is now (2006) considered to have decreased too much in many areas in the US, and is also feared to have been lowered in many parts of Europe (also early on as a result of harmonization when the EPC was introduced), although this is difficult to confirm with systematic studies. To determine a suitable (optimal) requirement for inventiveness is also hard

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15 See further Granstrand (2003). See also Merrill et al. (2004).

and arguable. For these and other reasons the issue is controversial.[16] However, an assessment of the available evidence and the risks associated with an all too low requirement lead to the above recommendation in line with some proposals in the US.[17]

How high the requirement should be set is a natural subsequent question. In the absence of sufficiently well-based analyses, this question must be answered with the help of further analyses as well as consultations with examiners in patent offices and courts, regarding historically more correct levels in different areas and the suitability of various guidelines and tests.

6.3.2 Technical character requirement The requirement that an invention must have a so-called 'technical character' in order to be patentable in Europe (and thus in Sweden) has a long history of use in practice and has become manifested for various reasons, not least historical and linguistic ones. It is intended to serve as a sorting concept and to be useful for delimiting the area of patentability, as well as individual patents' scope of protection, and for distinguishing patent rights from other IP rights. As with all concepts for sorting and delimitation, two kinds of errors could be made: Undesirable elements are sorted in and desirable ones sorted out. However, there are no clear economic arguments or motives for a requirement of a technical character, and the legal motives to the extent that they exist are dubious, since the requirement is not explicitly stated in the Swedish patent law from 1967 – where instead the concept of industrial applicability is used, a concept more closely related to industrial economics.[18] Nor has the technical character requirement

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16 Another reason is that 'small' patents could be useful for incumbents attempting to 'evergreen' their product protection through repeated patenting of small improvements, when enjoying learning benefits from cumulative production and marketing as described in Granstrand (2003, ch. 10).

17 See further Granstrand (2003). See also Merrill et al. (2004).

18 The preliminary work for the patent law of 1967 describes the practice which had been developed over the years, whereby an invention in the sense of patent law was regarded as something with technical character and technical effect, among other things, and which must be reproducible. But it was considered impossible to state such conditions in the law text. Instead, the text gave a short determination of the object of patent law as being 'an invention that can be utilized industrially'. The expression 'industrially' thereby referred primarily to the requirement that the invention should be of a technical character, whereas other demands in this context were included in the concept 'invention'. That an invention has a technical character was then thought to mean that it solved a problem with the help of natural forces, that is, that it exploited the laws obeyed by nature's materials and energy. The term 'industry' would thereby be interpreted widely and comprise all areas of technology, not limited by the general use of language. (See Hesser and Essén 1968.) Against this background, for instance, a computer program that exploits semiconducting materials in order to find a solution

been signed into law in Europe. (Cf. EPC Article 52(1) . . . 'inventions which are susceptible of industrial application'.) The concept 'industrial' has long come to be broadened and thereby, for example, to include the service sector as well (compare the expression 'service industries'). Since the patent system and its framework essentially (i.e. apart from aspects of moral rights) aim at fulfilling an economic function, the requirements of patentability must be, if not economically optimal (which is hard and thus costly to determine), at least sufficiently functional in economic terms and, in particular, not dysfunctional (e.g. growth-hindering). The patent system fulfils a function in cases where underinvestment in R&D can be considered to occur, and which can be corrected better by patentability than by any alternative means without creating expensive side-effects (e.g. costs for patent administration or transaction costs on the market). Such cases of underinvestment may occur in many areas, and not only technical ones, even though the technical cases can be substantial and frequent.[19] Against this background, there is no reason to limit patentability solely to technical inventions in the narrow sense (inventions with technical character). Naturally, mistakes may have been made historically in the design of requirements of patentability, mistakes that have led to a situation where the cost of correcting them is not outweighed by the discounted profits from eliminating mistakes. The latter is scarcely true in view of the general problem of underinvestments in R&D and innovations, both technical and non-technical, in a market economy – as compared with the marginal problem, at least in the medium term (three to five years), of reformulating and supplementing the requirement of a technical character (which does not exist in the US). A better formulation of the requirement of 'technical character' also decreases the linguistic, and thereby the legal, uncertainty about what is 'technical'.

The conclusion is that the requirement of technical character, as it has hitherto emerged in practice without being written into Swedish patent law, is neither directly grounded in law texts nor economically well-founded. It follows that, for example, the patenting of computer-related inventions and of therapeutic methods should not be hindered by requirements of technical character. These inferences need not mean that patents on all computer-related

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to, for instance, an optimization problem seems able to be applied industrially, for example, in the financial sector or in manufacturing industry.

[19] The theoretically pioneering work is by Arrow (1962), who pointed out that a risk of underinvestment exists for all types of inventive activity in the form of production of new information (including knowledge), that is, not only for technical inventions, due to difficulties of selling information and thereby appropriating profits to cover investment expenses (the so-called 'information paradox'). A positive difference between social and private economic returns on innovations is thereby created, which was later empirically verified by Mansfield et al. (1977) and others.

inventions and therapeutic methods should be allowed. Other criteria may be hindrances. In the case of computer-related inventions, almost no hindrances exist as long as the inventions fulfill requirements of novelty, utility (i.e. industrial applicability and reproducibility without being generally harmful or indecent), and inventiveness. But it is very important that the latter requirement be raised according to the foregoing, in order to sort out small inventions and 'junk inventions' which do not demand large investment incentives but create high transaction costs. In this context, it is also worth noting that principles should be worked out to delimit a patent's scope of protection. As mentioned, this often becomes too large in new areas, which risks hindering continued development in the area.[20]

Hence, there are two paths to embark upon – an economic one with the above argumentation and a legal one with a renewed interpretation of 'industrially applicable' and/or a broadened interpretation of 'technical'. The last is not difficult to argue for.[21] Technology penetrates virtually all fields to an ever higher degree, as is well known. Thus takes place a 'technification' also of the social sciences, humanities, cultural life, forms of art etc. Technical colleges broaden their activities, not least in computer engineering and IT, and most companies are in some sense technology-based. At the same time, the limits are increasingly blurred between science (including mathematics) and technology. Development of, for example, new computer languages, translators and algorithms, requires large investment, involves a large measure of basic research, and possesses a clear technical character and industrial applicability potential. Technical aids are innumerable in virtually all research and invention work of any size, and so on.

The difficulties of implementing a broadened interpretation of 'technical' should not therefore be underestimated.[22] At the same time, an adaptation of terminology to new technologies is an important ongoing task for patent offices and courts in the area, a task which such authorities have much experience of.

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[20] Compare the limited geographical scope of a mining right resulting from a discovery of say a copper ore deposit, a right which does not extend far beyond the discovered site and thus does not cover more distant sites subsequently discovered, and in particular not all future copper ore deposits in the whole region or nation.

[21] It can be mentioned that 'technical' etymologically derives from the Greek concept 'techne', which had a much broader meaning in ancient Greece than in present-day interpretations of technical character (see e.g. Peters 1967 and Moravcsik 1992).

[22] Here one should weigh up the costs of a new delimitation and 'border control'. In principle, a theoretically less suitable delimitation may then be economically justified because its application (including border control) leads to lower total costs. In this way, for example, zero-tolerance limits can be motivated in certain cases.

To design supplementary requirements that are economically well-grounded is a larger, more difficult task, also due to the paucity of economic research in the area. This justifies seeing the proposal made here as a long-term one. Supplementary requirements should at least take account of an invention's investment character in regard to size, productivity and degree of original thinking (which is productivity-related), the invention's transaction-cost character, and its financing character. These types of requirement are closely connected with the requirement of inventiveness. Finally, it should be emphasized that a reformulation of the requirement of technical character in terms of investment character presupposes some coordination with raising the inventive step requirement. The latter should be carried out even if a requirement of technical character is retained, however. On the whole, therefore, these proposals do not mean that it necessarily becomes easier to obtain patents.

6.3.3 Surgical, therapeutic and diagnostic methods Surgical, therapeutic and diagnostic methods to directly achieve a medical effect are non-patentable in Europe according to the European Patent Convention (EPC), Article 52(4) while pharmaceutical products and processes (mostly) are patentable. In the case of the patenting of surgical, therapeutic and diagnostic methods or procedures ('STD methods' or 'STD procedures'), ethical motives can be formulated as hindrances. Non-economic motives must in such cases be considered generally to weigh more heavily than economic motives. However, economic motives also entail considering costs for individuals and society due to omitted or delayed new STD methods, considerations which in turn lead to ethical questions. STD procedures are currently developed mainly by medical practitioners on a small scale but the scale of development teams and resources needed generally tend to increase, for example, in connection with clinical testing. The question then is how costly a ban on STD methods or procedures is in terms of possible underinvestment in STD-procedure development and testing. Also the costs of administering the current exception from patentable subject matter should be taken into account, as well as the legal uncertainty associated with it. That ethical motives should in a non-discriminatory way hinder all STD methods is difficult to justify on economic grounds, and probably increasingly so due to the increasing costs of developing and testing STD methods. This is in addition to the difficulty of balancing contrary ethical concerns and the difficulty of weighing economic concerns in the total balancing act. Introducing exemptions and fair use principles, similar to US statutory law and practices, then seems to be more appropriate in the medical procedure area.[23]

[23] In these matters, discussions with Bengt Domeij have been very helpful. See also Domeij (2000).

More discriminatory principles for judging the patentability of STD methods thus must be worked out. This applies not only to STD methods, but to all inventions which may be reviewed for patenting if the requirement of technical character is reformulated and supplemented. Business methods require a special inquiry in this respect and what has been said above should not be taken as the wholesale acceptance of business method patents, far from it. Business methods are associated with managerial inventions which are special and require a special analysis. This must be set aside here, however.

7 How country specific are patent and innovation policy issues?

How far can the results, recommendations and policy issues presented in this chapter be generalized to other countries? First, patent policies and IP policies more broadly are international in nature as they pertain to an international patent system with a great many cross-country commonalities and harmonizing treaties. Thus, issues and recommendations related to the effectiveness of this system in general apply across countries (with some exceptions, e.g. regarding the role of national patent offices). Second, many countries have similar economic and technological conditions and increasingly so in a globalizing world. Small European countries like Sweden, Finland, the Netherlands, Switzerland etc. have a number of similarities, for example, being dependent upon a number of large multinationals with a high share of domestic R&D. Third, many of the governance issues in a knowledge-based and globalizing economy tend to be similar in nature across countries, at least in advanced countries. Fourth, since Europe is generally seen as lagging behind the US and Japan, and R&D, innovations and entrepreneurship issues are seen as the key for catching up, key patent and innovation policy issues can by and large be expected to be similar across countries in Europe. Fifth, a review of a number of patent policy and innovation policy studies shows a substantial number of similarities as to innovation policy issues and general recommendations, albeit a number of specific legal and economic differences exist regarding for example patent laws, institutional structure and industrial structure. This is also apparent from the literature on national innovation systems (see e.g. Nelson 1993). Primary discriminating country variables apparently include size of country and its stage of industrial development.

Thus, there are good reasons to believe prima facie that a number of the recommendations and policy issues raised in a Swedish context carry some weight in other European countries, especially other small countries and other advanced countries. At the same time generalizability can easily be exaggerated (for reasons of convenience if nothing else). A short summary of the investigation's recommendations which are not primarily specific to Sweden is therefore given in the appendix to this chapter.

It may finally be added as a matter of emphasis that to the extent that there

are substantial and increasing international commonalities as to patent and innovation policies for technology-based entrepreneurship much duplicative work could be avoided across countries. To the extent that there are international differences much policy research leverage could be gained in this area by comparative law and economics studies across countries. Altogether, this underscores the need for more international and interdisciplinary research and evidence-based policy making in the area of patents and innovation policies, not the least for harmonization purposes, as well as a certain harmonization of methodologies for IP and innovation policy studies.

8 Conclusion

The patent and intellectual property (IP) system is an institution for stimulating entrepreneurship toward economic growth and welfare. However, patent systems differ across nations and entrepreneurship comes in many forms (autonomous, corporate, state, university, military, etc.) as do innovations and new technologies. This creates growing tensions and misfits in an increasingly globalized and knowledge-based economy.

This chapter has briefly reviewed the linkages between R&D, patents, innovations, entrepreneurship and growth, based on a large set of empirical studies of Swedish conditions made for policy-making purposes. A number of issues are raised which generalize to European conditions, for example the role of patents in incentivizing R&D investments and entrepreneurship in various forms, software patenting and problems for SMEs in an increasingly patent-intensive world with patent-rich large firms and new entrants from Asia. The chapter concludes with a set of general as well as specific policy recommendations for strengthening entrepreneurship in Sweden and Europe. Among the specific recommendations are (a) the removal and reformulation of the technical character requirement, which is neither codified in law nor justified by economic principles; (b) the raising of the inventive step requirement; and (c) a differentiated reformulation of the patentability ban on surgical, therapeutic and diagnostic methods. The current situation in Europe in these three aspects limits entrepreneurship outside more narrowly defined technology-based entrepreneurship (e.g. in the service sector) and may distort entrepreneurship, for example by favoring incumbents.

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Appendix[1]

A General recommendations

1. Change the roles of, and the interplay between, state and industry in an economy which is ever more knowledge-based, more internationalized, and more IP-oriented.
2. Build up a national culture for IP and business development/entrepreneurship.
3. Strengthen the national entrepreneur system by:
   3.1 strengthening state (public) entrepreneurship, especially within the technology-based service sector, and in particular:

[1] The recommendations have been adapted to European conditions.

- the university and college sector (university entrepreneurship);
- the telecom and energy sector;
- the financial sector;
- the defense and security sector;
- the medical and health sector;

3.2 strengthening innovation-based entrepreneurship in small- and medium-sized firms ('SMFs'), taking account of the conditions for:

- SMFs outside the seats of universities and colleges;
- SMFs connected with universities and colleges;

3.3 safeguarding large companies' will and ability to create new business areas in addition to renewing the existing ones;
3.4 strengthening collaboration between innovation efforts in large and small companies;
3.5 strengthening the regional entrepreneurship;
3.6 raising the economic competence in the entrepreneur system and refining its financial support institutions.

4. Safeguard national growth appropriation.
5. Strengthen Nordic and European cooperation within the IP sector and in business development.
6. Promote English as an international language parallel with the domestic language.
7. Strive for greater effectiveness of the international patent system, especially regarding:

- harmonization of the international patent system;
- rationalization of the international system of patent offices;
- support for development of the PCT system;
- support for development of a unified patent system in Europe;
- support for development of a unified European court system specializing in patent cases;
- the assessment of patentability in some respects, namely:
  - raising the inventive step requirement;
  - reformulating the requirement of technical character and supplementing it with economically and ethically motivated requirements;
  - developing economic principles for patenting therapeutic methods within an ethical framework.

8. Transform selected local Patent and Trademark Offices offensively towards internationalization, diversification, rationalization and integration into a multinational EPO. The PTOs should thereby be commissioned to investigate the legal situation and need for legislation and changed instructions in order that the PTO can:

    - handle applications in English without requiring translation;
    - use price differentiation and subsidy of application costs in line with the present inquiry's recommendations;
    - make non-binding assessments of validity and infringement according to the British model
    - replace the requirement of technical character with a reformulated interpretation of the concepts 'industrially applicable' and 'investment character'.

9. Create a European Strategy Council for IP and innovation policies at the highest political level.

B Special recommendations to increase understanding, insight and propensity with regard to patenting

1. Raise the awareness of patents and the contribution of advice.
    1.1 Raise awareness of patents by

        - conducting state-supported programs for raising IP awareness ('IP-awareness programs');
        - carrying out a special 'patent year';
        - establishing competitions and prizes;
        - procuring broad national studies and inquiries which also in themselves yield increased awareness of patenting;
        - providing media support for IP-oriented publication;
        - carrying out special program measures directed at 'under-aware' company types and sectors;

    1.2 Increase advice by:

        - subsidizing advisory activities;
        - establishing and locating a number of positions (say about two per million population) for advisers in IP and business development;
        - coordinating efforts within EU;
        - ensuring patent and license competence for contract agreements and promoting a common European jurisdiction.

2. Improve the understanding of patents by:

    - building up education in IP and innovation economics by means of:

        - master programs;
        - graduate and teacher education;
        - obligatory minimum education ('conscript training');
        - procurement of teaching aids and information material;
        - specialist education for EPO certification;
        - education of IP advisers and IP managers;
        - continued education;
        - company-internal training;
    - establishing three to four national competence centers for education, advice and research in IP and innovation economics;
    - establishing three to four new professorships in IP and innovation economics, coupled with national competence centers;
    - developing and introducing a certification system for IP competence.
3. Stimulate companies' possibilities and will to patent by:

    - creating greater awareness of patents and understanding of patent economics as specified above;
    - introducing a special state patent fund for investments in patenting and patent education, coupled with other state R&D funding;
    - giving special stimulation to employment of internal patent specialists;
    - supplementing companies' internal stimulation measures and reward systems;
    - supporting the design of guidelines for handling patents and IP by company boards and business managers;
    - carrying out specially focused measures;
    - increasing resources for R&D;
    - improving the financing possibilities for patenting in SMFs, particularly during early innovation phases;
    - improving the patent economy in cases of dispute;
    - striving to expand the area of patentable inventions in the long run;
    - integrating active patenting policies with general R&D, innovation and growth policies, for example through better utilization of patent information;
    - earmarking 4 per cent ± 1 per cent of state R&D for patent and IPR efforts.

3 History of the patent system

John N. Adams

Introduction

Unlike trademarks, which can develop even in comparatively primitive societies in which particular makers' marks can acquire goodwill as people come to rely on them,[1] or copyright, which seems to represent a fairly basic instinct about the relationship of an author to his or her works,[2] patents seem to be a creation of advanced societies. Although it has sometimes been asserted that the earliest form of patents might have existed in 500 BC in Sybaris, Greece, where monopolies were granted to new dishes for a period of one year, and that the patents may also have existed in the Roman Empire where guilds existed, the only reliable historical evidence is that the system originated in Venice in the fifteenth century. A few patents had already been granted prior to 1474 when Venice promulgated its patent statute, probably the first modern patent law.

> We have among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our city, more such men come to us every day from divers parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honour away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth. Therefore:
>
> > Be it enacted that, by the authority of this Council, every person who shall build any new and ingenious device in this City, not previously made in our Commonwealth, shall give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and similar to said one, without the consent and license of the author, for the term of ten years.[3]

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1 *See* Schechter 40 HLR 813 (1927).

2 *See* Dock, 'The Origin and Development of the Literary Property Concept' [1975]. *Revue Internationale du Droit d'Auteur* 126; Phillips, 'St Columba as Copyright Infringer' [1985] EIPR 350; K. Bowrey [1996] EIPR 322.

3 Translation provided by Vishwas Devaiah I., *A History of Patent Law*, Alternative Law Forum website.

The next part of the story takes place in England and Wales. The ending of the wars in France in the mid-fifteenth century was succeeded by the dynastic Wars of the Roses, which ended with the battle of Bosworth in 1485, and the beginning of the Tudor monarchy. Quite a lot is known about the conditions in England in the early sixteenth century.[4] It was fertile, but in comparison to France, very underpopulated. It was also still essentially a mediaeval society. By the end of the Tudor dynasty in 1603 the country had changed dramatically. The dissolution of the monasteries, and subsequent break up of the monastic lands after 1535, which were concomitant with the Church of England's split with Rome, had released large amounts of capital. Major civil engineering projects such as the draining of the fens began to be undertaken, and the pre-conditions for the economic developments that would lead to England becoming the first industrial nation were beginning to fall into place.

A significant development in this respect was the beginning of the modern patent system. Historians have argued about how the practice of granting a patent monopoly to a deserving inventor as a reward for invention arose. A clear statement anticipating modern thinking can be found in the grant of a patent to Jacobus Acontius:[5] '. . . it is right that inventors should be rewarded and protected against others making profit out of their discoveries'.[6] Acontius may well have known about the Venetian patent system, but whether or not he, in effect, caused the invention of the English patent system has been much debated.[7] At all events in the decades following this grant, there came to be two distinct kinds of patents: those granting monopolies over things already invented including consumer staple products such as the manufacture of playing cards,[8] and those granting monopolies in inventions. The former were generally resented by both Parliament and the public, but the latter were viewed favourably. After the *Case of Monopolies*[9] which struck down the grant of a monopoly in the manufacture of playing cards, and the Statute of Monopolies 1623–4, the Crown's right to grant monopolies was restricted, saving the grant of monopolies for new and useful inventions. Section 6 of the

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4 *See* Hoskins, *The Age of Plunder*, Longman: London and New York (1976).

5 Acontius was born in Trent in Northern Italy around the end of the fifteenth century. He qualified as a lawyer, but was also a talented engineer, undertaking amongst other things the fortification of the town of Berwick on Tweed, and the draining of the Plumstead Marshes – *Dictionary of National Biography*, vol. I, p. 63.

6 Calendar of Patent Rolls, 7 Eliz 331.

7 *See* Phillips [1983] EIPR 41. The grant of patents to foreigners who wished to practise their crafts in England started in 1331, but it was not linked to any requirement of inventiveness. Indeed the grant of patents was largely a money-raising device for the Crown.

8 *See Darcy v. Allen* (1602) 11 Co Rep 84b.

9 *Darcy v. Allen* (above).

Statute of Monopolies allowed patent monopolies for 14 years[10] for 'any manner of new manufacture' within the realm to be granted to the true and first inventor.[11] The terms of the section make it clear that the statute was an instrument of economic policy; rather than being motivated by the desire to do justice to the inventor, it was meant to encourage industry, employment and growth. The patentee's consideration for the grant was that he would put the invention to use.

Between the passing of the Statute of Monopolies and 1800, the Union of Scotland, and England and Wales, took place[12] and the United Kingdom emerged as the first industrial nation.[13] Although, as it were, the building blocks for the emergence of a modern patent system were in place by 1700, the transformation of the system in the course of the eighteenth century is a crucial part of our story.

The development of the United Kingdom patent system during the eighteenth century

Little work has been done on the history of patent law in the eighteenth century since the pioneering articles of Wyndham Hulme and Seaborne Davies at the turn of the nineteenth and twentieth centuries.[14] Holdsworth relied heavily on this work.[15] Holdsworth took the view that Lord Mansfied's

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[10] This period seems to have been arrived at on the basis of two apprenticeship terms which were considered sufficient to teach the art to the unskilled. The fact that the term for copyright was set at the same period by the Statute of Anne 1709–10, and that trademarks were renewable for seven-year terms down to the Trade Marks Act 1994 shows the lasting influence of the 1623–4 Act.

[11] This must be understood as the first introducer of a new technology into the realm, not the first inventor in worldwide terms as is the modern requirement – *Edgebury v. Stephens* (1693) 1 WPC 35.

[12] Through the Acts of Union which were a pair of Parliamentary Acts passed in 1706 and 1707 by the Parliament of England and the Parliament of Scotland respectively that took effect on 1 May 1707. These Acts were the implementation of the Treaty of Union negotiated between the two countries. The Kingdom of Great Britain was created by merging the Kingdom of England and the Kingdom of Scotland. Since the Union of the Crowns in 1603, the two countries shared a monarch but retained separate and sovereign parliaments. The Acts of Union dissolved both the parliaments of England and Scotland and replaced them with a new parliament, called the Parliament of Great Britain. This new parliament was (and still is) based in Westminster, the former home of the English parliament.

[13] *See* Mathias, *The First Industrial Nation: An Economic History of Britain 1700–1914*, Scribners: New York (1969).

[14] Hulme (1896) 12 LQR 141; (1897) 13 LQR 313; (1900) 16 LQR 44; (1902) 18 LQR 280; (1907) 23 LQR 348; (1917) 33 LQR 63; Davies (1932) 48 LQR 394; (1934) 50 LQR 86, 260.

[15] XI HEL 424 *et seq.*

decision in *Liardet v. Johnson* (1778)[16] was crucial to the development of the modern law. Hulme believed that with *Liardet v. Johnson* the law took a wrong turn. Under the old practice the test of novelty was whether or not the invention had already been used and worked in the realm. Under the 'new' practice, the test was whether prior disclosure within the realm in any form had been made (i.e. the law was moving towards the modern test). The result was first of all to attach undue importance to the patent specification, and secondly to debar the inventor from incorporating into his claims unused public knowledge. He considered that the valuable consideration which the inventor brings in return for the patent monopoly is the expenditure of personal effort and capital, and that this obligation should never have been allowed to disappear from the law.[17] It is worth quoting Hulme's views on the significance of *Liardet v. Johnson* at length, for in the course of this chapter it will be argued that they are largely wrong. He suggested that:[18]

> In 1778 Lord Mansfield in *Liardet v Johnson* – a trial which may be regarded as a landmark in the history of English patent law – invested the patent specification with a character and function totally distinct from that with which it had originally been introduced . . . From [Bramah's letter[19]] we gather that the doctrine of the instruction of the public by means of the personal efforts and supervision of the grantee was definitely and finally laid aside in favour of the novel theory that this function belongs to the patent specification, an instrument introduced by the irony of fate to make the grant more certain! At the same time, the novelty of the invention was subjected to a new and more searching test. Hitherto the novelty of no grant appears to have been successfully challenged except upon the ground of prior user within the Realm, but in this trial the practice of what is known as 'mosaic anticipation', was admitted in impeachment of the inventor's privilege. So complete a *volte face* could hardly have been effected if the history of the law had possessed some sort of continuity. This however does not appear to have been the case.

He goes on to note that for over a century the reports are destitute of any decision of importance in this branch of jurisprudence.[20] At the end of the eighteenth century, therefore, the common law judges were left to pick up the threads of the principles of law without the aid of recent and reliable precedents.

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16 The references to this case are given under the relevant points in the text.

17 (1917) 33 LQR 194–5.

18 (1897) 13 LQR 313.

19 Joseph Bramah was a notable British inventor and the holder of many patents. He was one of the first people to propose the use of the screw propeller for ships.

20 There are no reported cases from *Edgeberry v. Stephens* (1693) Salk 447 to *Turner v. Winter* (1787) 1 TR 602. However, cases such as *Dolland's* (1766) did find their way at a later date into the specialist series of reports produced by Davies, Carpmael and Webster.

A re-examination of this topic is timely in view of the proposals made by Professor Kingston of Trinity College Dublin over the last quarter century that something like the old system should be re-introduced, and limited monopolies granted in return for the introduction of new industries.[21]

There are other reasons too for taking a fresh look at this topic. Since Hulme and Davies's time much work has been done on eighteenth-century patents by historians of science, and by economic historians,[22] but, interesting as these are, they have tended to neglect the legal aspects. Professor Robinson's work on the Boulton and Watt papers has also revealed some exceptionally interesting material.[23] The Mansfield Court Notebooks have been found, and these contain the notes of one of the two *Liardet v. Johnson* hearings as well as other cases of interest. Moreover, a great deal of work has been done on the background to *Liardet v. Johnson* by Frank Kensall.[24] Finally, it has become much easier to gain access to law-related materials such as printed pamphlets through the *Bibliography of Eighteenth Century Legal Literature*,[25] and in the case of British Library holdings, through the Eighteenth Century Short Title Catalogue which is available on-line through the British Library Catalogue. All these sources were used in writing this chapter.

The traditional account

Holdsworth writes:

> Perhaps the greatest change in patent law, which [the transfer from the Council] to the courts made,[26] was the view taken by the courts as to the consideration for the grant of the patent. Under the old practice the consideration for the grant was the introduction into, and working of, a manufacture which was new to Great Britain.

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21 *See, e.g.*, Kingston. 'The Political Economy of Innovation' 15 *R & D Management* 251 (1985). These proposals have been much misunderstood. What Professor Kingston proposes is not replacement of the present patent system, but the introduction of a parallel system to encourage innovation directly (which the patent system only does indirectly).

22 *See, e.g.*, Mountfield 2 *Industrial Archaeology* (1978); Winship 16 *Industrial Archaeology* 261 (1981).

23 'James Watt and the Law of Patents' 13 *Technology and Culture* 18 (1972).

24 Frank Kelsall worked for the Greater London Council as an architectural historian from the 1960s to 1986. He then joined English Heritage as an inspector of historic buildings. Since early retirement in 1998 he has acted as casework adviser to the Ancient Monuments Society and, with Dr James Anderson, has founded the Architectural History Practice. A copy of his paper was kindly made available to me by the author.

25 Adams, Averley and Robinson. Newcastle upon Tyne. Avero. 1982.

26 That is, the transfer to the courts of the Council's jurisdiction in patent cases.

> Under the new practice the consideration is the written disclosure of the invention contained in the specification.[27]

He goes on to point out that the reason why the courts were able to introduce this new principle into the law was a change in the kinds of invention for which patents were sought. He goes on to cite Hulme:[28]

> So long as the monopoly system aimed at the introduction of new industries such as copper, lead, gold and silver mining, or the manufacture of glass, paper, alum etc. etc., the requisition of a full description would have required a treatise rather than a specification . . . But when, by natural development, the system began to be utilised by inventors working more or less on the same lines for the same objects, the latter for their own protection drafted their applications with a view of distinguishing their processes from those of their immediate predecessors, and of ensuring priority against all subsequent applicants. Hence, while the recitals of the sixteenth century deal almost exclusively with suggestions of the advantages which would accrue to the State from the possession of certain industries, or with statements respecting steps taken by the applicants to qualify themselves for the monopoly, those of a later date not infrequently deal with the technical nature of the proposed improvement. These recitals, therefore, while forming no part of the consideration of the grant, are undoubtedly the precursors of the modern patent specification . . . About the year 1730 the form of proviso voiding the grant in the case of non-filing a specification was substituted. Still the practice of requiring a specification cannot be said to have been recognised as essential to the validity of the grant prior to the middle of the eighteenth century.

Now the question of the origin of the practice of enrolling specifications is of some importance. If enrolment were *required* from the outset, it would suggest that the function of the specification had always been the dissemination to the public of information about the invention,[29] in which case *Liardet v. Johnson* looks much less revolutionary. Hulme had another explanation for the origins of the practice, however. He suggested that the enrolment of specifications was done in the first place at the suggestion of the grantees, to make the grant more certain. This suggestion was largely based on certain words in Nasmyth's Patent 1711, which is the first patent to involve enrolment of a

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27 XI HEL 427.

28 (1897) 13 LQR 313, 317.

29 The distinction between the description element of the specification and the claim was a statutory creation – Patents Act 1883 s. 5 – First Schedule. Actual practice long pre-dated the Act, however, to the extent that patentees did end their specifications with a statement of the features of the invention that they considered new and important. See *R v. Else* (1785) Dav Pat Cas 144, 1 Web 76, Carp 103; *Bovill v. Moore* (1816) 2 Marsh 211. The requirement of a claim was introduced in the United States by the Act of 1836.

specification,[30] in particular the words that the grantee had 'proposed to ascertain the same in writing'. He also relied on an apparent anticipation of enrolment in Sturtevant's Patent of a hundred years before. However, Davies demonstrates that Hulme may have over-estimated the importance of this particular instance.[31] Seabourne Davies however adduced two further arguments to support Hulme's view: (1) if the Crown had insisted on enrolment, it is strange that for the next 20 years[32] or so, enrolments are intermittent, and it is not until 1723 that it is definitely stated that a patent will be voided for non-enrolment within the time specified;[33] (2) a letter in State Papers Domestic dated 20 May 1710 addressed to Boyle, the Secretary of State, from one 'T. T.' discloses the dangers of piracy to which inventors were exposed,[34] suggesting that inventors at the time were exercised to find a solution to this problem. We will argue that alternative explanations are available both for the fact that enrolments were at first sporadic, and for the fact that the system of enrolment was introduced in 1711. The best support for Hulme's argument is the wording of Nasmyth's Patent. As Seaborne Davies pointed out, however, it is dangerous practice to rely too much on the exact language of historical documents. Even in the limited field of patent law, examples can be found of suggestions emanating from the Crown being embodied in patents in language which suggests they were made by the patentees, and vice versa.[35]

No direct evidence appears to exist about the origin of the practice, and we must therefore make what we can of the circumstantial evidence. In this respect both Hulme and Davies seem surprisingly to have overlooked two obvious facts. In the first place, there is a time stipulated in the proviso for the filing of the specification and the time stipulated differs from patent to patent throughout the century.[36] Secondly, the filing of drawings and plans of mechanical inventions becomes increasingly common from about 1741.

The fact that the time stipulated for filing is sometimes one month, sometimes two, sometimes three, sometimes four and sometimes six months is difficult to explain if the filing of the specification was suggested by the

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30 Patent Roll 10 Anne Part 2.

31 (1934) 50 LQR 86, 91.

32 It did not become the rule until after 1734, and was not uniformly required until after 1740. There are exceptions thereafter, e.g. Nos. 581 and 653 – Davies, *loc. cit.*

33 Davies does not give the reference, but it is in fact Champion's Patent 1723 No. 454. See also Barlow's Patent 1731 No. 526.

34 S. P. Dom. Anne, Bd. 12 No. 74.

35 (1934) 50 LQR 86, 91.

36 Towards the end of the period it is generally, but not always, one month.

patentees.[37] Surely a uniform time would have been fixed. More importantly, why in fact stipulate a time at all? It looks more likely that a bargain was struck between the Crown and the applicant on a case-by-case basis.[38] Why then were specifications not filed in all cases between 1711 and 1734? A clue may possibly be gathered from the early practice of the American patent system. The Patent Act of 1790 provided for an examination for conformity with the laws, and for novelty, by a Board of Examiners consisting of the Secretary of State (Thomas Jefferson), the Attorney-General and the Secretary of War. It was soon discovered however that the Board of Examiners could not cope with the workload. The burden of work involved proved too much for these busy officials, and after three years the examination requirement was dropped and replaced by a simple registration system, validity being determined by the district courts. Registration therefore involved simply a clerical act.[39] Now the English patent system throughout the eighteenth century similarly involved purely clerical acts. The procedure for the grant described by Collier in this *Essay on the Law of Patents* of 1803 is the same as at the beginning of the eighteenth century, with of course a requirement of enrolment of a specification by then being invariable. A petition accompanied by an oath taken before a master in Chancery declaring the invention to be new was formally made to the Crown. It was dealt with by the Secretary of State, who in turn passed it on to the Attorney-General or Solicitor General for a report. The particular Law Officer then reported to the Crown as to whether it should be granted. Assuming the reports were favourable, the patent would be issued and the specification would then have to be enrolled within the time specified. The report of the Law Officers was a matter of course.[40] At no point did the system offer any real opportunity for examination as to novelty, nor in due course as to the adequacy of the specification. These matters would only be tested if the validity of the patent were challenged. The fact that the Law Officers probably administered the system in the most cursory way is

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[37] In Nasmith's grant itself, a period of one month was originally fixed, but at his request the period was extended to six months – S. P. Dom. Anne, Bd. 16 No. 88. This is cited by Davies, *loc. cit*. Indeed we can find the odd example of what amounts to a specification being included in the grant itself until quite a late period, e.g. Plenius Patent 1745 No. 613.

[38] *See, e.g.*, Puckle's Patent 1718 No. 418 which was for a precursor of the Gatling gun. It recites that the Petitioner 'having humbly prated etc. buy thinks it not safe to specify wherein the new Invention consists . . . ascertained etc. . . . three months'. A plan of the gun was enrolled.

[39] *See* Coryton, *A Treatise on the Law of Letters Patent*, H. Sweet: London (1855).

[40] Godson, *Treatise on the Law for Patents and Inventions*, Saunders & Benning: London, p. 140.

suggested by a case as late as 1774 where the Lord Chancellor refused to append the Great Seal to a patent, presumably on the ground that the claim was so obviously fraudulent.[41] Indeed the very fact that the specifications were required to be enrolled in Chancery, rather than form a part of the petitioning procedure, suggests that the Law Officers did not wish to be encumbered with additional administrative work. We must remember that they were busy men, who throughout the century had to handle their work through their chambers. No doubt enrolment could be helpful to inventors themselves in assisting them in asserting their patent rights against infringers and the idea of requiring some form of enrolment may have gained currency among them.[42] Equally, however, it seems probable that it was the Law Officers themselves who, having become dissatisfied with the dissemination of information about inventions, hit upon the idea of requiring enrolment where they thought fit, and when they thought fit, which in the early days was no doubt when, occasionally, they actually put their minds to it.[43] It is also to be noted that, throughout the century, specifications were enrolled which could in no way have enabled those skilled in the art to carry out the invention, and which would have been valueless in an infringement action, suggesting therefore that enrolment was always a requirement imposed upon persons often reluctant to disclose their inventions.[44] There were two opposing views on the desirability of permitting

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41 Hannay's Patent 1774. The subject was a protective wash against venereal disease. See also *ex parte Reilly* (1790) 1 Ves Ch 112 – refusal to seal a patent for presenting Italian operas.

42 *See* Davies (1934) 50 LQR 86 and 260 for possible seventeeth-century anticipations.

43 Nasmyth's application passed through the hands of the Attorney-General. It is unlikely however that such an innovation would have been made without consultation. In Lombe's Patent No. 422 (1718) which involved the pirating of an Italian machine for making organzine (silk), the discovery of the Italian secret was considered so important that a requirement that models (presumably plans) be permitted to be taken and lodged in the Tower was inserted.

44 The validity of the patent may not have been of prime importance to many 'inventors'. Merely to describe the goods as 'patented' seems to have had a marketing draw. 'The Patent', a poem by the author of 'The Graces' (1776) contains the following lines:

> Hail to the Patent! which enables man
> To vend a folio . . . or a Warming-pan.
> This makes the Windlass work with double force,
> And Smoke-jacks whirl more rapid in their course;
> Confers a sanction on the Doctor's pill,
> Oft known to cure but not unknown to kill.
> What man would scruple to resign his breath,
> Provided he could die a Patent death.

patents for useless inventions. One view was that it did not matter: if an invention were a commercial success, that indicated its utility (a view which survives to this day); if not, no harm was done because obviously no one wanted the thing. The other view was that these valueless patents were an oppression.[45]

It seems likely moreover that from the outset failure to enrol, or failure to enrol an adequate specification, would have been liable to render the patent void *if challenged*. If it is correct to assume that enrolment was from the outset a requirement, it is unlikely that anyone would be required to enrol a specification which did not necessarily have to convey any useful information at all. Why indeed, as we have just observed, are so many specifications vague and evasive if patentees were trying to make their grants more certain?[46] Why bother to enrol such specifications? The fact is that it is not specifically declared that a patent is void for failure to file until 1723[47] is not necessarily particularly significant.

Why then did enrolment first become a requirement in 1711? We have noted the evidence adduced by Seaborne Davies that inventors themselves were concerned about piracy. However, a possibly more significant development which supports our argument has been suggested by Dr Jeremy Phillips. From 1709 a proprietary monopoly in books was granted, actionable when copies were deposited, the value of the 'monopoly' depending on the text of the book.[48] It seems quite likely that this system was transferred to patents, and indeed the tendency to confuse the two types of monopoly continued for most of the century. For example, 'The Patent'[49] begins with the lines –

> Hail to the Patent! Which enables Man
> To vend a *folio* [emphasis added] or a warming pan

The second point we believe to be significant is the tendency to file plans and drawings after about 1741. This is no doubt connected with the increas-

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45 See *Hornblower v. Boulton* (1799) 8 TR 95, 98 per Kenyon CJ (later Lord Kenyon), and see 'Observations on the Utility of Patents' (1791), catalogued in the BL under 'Kenyon, Lloyd', passim, but especially pp. 18–19. It is probably by Beetham, the inventor of a washing mill, given the extensive 'plug' given for that apparatus.

46 Most of the early specifications are vague, but some are particularly so. See e.g. Allen's Patent No. 513 (1729); Churchman's No. 514 (173) and 539 (1733); and Henry's No. 601 (1744).

47 Champion's Patent No. 454 (1723).

48 9 Anne c. 19 (1709–10). Copyright is not of course a monopoly in the same sense that a patent is. *Millar v. Taylor* (1769) 4 Burr 2303 illustrates this tendency to equate the two, see especially pp. 2387 *et seq*.

49 Above n. 44.

ingly technical nature of inventions, which were difficult to explain in words, but it is consistent with the view that the doctrine that the function of the specification was to instruct the public long preceded *Liardet v. Johnson*. The older doctrine of instruction by means of personal efforts and supervision must simply have fallen into disuse: it was certainly not expressly abolished in *Liardet v. Johnson* or in any other known authority. The filing of plans must also have become increasingly necessary because many inventions were improvements to existing manufactures, rather than entirely new manufactures. Coke had held in *Bircot's* case[50] that an addition to an existing manufacture was not patentable, but in the quite different industrial climate of England in the eighteenth century this view was clearly untenable, and actual practice seems to have significantly anticipated an actual decision to this effect.[51] Apart from anything else, adherence to Coke's view would have begged the awkward question as to when an improvement transformed a machine into another machine. In general, from quite early on, specifications for well-known but complicated machines spell out the novel features and make these the specific subject of the patent. This is well illustrated by the harpsichord and piano patents.[52] It was not always the case, however. In this respect too, specifications are sometimes vague and evasive and, as has been pointed out above, this was inevitable in the absence of an examination system.[53] Moreover, as we will see later, there is clear evidence that even before *Liardet v. Johnson* inventors had to confront the agonising choice between exact specification, with the risk of 'inventions' being distinguished by minor variations, and over-general specifications, with the risk of invalidity.

Finally, if *Liardet v. Johnson* were of central importance, we would expect it to be well recorded, and much used in the literature on patents which appeared from early in the nineteenth century. As we shall see, it is not. After a short popular notoriety, because of the parties involved in the litigation, it virtually passed out of public consciousness. Let us now consider the case.

The patent

On 3 April 1773[54] John Liardet was granted a patent for a composition or

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50 Inst. 181, 182–3.

51 *Morris v. Branson* (1776) a decision of Lord Mansfield referred to in *Boulton & Watt v. Hornblower* (1795) 2 HY Bl 489.

52 *See* Nos. 581 (1741), 613 (1745), and 1081 (1774). Similarly, watch patents, e.g. No. 698 (1755). In *Jessop's* case, referred to in *Boulton v. Bull* (1795) 2 H Bl 487, 489, a watch patent was held void because it extended to the whole watch, not the particular movement.

53 *See, e.g.*, No. 947 (1769) Shudi's Patent for a harpsichord.

54 Part 15 No. 5 ms. 10–12.

cement upon what was by this time the usual proviso that he should enrol a specification in this case within four months.[55] According to his naturalisation bill[56] John Liardet was born in Lausanne, in the canton of Berne, Switzerland. He was the son of George and Margaret Liardet. He was a Protestant and apparently a clergyman. For many years before 1773 he had 'employed his time and thoughts in philosophical and mercantile researches for the improvement and embellishment of arts, and your orator attentively pursued a course of speculation and experiments for that purpose, with a prospect and view of deriving some profit and emolument from such his discoveries'.[57] These researches produced his patented stucco, which formed the bone of contention in *Liardet v. Johnson*. This invention had been taken up by the Duke of Northumberland who put Liardet in touch with the Adam family.[58] The Duke recommended a partnership, Liardet being 'a very studious abstracted man and wholly inexperienced in transactions of that nature'. In April 1774 Samuel Smith, an attorney of Marylebone, drew up an agreement. Liardet, it appears, could not understand English, and Lady Straughan, a friend of Liardet's wife, approved the draft. The partnership was dated 20 May 1774, and in consideration of £100 paid on that date, and £400 to be paid later, Liardet assigned the patent to the Adams family.

The patent was reassigned to Liardet on 10 February 1776 so that Liardet could apply for an Act of Parliament extending the term. An Act extending the term to 18 years was duly passed. The Act required Liardet to enrol a specification within four months, giving details of improvements to his original specification.[59] The enrolment was made on 4 September 1776. This Act fixed the prices which could be charged to the public at 6d per square foot on the surface of all plain buildings, and 2d per foot running measure for arrises. No reassignment of the patent to the Adams family took place, but they continued making and using the composition (presumably by implied licence from Liardet).

John Johnson who, at the time of the trial, was living in Berners Street, came originally from Leicester. He was at the beginning of a successful career in the course of which he built up a successful practice in London and designed several country houses. He also became county surveyor to Essex,

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55 Enrolled 3 August 1773 – i.e. within the time. 1 Y & CC 527.

56 16 Geo III c. 41 passed 25 March 1776.

57 For the following account of the background to the case, and the subsequent case of *Liardet v. Adam*, we are indebted to Frank Kelsall of the then GLC Historic Buildings Division, and particularly to his paper to the BIBA Library Group on 28 January 1974.

58 The architects.

59 2 B 411 Hil 1777.

and designed several buildings in Chelmsford. The Shire Hall there is perhaps his most famous work. The substantial allegation against Johnson was that he had inspected the specification,[60] copied it, and used the composition. There was also, however, an allegation that he had suborned some of the Adams's workmen to acquire the trade secrets.

In May 1777 a bill[61] was filed by Liardet and the four Adam brothers: John, Robert, James and William against John Johnson, Edward Downes and Edward Bellman, and praying an account and an injunction.[62] An affidavit setting out the grounds of complaint was filed on 27 May 1777. Johnson in reply put in an affidavit which tended to impeach the novelty of Liardet's cement and also to prove that what he had used was materially different from it, but which did not directly deny the novelty of Liardet's composition.[63] Counsel having been heard, Bathurst LC on 12 July 1777 issued an injunction against Johnson and his servants restraining him from making, using or vending the composition, on the plaintiff's undertaking to bring an action at law and proceed to trial without delay. Johnson, Downes and Bellman[64] put in Answers on 2 September 1777.

Johnson's Answer first of all asserted that he had been told that Liardet was not the inventor, nor were the 'imaginary improvements' made by Liardet.[65] The allegation was supported by citing supposedly similar recipes to those of Liardet's specification: (a) *A New and Universal Dictionary of Arts and Sciences* published by John Hinton (1751) and the second edition of this work published by Mr Owen (1764); (b) Charles Rawlinson's patent for a composition for slates on roofs (published in his *Directory for Patent Slating* (1772)). He also asserted that his own invention did not infringe Liardet's but improved on it by the addition of serum of blood. He had inspected Liardet's second specification to make sure that he was not infringing the patent.[66] John Johnson's Answer was signed by Johnson himself, and by Lloyd Kenyon and John Mitford his counsel.

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60 This allegation presumably referred to the second specification. In fact he appears to have inspected both – n. 66 below.

61 That is, a bill in Chancery, a document setting out the plaintiff's case.

62 PRO/C. 12/.1346/22.

63 1 Y & CC 527, 528.

64 'I suppose though, as no proceedings were had against him, his answer was not stated in the briefs for the Plaintiff' – 1 Y & CC 527, 530. This insertion is presumably the actual reporter of the case, Douglas.

65 He also questioned whether the original specification was enrolled in time, but this point does not seem to have got anywhere – 1 Y & CC 527.

66 Probably both specifications – see *An Appeal to the Public on the Right of Using Oil Cement* (1778).

Upon the Answers coming in, the plaintiffs brought an action on the case against Johnson. The declaration contained four counts:

(1) 'making, using and putting in practice' his invention;
(2) 'making, using and putting in practice' part of his invention;
(3) 'counterfeiting, imitating and resembling it';
(4) 'making and causing to be made additions to his invention, whereby to pretend himself the inventor and for pretending himself the inventor'.

The case was first tried before Lord Mansfield on Saturday 21 February 1778 at Westminster Hall. The trial lasted six hours, and the jury was out one hour and brought a verdict for the plaintiff.[67] The fact that the Adam brothers were fellow Scots, and had stuccoed Mansfield's own house at Kenwood (Caen Wood) with the composition, caused some unfavourable comment and allegations of bias.[68] It may explain Mansfield's subsequent readiness to grant a new trial, on what does not seem to have been markedly different evidence from that given at the first trial.[69] He granted a rule saying that they ought to consider whether on the first trial the cause had been so completely discussed as to be a ground of perpetual injunction.[70] The second trial, which is reported as having taken place before Mansfield on 18 July 1778[71] at the Guildhall, lasted 14–15 hours.[72]

The cements

As Frank Kelsall has noted,[73] the trial, which should have been on the law of patents, rapidly turned into a trial of the relative merits of the cements.

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67 *London Chronicle*, Tuesday 24 February 1778, *Daily Advertiser*, 24 February 1778. A fuller report combined in the *Morning Post and Daily Advertiser*, 23 February 1778, is quoted verbatim by Hulme in (1897) 13 LQR 313. Mansfield's own notes of this trial survive in his Notebooks, but not of the second trial.

68 Evidence to the effect that Mansfield's house had been done four years previously was given by [Thomas] Rose, a well-known plasterer.

69 This is confirmed by the notes on the first trial taken by Mansfield. The evidence given at the second trial appears in *An Appeal to the Public on the Right of Using Oil-cement or Composition for Stucco*.

70 1 Y & CC 526.

71 It is reported in the *Morning Post and Daily Advertiser* 20 July 1778 and the *Gazeteer and New Daily Advertiser* of 20 July 1778. The Notebook which must have contained Mansfield's notes of the trial is missing.

72 Open letter, Joseph Bramah to Eyre CJ, BL Law Tracts 1716–1816. Bramah asserts that he was present throughout the trial. 1 Y & CC 526 gives it as lasting from 9.00 am to 11.00 pm.

73 *See* n. 24 above.

The practice of stuccoing buildings went back as far as the sixteenth century, but became widespread only in the eighteenth century, with the fashion for Palladian architecture. The trouble was that the English climate is not as kind to stucco as the Italian, and the search therefore began for a more durable and lasting composition than lime plaster. In general the supposition seems to have been that an oil-based cement would be more durable, and the compositions considered in *Liardet v. Johnson* all employed this medium. It was not until the scientific experiments conducted by Dr Bryan Higgins (a witness in *Liardet v. Johnson*)[74] and by Smeaton demonstrated the fallacy of this theory, that a durable stucco emerged. Oil-based cements are a kind of putty, and as we all know, oil dries out and cracks develop. Water can penetrate these cracks and the frost then causes the stucco to come away from the wall. This in fact seems to have happened to Liardet's cement, as is apparent from the subsequent case of *Liardet v. Adam* in which he attempted to obtain from the Adams family an account of the profits they had made.[75]

The plaintiff's invention consisted of a mixture of whiting, sand, lead (white or red), oil and drying ingredients, mixed together in certain proportions for the first coat, and differing proportions for the second coat. The chief novelty of this invention allegedly lay in the addition of a drying agent. The defendant alleged that his composition consisted of lime and sand, oil and serum of blood, in other words, that the plaintiff's recipe had no serum of blood, the defendant's no lead and no drying ingredients. However, as the evidence came out in court, it appeared that serum of blood was a useless addition, and that the defendant did in fact use both lead and drying ingredients. Dr Higgins performed an experiment upon a sample provided by the plaintiff, and upon a sample removed from a house which Johnson had plastered. He found the differences trifling.[76]

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[74] Higgins was working on his own recipe at the time of the trials and obtained a patent on 8 January 1779. See Gibbs, 'Bryan Higgins and his Circle', *Chemistry in Britain* (1965), pp. 60–63. Reprinted in A.E. Mussan (ed.), *Science, Technology and Economic Growth in the Eighteenth Century*, London: 1972.

[75] Complaint of the Reverend John Liardet, 18 December 1782. PRO/C12/921/11. Again Frank Kelsall must be thanked for details of this case. The Answers filed by the Adams complain about the failures of the cement.

[76] This evidence by Higgins provoked the following lampoon from the Johnson camp:

> Mr Alderman Cuttle, of Pudding Lane being much disordered on the morrow of the last city feast, dispatched his apothecary with four ounces troy of the indurated faeces, protruded *a retro* in the form of a Bologna sausage, requesting the Doctor to make an assay of the compound, and return the particulars of the analysis; a request he complied with in the terms and manner following:

Thus the question of the validity of the plaintiff's patent came to be raised. Was the cement a new invention or not? On this question much evidence was adduced, which in effect amounted to a challenge to the validity of the patent on the ground of 'mosaic anticipation';[77] Alberti's book,[78] a dictionary of 1726,[79] and four more to 1764. None of the recipes contained in these sources contained lead. Next Emerton's specification of 1737 and Rawlinson's of 1772 were produced. Rawlinson's patent was for a mortar for laying slates in, and it contained neither sand nor drying ingredients. Rawlinson alleged that in 1772 he had used a recipe similar to the plaintiffs, but had not patented it. Dr Higgins again did experiments on Rawlinson's three recipes and found the differences between them and the plaintiff's recipe to be very great. The questions for the jury were therefore: (1) whether the defendant had used the composition; (2) whether it was new or old; (3) whether it was in use in the trade, or really was a new invention; (4) whether the specification was sufficient to teach other artists to make use of the compound. Mansfield, it may be noted, relied on no authorities in posing these questions, but it is clear that the important fourth question reflected a view current before the case.[80] The jury brought in a verdict for the plaintiffs, and on 5 July 1780 Eyre B issued a perpetual injunction against Johnson.[81]

The subsequent record of the case

The *nisi prius* trials are not reported in any law report series. The first trial was

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Of turtle 3oz 0dt 0gr
Of green fat 0oz 10dt 0gr or more
Of marrow pudding 0oz 0dt 4gr or less
Of crumb pudding 0oz 0dt 4gr or less
Total 4oz 0dt 0gr

Let the world judge if an adept capable of decompounding aliment, so levigated by the animal organs or secretia and excretia as must have been the calipash, palipee, marrow pudding etc above mentioned – Let the impartial world judge, we say, if such an adept in chemistry can be incapable of discriminating in like manner the same quantum of sand, calcarious earth, linseed oils, and calx of lead, made up in the form of stucco.

Magna est veritas et prevalebit

[77] According to Hulme, this was a further innovation for which this case was responsible – see text above n. 17.

[78] Presumably the 1726 translation of his works by J. Leoni, see *An Appeal*, p. 52.

[79] *See An Appeal*, p. 56, and Mansfield's summing up in *A Reply to Observations and Two Trials at Law* (1778).

[80] *See* letter written to Wolf in 1769 by William Small, cited in Robinson, *loc. cit.*

[81] 1 Y & CC 526.

reported in *The Morning Post* of 23 February 1778, *The Public Advertiser* of the same day and the *St James's Chronicle* 21–4 February 1778.[82]

The second trial is known to us principally through pamphlets published by the parties after the second trial. Johnson caused to be published *An Appeal to the Public on the Rights of Using Oil-cement or Composition for Stucco*.[83] The Adams party published a *Reply* to this pamphlet which sets out Mansfield's summing up to the jury and Wallace's reply to Dunning, who had been one of Johnson's counsel.[84] Joseph Bramah also wrote an account of the case in an open letter to Eyre B when he was involved in *Boulton v. Bull*.[85]

As soon afterwards as 1787 in *Turner v. Winter*,[86] Buller J mentions only the case of trusses,[87] but not *Liardet v. Johnson*. The reporter has added a reference to the fifth edition of Buller's *Nisi Prius* at p. 75 which is in fact *Liardet v. Johnson*. This is no doubt the source of subsequent confusion, for a number of later authorities identify *Liardet v. Johnson* as the case of trusses. Buller's *Nisi Prius*[88] in fact incorrectly records the outcome. His version is evidently based on the defendant's pamphlet.[89] This version finds its way into Carpmael's[90] and Webster's[91] Patent Cases, which therefore also mis-record

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82 Wyndham Hulme records having found only these three reports, having searched the: *Morning Chronicle*, *Gazetteer & New Daily Advertiser*, *Daily Advertiser*, *London Chronicle*, *London Evening Post*, *General Advertiser and Morning Intelligencer*, *General Evening Post*, *Westminster Journal* and *London Political Miscellany* – see the documents placed by him in the Patent Office Library (now the British Library) under the title '*Liardet v Johnson*'. It also appears however in the *London Chronicle*, 24 February 1778. It is by no means clear that he realised that a second and longer trial had taken place on 18 July 1778, and that it is that to which the pamphlets mentioned in the following paragraph refer.

83 Printed 1778 and sold by J. Hand, 409 Oxford Street, J. Ben, Paternoster Row, and J. Pridden, 100 Fleet Street. See also the reports in the *Morning Post* and *Daily Advertiser*, 20 July 1778.

84 *A Reply to Observations on Two Trials at Law* (1778).

85 BL Law Tracts 1716–1816, *A Letter to the Rt Hon Sir James Eyre CJCP on the subject of the cause Boulton & Watt v. Hornblower & Maberley*, John Stockdale, Piccadilly 1797.

86 (1787) TR 602, Web 77, Buller J observed that 'Many cases upon patents have arisen within our memory, most of which have been decided against the patentees on the ground of their not having made a full and fair disclosure of their inventions' – he held the specification bad in that case.

87 This appears to involve Brand's Patent No. 996 (1771). The case does not appear in the Mansfield Court Notebooks. It is the only patent case referred to in Sir William David Evans, *Decisions of Mansfield*, vol. 1 (1803), p. 404 under 'Patents'. Evans cites Buller J in *Turner v. Winter* as his source.

88 5th ed., p. 75.

89 Hulme (1902) 18 LQR 280, 287.

90 (1843), p. 118.

91 (1884), p. 53.

the outcome. Davies's collection of cases published in 1816 only has Lord Ellenborough's citation of the case in *Hamar v. Playne*[92] (*sic*) for the proposition that the specification must teach persons of reasonably competent skill to make the invention, not persons utterly ignorant of the whole art. This is interesting, as Davies worked in the Rolls Chapel Office and clearly had a fairly good knowledge of the case. His collection begins with the *Arkwright* cases.[93] These, *Turner v. Winter*[94] and the cases on Watt's steam engine[95] are the principal cases relied on in the treatises for the principles of law they expound. The only decision of Mansfield correctly and regularly relied on is *Morris v. Branson*[96] mentioned above.

Liardet v. Johnson does not fare well in the treatises either. Colliers's *Essay on the Law of Patents*[97] does not list the case in the table of authorities, though it is mentioned at p. 99 where the somewhat enigmatic assertion appears that it was decided 'consistently with the principle that grants of any known trade are void as against freedom of trade'. Godson's *Treatise on the Law of Patents*[98] and John William Smith's *Epitome of the Laws Relating to Patents*[99] confuse it with the case of trusses. We can find no mention of the case at all in Carpmael's *Law of Patents*.[100] Webster's *Law and Practice of Letters Patent*[101] correctly states that the subject-matter was stucco, but mis-records the outcome. Hindmarch's *Treatise on the Law of Patents*[102] also confuses *Liardet v. Johnson* with the case of trusses. Billings *Law and Practice of Patents*[103] mentions the case twice,[104] once for the famous 'water tabby' example of an accidental discovery,[105] and once for the proposition that the

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92 At p. 318.

93 *Arkwright v. Mordaunt* (1781), Webster 59, *Arkwright v. Nightingale* (1785), Webster 60.

94 (1787) 8 TR 95.

95 *Boulton & Watt v. Bull* (1795) 3 Ves Jun 140, 2 H Bl 463. *Hornblower v. Boulton & Watt* (1799) 8 TR 95.

96 (1776) Webster 51.

97 (1803) – see below for a description of this work.

98 (1823), p. 12.

99 (1836), p. 18. This carries Amos's lectures at London University on Patents as an Appendix. Amos cites Buller's *Nisi Prius* and the case of trusses.

100 (1832).

101 (1841), p. 45.

102 (1845).

103 (1841), p. 45.

104 Pp. 25 and 89.

105 Cited by Buller J in *Boulton v. Bull* (1795) 2 H Bl 487. Mansfield does refer to accidental inventions in *Liardet v. Johnson*, but cites Sir Epicure Mammon's discovery of the cure for the itch (Johnson's *The Alchemist*) not the water tabbies (a kind of watered silk).

meaning of a specification is that others may be taught to do the thing for which the specification (*sic*) is granted.[106]

The only law report of *Liardet v. Johnson* concerns the Chancery proceedings of 5 July 1780 in Lincoln's Inn Hall subsequent to the trials at *nisi prius*.[107] It records that the plaintiffs in Chancery, having replied, the cause was at issue and the defendants examined a number of witnesses, chiefly those who had been produced by them at the trials at law, with a view to establishing the same points on which they had relied before the jury. The plaintiffs only proved the records of the two verdicts in their favour, contending that as no new trial had been moved after the second verdict it was too late to impeach its truth, and that the temporary injunction ought now to be made perpetual. The defendants replied that the Court would never grant a perpetual injunction upon a verdict at law, that it would always direct an issue first and if dissatisfied with the verdict direct a new trial, that the defendants' evidence most completely contradicted the verdict as to novelty, fitness and clearness of the specification and infringement by the defendants. Eyre B and Masters Graves and Leeds sitting for the Lord Chancellor decided that the injunction should be granted. It was observed that if the verdict was not to be conclusive, the plaintiff had been deceived by being brought into an undertaking to bring action, the result of which could not ascertain the right. Eyre B observed, however, that the injunction might not benefit the plaintiffs, because if the defendant were subsequently to be alleged to be infringing the patent, the defendant might adduce the evidence adduced to the Court of Chancery and perhaps show that no infringement had taken place.

This report is appended to the report of *Thomas v. Jones*[108] with a note that it had been extracted from the twentieth volume of Sergeant Hill's manuscripts, and, though not cited in that case, it would have been had argument been addressed to the Court on the question whether the Court would grant a perpetual injunction after a verdict at law, where the verdict was in an action brought by the plaintiff in equity, and not in an issue or action directed by the Court. The reporter is stated to have been Douglas.[109]

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106 Citing Buller's *Nisi Prius*.

107 (1780) 1 Y & CC 527. Counsel for the plaintiffs at this hearing were [James] Mansfield, MacDonald, Arden, Thompson and Douglas. Counsel for the defendants were Maddocks, Kenyon and Mitford.

108 (1842) 1 Y & CC 510.

109 A technical note on *Liardet v. Johnson*: the lead compounds added to Liardet's composition would act as driers. Johnson's composition seems to have been seriously defective in having no driers. Serum of ox blood was added to cements down to modern times, but for the purpose of causing apparent ageing. It is possible that Johnson's serum of blood was in fact red lead or potassium permanganate, well-known linseed oil driers, and that Johnson was simply trying to conceal his activities.

The law of patents in 1800

In 1785 a Committee of Patentees was formed with a view to effecting reforms and improvements in the law of patents. Abraham Weston, one of Boulton and Watt's attorneys reported to the Committee:

> . . . the books are silent in agitating the question: What is the law of Patents? In the reports since last Mansfield has sat on the bench, there are not even the Titles 'Patent' or 'Monopoly' in the Indexes to any of the reports of Cases adjudged in his time, tho' it is very well known, that a great number of Patent Cases have been tried before him; nor are there any other of the Books that furnish any information on this head.[110]

In fact it was not until after the *Arkwright* and *Boulton & Watt* cases that any significant literature appeared.

A note in Watt's hand probably dating from 1795 lists his own 'Doubts and Queries on Patents':

(1) Whether the King can grant a patent for a method of doing or performing a mechanical process.
(2) Whether in such a case patents would be valid without a description of an *organised* machine.
(3) Whether a man improving his invention after patent granted, does not invalidate the patent.[111]
(4) Whether patentee refusing to add his patent to an old machine does not render patent void [i.e. for failure to exploit the invention presumably].
(5) Whether a patentee asking more than a common fair profit does not invalidate.
(6) Whether a patent for an improvement of an old invention is valid.
(7) Whether a patent for a new mode of using old instruments is valid.
(8) Whether a patent for a chemical process is valid?[112]

Questions (1), (2) and (8) were in fact resolved in the Watt litigation. Question (6) had been discussed by Mansfield in *Morris v. Branson* cited in *R v. Else*.[113] Watt himself seems to have thought that Question (7) should be answered in the affirmative, as it subsequently was. Question (3) remained unanswered even by the time of the 1829 Commons Select Committee.

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110 Observations on Patents Parcel E, Boulton & Watt Collection, Birmingham Reference Library cited by Robinson, *James Watt on the Law of Patent* in *Technology and Culter* (1972), p. 115. The *General View of the Decisions of Lord Mansfield* by William David Evans, which appeared in 1801, gives only Buller J's citation of the case of trusses under the heading 'Patents'. That citation is alleged to have been made in *Farrer* (*sic*) *v. Winter* 1 TR 602.

111 It will be recalled that Liardet had done this, and had his patent extended.

112 *See* Robinson, *loc. cit*.

113 (1785) Dav Pat Cas 144, 1 Web 76, 1 Carp 103.

Questions (4) and (5) seem to reflect the old fears about monopolies and involve issues that are debated to the present day.

Watt himself was much concerned to effect reform of the law of patents and actually drafted a Bill. It never, of course, reached the statute book. Probably vested interests in the fees which the existing system provided fairly abundantly were as much a block on change as lack of general understanding and sympathy.

Two publications, which it is not clear were known to Hulme, nor possibly to Davies or Holdsworth (though the first of them is listed in the old Sweet & Maxwell *Bibliography of the Common Law*) are of some interest in trying to evaluate the extent to which the law and practice had developed by 1800. These are John Dyer Collier's 'Essay on the Law of Patents' (1803) and John Clennel's paper on the 'Expediency of Disclosing the Process of Manufactories' delivered to the Literary and Philosophical Society of Newcastle upon Tyne.[114]

Collier appears to have been a patent agent.[115] His Preface attributes the obscurity of English law (he means the law generally, rather than just patent law) to the technical phraseology to which professors are confined and the comprehensive nature of the subject-matter. He asserts that Mansfield facilitated the formation of Digests by instructing juries on the legal principles of cases, and that since this time there have been special cases on point of law which his book attempts to collect. His only other reference to Mansfield in the Preface is for the observation that if patent grants were examined with rigorous attention, they might all, with very few exceptions, be rendered nugatory. The book is divided into 14 chapters with an appendix listing new inventions since 1800. The chapters of principal interest are chapter IX onwards.

Chapter IX deals with the question as to what is a new manufacture. It is something made by the hands of man.[116] It can be granted for improvements only.[117] An import can be a new manufacture.[118] A mere method is not a manufacture,[119] the product ought to be vendible. Machinery or substances

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114 I am grateful to Dr F.J.G. Robinson for this reference, which he found in the course of his work on the Nineteenth Century Short Title Catalogue.

115 There is a flier inserted at the end of the Bodleian copy of the book offering the author's services, and giving his address as Little Smith Street, College Street, Westminster.

116 Citing *Hornblower v. Boulton* 8 TR 95.

117 There is no citation at this point; *Morris v. Branson* is cited later. See also *Observations on the Utility of Patents*, London (1791), pp. 16 and 54, catalogued under 'Kenyon, Lloyd' in the BL Catalogues.

118 Citing *Edgebury v. Stephens* 2 Salk 447.

119 *Watt v. Bull*, i.e. *Boulton & Watt v. Bull* (above).

such as medicines are 'manufactures'.[120] Chemical method patents in reality are patents for a vendible substance. You could not on the other hand patent the principle of using steam, only the engine.[121] Dr James could not have got his patent for the principles of using antimony, only for a special compound or powder.[122] The remainder of the chapter is devoted to an extensive reproduction of the case of *Boulton & Watt v. Bull.*

The only mention of *Liardet v. Johnson* is in the following chapter, for the enigmatic assertion already mentioned that all grants of a known trade are void.[123] This chapter however contains the important observation that an invention must not have been published prior to the patent. A patent is an agreement between the King and the inventor that the subject will put the public in possession of a useful secret. If the public is already in possession of the knowledge, the inventor can make no compensation or return for the grant.[124] Although this is consistent with the views of Mansfield expressed in *Liardet v. Johnson*, and inconsistent with the view that it was working the invention which mattered, there is no mention of that case as an authority supporting this proposition (nor indeed any authority). Yet, as we have already suggested, if that case were so revolutionary it would surely have been mentioned at this point.

Chapter X is also of some interest. It deals with the specification. It begins by citing the proviso requirements that a particular description is required of the invention to be enrolled within one month.[125] As to what description is required, it cites Buller J's dictum in *R v. Arkwright* that the patentee must 'disclose his secret, and specify his invention in such a way that others of the same trade may be taught to do the thing for which the patent is granted, by following the directions of the specifications without any new invention or addition of their own'. The above case, and *Boulton & Watt v. Bull*[126] and *Turner v. Winter*[127] are the only cases cited in this chapter, though Dr James's patent and Dolland's are discussed. The summing up to the jury in *R v. Arkwright* is set out *in extenso*.

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120 *Id*. citing Heath J.

121 Citing Buller J in *Boulton & Watt v. Bull* (above).

122 Dr James's Powders were a very popular patent medicine – see 'The Patent', n. 44 above, and the Torrington diaries. Mansfield in *Liardet v. Johnson* doubted the validity of his patent, and Hulme considered that it might have been threatened litigation over Dr James's patent which resulted in the transfer of jurisdiction from the Council to the courts – see (1917) 33 LQR 194.

123 P. 99.

124 *Id.*

125 As noted above, however, this time varied to the end of the eighteenth century.

126 (1795) Bl Rep 479.

127 (1787) 3 TR 602.

Ashurst J's observations in *Turner v. Winter* that every patent would be against the principles of law, were it not for the public advantage derived from it, is also cited. He also states that it could not be dispensed with, even on the argument that it would benefit foreigners.[128]

There are other interesting developments noted by Collier. The rule that a patent licensee can challenge the validity of a patent was laid down in *Hayne v. Maltby*.[129] By contrast, a patentee could not challenge the patent's validity *vis-à-vis* an assignee.[130]

He also gives an account of a procedure for protecting priority while the invention is being perfected.[131] This consisted of lodging caveats at the chambers of the Attorney-General or the Solicitor-General. These were effective for one year, but renewable. The practice was that if applications were made by a third party, notice would be given to the person lodging the caveat, and evidence could than be presented to the Attorney-General by both parties as to who in fact had priority.[132]

In general the book is very crude. It is much padded out, with *R v. Arkwright* and *Boulton & Watt v. Bull* forming a substantial part of it, a fact not without significance in indicating the paucity of material known to the author.

John Clennel's paper is specifically concerned with the importance of disclosure of inventions. He first of all catalogues inventions lost to the world through non-disclosure, and asserts that the progress of science through the eighteenth century was through disclosure. His preferred solution was a system of rewards given by the government to inventors in return for putting the invention into the public domain, an idea which he may have borrowed from France. It is not altogether clear whether Clennel was aware that specifications were enrolled. He may well not have been for his alternative is disclosure at the expiry of the patent. He may possibly, however, simply have considered the existing system ineffective. At all events, his concerns include trade secrets generally, and not merely patented knowledge. In fact, the specifications in the patent rolls do seem to have been

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128 P. 173 citing *Ex parte Hoops* (*sic*) (1802) 6 Ves 559.

129 (1789) 3 TR 438.

130 *Oldham v. Langmead*, cited in *Hayne v. Maltby* at p. 439.

131 As distinct from the period of grace for enrolling the specification, which as we have seen, Mansfield laid down to enable the invention to be perfected.

132 This practice led to abuse. So-called 'floating caveats' would be lodged as a means of getting wind of inventions, so that the unfortunate inventor's workmen could be bribed to disclose their master's secrets – John William Smith, *op. cit*., pp. 15–16. Evidence on this was given to the Commons Select Committee on the Law of Patents (1829).

inspected by the public.[133] Collier actually gives information about this and the opening hours of the Petty Bag Office.[134] Perhaps this information had not penetrated as far north as Newcastle or possibly Clennel, who was a schoolmaster and popular lecturer, simply did not know his subject well enough.

The central criticism of the law at that time was in fact that it had been impossible to specify a patent in a way which would satisfy the courts.[135] If the invention were specified too exactly, pirates could seize on minor variations to distinguish their 'inventions'; if too generally, the specification would be invalid. This problem can be seen in the agonising over the drafting of the Watt specification. In a letter to Watt of 5 February 1769 (nearly a decade before *Liardet v. Johnson*) William Small wrote that Boulton and he considered that

> . . . you should neither give drawings nor descriptions of any particular machinery (if such omissions be allowed at the office) but specify in the clearest manner you can . . . as to your principles, we think they should be enunciated (to use a hard word) as generally as possible, to secure you as effectively against piracy as the nature of invention will allow.[136]

It was subsequently felt that this advice was erroneous, both in not appending a drawing and in apparently attempting to patent a principle of action rather than an application of principle, and indeed, the patent came close to being declared invalid in the subsequent litigation. In 1784 we find Argand wrestling with the same problem on drafting the specification for his lamp, as Watt and his partner had in 1769. As Robinson pointed out,[137] clearly *Liardet v. Johnson* only six years earlier had done little to clarify the law on how a specification should be drafted in the intervening period. Argand specified in general terms and filed no drawing. Subsequently, he had his patent declared invalid for want of novelty; it could well have been invalidated, however, for insufficiency of specification.

Apart from the defects of the system we have already mentioned, the most obvious problem for inventors throughout the century was the expense of the procedure.[138] This is the substance of the poem 'The Patent' referred to above.

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133 The Committee of Patentees formed in 1785 actually strongly objected to the ease with which the specifications could be consulted; see Robinson, *loc. cit.*

134 10.00–2.00 and 5.00–8.00.

135 *See* Robinson, *loc. cit.*

136 Cited Robinson, *loc.cit.*

137 *Loc. cit.*

138 See Collier, *op. cit.*, ch. XIV. According to the evidence given to the Commons Select Committee on the Law of Patents, a simple English patent was about £20 but a lengthier one about £200. Patents to cover England, Ireland and Scotland cost about £300. See also Charles Dickens, 'A Poor Man's Tale of a Patent'.

In *R v. Eley*[139] Kenyon CJ (later Lord Kenyon) had apparently described patents as a 'great oppression practised on inferior mechanics by those who are more opulent', which in turn provoked a pamphlet apparently written by the inventor of a patent washing machine mentioned above.[140] As suggested above, vested interests in the fees involved probably operated as a block on the reform of the system.

Summary

Such developments in the law and practice of patents as took place in the eighteenth century were almost certainly gradual. The few legal decisions probably followed commercial thinking and practice, rather than anticipating and instigating it. It is highly unlikely that *Liardet v. Johnson*, or indeed any of Mansfield's decisions, differed from this pattern. Perhaps the most interesting aspect of the case for us today is the way in which the outcome turned on the opinion of expert witnesses, who continued to be used after the modern rule against opinion evidence emerged,[141] and Mansfield himself naturally adhered to the view that in scientific matters experts should be called.[142] However, the length, technicality and no doubt expense of the hearings in *Liardet v. Johnson* must have been unusual at the time, though they are familiar enough to us in patent actions at the present day.[143] In retrospect, that is probably the most significant feature of the case.[144]

Reform of the system

In spite of the trenchant criticisms of the then patent system offered to the Commons Select Committee in 1829, and the celebration of the UK's technical

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139 Unreported. This case is possibly *R v. Else*, n. 113 above, but the citation should probably be *Hornblower v. Boulton* (1799) 8 TR 95, 98.

140 'Observations on the Utility of Patents' (1791) catalogued in the BL under Kenyon, Lloyd. See also the report of the *Boulton & Watt v. Hornblower* case, *The Times*, 26 January 1799.

141 *See* IX HEL 212.

142 *See, e.g., Folkes v. Chadd* (1782) 3 Doug 157, 159.

143 The study of expert witness cases can provide important evidence of the current state of scientific knowledge and opinion on particular topics. For a good example from outside the field of patents see Fullmer 21 *Technology and Culture* (1980), p. 1, which describes the evidence given in the case of *Severn & King v. Imperial Insurance Co*, 11 April 1820.

144 There is an interesting and lengthy case in Mansfield's Court Notebooks shortly after *Liardet v. Johnson* which also involved technical evidence. The plaintiff, Joseph Medlin, was patentee of a 'compound harpsichord' i.e. an instrument combining the harpsichord and forte-piano action. One Ephraim Coulson had allegedly infringed this patent. John Broadwood (the piano manufacturer), among others, gave expert evidence.

pre-eminence in the Great Exhibition of 1851, the old system survived until the Patent Law Amendment Act 1852, which followed the Report of the Select Committee on Patents 1851.[145] This Act made obtaining a patent cheap,[146] and simple. The applicant could in effect attain his patent by simply filing a specification. There was no examination for novelty or inventive step. A provisional specification could be filed first, followed by a full specification within one year. Unsurprisingly, the amount of patenting activity increased markedly.[147] This in turn, however, had obvious undesirable consequences in that the system could be used to block competitors, rather than fostering inventiveness. Further reform came slowly, however. The 1852 Act had entrusted the operation of the system to Commissioners; in 1883[148] their role was taken over by a newly established Patent Office.[149] This began to examine for formal defects in the application, and for sufficiency of description in the specification. It was not, however, until after the report of the Fry Committee 1901, which suggested that over 40 per cent of patents granted were for inventions which had been described in earlier British specifications, that a substantive examination was introduced.[150] This was confined to the issue of novelty alone, but a patent could be attacked in court for obviousness *or lack of inventive step*.[151] The inclusion of claims in the specifications had grown up naturally as inventions became more complex and built on prior art to produce improved machines; however it only became a formal statutory requirement with the Patents Act 1883.[152] After that the use of juries in patent cases was discontinued, and the result was a sharpening up of legal doctrine applicable to patents. Statutory revisions of 1907, 1919, 1932, and above all 1949, had the effect of codifying the law. The last major revision to UK law was effected by the Patents Act 1977 which implemented into domestic law the European Patent Convention signed at Munich in 1973. This treaty also established the European Patent Office in Munich, which opened for business on 1 June 1978.

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145 BPP 1851 (486) XVIII.

146 The initial cost fell to £25, the cost under the old system was set out above: for a patent covering the UK it was around £300.

147 *See* Boehm, 'The British Patent System: I Administration', *Economic History Review* (1967).

148 Patents Designs and Trade Marks Act 1883.

149 This Act also further reduced the fees payable.

150 Patents Act 1902. The Patent Office began to search prior British specifications in 1905.

151 Fox, *Monopolies and Patents*, University of Toronto Press: Toronto, Canada (1947), Part II traces the origins of the doctrine to *Crane v. Price* (1842) 1 WPC 383, 411.

152 S. 5(5).

The spread of the patent system

Introduction

This section is presented merely as an overview, as more detailed treatment of the points made about the various national systems appears elsewhere in this work.

The United States

When the American colonies became independent from England, establishing an independent patent system was one of the tasks facing the country. The constitution of the federation, adopted in 1787, stipulated that 'the Congress shall have power . . . To promote the progress of science and useful arts, by securing to . . . inventors the exclusive right to their . . . discoveries'. This provision, Article 1(8).8 still provides the constitutional basis for a Federal patent and copyright law. The Patent Law 1790 was based on these constitutional provisions. It is also this constitutional basis that gives the US system a feature that is unique today: the person entitled to a patent is the first inventor, not as elsewhere the first to file.

The dropping of the examination requirement led to 'rent seeking' which is evidenced by the rapid increase of patent applications: these by 1812 had reached 238 (compared to 119 for the UK, a much more industrialised country at the time). Clearly the situation was unsatisfactory, and a statute was passed in 1836 which set in place the essential structure of the current patent system. In particular, the 1836 Patent Law established the Patent Office, whose trained and technically qualified employees were authorised to examine applications. Employees of the Patent Office were not permitted to obtain patent rights. In order to constrain the ability of examiners to engage in arbitrary actions, the applicant was given the right to file a bill in equity to contest the decisions of the Patent Office with the further right of appeal to the Supreme Court of the United States.

France

The initial Patent Law was enacted in France in 1791 (amended in 1800 and 1844). Patentees filed through a simple registration system without any need to specify what was new about their inventions (i.e. there were no claims), and could prosecute to grant even if warned that the patent was likely to be legally invalid. On each patent document the following caveat was printed: 'The government, in granting a patent without prior examination, does not in any manner guarantee either the priority, merit or success of an invention'. The inventor decided whether to obtain a patent for a period of five, 10 or 15 years, and the term could only be extended through legislative action. Protection extended to all methods and manufactured articles, but excluded theoretical or

scientific discoveries without practical application, financial methods, medicines, and items that could be covered by copyright.

The 1791 statute stipulated patent fees that were costly, ranging from 300 livres through 1500 livres, based on the declared term of the patent. The 1844 statute maintained this policy since fees were set at 500 francs (about $100) for a five year patent, 1000 francs for a 10 year patent and 1500 for a patent of 15 years, payable in annual instalments. In an obvious attempt to limit international diffusion of French discoveries, until 1844 patents were voided if the inventor attempted to obtain a patent overseas on the same invention. On the other hand, the first introducer of an invention covered by a foreign patent would enjoy the same 'natural rights' as the patentee of an original invention or improvement.

Patentees had to put the invention into practice within two years from the initial grant, or face a tribunal that had the power to repeal the patent unless the patentee could point to unforeseen events which had prevented his complying with the provisions of the law. The rights of patentees were also restricted if the invention related to items that were controlled by the French government, such as printing presses and firearms.

In return for the limited monopoly right, the patentee was expected to describe the invention in such terms that a workman skilled in the art could replicate the invention and this information was expected to be made public. However, no provision was made for the publication or diffusion of these descriptions. At least until the law of 7 April 1902, specifications were only available in manuscript form in the office in which they had originally been lodged, and printed information was limited to brief titles in patent indexes. The attempt to obtain information on the prior art was also inhibited by restrictions placed on access: viewers had to state their motives; foreigners had to be assisted by French attorneys; and no extract from the manuscript could be copied until the patent had expired.

The state remained involved in the discretionary promotion of invention and innovation through policies beyond the granting of patents. In the first place, the patent statutes did not limit their offer of potential appropriation of returns only to property rights vested in patents. The inventor of a discovery of proven utility could choose between a patent or making a gift of the invention to the nation in exchange for an award from funds that were set aside for the encouragement of industry. Secondly, institutions such as the *Société d'encouragement pour l'industrie nationale* awarded a number of medals each year to stimulate new discoveries in areas they considered to be worth pursuing, and also to reward deserving inventors and manufacturers. Thirdly, the award of assistance and pensions to inventors and their families continued well into the nineteenth century. Fourthly, at times the Society purchased patent rights and turned the invention over to the public domain.

The basic principles of the modern French patent system were evident in the early French statutes and were retained in later revisions. Since France during the *ancien régime* was probably the first country to introduce systematic examinations of applications for privileges, it is somewhat ironic that commentators point to the retention of registration without prior examination as the defining feature of the 'French system' until 1978 when French law was brought into line with the system laid down in the European Patent Convention.

Germany

Germany did not, of course, exist as a state prior to unification, though some of the states which would form part of the unified state had. The Unification of Germany took place on 18 January 1871, when Prussian prime minister Otto von Bismarck managed to unify a number of independent German states into one nation. Before that, the enactment of intellectual property laws was a matter for the individual states. The new state enacted a comprehensive Patent Law which was based on the principle of mandatory examination, the first such system in the world, in 1877.

German patent policies encouraged diffusion, innovation and growth in specific industries with a view to fostering economic development. Patents could not be obtained for food products, pharmaceuticals or chemical products, although the process through which such items were produced could be protected. It has been argued that the lack of restrictions on the use of innovations and the incentives to patent around existing processes spurred productivity and diffusion in these industries. The authorities further ensured the diffusion of patent information by publishing claims and specification before they were granted. The German patent system also facilitated the use of inventions by firms, with the early application of a 'work for hire' doctrine that allowed enterprises access to the rights and benefits of inventions of employees. Although the German system was close to the American patent system, it was in other ways more stringent, resulting in patent grants that were lower in number, but probably higher in average value.

In 1981 Germany also introduced the *Gebrauchsmuster* or petty patent, which was granted through a simple registration system. Patent protection was available for inventions that could be represented by drawings or models with only a slight degree of novelty, and for a limited term of three years (renewable once for a total life of six years). About twice as many utility patents as examined patents were granted early in the 1930s.

The Paris Convention

Again, this section provides only a brief overview, as detailed treatment of its subject matter is provided elsewhere in this work. After a diplomatic conference

in Paris in 1880, the Convention, the first international treaty on intellectual property, was signed in 1883 by 11 countries: Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain and Switzerland. It was revised at Brussels on 14 December 1900, at Washington, DC on 2 June 1911, at The Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967, and was amended on 28 September 1979. It is one of the treaties now administered by the World Intellectual Property Organization (WIPO).

The Paris Convention for the Protection of Industrial Property was an important development. Through this treaty, industrial property systems, including patents, of any contracting state are accessible to the nationals of other states party to the Convention (the principle of 'national treatment'[153]). It also introduced a 'priority right': the 'Convention priority right', also called 'Paris Convention priority right' or 'Union priority right'. This provides that an applicant from one contracting state is able to use its first filing date (in one of the contracting states) as the effective filing date in another contracting state, provided that he or she files another application within six (for industrial designs and trademarks) or 12 months (for patents and utility models) from the date of first filing.

Patent Co-operation Treaty

The World Intellectual Property Organization also administers filings pursuant to the Patent Co-operation Treaty, signed at Washington in 1970 and put into effect 1 June 1978. This allows applicants to submit a single application designating the member states in which patents are wanted. Chapter I of the Treaty establishes an international search conducted by national Patent Offices in Australia, Japan, Russia and the United States as well as the European Patent Office and to a more limited extent the Austrian and Swedish Offices. It has proved popular, especially as it enables an applicant to seek patents in numerous countries by a single application, and to delay a final decision to proceed with the prosecution for 30 months from the priority date, thereby postponing the incurring of significant official fees, attorney's costs and translation costs (which are usually considerable).

Chapter II established an International Preliminary Examination. Participating states are not obliged to adhere to both chapters nor is the applicant obliged to have a Preliminary Examination.

TRIPs and the World Trade Organization

A weakness with treaties such as the Paris Convention is that there is no mech-

153 On this principle as it affects patents see Evans [1966] EIPR 149.

anism to force signatory states to comply with the minimal standards set in them. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property (IP) regulation. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. The provisions contained in it on patentable subject matter and on disclosure bear a family resemblance to those in the European Patent Convention, and similarly those on the patent term and the scope of rights.[154] The treaty also restricts the right of member states to grant compulsory licences. TRIPs is sometimes referred to as 'Paris plus' (and 'Berne plus') because it ensures that member states adhere, *inter alia*, to the minimal standards set out in those conventions.

Conclusion

Perhaps the most striking feature of the development of the patent system which was exhibited early in that of England and Wales, the first modern system, was how early it moved from the protection of innovation to the protection of invention. Although it might be regretted by historians such as Hulme, and leave a lacuna which modern economists such as Professor Kingston have argued ought to be filled, it was probably an inevitable development. Given the bureaucratic constraints on those administering the system, the protection of invention was probably the only way to go. It is, however, no accident that in modern times the heaviest users of the system are those industries where the link between invention and innovation is closest, for example pharmaceuticals and aerospace. Backed by TRIPs we now have what potentially may develop in the future into a world patent system.[155]

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[154] But rights do not have to be defined by reference to claims in a specification – Articles 28, 30, 33 and 34.

[155] See Cornish and Llewellyn, *Intellectual Property*, 5th ed., Sweet & Maxwell/Thomson (London: 2003), 3–21 at p. 123.

4 A spanner in the works – or the spanner that works? Patents and the intellectual property system

Jeremy Phillips

Introduction

The word 'patent' has become so heavily overlaid with secondary meanings and subjective baggage that it is difficult to evaluate it for what it is. To some it is the epitome of capitalist greed, vesting in a single party the right to exercise exclusive and absolute control over the sector of the market that falls within its scope, with no concomitant responsibility to confer any benefit upon the marketplace or upon society as a whole. To others it is a symbol of the purity of the incentive to divulge an innovation and to share its benefits, by protecting the inventor's investment of time and effort in creating it and bringing it to fruition.

This chapter sets out to contextualise the patent right, its limitations and its exceptions. It proposes to do so at a high level, within a fluid market in which other intellectual property rights may enhance or weaken its effect as a means of facilitating or controlling access to and use of its subject-matter. In metaphorical terms, the following pages represent a gentle attempt to describe the patent as one of a number of available legal tools within a toolbox from which a handyman may seek to perform a range of complementary or contradictory functions upon an ever-moving object – the consumer.

The informed reader will observe that much of the content of this chapter is based upon generalised and widely accepted observations concerning the operation of patent law rather than upon the laws of any one jurisdiction. Since this book is addressed to an international audience, a conscious decision has been taken here to let it float relatively free of parochial jurisprudence, more at the level of the broad norms that are expressed in those international law documents that help shape patent law's parameters. Accordingly while this chapter depicts the patent as a live and vital component of current commercial and industrial activity, it should surprise no-one if in no specific country will a patent be found which corresponds precisely to the operative description of it in the following pages.

Strategic strengths of the patent right

The advantages conferred by the patent right upon its holder are potentially immense. In summary

- *The patent right confers an absolute power upon its holder to prohibit the unauthorised use of its subject-matter by others*. Infringement of a patent is an act of trespass upon the patent owner's intellectual estate, the boundaries of which are defined by the claims and description of the invention that are contained within its specification. Once an act falls within the scope of the claims, it is categorised as an infringing act against which the relief provided by the law may be directed. This is so, regardless of whether the trespasser is conscious of the existence of the patent and the scope of its claims and of whether the acts of trespass are intended or inadvertent. As a bonus to the holder of the patent right, even acts that fall outside the scope of the patent claim may be regarded as infringing acts, for example where a competitor has implemented some changes or even added some original features of his own to the invention as claimed in the patent.[1] By analogy, this would be rather like the owner of a plot of land having the right to sue not only the person who without permission enters his land but also the person who comes very close to doing so.
- *The patent is presumed valid until the contrary is asserted and proved*. Before grant, the patent application is subjected to a close and critical expert scrutiny in which its content is weighed against the totality of publicly available knowledge at the date from which protection is asserted and measured against the probability that the invention could

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[1] The extent to which the construction of patent claims may confer rights that are not literally within the scope of the patent as drafted is the subject of a vast literature. See for example the case law and academic writing directed towards the interpretation and application of the Protocol to Article 69 of the European Patent Convention ('EPC') in its original 1973 and revised 2000 versions (the speech of Lord Hoffmann in *Kirin-Amgen Inc. and others v. Hoechst Marion Roussel Limited and others; Kirin-Amgen Inc. and others v. Hoechst Marion Roussel Limited and others* [2004] UKHL 46, 21 October 2004) provides a good overview of the position in Europe). In the USA an equally vast body of analysis has both led to and followed from bellwether litigation such as *Festo Corp. v. Shoketsu Kogyu Kabushiki Co. ('Festo III')* 535 US 722 (2002). For a helpful note of post-*Festo* developments, culminating in *Primos Inc. v. Hunter's Specialties Inc.* 451 F.3d 841 (Fed. Cir. 2006) see David Berry, ' "Tangential Relation" Criterion Clears Way for Infringement of Amended Patent Claim Under Doctrine of Equivalents' [2006] JIPLP 631–3. A good comparison of the US and European approaches is that of Toshiko Takenaka, 'Claim Construction and the Extent of Patent Protection: A Comparative Analysis of the *Phillips en banc* Federal Circuit Decision' [2006] JIPLP 119–30.

have been derived from an intellectual process that involved no more than a putting together of existing knowledge and expertise by a hypothetical person skilled in the technical area of the invention. Scrutiny of the application also arises upon its publication, at which point third parties may submit 'killer' observations as to its patentability. If the application passes unscathed through this initiation ordeal, it is not only presumed valid as a point of technical law but is generally reckoned to be robustly so in those jurisdictions where examination standards are reckoned to be highest. A potential challenger of the validity of a patent may thus be deterred from basing his challenge on the citation of prior art that was considered and dismissed by skilled and highly trained patent office staff in the course of carrying out a rigorous grant procedure.

- *The power of a patent grows exponentially when it grows from an individual right into part of an expanding portfolio of patent rights*. The models upon which many economic analyses of the operation system have been based appear to be founded on an unstated assumption that there is a one-to-one correlation between a granted patent and a product or process protected by it. This model does not reflect the complexity of modern products in sectors such as telecommunications and consumer electronics, in which a single item on sale may be comprised of a large multitude of separate patented inventions. Likewise, in the pharmaceutical sector a single product may be referable to a basic patent, further patents in respect of separate improvements in terms of improvements involving subsequent medical uses as well as patents that govern its means of manufacture. Where a one-to-one model exists, invalidation of the patent renders the formerly patented product free to be copied by all, while a product derived from a raft of overlapping patents may shed a good many of them and still remain under the control of the patent owner. This applies equally where there is not a single patent owner but a group of proprietors which has come together in order to impose an industrial standard that others are invited to use under licence.[2]

Strategic weaknesses of the patent right

On account of its potential market power, the patent is subject to various checks. These relate to the stringency with which their suitability as protectable subject-matter is examined and to the interest of competitors and

[2] For a good review of patent standards and their potential for use and abuse see Piotr Staniszewski, 'The Interplay between Intellectual Property Rights and Competition Law in the Context of Standardization' [2007] JIPLP 666–81.

others in being able to challenge and invalidate a patent that should not have been granted. Each check upon the power of a patent is generally accepted to be reasonable in itself, but collectively they paint a picture of a right that is so hedged about by negative factors as to create the appearance of relative frailty. This image is enhanced by the commercial reality of the markets in which innovations are made and exploited: the patent confers no duty upon anyone to use or purchase the patented invention, which is subject to the whim of the consumer and may be bypassed by technological developments over which the patent owner has no control.

In short, the following points appear significant when considering the weakness of the patent:

- *The patent right is a negative right*. Its holder may restrain others from doing or making anything that falls within the subject-matter contained in the patent's claims. The patent does not however entitle its owner to do anything in a positive sense. In the pharmaceutical and agrichemical sectors, use of a product incorporating a patented invention will be contingent upon the fulfilment of regulatory conditions relating to the safety and the efficacy of that product.[3] The owner of a patent in either of these sectors must be prepared to accept the commercial reality that the contingency may never come to pass.
- *The patent is a vulnerable right*. Although a patent is granted at the end of what is always a substantial and sometimes extraordinarily lengthy process of examination and is presumed valid, its holder may be required to defend its validity. There are numerous grounds upon which a patent's validity may be challenged[4] and there is no limit to the number of parties who may make that challenge. Even once the validity of a patent has been upheld, it remains open to challenge on each subsequent occasion that further evidence is unearthed that might undermine the basis of its presumed novelty and inventive quality.

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[3] Regulatory conditions are monitored by organisations such as the Food and Drug Administration in the United States, the Pharmaceutical and Medical Devices Agency in Japan and the European Medicines Agency in the European Union. As in the case of patents there is a degree of cooperation between the major regulatory agencies, but the agencies are generally free to establish their own criteria at national level, thus increasing the cost and expense of clearing a patent for use and increasing the risk that exploitation of a patented invention will be prohibited.

[4] These grounds broadly fall into three categories: failure to meet the criteria of patentability, failure to disclose the claimed invention sufficiently and a deficiency in title to the invention.

- *The patent is a national, or at best a regional, right*. There is no such thing as a single patent grant that yields to its holder a right to restrict the use of the protected invention throughout the world. With some relatively minor exceptions[5] and one large one,[6] patents must be acquired, administered and protected on a country-by-country basis. Although the Patent Cooperation Treaty has established a popular and still-maturing system that enables an applicant, through a single application lodged with the International Patent Bureau, to designate almost all the countries in which he is ever likely to need legal protection,[7] the manner in which the criteria of patentability are applied to the same application once it reaches the national phase of the application process is dependent on local understanding and legal doctrine, as indeed are tests of infringement and many other issues of a legal and commercial nature.
- *The patent is a short-lived right*. Patents last for a relatively short time when compared with other statutory intellectual property rights. The registered trade mark right, if well managed, may be renewed in perpetuity,[8] and copyright in the author's right may easily exceed a century or more.[9] The patent fares poorly in comparison. The *maximum* term of a patent is normally 20 years from the date of filing, which works out at between 16.5 and 17.5 years from its grant; most patents are allowed to lapse or are revoked well before then. Statistical evidence shows that

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[5] The African Intellectual Property Organization (OAPI) grants a single patent right that covers the territories of Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo. Also, under the Eurasian Patent Convention a single patent application will cover the territories of Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, the Russian Federation, Tajikistan and Turkmenistan.

[6] The separate states within the United States may not grant their own patents, as the power to legislate for patents and some other intellectual property rights is a subject of federal pre-emption: see *Sears, Roebuck & Co. v. Stiffel Co*., 376 US 225 (1964), *Compco Corp. v. Day-Brite Lighting, Inc*., 376 US 234 (1964), *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 US 141 (1989), cf. *Kewanee Oil Co. v. Bicron Corp*., 416 US 470 (1974) in which it was held that the protection of patentable trade secrets under state law was not pre-empted.

[7] As of 9 July 2007 this figure stood at 137 countries.

[8] The norm for the term of trade mark protection may be found in the Agreement on Trade-Related Aspects of Intellectual Property Law (TRIPS), Article 18: 'Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely'.

[9] The British author Barbara Cartland, who died on 21 May 2000, published her first novel, *Jigsaw,* in 1923. As the law stands at present, copyright in her works will expire on 31 December 2070, giving *Jigsaw* a remarkable copyright term of 147 years.

most patents are not renewed beyond their twelfth year. Put another way, the life expectancy of a granted patent is around the same as that of the standard poodle.[10] In the case of pharmaceutical and agrichemical patents some jurisdictions permit the extension of the patent term on proof that regulatory requirements have substantially eroded the opportunity for the patent holder to obtain a reasonable commercial return on its investment[11] – and in the United States an extension may be granted on other grounds, such as where the patent grant was subject to avoidable administrative delay or interference proceedings[12] – but in these cases the maximum period of any extension is relatively short.

- *The patent is expensive to acquire*. Unlike other intellectual property rights, where little or no outlay may be attached to their acquisition, the cost of acquiring a patent is sufficiently significant to require budgetary prudence. Although official fees associated with the filing and prosecution of a patent application are relatively small, the writing of a specification that encapsulates the nature of an invention and the drafting of the claims that delimit its scope of protection is highly skilled work for which the services of a trained patent attorney are needed. To avoid the unnecessary expenses of preparing a patent application in respect of an invention that has already been made available to the public, a search of the prior art is necessary. This too can be very expensive, particularly if earlier publications are made in a language other than that of the prospective applicant. Further, while an inventor may conceive of his invention in unitary terms, the product or process which he envisages may incorporate different elements each of which must be the subject of a separate application, thus increasing his outlay. Once an application is filed, it is frequent (and in most fields usual) for it to be the subject of delicate negotiation between the patent applicant (or more usually his professional representative) and the examiner, narrowing or redirecting the claims so as to avoid trespassing on earlier patents or being anticipated by earlier publicly available information: this too may incur unforeseen expense while incidentally reducing the desired breadth of protection that underpinned the applicant's initial business plan.
- *The patent can be expensive to maintain*. Once acquired, a patent is

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[10] See 'Life Expectancy in Dogs – How Long will my Dog Live?', <http://www.pets.ca/pettips/tips-46.htm> (accessed 9 July 2007).

[11] See, for example, in the European Union, Council Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products and Regulation 1610/96 concerning the creation of a supplementary protection certificate for plant protection products.

[12] 35 USC 154(b).

usually subject to annual or periodical renewal fees. Viewed objectively these are not usually regarded as oppressive although their cumulative effect can be great where, for example, a product incorporates many patents for separate components, their interrelationship and their assembly.

- *The patent is expensive to preserve*. When the validity of a patent is challenged, its proprietor is not required to rise to the challenge and defend his granted right. But, should he do so, he must be prepared to bear the expense of doing so. Typically this will include the cost of engaging legal representation and may also include such potentially burdensome items as the cost of expert witnesses and the carrying out of laboratory experiments. Although a successful defence of a patent may entitle its owner to the payment of its costs by the unsuccessful challenger, in practice such an award will generally meet only a proportion of the actual outlay. On account of the great commercial value of a market controlled by a patent, judicial decisions that result in a patent being upheld are often subject to the additional expense of one or more appeals.[13]
- *The patent is expensive to enforce*. In much the same manner as the defence of a patent will incur expense, so too will its enforcement against an alleged infringer. This factor may encourage the patent proprietor to turn a blind eye to small and commercially relatively insignificant infringements, in respect of which the benefit secured by a successful outcome to the litigation is unlikely to outweigh the cost and effort of initiating it. The availability of patent litigation insurance as a means of strengthening the hand of the small- or medium-sized patent-owning enterprise has not as yet proved popular since, in relation to a small business budget, the insurance premiums must be high in order to reflect the risk to which the underwriters of such insurance are exposed and, in any event, any insurance cover that entitles the insurer to stand in the shoes of the insured, through the doctrine of subrogation, may permit the insurer to settle a claim on terms that are objectively reasonable in relation to the alleged scale or nature of the infringement but which run contrary to the business preferences of the insured – for example, by granting the alleged infringer who challenges a licence to use a patent the validity of which he has contemplated challenging.

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[13] Curiously, TRIPS, Article 32, confers upon the patent owner an automatic entitlement to a right of appeal in the event that a patent is held invalid or forfeited, while no corresponding entitlement to appeal is given to the party that has unsuccessfully challenged it.

- *The patent may be subjected to a regime of compulsory licensing*. While the business plans of the patent owner may be based upon the premise that no other trader may use or make the patented invention, this premise may be undermined by the facility of a third party, which may be a competitor, a trader in a complementary market or indeed an organ of state, to obtain a right to use the erstwhile exclusive invention on a pay-per-use basis. This facility may arise in circumstances in which the patented invention has not been exploited at all, or has not been exploited to an adequate extent, particularly where the exigencies of national emergencies or war may override the patent owner's expectation of quiet enjoyment.[14] Not all patents are equally exposed to compulsory licensing. Following the Doha Declaration in 2001[15] it has become apparent that the healthcare sector was particularly susceptible to government-led initiatives relating to the non-consensual licensing of pharmaceutical patents, given the convergence of a number of factors not found together in other industrial sectors: the magnitude of the differential between market price and manufacturing cost, the need to control sickness and disease in developing countries and the need to prevent the spread of pandemics. Increased reliance on post-Doha compulsory licensing has provoked questions as to whether, under cover of Doha, some governments have been making provision for compulsory patent licences beyond the limitations imposed by TRIPS.[16]

Patents in history: growth of roles

The versatility of the patent is reflected in the many different roles it has played. It has served as a technology transfer mechanism which is designed to attract foreign creators of inventions to migrate into a jurisdiction in which, whether in exchange for the disclosure (as in Venice) or not (as in England), they are accorded an exclusive right to practise their art. The choice of *litterae patentes*[17]

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[14] Relatively detailed provisions regarding the entitlement of member states to provide for the compulsory licensing of patents on various grounds are articulated in the Paris Convention for the Protection of Industrial Property, Article 5A(2), and TRIPS, Article 31.

[15] Doha Declaration on the TRIPs Agreement and Public Health, 14 November 2001.

[16] See Lisa Peets and Mark Young, 'Is the Exception Becoming the Rule?' (2007) 195 *Patent World* 21–4.

[17] Latin for 'open letters'. Unlike a letter that was folded closed or placed in an envelope and then sealed, the patent was an open letter in which the seal did not close the letter but was placed at the bottom of the page. Retained in scrolled form, the letter could be opened and re-opened without breaking the seal – which had to be kept intact because it bore the authority of the monarch's signet.

as the documentary evidence of entitlement suggests that the holder may have needed to employ it as a sort of safe conduct pass when confronted by local guildsmen or traders whose livelihood was threatened by competition from the newly imported technology.[18]

Once it was recognised that it was necessary for a patent application to describe the technical information that distinguished it from the prior art and, more importantly, from the inventions for which other parties held identically or similarly titled patent grants, the role of the patent developed into that of an information-bearing instruction with regard to the nature of the invention and sometimes also the manner of its implementation. The value of patents to the information community has continued to rise following the creation of patent classification standards, culminating in the International Patent Classification system,[19] which enable searchers to home in on any known form of technology by making reference to the classification codes applicable to it.

In more recent times patents have been described as playing the roles of providing incentives to invent, incentives to disclose useful information, incentives to invest and security for the advancement of investment capital. Though much lip-service has been paid to the notion of the patent as incentive to invent, as justifying an ethical basis for the grant of a monopoly that limits the scope of action of all but the patentee, there is no empirical evidence to suggest that the availability of a patent incentivises either an otherwise uninventive person to invent or a moderately inventive person to become more so. Moreover, since (i) the preponderant majority of patents are granted to corporations rather than to individuals[20] and (ii) judging by the frequency with which several members of a team of co-inventors are named in the patent application, it is difficult to see how the availability of a patent might indeed motivate inventiveness on the part of an individual whose contribution to the

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[18] The importance of developing a structure for the identification and retrieval of patent information was first recognised by Bennet Woodcroft, who founded the Patent Office Library in London, England, becoming Superintendent of Specifications in 1952.

[19] The Strasbourg Agreement concerning the International Patent Classification (IPC) was concluded in 1971, since which year the scheme of classification employed throughout the patent-protection zones of the world has run to its eighth edition. The scheme is constantly under review in light of the invention of new technologies and experiences derived from working with the scheme.

[20] The author is not aware of any accurate and contemporary figures relating to the proportion of patented inventions made by inventions in the course of their employment; anecdotal evidence suggests that, at least in Europe, the figure is likely to be around 90 per cent. This would suggest that the offer of a patent to an inventor by way of incentive is about as efficacious as trying to incentivise a donkey to pull a cart by offering a carrot to the cart's owner.

whole inventive process – and therefore his expectation of any further remuneration – might be small. The validity of the other roles is however well documented and there is an ample literature relating to the patent's investment aspects.[21]

Patents in economics[22]

As a monopoly right, conferring the right to exclude competitors from the market or to admit them only on payment of an entry fee, the patent has been seen by economists as a useful index of economic activity: one might expect a rise or fall in the number of patents granted and renewed in any market sector to reflect the level of research and development activity that took place previously and the level of manufacturing and sales activity that occurred subsequently. In a gross sense this is true: the complete absence of patent activity may quite reasonably suggest a lack of investment of effort and resources that might lead to such activity, while the existence of a large number of valid patents in a market suggests that there is keen competition in the race to capture custom by offering innovative and more attractive products and processes.

The descriptive quality of statistics concerning granted patents as an index of economic activity is regrettably imperfect, for at least the following reasons:

- As mentioned above in the context of the expenses incurred in obtaining adequate patent protection, there is rarely a one-to-one correlation between the number of patents in force and the number of patented products that incorporate them, since some products incorporate many patented integers while other patents may be relevant to the manufacture of a wide range of products in different sectors. In techno-historical terms there appears to be a long-term evolutionary trend away

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[21] A particularly good source of current news and analytical articles relating to the patent in terms of asset management and investment is the bi-monthly journal *Intellectual Asset Management*, published by Globe White Page Ltd.

[22] There is a vast literature on topics such as the economic analysis of the effect of the patent and the use of patents as a measure of economic and/or innovative activity. A recent compendium of writings on the subject is John Cantwell (ed.), *The Economics of Patents* (Cheltenham, UK and Northampton, MA: Edward Elgar, 2006). The first volume is subtitled *The Patent System and the Measurement of Invention*, the second *Corporate Patenting.* This collection, and the works referred to by its contributors, reflect scholarship that goes back to the first half of the twentieth century and data that goes back to the nineteenth. How much of this scholarship remains relevant to the current patent system and economic structures that relate to it is however open to question.

from simple devices, caused in part by the technologies of convergence and partly by the potential of each disclosure of an invention to further opportunities for its use in fields that may not have been appreciated by its inventor. To give a simple example, while a century ago a patent might have been granted for a toothbrush possessing new and non-obvious features that conferred some advantage over its competitors, we might now expect a single toothbrush product to incorporate patents concerning, respectively, the shape of the handle and of the head, the materials from which the bristles are made and their specific configuration and the industrial process by which these products are assembled, not to mention the interactive system for informing the user regarding his parameters of performance with the brush, the configuration that enables the system to be installed and maintained and the software that drives it.

- Many patents are taken out which are never used, since their owners are unable to attract the level of financial investment necessary to take them from drawing board to fruition.
- Other patents remain unused because, despite their technical merit, they do not correspond to any measure of consumer demand and no such demand can be effectively stimulated.
- Some innovations which might qualify for patent protection are commercially exploited under the cover of other intellectual property rights, such as rights in utility models or designs or as licensed know-how.
- When a technology is in its infancy there may be few patents but the scope of protection claimed within them may be broad, while in a mature or declining technology there may be large numbers of patents, each laying claim to a thin incremental slice of the techno-evolutionary layer-cake.
- The number of patents in force is also a function of legal and administrative criteria that lie outside the immediate cycle of investment, development and marketing. For example, legislative amendments to substantive patent law may enlarge or contract the field of patentable subject-matter and judicial decisions may broaden or narrow the scope of an infringing act. The issue of guidelines for patent examiners and the implementation of training programmes to enhance the consistency of their decision-making processes may also cause localised irregularities when plotting statistical shifts in patenting activity.

The level of patent litigation is also an inevitably inaccurate index of economic activity. In most countries the number of litigated patent infringement disputes between competing businesses, or even between manufacturing

businesses and rent-collectors such as research institutes or patent trolls, is far too small to be of statistical significance. Many disputes that might otherwise be litigated – and which might otherwise swell those figures – are the subject of arbitration or mediation and may not surface publicly.

Patents and ideas

The claim is sometimes made that the patent right confers a monopoly upon the use or commercial exploitation of ideas. There is no basis for this claim in patent law itself, either in the manner in which its norms are expressed in international law[23] or through the legislative techniques by which those norms have been incorporated into law at national level. This is because patent law requires the disclosure of, and grants corresponding protection to, a particular manner in which an idea is embodied in practice as a product or a process rather than as a concept that may be embodied in a number of ways that reflect it. If the effect of granting a patent is to confer a monopoly upon an idea in circumstances in which there seems to be a direct and necessary correspondence between the idea behind an invention and its means of implementation, it is probably because the patent has been wrongly granted.

Patents and traditional knowledge

There is much tension today between the patent – the world's oldest regularly established intellectual property right – and the laws and sentiments that have clustered around an amorphous body of traditional knowledge in many developing countries which preceded the adoption of patent laws in many of those countries and which often provides a valuable complementary and affordable alternative to modern medicines.[24] On the one side, defenders of traditional knowledge object that it is sometimes made the subject of patent applications,[25] with the threat that well-tried treatments may be monopolised by

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[23] Protectable subject-matter must be a product or a process, not an idea. See for example Paris Convention, Article 1: '(2) The protection of industrial property has as its object patents, utility models . . . and the repression of unfair competition; (3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour'. TRIPS, Article 27(1): '. . . patents shall be available for any inventions, whether *products or processes*, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'.

[24] On the farmer's right to harvest a crop grown from patented seed – a classic point of conflict between modern patent philosophy and traditional knowledge-based practice – see Elizabeth Verkey, 'Shielding Farmers' Rights' [2007] JIPLP 825–31.

[25] The use of terms such as 'bio-piracy' is to be deprecated because it seeks to

foreign corporations and the high probability that those communities which have created and transmitted traditional knowledge will receive nothing in return. On the other side, pharmaceutical companies and bio-prospectors forcefully deny that any wrongful monopolisation will take place, since the fundamental requirements of patentability such as the requirement that an invention be novel and non-obvious and the defence of prior use will ensure that traditional practices may be maintained. Moreover, they add, the patent system provides an incentive that enables them to invest in the improvement of folk remedies, the isolation and purification of the active ingredients of plants and herbs and the publication, in the patent application, of valuable information that will increase understanding of how traditional medicines work, thereby saving life and enhancing its quality.

Politicians are asked to side with the one camp or the other, which is a shame. Both sets of protagonists raise valid points and the interests of both are served by the vitality of both systems. It is for this reason that the negotiation of solutions that respect the interest of developing societies in securing a twofold advantage is welcomed.

Patents, confidentiality and disclosure of information

From the point of view of information management policy, the patent system is a system which has successfully engineered the passage of a very considerable quantity of technologically and commercially valuable information from the entirely private domain of the patent monopoly and onward into the ever-growing and entirely non-exclusive public domain. Before a patent is granted, the law demands that the subject of the patent grant be unavailable to the public as a precondition for its protection. This is because there is seen to be no economic or moral justification for conferring upon a patent applicant an absolute monopoly to control the commercial exploitation of a product or process that is already available to the patent applicant and its competitors. After the patent has expired, the information disclosed in its specification may be freely used by all: it has shed its status as private property and has joined the commons.

During the period of the patent grant, the contents of the patent are open to all and thus become freely accessible knowledge that may educate, stimulate and inspire further innovative thought. However, a restriction is placed upon its use in that any activity that falls within the patent's claims – that is, any activity that relates directly to the novel and inventive content of the specification which would have remained confidential but for the patent – may not

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stigmatise a practice which is lawful and potentially beneficial to a wider audience than the community that considers itself to have been dispossessed of an important intellectual asset.

be performed without the permission of the patent owner. This policy of 'you can look but you can't touch . . . yet' is regarded by many as the safeguard that gives patent applicants the confidence to expose their inventions to a hostile world of competitors and critics.

There are times when a conflict may exist between the demands of confidentiality and the entitlement of an inventor to apply for a patent. This is the case where, making use of confidential information that has been made available to him by virtue of his employment or by reference to the position of trust he holds in relation to another, an inventor wishes to apply for a patent the specification of which would, upon publication, destroy the confidentiality. Which takes precedence – the private interest in the preservation of the confidentiality of that information or the public interest in the disclosure of that information through the formal mechanism of the patent system? The private interest in keeping the information confidential is supported by considerations of equity in common law countries and may be buttressed by explicit contractual terms that assert the obligation of confidentiality; the right to privacy of one's unpublished information is also protected as a human right. Against that, the patent system is a powerfully articulated expression of the public interest in the disclosure of meritorious innovations and the inventor may invoke his right of communication, also a human right, in support of his right to apply for a patent. In the event, it is probable that the entitlement to confidentiality prevails over the entitlement to assert one's right as an inventor. While in the United Kingdom this end is secured by a specific statutory provision,[26] in civil law countries the assertion of the right to apply for a patent may be characterised as an *abus de droit* which the law will not tolerate.

Patents, copyright and designs

The subject-matter of patent protection is quite distinct from that of the many species of work in which copyright is vested. Notwithstanding this, overlap of and collision between the respective rights is common because the same end-product may possess qualities that attract both patent and copyright law. For example, computer programs are generally regarded as being an appropriate subject of copyright protection as original literary works under the Berne Convention.[27] However, those programs that meet the criteria of patentability

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[26] Patents Act 1977, section 42(3), applying in respect of information communicated within the employment relationship.

[27] Berne Convention on the Protection of Literary and Artistic Works (1886). TRIPS, Article 9, requires TRIPS members to comply with the substantive provisions of the Berne Convention, and Article 10 states: '1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971)'.

and are not otherwise excluded from being considered 'inventions'[28] are patentable too. This raises obvious issues regarding the doing of any act that would have been considered a patent infringement had the patent not expired or ceased to be valid, but which involves the performance of an act that is restricted by the long-lasting copyright. There appears to be no general legal principle on the basis of which one might deprive the copyright owner of the right to assert copyright on the sole ground that a patent covering all or part of the patent has ceased to be valid. Freedom to use such a work may be governed by such issues as whether the owner of the patent and the author of the copyright were the same or different persons or whether any implied licence or acquiescence may be said to exist.[29]

Similar issues to those involving the interrelationship of patent rights with copyright arise in respect of design rights in those countries which have them, and have the potential to occur with greater frequency where, for example, the novelty of a patented invention arises from its specific shape and the patent description contains sketches and diagrams that are later used as design drawings upon which a third party's product is based.

Patents and utility model

The Cinderella of intellectual property rights, the utility model, together with its close cousins the petty patent and the *Gebrauchsmuster*,[30] are neglected in the current patent law debate. Although the utility model is recognised in the Paris Convention of 1883 as a species of industrial right, it is not accorded a section in TRIPS and has not been the subject of any seriously credible harmonisation or approximation initiatives[31] within the European Union – a

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28 See EPC, Article 52(2)(c).

29 Section 39(3) of the Patents Act 1977 in the United Kingdom provides that nothing done in the course of filing a patent application or working a subsequently granted patent shall be regarded as the infringement of any copyright or design right in 'any model or document relating to the invention', but that provision applies only where the patent applicant/proprietor is an employee and the owner of the copyright or design right is his employer.

30 The *Gebrauchsmuster*, a form of utility model developed in Germany and Austria, has proved influential in other jurisdictions too, notably Japan.

31 A Proposal for a European Parliament and Council Directive approximating the legal arrangements for the protection of inventions by utility model (COM (97) 0691 final – Official Journal C 36 of 3.2.1998) was presented by the European Commission in 1997, which would require member states to implement utility model protection measures. Work on the proposal was suspended in March 2000, most member states taking the view that priority should be given to introducing a Community patent. In 2005 the Commission withdrew the proposal on the ground that it was unlikely to advance further in the legislative process.

region in which most member states operate some form of utility model protection under domestic law.

Yet potentially the utility model is the most interesting species of IP right with which to compare the patent: it is in general accorded the same or similar criteria to those of a valid patent, in terms of the requirement of a degree of novelty, inventiveness and industrial applicability, and its monopoly, like that of the patent, is based on interpretation of the claims asserted by the applicant. But there are important differences. The utility model is cheap to obtain because the application is normally not examined unless its validity is challenged in the course of a dispute. The term of protection is also shorter, ten years from deposit being common. This term appears unfavourably short when compared with the 20-year term enjoyed by the fully examined patent, until one recalls that more than four-fifths of patents have lapsed or been cancelled before the end of their maximum term.

The utility model is offered as an alternative to the patent for the small-time applicant, but it could very well serve as a replacement for it.[32] In those countries in which it is offered it is often extremely popular. China, Korea, Japan and Germany are among the countries that make the greatest use of it, the applicants being mainly domestic in origin. This creates the impression that a raft of admittedly challengeable but easily obtainable monopoly rights can establish an excellent means for local businesses to repel foreign imported products and keep the domestic market for themselves.

Patents and trade marks

While the objects of patent law and trade mark law are quite different, those bodies of law are by no means unconnected. In the commercial sphere, for example, prior to the growth of the pharmaceutical generics industry it was normal for pharmaceutical drug companies to seek to extend the advantage of the patent monopoly beyond the patent's statutory term by encouraging the public to request, and the medical profession to prescribe, a product under the trade mark by which it was familiarly known. Another point of intersection between the two rights lies in the field of three-dimensional items such as products and their packaging, which may be both novel and inventive in their form and distinctive in their appearance.

This very small interface between patents and trade marks has not, however, proved to be significant in terms of the operation of the patent

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[32] For a recent review of the utility model in Europe and beyond see Uma Suthersanen and Graham Dutfield, 'Utility Models and Other Alternatives to Patents' in the book edited by them, *Innovation Without Patents: Harnessing the Creative Spirit in a Diverse World* (Cheltenham, UK and Northampton, MA: Edward Elgar, 2007).

system, almost certainly because of the very different mode in which they operate: the patent protects the functionality of an invention *because* it is functional, which is why it is typical for a patentable invention to contain a new manner of manufacture[33] or to be capable of industrial application.[34] A competitor who is barred from utilising that functionality cannot directly compete. The trade mark, in contrast, is a right which is protected because it is *not functional*.[35] Being no more than a means of identifying the origin of goods or services, it imposes no bar on the copying of functionality and does not therefore prevent the entry into the market of identically functional goods and services. The fact that patents and trade marks, which are embodied in the same item, serve entirely different purposes was recently acknowledged by the US Circuit Court of Appeals in a ruling that, in the absence of evidence that an infringing act had inflicted damage upon each of the patent and the trade mark, the sum of damages awarded would reflect the fact that no separate loss to the rights owner had been identified.[36]

Patents as property

The European Court of Human Rights has accepted that statutory intellectual property rights are property in respect of which there exists a right to the enjoyment of possession under the European Convention on Human Rights.[37] After some initial disagreement,[38] that Court has also agreed applications to

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[33] The term 'manner of new manufacture' was first employed in England in the Statute of Monopolies 1623, section 1. It was later exported to many common law jurisdictions that were influenced by English legal principles.

[34] This terminology is employed by TRIPS, Article 27. It appears to have its origins in the EPC, Article 52(1), which borrowed it from the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Strasbourg, of 27 November 1963. The Paris Convention of 1883 lays down no corresponding requirements of patentability.

[35] Functionality as a ground for disqualifying a sign from being registered as a trade mark is either the subject of explicit legislative provision or case law doctrine. Typical of the former is Council Regulation 40/94 on the Community trade mark, Article 7(1)(e)(ii), which absolutely bars the registration of '. . . the shape of goods which is necessary to obtain a technical result'.

[36] *Aero Products International Inc and Chaffee v. Intex Recreation Corp, Quality Trading Inc. and Wal-Mart Stores Inc*., 466 F.3d 1000 (Fed. Cir. 2006).

[37] European Convention on Human Rights, Protocol 1, Article 1: see *Anheuser-Busch Inc v. Portugal* [2007] ETMR 24.

[38] See *Anheuser-Busch* [2007] ETMR 24*; ITP SA v. Coflexip Stena Offshore Ltd* (First Division, Inner Court, Court of Session, Scotland, 19 November 2004), ¶ 25. The human right to the enjoyment of property in a patent does not however confer upon national courts any jurisdiction over the European Patent Office, a creation of international convention under human rights legislation (*ITP, ibid*.) or through the invocation of natural justice: see *Lenzing AG's European Patent (UK)* [1997] RPC 245 at ¶ 21–2.

obtain those rights are 'possessions' even though they are of a contingent nature in the sense that, if an application is refused or withdrawn, no patent monopoly will result.

The rulings of the European Court of Human Rights are important, but not because they establish any principle that is new but because they confirm the validity of long-standing commercial practice. Patents and applications for patents have been treated as property in accordance with the provisions of most domestic statutes. These typically confirm that patents may be assigned, licensed, mortgaged, held as security and treated in much the same way as any other chattel. The main difference between the patent and tangible forms of personal property is that the former require registration of interests, while the latter in general do not.

The register upon which the details of ownership, transactions and changes in legal status are recorded is often regarded as an inconvenience by the parties to a patent-related transaction and as another annoying fee-generating activity by whoever must meet the official fees that appear to be charged for the great majority of recordals and amendment to them. Yet the register is not only a valuable record of who is actually entitled to the patent – it is also a document that is laden with significance for anyone carrying on research into current or past commercial history.

Patents and game theory

Game theory is a methodology that informs the decision-making processes of competitors in any situation in which the outcome of each player's actions is affected by the decisions made by the others, these being decisions the outcome of which he is typically unaware at the moment of making his own decisions. The manner in which a patent (or indeed any intellectual property right) may be brought to bear in any commercial or legal dispute, and the outcome of its deployment, are a suitable subject-matter for the application of game theory.[39]

The significance of game theory is that, when applied properly, it does several things. It enables the owner, his competitors, licensees and active or putative infringers (i) to identify the further information which they need in order to make their commercial patent- and innovation-based decisions, (ii) to embark upon a given course of action, such as suing for infringement or seeking revocation of a patent, with the confidence that they have done so on the basis of reasoning that is firmly founded on principles of probability theory as

[39] For an IP-friendly introduction to game theory for intellectual property analysis see Jeremy Phillips, 'How to Win at Monopoly: Applying Game Theory to the Enforcement of IP Rights' [2007] JIPLP 540–552.

well as legal advice and (iii) to respond firmly and decisively to the unexpected responses of others.

It is comprehensively understood that an understanding of patent law is a necessary condition for the maintenance of a successful business in an innovation-rich environment, but not a sufficient one. To know that another business is infringing a patent is helpful, but it is not tantamount to saying that it is wise to sue for patent infringement. Likewise, to understand that another's patent is invalid is not to say that it is worth instituting proceedings to invalidate it. For example, A holds a patent which competitors B, C and D believe to be invalid, B is a wealthy company with a dominant market share while C and D are small businesses that lack the resources to challenge the patent's validity through expensive litigation. B may wish to challenge the validity of A's patent by itself, or it may wish to negotiate a royalty-free licence by explaining to A that, if the patent is found to be invalid, A will have expended money in vain in seeking to defend it; but if it grants B a licence, the patent remains validly registered and it can still either keep C and D from entering the market or charge them to do so. A will then calculate the risk inherent in each course; he may choose to fight an invalidity claim or grant B the free licence he requests. Or he may devise a third strategy, such as (i) proposing a royalty that is higher than the zero rate sought by B but which would still leave B in a more profitable position than if B had applied to revoke the patent, (ii) reporting B to the competition authorities for seeking to abuse its dominant position,[40] (iii) offering to pay B neither to challenge the patent nor to work it[41] or even (iv) making an exit from the market and putting the patent up for auction.[42] In each case the risk of an uncertain outcome would be calculated in accordance with principles of probability which game theory demands. Thus it can be seen that, by applying principles of game theory, one is forced to take into account factors that are based neither upon law nor upon economics, nor upon the two together, but upon wider psychological and strategic factors.

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[40] For a recent example of this strategy see the decision of the Italian Competition Authority A364, *Merck – Principi Attivi*, 21 March 2007, *Boll.* 11/2007, discussed in depth by Rita Coco and Paolisa Nebbia in 'Compulsory Licensing and Interim Measures in *Merck:* A Case for Italy or for Antitrust Law?' [2007] JIPLP 452–62.

[41] On this strategy, which may invoke the involvement of competition law authorities, see Alden F. Abbott and Suzanne Michel, 'Exclusion Payments in Patent Settlements: A Legal and Economic Perspective' [2006] JIPLP 207–22.

[42] The patent auction is currently in its infancy as a means of disposing of patents in an open market. For some early comments see Hidero Niioka, 'Patent Auctions: Business and Investment Strategy in IP Commercialisation' [2006] JIPLP 728–31 and Jeremy Phillips, 'A Bid for Recognition' [2007] JIPLP 499.

Patent power

If a playground bully hits a small child with a stick, the child will have no difficulty in identifying his assailant as the cause of his woes. Yet when a large and unforgivingly over-competitive business hits a small trader with a patent, the victim is apt to blame the patent, not the party wielding it. For this reason the patent system has been charged with the misdemeanours of businesses and enterprises whose conduct, whether it is reprehensible or not, is brought about by means of the patent system but is not actually part of it. Thus calls for the curbing of the anticompetitive activities of monopolists are better directed at the mechanisms of competition and antitrust laws that regulate that activity from the more sophisticated perspective of market analysis and a balancing of the advantages and disadvantages of the objectionable course of conduct; those bodies of law, and those whose expertise crosses the divide between law and economics, are far better able to deal with them.

In this context the example of the no-challenge clause is instructive. The owner of a patent may require, as a condition of granting a licence, that the licensee agree that it will not challenge the validity of the patent. Principles of freedom of contract give such conditions legal force; patent law itself is silent, while competition law possesses the mechanisms with which to ascertain whether the conduct of the patent licensor is reasonable and indeed necessary or constitutes an abuse of its power that may have the effect of placing the licensee in a more disadvantageous position than unlicensed third parties. An attempt under US Federal Circuit case law to require an actual contract-based controversy between the parties before a licensee may bring a declaration of invalidity, thus seeking to place the no-challenge obligation within the scope of contract and patent doctrines rather than leaving it to competition principles, as is the case in Europe,[43] has been eliminated by the US Supreme Court.[44]

Another instance of unacceptable exercise of the patent proprietor's power lies in the area of the making of groundless threats to bring infringement proceedings against third parties that do not make the allegedly infringing products themselves but merely deal with them in some way, for example as wholesalers, retailers or distributors. Where a retailer, for example, sells a

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[43] Commission Regulation 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, Article 5, regards no-challenge clauses as being absolutely unacceptable in intellectual property licences to which the Regulation applies.

[44] *MedImmune Inc v. Genentech Inc*, 127 S. Ct. 764 (2007), discussed in Scott T. Weingaertner and Christopher C. Carnaval, 'US Supreme Court Holds that Patent Licensee Need Not Repudiate Licence Before Challenging Licensed Patent in Court' [2007] EIPR 278–86.

range of several hundreds of items and one of those items is alleged to infringe a patent, that retailer will not normally consider it a justifiable investment of time, effort and money in defending a court claim when all it need do is agree to desist from selling the allegedly infringing product and stock that of the patentee instead. This being so, it is easy to understand how a market position can be buttressed by the making of false infringement claims. No international treaty or convention expressly requires signatory states to take measures to protect traders against the effect of groundless threats, though some national jurisdictions make such provision in their patent law[45] and others may regard it as actionable under local rules relating to unfair competition or unfair marketing practices.

Aggressive, well-funded and asset-rich traders are apt to throw their weight around in the marketplace irrespective of the nature of their intellectual property portfolios. Thus while corporations such as IBM and Microsoft have built up remarkable dominance within their markets on the strength of patent rights even though their sectors are characterised by technological complexity and high market entry costs, businesses such as McDonald's, Wal-Mart, Coca-Cola and Starbucks have achieved an equally remarkable degree of penetration and market share in sectors where barriers to market entry are low or negligible and the cost of market entry is relatively cheap, and have done so without the benefit of the exclusionary monopolies conferred by patents.

A different consideration relates to the so-called patent troll, the business that may be quite unproductive of profits and goods or services and which may exist solely to demand rents from those who trespass upon its patent portfolio.[46] The term 'patent troll' is an emotive and unfortunate one, which is not normally associated with other forms of property. For example, a landlord who lets out an unfurnished apartment in exchange for a monthly rent is not normally characterised as an 'apartment troll'; nor are copyright collecting societies – which exist for the sole purpose of gathering licence royalty income for their members – deemed 'copyright trolls'.

It is true that the patent troll, like the owner of any other asset, may have opted to exploit that asset's commercial value passively, through the collection of rent, rather than through its active participation in the economy of product development or marketing. But that is neither a legal wrong in itself nor, in economic terms, necessarily a bad thing. It may be speculated that situations

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[45] See for example the Patents Act 1977, section 70 (United Kingdom); Patents Act 1992, section 53 (Ireland).

[46] For an account of the manner in which patent licensing businesses manipulate local legislation and market forces, offering a tabular scheme of trolling tactics, see William Cook and Dafydd Bevan, 'The Ultimate Leverage Tacticians' [2007] Managing Intellectual Property 24–8.

exist in which the patent troll, in paying a market price for the patent, is thereby enabling the patent's former owner to recoup some of his outlay and dispose of a potentially high-maintenance asset, thereby freeing up his resources for the purpose of engaging in further original research or other beneficial and praiseworthy activities.

The spanner that works

This chapter has sought to place the patent within the context of other intellectual property rights and to view it, in terms of its functionality, as a legal device of wide application. In doing so, the patent has been depicted in terms of its strengths and its weaknesses. In truth, the patent is not just one or another of the various gadgets in the socio-economic toolbox but, within legal boundaries, every single one of them. The patent is a versatile device, its potential being limited only by our failure to imagine further ways in which it may be deployed. Most importantly, we must understand that a patent is neither a good thing nor a bad thing: it is merely a means by which good and ill may be successfully achieved.

5 International treaties and patent law harmonization: today and beyond

*Tomoko Miyamoto**

1 Introduction

Since the conclusion of the Paris Convention in 1883, an international patent law has been progressively developing. Commonalities in national patent laws have been steadily increasing. International norm setting, however, is facing new challenges today due to the increased recognition of the role of the patent system in the knowledge-based economy. On the one hand, the patent system is enjoying success in the sense that patent protection is sought in wider sectors of business and commerce in increasingly broader geographic territories.[1] On the other hand, many concerns have been raised with respect to the social and economic roles of the patent system. Some critics go even further to question the concept of intangible property in the information age, whereby intangible information as such is increasingly becoming a core element of the innovation which shapes our society.

Over the course of human history, numerous theories have been introduced to justify exclusive rights on intangible technical ideas.[2] Among those, one of the well-accepted theories is the economic incentive theory, that is, that the principal objectives of the patent system are to encourage innovation, to promote the development of technology and to foster dissemination of innov-

* The statements and views expressed in this chapter are solely those of the author and do not represent any official position of WIPO. This chapter is partly based on an earlier article, Philippe Baechtold and Tomoko Miyamoto, 'International Patent Law Harmonization – Search for the Right Balance' (2005) Journal of Intellectual Property Rights, 10: 177–87.

1 *WIPO Patent Report – Statistics on World Patent Activities 2006* (WIPO Publication No. 931) shows that the use of the patent system internationally has increased markedly in recent years. This can be seen in the growth rate of patent filings by non-residents (7.4% average annual increase since 1995) and in the increase in patent filings in countries such as Brazil, China, India, the Republic of Korea and Mexico (http://www.wipo.int/ipstats/en/statistics/patents/).

2 Robert P. Merges, Peter S. Menell and Mark A. Lembley, *Intellectual Property in the New Technological Age* (2nd edn, Aspen Law & Business, New York, 2000) pp. 2–21.

ative knowledge to the public.[3] Because those objectives closely relate to national policy strategies on scientific and technological development, economic growth and wealth creation, national patent policy is often an integral part of long-term national economic policy and strategy. An interaction among innovation, intellectual property laws and economics is also demonstrated by a bibliometric analysis of academic articles in the field of intellectual property, which shows a greater convergence of law and economics over the years.[4]

Thus, national authorities have been taking a number of measures to support the promotion of technological innovation and the transfer and dissemination of technology within the national framework. Since patent rights are territorial rights, when social, cultural and economic barriers between nations were relatively high, national legislators might have been able to concentrate primarily on achieving the right balance within the patent system in their own country. Such higher barriers existed for a number of reasons such as geographical conditions that hindered access to other territories and discriminatory man-made rules that limited the flow of goods by, for example, exorbitant importation taxes.

The appropriateness and effectiveness of patent protection under national legislation, however, has been reviewed increasingly from an international perspective. Countries operate more and more on the basis of interdependence in terms of social, cultural and economic relations. It is no mere coincidence that the Paris Convention on the Protection of Industrial Property (the Paris Convention), the first multilateral treaty in the field of intellectual property, was concluded in the late 19th century, when, following the industrial revolution, an increase in internationally oriented exchange of technology and trade flows was observed.[5]

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[3] Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) states that 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

[4] Ove Granstrand, 'Innovations and Intellectual Property Studies' in Ove Granstrand (ed.), *Economics, Law and Intellectual Property* (Kluwer Academic Publishers, Dordrecht, 2003).

[5] It is interesting to note that, in his book, *Treaties and Alliances of the World* (3rd edn, Longman, Detroit, 1981), Henry W. Degenhardt described the earlier conventions for protection of intellectual property as one of the early international agreements, along with the agreements on the conduct of war and treaties concluded in the wake of World War I.

2 International treaties: setting a framework

Article 2(1)(a) of the Vienna Convention on the Law of Treaties defines the term 'treaty' as 'an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation'. In practice, international instruments of binding international law may be referred to under a variety of denominations, such as 'treaty', 'agreement', 'convention', 'accord', 'charter', 'protocol' and 'declaration'. Some of the terms can be used as a common generic term, while the choice of title may follow habitual uses or may relate to the particular character, importance or degree of formality sought to be attributed to the instrument by its parties.[6] Whichever term is used, those instruments are accepted by the States as binding norms in their mutual relations that establish rights and obligations among themselves.

Although all treaties administered by the World Intellectual Property Organization (WIPO) were adopted unanimously by its member States, every sovereign State obviously possesses the prerogative to decide whether or not to enter into any international agreement. There is no legal obligation to ratify. However, according to Article 18(a) of the Vienna Convention on the Law of Treaties, a State is obliged to refrain from acts which would defeat the objective and purpose of a treaty when it has signed the treaty subject to ratification, acceptance or approval, until it shall have made its intention clear not to become a party to the treaty. Despite the obvious shortcoming of the treaty mechanism, that is, timeliness and effectiveness, it is perhaps this binding sense of commitment in the international community that motivates parties to conclude a treaty rather than to opt for a soft law solution.

In the area of patents, a number of multilateral treaties have been concluded, attempting to deal with areas which are impossible, or impractical, to be dealt with solely under national patent legislation. Those areas have been identified by the States involved in formulating an international legal framework against the backdrop of the specific technical, political or economic circumstances of the time. Thus, the international instruments are, by their nature, not static. They will evolve and progressively develop closely with the needs of our society. The fact that those instruments are negotiated by the sovereign States, which may or may not represent the common interests of humanity, makes the process of international norm setting rather slow in responding to changes at the international level. Nevertheless, as long as the

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[6] United Nations Treaty Collection, Treaty Reference Guide provides the overview of various terms which are employed to describe international binding instruments (http://untreaty.un.org/English/guide.asp).

States can share the principal objectives of the patent system, such as encouraging innovation, promoting the development of technology and fostering dissemination of innovative knowledge to the public, they should be able to agree on a number of common aims to establish international norms. These include:

- increase legal certainty and ensure fair and equitable protection at the international level;
- establish an efficient and effective international mechanism for the grant, maintenance and enforcement of patents in order to create an accessible and affordable international patent system;
- facilitate access by the public to patent information internationally.

With respect to ensuring equitable legal protection at the international level, the principle of an equal treatment is a fundamental principle in the international patent framework. The principle of 'national treatment', provided for in Articles 2 and 3 of the Paris Convention, requires each member State of the Convention to apply to nationals of other member States (and nationals of non-member States who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the member States) the same treatment as it gives to its own nationals. Prior to the adoption of the Paris Convention, the lack of a multilateral framework required the States to conclude a number of bilateral agreements to ensure equal treatment on a reciprocity basis. The idea of the Paris Convention is that such reciprocity is sufficiently assured by the obligation involved in adherence to the Convention.[7] Such non-discriminatory treatment against non-nationals is not an absolute rule. Even when a national law requires its nationals to be domiciled or established in the country in order to claim industrial property protection, such a requirement cannot be imposed upon nationals of other member States (Article 2(2) of the Paris Convention). Further, each country is free to treat nationals and non-nationals differently with respect to judicial and administrative procedure, to jurisdiction and to the designation of an address for service or the appointment of a representative (Article 2(3) of the Paris Convention). By virtue of Article 3.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the principle of national treatment under Articles 2 and 3 of the Paris Convention is applicable among the Members of the World Trade Organization (WTO). However, comparing the language of Article 2(3) of the Paris Convention and Article 3.2

[7] G. H. C. Bodenhausen, *Guide to the Application of the Paris Convention* (BIRPI 1969, WIPO reprinted 1991) p. 12.

of the TRIPS Agreement, permissible discrimination against non-nationals is more limited in the latter provision, since those exceptions are allowed only 'where such practices are not applied in a manner which would constitute a disguised restriction of trade'.

Another major function of international instruments in the field of patents is to adopt common rules that increase legal certainty at the international level and enhance accessibility to the international patent system. Typically, such common rules can be achieved by the States' commitment to bring national laws closer together. In other words, the States submit themselves to implement the same or similar legal standards to those prescribed in the international instruments. Among the existing patent-related treaties, the substantive provisions of the Paris Convention, the TRIPS Agreement and the Patent Law Treaty (PLT) are transposed, either directly or indirectly through the national legislation, to the rules applicable under the national systems of each member State.

Another way of adopting common rules at the international level is to set up a 'system' under which participating States mutually recognize certain processes in, or actions taken by, other member States, for the purpose of patent protection at the national level. With a view to diverging substantive patent laws and the importance attached to the sovereignty of the States regarding national patent procurement, so far, States have pursued such mutual recognition only in limited areas of patent law. A notable example is the right of priority under Article 4 of the Paris Convention, which requires the member States to recognize a filing date accorded to a regular national filing under the domestic legislation of other member States. Further examples may be found in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, under which the member States must recognize the deposit of microorganisms with any 'international depositary authority (IDA)' for the purposes of patent procedure.

Another good example of international cooperation is the Patent Cooperation Treaty (PCT), which establishes simplified and cost-effective patent procedures at the international level through creating the international phase that allows an international filing, publication, search and examination of international patent applications. Even if the PCT Contracting Parties are not obliged to accept the results of an international search and an international preliminary examination conducted during the international phase, 137 PCT member States agree on the common form and contents of an international application and on the common procedures during the international phase.

Since one of the objectives of the patent system is to disseminate technological information in order to avoid 're-inventing the wheel', the international instruments that facilitate and accelerate access to patent documents by the public play an important role in the good functioning of the patent system

worldwide. The practical significance in the patent community of the Strasbourg Agreement Concerning the International Patent Classification and the WIPO Standards, Recommendations and Guidelines on patent information and documentation is undeniable, although they may not attract the same attention given to other international instruments. The Strasbourg Agreement establishes the International Patent Classification (IPC), which classifies all fields of technology in a hierarchical structure. The IPC is indispensable for the retrieval of patent documents. Since an increasing number of patent documents have been stored in a digital form being made accessible on-line, in order to ensure the interoperability of the systems and availability of patent information all over the world, the international standardization in this area will be increasingly important.

Although international common rules have significantly shaped international patent norms, it should be noted that international instruments, in actual fact, regulate only a limited part of the patent system. They leave considerable freedom to the member States to legislate in a flexible manner in accordance with their interests and political priorities. There is no doubt that more and more commonalities will be found in national patent laws. However, the current stage of harmonization of patent laws is far away from a single global patent system, and it is very unlikely that such a single international framework will be realized in the near future. The following sections will review existing international norms in a chronological order from the perspective of what has been codified and what has been left out of the international legal framework.

In addition to global international instruments, the role of regional agreements in the harmonization of the relevant legislation should not be underestimated. In general, the objectives of intergovernmental regional cooperation are to establish a cost-effective patent system (or systems) and to foster trade and investments within the region. Either by way of establishing a common patent office[8] or by way of adopting common rules applicable to the States,[9] the harmonization of national legislation is an important prerequisite of any consideration of regional systems, although the degree of harmonization required will depend on the nature of the regional arrangements, which is beyond the scope of this chapter.

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[8] The African Intellectual Property Organization (ARIPO) and the Organisation Africaine de la Propriété Intellectuelle (OAPI) in Africa, the Eurasian Patent Organization (EAPO) in the Eurasian region, the European Patent Organisation (EPO) in Europe and the Gulf Cooperation Council (GCC) Patent Office in the Gulf region.

[9] For example, Bolivia, Colombia, Ecuador and Peru form the Andean Community which harmonizes the national legislation of those States via Community Decisions.

3 International norm setting until the year 2000: overview

3.1 Paris Convention for the Protection of Industrial Property (Paris Convention)

By the second half of the 19th century, many countries had recognized the value of the patent system as a tool for technological and economic development. Consequently, they established a system for the protection of invention at the national level. Since no international convention in the field of industrial property existed at that time, it was rather difficult to obtain patents in foreign countries. For instance, a stringent working requirement[10] and differential treatments between foreign applicants and national applicants were often observed. Moreover, patent applications had to be filed roughly at the same time in all countries in order to avoid publication in one country destroying the novelty of the invention in the other countries.[11] Such inadequate protection for foreign inventors made them refuse to participate in an international exhibition on inventions hosted by the Government of Austria-Hungary in 1873 in Vienna. This led the government to host the Congress of Vienna for Patent Reform in 1873 and eventually, the Paris Convention for the Protection of Industrial Property was adopted in 1883. Having been revised several times, the Paris Convention provides basic principles that still play a fundamental role in today's international industrial property system.

The historical context required governments to establish an international framework to secure the right of applicants to obtain adequate industrial property protection abroad. This led to the adoption of the principle that guarantees a basic right known as the right to national treatment in each of the member States. Further, another basic right known as the right of priority was adopted in view of the costs and additional works involved in preparing and filing patent applications in foreign countries.

In addition to the above principles, the Paris Convention provides certain common rules that are either required or permitted to be implemented under national legislation. In the field of patents, these include the right of the inventor to be mentioned in the patents (Article 4*ter*), the questions of importation of articles covered by patents, failure to work the patented invention and

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[10] A government may forfeit a patent where a patented invention has not been worked by the patentee in the country concerned. Austrian law had a one-year period to work in the country.

[11] *WIPO Intellectual Property Handbook* (WIPO, Geneva, 2004) p. 241. Christopher May and Susan Sell, *Intellectual Property Rights – Critical History* (Lynne Rienner Publishers, London, 2006) pp. 111–20 also describes the situation up to the adoption of the Paris Convention.

compulsory licenses (Article 5A), the grace period for the payment of maintenance fees (Article 5*bis*), limitation of patent rights where the patented invention is on a means of transportation temporarily entering the territory (Article 5*ter*) and temporary protection in respect of goods exhibited at international exhibitions (Article 11). Many of those provisions left a number of issues open to national legislators. For instance, Article 11 requires member States to provide temporary protection in respect of goods exhibited at international exhibitions, leaving member States to choose the means of implementing such protection through domestic legislation.[12] The Convention also leaves the member States free to establish a number of fundamental issues concerning substantive patent law, such as the criteria for patentability, term of protection, rights conferred by a patent and enforcement of rights. The sovereign right of the member States to decide on the grant of a patent is somewhat confirmed by Article 4*bis* of the Paris Convention, whereby patents applied for in a member State shall be independent of patents obtained for the same invention in other countries. Due to a great divergence among national laws, idealistic aspirations expressed at the Vienna Congress to harmonize divergent national laws through international instruments had to be boiled down to realistic provisions in order to be adopted as an international binding instrument by participating governments. This, however, does not diminish the importance of the Paris Convention, which provided a critical foundation for the international patent system.[13]

3.1 Patent Cooperation Treaty (PCT)

Although the Paris Convention had established fundamental principles and some substantive rules, national procedural and substantive rules continued to be significantly different, while international movement of goods and services had expanded considerably since the adoption of the Paris Convention. The Patent Cooperation Treaty (PCT), an agreement for international cooperation, with regard to the filing, searching and preliminary examination of patent applications and dissemination of technical information contained in patent applications, was adopted in 1970 with a view to streamlining the patent granting procedures at the global level. The PCT became operational in 1978 with 18 Contracting States. Being responsive to applicants' needs, it is one of the most successful treaties in the field of intellectual property with 138

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12 National legislation may, for example, grant a right of priority, consider the public disclosure through such exhibition as not destroying novelty or recognize a right of prior use in favor of the exhibitor.

13 The text of the Paris Convention is available at: http://www.wipo.int/treaties/en/ip/paris/.

Contracting States and around 145,300 international applications filed in 2006.[14]

The objectives of the PCT can be extracted from the preamble of the treaty, which states that the Contracting States desire to 'make a contribution to the progress of science and technology', 'perfect the legal protection of invention', 'simplify and render more economical and obtaining of protection for inventions where protection is sought in several countries', 'facilitate and accelerate access to the technical information' and 'foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems'.

The PCT system consists of two phases: the international phase and the national phase. The procedures in the international phase include:

- Filing – instead of filing a national patent application in each country in which protection is sought, a single international application, filed with a single patent Office ('receiving office') in one language has effect in each of the States party to the PCT;
- Formality examination – the receiving office conducts the formality examination to check whether the formality requirements under the PCT are complied with;
- International Search – an 'International Searching Authority' (ISA) (one of the patent offices that comply with the requirements under the PCT and appointed as ISA by the PCT Assembly) prepares an international search report citing the relevant prior art and establishes an opinion on potential patentability;
- International Publication – the centralized international publication of applications with the related search report is made as soon as possible after the expiration of 18 months from the priority date;
- International Preliminary Examination – upon request by the applicant, an 'International Preliminary Examining Authority (IPEA)' (one of the patent offices that comply with the requirements under the PCT and appointed as IPEA by the PCT Assembly) carries out an additional patentability analysis, usually based on the claims amended by the applicant taking into account the search report and the opinion of the ISA.

Once the procedures under the international phase have been completed, the applicant decides whether, and in respect of which States, the applicant wishes to continue the procedure after reviewing the results of the search and the

[14] Information regarding the PCT is available on the WIPO web site: http://www.wipo.int/pct/en/.

preliminary examination, if any. Only in that event shall the applicant fulfill the requirements for entry in the national phase. These requirements include the paying of national fees and, in some cases, filing translations of the application or appointing a local patent attorney, in each country in which the applicant seeks patent protection. These steps must be taken, in principle, before the end of the 30th month from the priority date. In the national phase, each patent office is responsible for granting a patent or refusing the international application, in accordance with its national or regional substantive patent law.

For applicants, the PCT system makes it possible to postpone the decision on the desirability of seeking protection in foreign countries and the payment of major costs associated with international patent protection, such as preparing the translation, payment of national fees and appointment of a local representative. The applicant can prepare a patent application complying with one set of harmonized formality requirements, which must be accepted by all Contracting States. Further, the PCT system provides the possibility of 'perfecting' the application based on the result of search and preliminary examination before entering the national phase, thus putting it in order before processing by the various patent offices. For the patent offices, the work relating to formality checks, publication of applications, search and examination can be considerably reduced. In particular, search and examination reports prepared during the international phase may provide valuable patentability information for deciding the grant of patents.

The PCT harmonized the form and contents of patent applications and established an international framework under which a unique, common procedure is established for certain parts of the patent granting procedures. Article 27(1) of the PCT states that 'no national law shall require compliance with requirements relating to the form or content of the international application different from or additional to those which are provided for in this Treaty and the Regulations'.[15] The PCT, however, explicitly ensures the freedom of the Contracting States to prescribe substantive conditions of patentability (PCT Article 27(5)), and thus is incapable of tackling the issues relating to substantive patent law, such as definition of prior art, novelty and inventive step. Consequently, the results of the international search and preliminary examination do not have a binding effect on the determination of the patentability at the national phase in each Contracting State. The terms 'form or contents of patent application' and 'substantive conditions of patentability' are not defined in the Treaty, thus, at least theoretically, leaving an ambiguity with respect to the rights and obligations of the Contracting States.

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[15] PCT Article 27(4), however, provides that the national law may provide for requirements regarding the form or contents of applications which, from the viewpoint of applicants, are more favorable than the requirements under the PCT.

3.3 Draft Patent Harmonization Treaty and the Patent Law Treaty (PLT)

Despite the fact that the PCT greatly simplified the filing of patent applications at the international level, substantive patentability requirements varied significantly in different jurisdictions. Further, considerable numbers of applications were filed abroad not using the PCT system.[16] In the mid-1980s, this led to the negotiation of a new global Treaty that addressed a number of substantive issues, the harmonization of which was considered indispensable for a better international patent system. The discussion started from the global harmonization of grace periods, recognizing that, without harmonization, an applicant must absolutely refrain from disclosing his or her invention to the public before the filing date, as long as one of the countries in which patent protection is sought does not provide the grace period. A number of other issues were subsequently included in the negotiation package, and a draft 'Treaty Supplementing the Paris Convention as Far as Patents Are Concerned' (draft 1991 Patent Harmonization Treaty) was discussed at the first part of the Diplomatic Conference, held in The Hague in 1991.[17] The substantive provisions of the draft Treaty covered a wide range of issues under patent law, including provisions related to patent applications and examination procedures,[18] standards for obtaining a patent,[19] rights and remedies granted by a patent[20] and post-grant procedures.[21]

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[16] Among the patents which were granted to non-residents, 50% in China, 32% in Brazil, 56% in Japan and 82% in the United States of America were patents granted with respect to national applications filed by non-residents not using the PCT system (source: WIPO Industrial Property Statistics, 2005: http://www.wipo.int/ipstats/en/statistics/patents/).

[17] The Draft Patent Harmonization Treaty is found in the Records of the Diplomatic Conference for the Conclusion of a Treaty supplementing the Paris Convention as Far as Patents Are Concerned (WIPO Publication No. 351).

[18] Article 7: Belated Claim of Priority; Article 8: Filing Date; Article 15: Publication of Application; Article 16: Time Limits for Search and Substantive Examination.

[19] Article 3: Disclosure and Description; Article 4: Claims; Article 5: Unity of Invention; Article 6: Indication and Mention of Inventor; Declaration Concerning the Entitlement of the Applicant; Article 9: Right to a Patent; Article 10: Fields of Technology; Article 11: Conditions of Patentability; Article 12: Disclosures Not Affecting Patentability (Grace Period); Article 13: Prior Art Effect of Certain Applications; Article 14: Amendment or Correction of Application.

[20] Article 19: Rights Conferred by the Patent; Article 20: Prior User; Article 21: Extent of Protection and Interpretation of Claims; Article 22: Term of Patents; Article 23: Enforcement of Rights; Article 24: Reversal of Burden of Proof; Article 25: Obligations of the Right Holder; Article 26: Remedial Measures Under National Legislation.

[21] Article 17: Changes in Patents; Article 18: Administrative Revocation.

The first part of the Diplomatic Conference could not resolve two major issues, that is, the worldwide introduction of a grace period and the 'first-to-file' principle. A number of European countries[22] considered that the acceptance of the grace period provision, combined with a mandatory article on prior user's rights, was conditional on the mandatory first-to-file principle. The United States of America could not concede on this point due to strong opposition by, in particular, national independent inventors. Although the dates for the second part of the Diplomatic Conference had been fixed, the draft Patent Harmonization Treaty faced deadlock in 1993 when the United States of America declared that they were not prepared to change their domestic system to first-to-file.

In parallel to the negotiation of a broad harmonization treaty in WIPO, another negotiation was taking place under the framework of the General Agreement on Tariffs and Trade (GATT). The negotiation on the TRIPS Agreement was officially launched in conjunction with the GATT Uruguay Round in 1986. In the early years of the TRIPS negotiations, developing countries argued that only WIPO had the competence to discuss substantive norms and standards relating to intellectual property rights, blocking substantive discussions on IPRs apart from counterfeit goods (which they considered the only 'trade-related' issue). However, the positions of developing countries gradually weakened, and the draft Final Act prepared in December 1991 (Dunkel Draft) was almost the same as the final text of the TRIPS Agreement.[23] Subsequent to such development at the GATT, when deciding on the dates of the second part of the Diplomatic Conference in 1992, the Assembly of the Paris Union also decided to delete from the draft Patent Harmonization Treaty a number of articles,[24] the contents of which had been included in the draft TRIPS Agreement. With the prospect of a successful conclusion of the TRIPS Agreement at GATT, major *demandeurs* of the draft 1991 Patent Harmonization Treaty were probably not able to see any benefit in making concessions at WIPO, and the momentum for the continuation of the discussion was lost.

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22 Belgium, Denmark, Finland, France, Norway, Sweden.

23 Daniel Gervais, *The TRIPS Agreement – Drafting History and Analysis* (2nd edn, Sweey and Maxwell, London, 2003), pp. 31–2 paragraph 2.01.

24 Article 10 (Fields of Technology), Article 19 (Rights Conferred by the Patent), Article 22(1) (Term of Patents), Article 24 (Reversal of Burden of Proof), Article 25 (Obligations o the Right Holder) and Article 26 (Remedial Measures Under National Legislation) were removed from the Basic Proposal. In addition, following a proposal by the United States of America, the Assembly noted the need to consider the possible removal of Article 20 (Prior User) in conjunction with the removal of Article 19.

Discussions resumed two years later in WIPO, after the adoption of the TRIPS Agreement, taking another approach to promoting harmonization, namely, limiting the scope of the negotiation to formalities of national and regional patent applications. The discussion on the draft Patent Law Treaty (PLT) started in 1995 and was concluded in June 2000. In expressly excluding substantive requirements, the PLT confined itself to a simplification of formality requirements set by national and regional offices and the streamlining of the procedures for obtaining and maintaining a national and regional patent. Prior to the initiation of the discussions on the PLT, in the field of trademarks, the adoption of the Trademark Law Treaty (TLT) in 1994 advanced the harmonization of formality requirements under national/regional trademark systems. Undoubtedly, this success inspired the idea of concluding a similar international instrument in the area of patents.[25]

The 1991 Draft Harmonization Treaty also included formality issues such as requirements for obtaining the filing date and belated claim of priority. The PLT includes those issues and other matters such as representation, signatures, change in names and addresses, change in ownership, and conditions for the extension of time limits and restoration of rights. Compared with substantive requirements, formality requirements are often considered less important since they are not concerned with the so-called 'patentability' of the claimed invention. However, since non-compliance with the formality requirement results in the refusal of a patent application, the importance of formality requirements should not be underestimated. The underlying consideration under the PLT is: what are the maximum formality requirements that the Contracting Parties may impose under the national/regional patent law in view of the fact that the formality requirements are not relevant to inventiveness (the degree of contribution to existing art by the inventor)?

Except for Article 5 (filing date requirements), the PLT regulates the maximum set of requirements that an Office of a Contracting Party may apply, that is, the office may not require any other formal requirements in respect of the matters dealt with under this Treaty. In other words, the PLT does not establish a completely uniform procedure for all Contracting Parties, but a Contracting Party is free to require fewer, or more user-friendly, requirements than those prescribed in the Treaty.

The filing date requirement in Article 5 is one of the key provisions in the PLT. The draft 1991 Patent Harmonization Treaty also contained filing date provisions in draft Article 8 and draft Rule 7. Comparing the texts of those

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[25] The TLT also provides provisions concerning, for example, a filing date (Article 5), a signature (Article 8) and a change in ownership (Article 11) and sets out the Model International Forms which shall be accepted by the Contracting Parties.

two instruments, the differences clearly show the evolution of the consideration in this area, that is, a clearer distinction between the minimum set of items that are necessary for according the filing date and other elements that are required in order to further process the application before the Office. A good example may be a question as to whether a claim and a filing fee shall be required for according the filing date. The draft 1991 Patent Harmonization Treaty, draft Article 8(2) provides a possibility for a Contracting Party to refuse the filing date where a claim is not contained in the application, and/or a fee is not paid, within a certain time limit. Draft Article 8(2) continues by saying that, where such requirements are complied with within the time limit, the filing date accorded shall be the date on which the minimum elements (an indication that patent protection is sought, indications allowing the identity of the applicant to be established and a section which appears to be a description) are complied with. It was a compromise between some countries which accorded a filing date on an application without claims and without payment of a filing fee and other countries which required the claims and the payment of the filing fee in order to accord the filing date. This was one of the controversial points which was also extensively debated at the PLT Diplomatic Conference in 2000. In the end, the delegations were able to agree the text in Article 5(1) that the three minimum elements (an indication that patent protection is sought, indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the office and a section which appears to be a description) are sufficient for according the filing date. As long as an invention is described in the application in a section which appears to be a description, there is no doubt that the applicant was in possession of such an invention at the time the application was submitted. Therefore, it would be justified to accord a filing date on such a date, and to claim priority based on such a date. The submission of claims and the payment of a fee are, like the submission of a translation, requirements that can be complied with after the filing date. Non-compliance with those other formality requirements does not revoke the filing date retrospectively (although the application would be refused), thus the applicant retains the right to claim priority based on the initial filing date.

Another controversy surrounding the filing date requirement was whether a reference in the application to another previously filed application could, for the purpose of the filing date, replace the main parts of the application. In the draft 1991 Patent Harmonization Treaty, two alternative solutions were provided: the first alternative obliges Contracting Parties to accept reference filing for the purpose of the filing date and the second alternative left it as a choice for each Contracting Party. The PLT answers this question by introducing a mandatory provision for the Contracting Parties to accept a reference filing for the purpose of the filing date in Article 5(7), subject to further

requirements that can be imposed by each Contracting Party. Those further requirements include the submission of a certified copy of the previously filed application and limitation of the reference filing to previous applications filed by the same applicant.

With respect to the filing date requirement, another provision, which had not appeared in the draft 1991 Patent Harmonization Treaty, was introduced in the PLT. In view of protecting the applicants from unintentional loss of substantive rights, PLT Article 5(6)(b) provides that, where the missing part of the description or the missing drawing is filed to rectify its omission from an application which claimed the priority of an earlier application, provided that the missing part of the description or the missing drawing was completely contained in the earlier application, the filing date of the application is the date on which at least the minimum elements that are required for the establishment of the filing date were filed, and not, as the general rule suggests, the date on which the missing part was submitted. In order to recognize the former date as the filing date, a Contracting Party may impose further requirements, such as submission of a translation of the earlier application or an indication in the application that the contents of the earlier application were incorporated by reference in the application. The underlying consideration is that, if the contents in the missing part were already contained in the earlier application, there is no doubt that, on the filing date of the subsequent application, the applicant has already been in possession of the knowledge contained in the missing part. Therefore, in this particular case, later inclusion of the missing part in the application does not result in loss of the filing date.

Apart from the filing date provisions, another main pillar of the PLT is to provide certain mechanisms to rectify mistakes made by an applicant or owner, taking into account the legal certainty and predictability for third parties and the administrative burden on offices. In order to avoid unreasonable loss of substantive rights as a result of failure to comply with formality requirements, the PLT sets out, among other things, (i) relief in respect of time limits in the form of an extension and/or continued processing (Article 11); (ii) reinstatement of rights where an applicant or owner has failed to meet a time limit and, as a consequence, has lost his rights with respect to an application or patent unintentionally or in spite of all due care required by the circumstances (Article 12); (iii) correction or addition of a priority claim after the filing date (Article 13(1)); and (iv) a remedy for the loss of a priority right due to innocent non-compliance with related time limits (Article 13(2) and (3)). On the fourth point, the draft 1991 Harmonization Treaty contained in draft Article 7(2) a provision[26] allowing an applicant to restore the right of priority

[26] The provision was placed within square brackets. According to the Rules of

where a subsequent application, which claims or could have claimed the priority of an earlier application, is filed within two months of the expiry of 12 months from the filing date of the earlier application despite all due care required by the circumstances, provided that certain other requirements are met. Although the provision was clearly designed to meet a *force majeure* situation, a majority of the delegations opposed the inclusion of such a provision, since they felt that it altered the principle of the 12-month priority period laid down in the Paris Convention. After nine years, in 2000, a similar discussion was held at the Diplomatic Conference for the Adoption of the PLT. This time, a majority of the delegations concurred with the argument that the corresponding provision was drafted in terms of relief under exceptional circumstances and by no means extended the 12-month priority period prescribed in the Paris Convention.[27]

Since the PCT already regulates formality requirements with respect to international applications in detail, creating a new and different set of international standards applicable to national and regional applications does not make sense. Therefore, the requirements relating to the form or content of international applications under the PCT, concerning both the international phase and the national phase, are incorporated by reference into the PLT, with minor exceptions (PLT Article 6(1)). Thus, with respect to national and regional applications, no PLT Contracting Party may apply requirements relating to form or contents different from, or additional to, those of international applications under the PCT. The expression 'form or contents of an application' is to be construed in the same way as the corresponding expression in PCT Article 27(1). During the course of the negotiation of the draft PLT, there was an attempt by the WIPO member States to clarify which requirements under the PCT relate to 'form or content'. The attempt, however, was not successful, confirming the practical difficulty of such demarcation. The sole outcome was that it would be wise not to raise this question. The lack of a definition has, so far, not caused any disputes over the interpretation of this expression in the context both of the PCT and of the PLT. However, there is a slight ambiguity when applying the PCT requirements to the PLT. The PLT incorporates by reference not only the relevant PCT Treaty provisions but also the relevant provisions under the Regulations and the Administrative Instructions Under

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Procedure of the Diplomatic Conference, a text presented within square brackets is not part of the basic proposal. In order to be discussed at the Diplomatic Conference, it has to be proposed as an amendment to the basic proposal by a member delegation and supported by another member delegation.

[27] In order to confirm the understanding that the PLT provision does not alter Article 4 of the Paris Convention, the words 'Taking into consideration Article 15' was included at the beginning of PLT Article 13(2) at the Diplomatic Conference.

the PCT, which are rather frequently amended or modified. Where any amendment or modification which is consistent with the articles of the PLT is made in those PCT-related instruments, the PLT Assembly has to decide on the applicability of such amendment or modification to the PLT. Without a clear line between the 'form or contents of an application' and the 'substantive conditions of patentability', at least in theory, there are no clear criteria as to which amendment or modification in the PCT shall be submitted to the PLT Assembly for its adoption.

The PLT is expected to result in cost reductions and in the avoidance of loss of rights, since it provides predictable and simple procedures for applicants and encourages efficient operations within patent offices. The PLT does not achieve absolute harmonization, but rather brings national/regional laws of the PLT Contracting Parties closer by providing the maximum requirements that the Contracting Parties can require under the applicable law. Nevertheless, it contains a number of provisions which ensure applicants will not be overburdened by the formalities. For patent offices, removing unnecessary formalities from its procedures would certainly improve efficiency. On the other hand, for those offices which have to introduce certain new user-friendly mechanisms as set out in the PLT, such as a reference filing, an extension of time limits and restoration of rights under certain circumstances, there could be more administrative work involved in order to carry out those procedures. The PLT, however, does not prohibit, and in many cases expressly allows, the offices to require fees in exchange for such kinds of additional works to be dealt with by the offices.

3.4 Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

The Uruguay Round of multilateral trade negotiations resulted in the adoption of the Agreement Establishing the World Trade Organization (WTO Agreement) on April 15, 1994 in Marrakech. The TRIPS Agreement was contained in the Annex to the WTO Agreement, which entered into force on January 1, 1995. Built upon the foundations laid by the Paris Convention and the Berne Convention, the TRIPS Agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability.[28]

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[28] As regards detailed analysis of the TRIPS Agreement, reference is made to Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International, The Hague, 2001), Gervais, n. 23 above; Carlos Correa and Abdulqawi Yusuf (eds), *International Trade, The TRIPS Agreement* (Kluwer Law International, The Hague, 1998).

As regards geographic coverage, the TRIPS Agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPS Agreement is the first international instrument to focus on trade-related aspects of IPRs. In view of the different levels of 'preparedness' among members to implement the TRIPS Agreement under national laws, the TRIPS Agreement sets out certain periods of time after the entry into force of the WTO Agreement before members are obliged to implement the TRIPS Agreement (Articles 65 and 66). Different periods were prescribed for developed countries (January 1, 1996), developing countries (five years from the date on which the TRIPS Agreement becomes mandatory for developed countries) and least-developed countries (ten years from the date on which the TRIPS Agreement becomes mandatory for developed countries). The targeted date for least-developed countries, which was January 1, 2006, has proved to be too ambitious, and was extended further to July 1, 2013.[29]

Unlike the treaties developed under the auspices of WIPO, the TRIPS Agreement covers a wide range of intellectual property in a single undertaking. The term 'intellectual property' refers to all categories of intellectual property that are the subject of Section 1 through 7 of Part II of the TRIPS Agreement, namely, copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs (topographies) of integrated circuits and undisclosed information (Article 1.2). The TRIPS Agreement also requires, in Part III, that certain enforcement procedures be available to permit effective action against any act of infringement of IPRs, including border measures. Such procedures must be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse (Article 41.1). Further, Part IV contains general provisions on principles concerning procedures for acquisition and maintenance of industrial property rights.

Compared with the treaties adopted under the auspices of WIPO, the particularity of the TRIPS Agreement is a dispute settlement system established under the WTO Agreement. Articles XXII and XXIII of GATT 1994 (except subparagraph 1(b) and 1(c) of Article XXIII), as elaborated and applied by the WTO Understanding on Rules and Procedures Governing the Settlement of

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[29] WTO document IP/C/40. With respect to pharmaceutical products, least-developed country members are not obliged to implement Sections 5 and 7 of Part II or to enforce rights provided for under these sections until January 1, 2016 in accordance with the Doha Declaration on the TRIPS Agreement and Public Health.

Disputes, apply to consultations and the settlement of disputes under the TRIPS Agreement. This means that benefits enjoyed in another trade area may be withdrawn in retaliation for the violation of the TRIPS Agreement (so-called cross-retaliation).

A number of substantive law provisions contained in the TRIPS Agreement are developed from the principles set out in existing treaties. Firstly, the TRIPS Agreement incorporates by reference almost all the substantive provisions of the Paris Convention, the Berne Convention and, in the area of layout designs (topographies) of integrated circuits, the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).[30] Coupled with the WTO dispute settlement mechanism, references to the above WIPO treaties in the TRIPS Agreement put teeth into the implementation of those WIPO treaties, since non-compliance with those WIPO treaties might result in a trade sanction. In addition, the TRIPS Agreement has achieved further harmonization of substantive law in all areas of intellectual property that are applicable to all WTO members.

In the area of patents, the TRIPS Agreement established the standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter (Article 27); (ii) in terms of the availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced (Article 27.1); (iii) rights conferred by a patent (Article 28) and exceptions to the rights (Article 30); (iv) conditions concerning the disclosure of the invention in a patent application (Article 29); (v) compulsory licenses (Article 31); (vi) availability of judicial review process for any decision to revoke or forfeit a patent (Article 32); (vii) the term of protection (Article 33) and (viii) the burden of proof in deciding whether a product was obtained by a patented process (Article 34). Issues such as patentable subject matter and exceptions, rights of patent owners, the term of protection and conditions and grounds for issuing a compulsory license, have been long-standing controversial topics that had been intensively debated in WIPO fora, whether in conjunction with the draft 1991 Patent Harmonization Treaty or with amendments to the Paris Convention. Setting international standards on a number of those issues is an extraordinary result achieved by the TRIPS Agreement. However, the controversy *as such* has not disappeared with the adoption of the TRIPS Agreement.

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[30] Members of the WTO shall comply with Articles 1 through 12 and 19 of the Paris Convention in respect of Parts II, III and IV of the TRIPS Agreement, Articles 1 through 21 (except Article 6*bis*) of the Berne Convention and its Appendix and Articles 2 to 7 (other than Article 6(3)), 12, and 16(3) of the IPIC Treaty.

Re-examination of provisions with respect to patents is under way as described below.

4 International norm setting in the 21st century: draft Substantive Patent Law Treaty (SPLT), policy debates and uncertainties

After the conclusion of the PLT in 2000, a considerable number of WIPO member States expressed their wish to consider the issues related to the harmonization of substantive requirements of patent law. This did not mean that the member States would simply come back and re-discuss the draft 1991 Patent Harmonization Treaty. The international landscape has significantly changed. Firstly, the conclusion of the TRIPS Agreement, which expressly recognized the interaction between intellectual property protection and trade in a global environment, changed the perspective of the international intellectual property regime. It appears that the frictions surrounding the TRIPS Agreement explain the two major challenges of today. The first is an increased focus on the interaction between intellectual property protection and other social, economic and cultural issues. Particularly, in the field of patents, public policy issues, such as public health, protection of the environment, food security and access to basic research, have been brought onto the agendas of international debates.

The second challenge is increasing regionalization and globalization in all areas of our activities. The globalization of commerce, in particular, challenges the design and operation of the international patent system. The increasing international dimension of trade flows requires protection of intellectual property assets beyond the borders of the inventor's home country. This applies not only to multinational and large-scale business in developed countries, but also to smaller entities, since regional trade and economy also call for the protection of intellectual property beyond national boundaries. Under the current international patent regime, this implies a higher cost of obtaining, maintaining and enforcing patents in each country in which patent protection is required. The higher cost of obtaining patent protection abroad stems, at least in part, from differences among national laws. In addition to differences of a more formal nature, such as the language of an application, differences as to substantive requirements, acceptable claim formats and the interpretation of claims oblige an applicant to 'customize' the application in accordance with the national/regional law. Such customization requires considerable effort and time with a thorough understanding of the relevant national/regional laws. Nevertheless, the number of patent applications filed worldwide is growing,[31] and patent offices have to cope with the increasing workload within their limited financial and human resources.

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[31] The number of patent applications filed worldwide remained around 900,000

Another type of challenge which is inherent in the operation of the patent system concerns the quality of granted patents. Although the question as to how to design a mechanism that only protects truly patentable inventions is nothing new, the question is more significant today in a situation where all WTO members, be they developing countries or least-developed countries, should put in place a patent system in compliance with the TRIPS Agreement. A further challenge concerning the quality of patents relates to new technological development. We have experienced in the past that a patent system has been flexible and general enough to bring in new technologies under a common set of rules called 'patent law'. Is it also true for information technology and biotechnology? In addition to the technological development, generally, the so-called 'service' sector has occupied an increasing part of our economy. Is a patent system feasible to promote innovative ideas in such sectors? Further, the business models surrounding innovative activities have also developed. In today's knowledge-based economy, the creation and management of innovation has become more institutionalized and systematic, which results in a growing number of patents and a growing amount of litigation. Is a patent system capable of standing still with such a labyrinth of rights?

Certainly, these are the questions which do not have definite answers today. In the midst of the wide range of views expressed, international debates on patent harmonization, however, are steadily under-way. In this section, three issues, namely, PCT Reform, a draft Substantive Patent Law Treaty (SPLT), review and amendment of the TRIPS Agreement and the Doha Declaration, will be presented.

4.1 PCT reform

By the 1990s, a number of efforts had been made to further develop the PCT system into a more efficient and useful international framework.[32] However, few changes have been made in terms of the basic architecture of the PCT system. One of the reasons is that member States have strong reservations about extending the PCT system to the area of substantive patent law. Another difficulty is that a large part of the PCT system is regulated in articles of the Treaty, the amendment of which needs to be adopted by a Revision

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per year between 1985 and 1994. In 1995, the number exceeded one million applications per year, and in 2004, 1,599,000 applications were filed worldwide (source: WIPO Patent Statistics).

[32] The International Bureau of WIPO explored the possibility of a 'PCT Certificate of Patentability', which could be obtained, if an applicant so wished, from the International Bureau on the basis of the results of an international preliminary examination by extending the international operation of the PCT system further into the national phase. The Certificate would have the same effect as national or regional patents of the countries which participate in the new system.

Conference. Even if such an adoption were successful, until the adopted changes entered into force in all member States, there would be a period where different versions of the Treaty applied to different States. This might cause practical difficulties in administering the system and, albeit temporarily, could further complicate the system rather than simplifying it. The PCT Reform project, started in 2001, thus took a two-step approach: as a first step, improvement of the system through the PCT Regulations, and as a second step, consideration of further reform that affects the provisions under the Treaty.[33] However, because of the difficulties stated above, discussions have been limited to issues under the first step without affecting the Treaty provisions.

The objectives of PCT Reform are, among other things, to simplify and streamline the PCT system, to reduce costs, to enable offices and authorities to meet their workload, to avoid duplication of work among offices and to meet the needs of large, medium and small offices. The last point is pertinent, since 138 States are members of the PCT as of January 15, 2008. During the last six years, a number of changes were made in the PCT system in view of the above objectives. The major changes are:

(i) the time limit in Article 22(1) was modified from 20 months to 30 months from the priority date, so that, in general, international applications enter a national phase at the expiry of 30 months from the priority date under both Chapter I procedure (without the international preliminary examination (IPE)) and Chapter II procedure (with the IPE);[34]

(ii) the international search system was expanded so that the International Search Authority (ISA) prepares a written opinion (WO) in addition to the international search report (ISR);

(iii) filing an international application now has the effect of designating all PCT Contracting States, thus the applicant's choice of designating countries can be deferred to the national phase;

(iv) various changes were made in order to conform with the PLT, for example, extension of the time limit for the national phase entry,

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33 Working documents and reports of the meetings relating to PCT Reform are available at: http://www.wipo.int/pct/reform/en/.

34 Prior to the modification, a number of applicants request the IPE only for the purpose of 'buying time' before the national phase entry which requires the applicants to submit translations, if needed, and pay national fees. Aligning the time limits for both Chapter I and Chapter II allows an applicant to request the IPE only where he is interested in obtaining the result of the preliminary examination. For the purpose of entering the national phase in Luxembourg, Switzerland, Uganda and United Republic of Tanzania, the time limit under Article 22 is still 20 months (as of February 8, 2008).

restoration of the right of priority and inclusion of missing elements and parts of the international application which are contained in the earlier application, the priority of which is claimed, without affecting the international filing date;

(v) patent documents of the Republic of Korea were included in the PCT minimum documentation used by the ISAs in carrying out international searches;

(vi) Arabic, Korean and Portuguese[35] were added as publication languages of international applications filed in Arabic, Korean and Portuguese, respectively;

(vii) the minimum requirements for ISAs/IPEAs were modified so that those Authorities must have a quality management system and internal review arrangement in place.

With the above achievements, the work of the PCT Reform was completed in 2007.

4.2 Draft Substantive Patent Law Treaty (SPLT)

In November 2000, the Standing Committee on the Law of Patent (SCP), which consists of WIPO member States and intergovernmental and non-governmental organizations, took the decision to undertake discussions on the harmonization of certain substantive patent law requirements. The objective of such undertaking was to find solutions, in particular, to the problem of the significant cost of obtaining international patent protection and to facilitate cooperation among patent offices through better utilization of search and examination reports issued in other countries in order to reduce the workload they face.[36] The items to be covered by the draft Substantive Patent Law Treaty (SPLT) should include, according to the SCP at that time, issues of direct relevance for the grant of patents, including provisions relating to the definition of prior art, novelty, inventive step (non-obviousness), and industrial applicability (utility), the sufficiency of disclosure of the invention in the application, and the structure and interpretation of claims.[37] The SCP further agreed that a number of additional issues, such as first-to-file versus first-to-invent, mandatory publication of applications at 18 months from the filing (priority) date and a post-grant opposition system, should be considered at a later stage. On the issue of the first-to-file versus first-to-invent, however,

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[35] As regards publication in Korean and Portuguese, it is applicable to international applications whose international filing date is on or after January 1, 2009.

[36] All working documents, including the draft SPLT and the reports of the SCP meetings are available at: http://www.wipo.int/patent/law/en/scp.htm.

[37] WIPO document SCP/4/2.

even if it is not expressly addressed, the draft SPLT provides a filing date as a critical date for the determination of prior art, novelty and inventive step.

During subsequent meetings, the draft SPLT underwent developments in different respects, following proposals by a number of delegations. The draft SPLT as discussed at the tenth session of the SCP in 2004 also includes, in addition to the issues above, provisions concerning exceptions to the applicability of the Treaty, a right to patent, unity of invention, contents, manner and order of description, amendments of applications and of granted patents, patentable subject matter and grounds for the refusal of applications and the invalidation of granted patents. The progressive broadening of the contents of the draft SPLT has given rise to significant difficulties in advancing the negotiation in many areas.

The first set of difficulties includes matters concerning claim interpretation, patentable subject matter and exceptions to patentability. Although those issues appear in most patent laws all over the world, the way in which they are implemented reflects the approach towards the patent system that different social and legal cultures have adopted. They are also closely linked to a question that goes to the very heart of the patent system: the achievement of the right balance between the patentee's exclusive rights and the interests of the public at large. The differences do not necessarily represent the so-called 'north-south divide'. There are a number of fundamental issues to be solved among developed countries. For instance, Article 11(1) of the draft SPLT states that 'the claims shall define the subject matter for which protection is sought in terms of the [technical] feature of the invention'. The United States of America suggests the deletion of the word '[technical]' so that the claimed invention may encompass 'non-technical' inventions, which is not acceptable to other countries. The question as to what extent equivalent elements could be taken into account when interpreting claims in Rule 13(5) is another area that is difficult to harmonize in view of various doctrines of equivalents developed under various jurisdictions.

The second issue concerns disclosure of origin of genetic resources and associated traditional knowledge in patent applications where the claimed invention is derived from, or based on, such genetic resources or traditional knowledge.[38] Some countries wish to establish a binding international instrument that obliges countries to provide a mandatory requirement for such disclosure, so that developed countries, from which a great majority of patent

[38] As regards detailed analysis of the disclosure of the origin of genetic resources and associated traditional knowledge in patent applications, reference is made to WIPO Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge (http://www.wipo.int/tk).

applications are generated, are obliged to implement such requirements in their respective national laws. The primary objective of such a requirement is to provide supportive measures to implement the provisions of the Convention on Biological Diversity (CBD)[39] which provide that, *inter alia*, (i) the national governments have authority to determine access to genetic resources; (ii) access to genetic resources shall be subject to prior informed consent on mutually agreed terms of the Contracting Party providing such resource; (iii) each Contracting Party shall take legislative, administrative or policy measures with the aim of sharing the R&D results and benefits arising from the commercial and other utilization of genetic resources, with the Contracting Party providing such resources; (iv) each Contracting Party shall encourage the equitable sharing of benefits arising from the utilization of indigenous knowledge subject to its national legislation. The idea is that, if a patent applicant is obliged to indicate the origin or source of genetic resources utilized in the invention, it would facilitate finding illegal access to genetic resources, since this application will be published for public scrutiny. It would also motivate the patent applicant to request the prior informed consent of the country proving the genetic resources. On the other hand, some other countries are of the opinion that the CBD-related issue should be dealt with entirely outside the scope of patent law. They believe that, unless the disclosure of the origin of genetic resources is required in order to comply with patentability requirements, such as the enabling disclosure requirement, the disclosure of the origin of genetic resources should not be imposed under the patent law. Some other countries do not oppose a patent law incorporating provisions that primarily address the issues under the CBD, and are of the opinion that, although the disclosure of the origin of genetic resources could be included in patent applications, the sanction for not complying with such a requirement should be outside the framework of patent law, that is, there should be no refusal of a patent application or revocation of patents. Certain countries wish to include such a new disclosure requirement in the context of the draft SPLT, while others consider that the question has been properly dealt with in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), another forum at WIPO, and the same question should not be addressed to the SCP in parallel.

A third set of issues relates to concerns about the available flexibility in respect to national policies, for example, for measures to protect public health and nutrition, and to promote the public interest in sectors of importance in socio-economic and technological development. Against any limitation on the existing flexibility recognized under current international treaties, such as

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39 The text of the CBD is available at: http://www.cbd.int.

Article 8 of the TRIPS Agreement, a number of countries supported the inclusion of a provision in the draft SPLT that expressly stipulates that nothing in the draft SPLT would prejudge the above-mentioned flexibility in respect of certain national policy choices. By the same token, draft provisions concerning the grounds for refusal of a claimed invention (draft Article 13) and the grounds for invalidation or revocation of a claim or a patent (draft Article 14) were viewed as problematic by some countries because those provisions provided a maximum list of grounds on the basis of which the Contracting Parties could refuse an application or revoke a patent. Therefore, they proposed the inclusion of a new provision that would allow a Contracting Party to also require compliance with the applicable law on various policy matters.

It is probably not fair to blame the scope of the draft Treaty as the only source of the problem. On a number of issues which were highly disputed during the negotiation of the draft 1991 Patent Harmonization Treaty, the same divergent arguments were presented at the SCP. For instance, the provision regarding a prior art effect of another application filed earlier, but published after, the filing (priority) date of the application under examination (draft Article 8(2) and draft Rule 9) raised the same four points debated in 1991: (i) whether or not to prohibit the 'Hilmer Doctrine' of the United States of America; (ii) whether such prior art should be taken into account for the novelty determination only or for the determination of both novelty and inventive step; (iii) whether PCT international applications which have not entered into the national phase in the respective country should be part of the prior art or not; (iv) if the applicant, or the inventor, of the earlier application is the same person as the applicant, or the inventor, of the application under examination, whether such earlier application should be part of the prior art or not. In a similar manner, the provision regarding the grace period (draft Article 9) contains a number of unsolved issues, such as (i) whether the duration of the grace period should be six months or one year; (ii) whether the grace period should cover all prior publication of another application filed by the inventor or his successor in title, published within the grace period, or should be limited to such publication which should not have occurred; (iii) whether the inventor or his successor in title should submit a declaration invoking the effect of the grace period within a certain time limit; (iv) whether or not to accord a prior user's right to a person who in good faith used the claimed invention between the public disclosure triggering the grace period and the filing (priority) date.

In view of those differences which made the discussions in the SCP difficult to advance, in May 2004, the United States of America, Japan and the European Patent Office submitted a joint proposal, designed to focus on an initial package of priority items, that is, the definition of prior art, grace period, novelty and inventive step. According to the proposal, once international

agreement was reached on those prior art-related issues, the SCP could then focus on other issues which may include topics such as the disclosure requirement, claim drafting, unity of invention and others. The choice of those four items was based on the following reasoning: (i) the degree to which the discussion had matured and the extent of agreement among the delegations; (ii) the technical nature of those provisions and the absence of political implications; (iii) the link between those provisions and the prospect of creating conditions for mutually exploiting search and examination results between offices; and (iv) the advantages of harmonization on those points for all countries.

On the other hand, the Group of Friends of Development, which consists of Argentina, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Egypt, the Islamic Republic of Iran, Kenya, Peru, Sierra Leone, South Africa, the United Republic of Tanzania and Venezuela, proposed that the following issues be included in the working program of the SCP: development and policy space for flexibility, exclusions from patentability, exceptions to patent rights, anticompetitive practices, disclosure of origin, prior informed consent and benefit sharing, effective mechanisms to challenge the validity of patents, sufficiency of disclosure, transfer of technology, and alternative models to promote innovation. While developed countries gave priority on technical issues, the harmonization of which directly facilitates the mutual exploitation of search and examination results between offices, the Group of Friends of Development's priority was to discuss in the SCP policy issues going beyond the processing of patent applications before patent offices. A compromise was not possible, and a formal session of the SCP has not been held since 2005.

In 2005, the deadlock at the SCP resulted in the formation of a group called 'Group B+', which consists of developed countries, more specifically, Australia, Canada, Japan, New Zealand, Norway, the United States of America, member States of the European Union and/or the European Patent Convention, as well as the European Commission and the European Patent Office. Seeking an agreement among those parties with respect to patent harmonization on the definition of prior art, grace period, novelty and inventive step, Group B+ has been holding meetings to negotiate texts in a treaty-language based on the relevant articles and rules of the draft SPLT. Here again, long-standing differences among countries on the prior art effect of earlier applications and grace period, as stated above, has made an agreement difficult so far.

4.3 Review and amendment of the TRIPS Agreement and the Doha Declaration

Through Article 71.1, the TRIPS Agreement establishes a mechanism for the Council for TRIPS to review the implementation of the Agreement and to undertake reviews in the light of any relevant new developments which might

warrant modification or amendment of the Agreement. Further, in the area of patents, TRIPS Article 27.3(b) provides that that provision shall be reviewed four years after the date of entry into force of the WTO Agreement.

In the context of the review of Article 27.3(b), in addition to the patentability of plants and animals and an 'effective *sui generis* system' for plant variety protection, topics such as the relationship between the TRIPS Agreement and the CBD, access to genetic resources and benefit sharing and protection of traditional knowledge and folklore quickly started to dominate the debate in the Council for TRIPS.[40] Consequently, the Doha Ministerial Declaration in 2001 mandated the Council for TRIPS, during the review of Articles 27.3(b) and 71.1 as well as negotiations on outstanding implementation issues, to examine the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the Council for TRIPS shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.[41] With respect to the disclosure of origin of genetic resources and associated traditional knowledge in a patent application, Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania submitted a proposal to include new Article 29*bis*.[42] New Article 29*bis* provides that, in essence, (1) members shall have regard to the objectives and principles of the TRIPS Agreement and the objectives of the CBD; (2) where the invention is derived from or developed with biological resources and/or associated traditional knowledge, members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom they were obtained, and as known after reasonable inquiry, the country of origin. Members shall also require information including evidence of prior informed consent to access and fair and equitable benefit sharing; (3) applicants and patent owners shall submit any new information concerning (2) of which they become aware; (4) members shall publish the above information disclosed; and (5) members shall put in place effective enforcement procedures. In particular, when the applicant has knowingly failed to comply with the disclosure obligation or provided false or fraudulent information, authorities have the power to prevent further processing of the application or the grant of

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40 The WTO Secretariat issued documents summarizing the issues raised and points made with respect to the review of the provision of Article 27.3(b) (IP/C/W/369/Rev.1), the relationship between the TRIPS Agreement and the CBD (IP/C/W/368/Rev.1 and IP/C/W/368?Rev.1/Corr.1) and the protection of traditional knowledge and folklore (IP/C/W/370/Rev.1).

41 WTO document WT/MIN(1)/DEC/1, paragraph 19.

42 WTO document WT/GC/W/564/REV.2, TN/C/W/41/REV.2, IP/C/W/474.

a patent and to revoke or render a patent unenforceable. While some members supported the inclusion of new Article 29*bis*, others are not in favor of amending the TRIPS Agreement, arguing that discussions on the disclosure of origin of genetic resources and associated traditional knowledge are adequately dealt with in the IGC/WIPO.

The issue of the relationship between the TRIPS Agreement and access to medicines, in particular, in developing and least-developed countries, was put on the agenda of the Council for TRIPS in 2001. Before the adoption of the TRIPS Agreement, many developing countries and least-developed countries did not protect pharmaceutical products under patents. Consequently, some of those countries which had manufacturing capacity for pharmaceutical products were in a position to legally produce and sell cheaper generics to other developing and least-developed countries that had no patents on the pharmaceutical product concerned. The TRIPS Agreement challenged such a supply chain by obliging all members to provide patent protection for the pharmaceutical products, subject to a transitional period. How can medicines under patents be made available in the necessary quantity at an affordable price at international level? What would be the consequence for the international procurement of medicines by, in particular, least-developed countries?

Faced with such questions, the Doha Ministerial Declaration recognized that, under WTO rules, no country should be prevented from taking measures for the protection of health at the levels it considers appropriate, provided that such measures are not applied in an unjustifiably discriminatory manner between countries where the same conditions prevail, or as a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements.[43] A separate declaration, the Doha Declaration on the TRIPS Agreement and Public Health,[44] was also adopted. The latter affirmed that the TRIPS Agreement should be implemented in a manner supportive of public health. It also reaffirmed the right of members to use, to the full, the provisions in the TRIPS Agreement that provide flexibility, which include: (i) the provisions of the TRIPS Agreement shall be read in the light of the objective and principles of the Agreement as expressed, in particular, in Articles 7 and 8; (ii) the right to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted; (iii) the right to determine what constitutes a national emergency or other circumstances of extreme urgency for issuing a compulsory license (a public health crisis can be one of those circumstances); (iv) each member is free to establish its exhaustion regime. It also states that least-developed country members will

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43 WTO document WT/MIN(1)/DEC/1, paragraph 6.
44 WTO document WT/MIN(01)/DEC/2.

not be obliged to implement Sections 5 (patents) and 7 (protection of undisclosed information) of Part II or to enforce rights provided for under these sections in respect of pharmaceutical products until January 1, 2016. As regards the extension of the transitional period, a separate decision by the General Council was made so that the obligations of least-developed countries under Article 70.9 (exclusive marketing rights) with respect to pharmaceutical products will not take effect until January 1, 2016.[45]

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health raised an important issue. According to Article 31(f) of the TRIPS Agreement, where a member allows for use of the subject matter of a patent under the so-called compulsory license or public non-commercial use without the authorization of the right holder, such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use. This means that, with respect to pharmaceutical patents, where the member does not have sufficient manufacturing capacities, it could face difficulties in making effective use of compulsory licensing. The Doha Ministerial therefore instructed the Council for TRIPS to find an expeditious solution. A number of legal options were discussed, and the General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration in August 2003, which allows WTO members to issue a compulsory license with a view to exporting patented pharmaceutical products to countries with no or insufficient manufacturing capacity under certain conditions.[46] Subsequently, the agreed solution was codified with the adoption of the Protocol amending the TRIPS Agreement by the General Council in December 2005.[47] New Article 31*bis* states that a member may grant a compulsory license for the purpose of production of a pharmaceutical product and its export to an eligible importing member. Where such a compulsory license is granted and patents have been granted in both the exporting member and the eligible importing member, adequate remuneration shall be paid in the exporting member taking account of the value to the importing member of the use that has been authorized in the exporting member. No further remuneration in the importing member is required. Further, in view of harnessing economies of scale for the purposes of enhancing purchasing power and facilitating local production, developing and least-developed countries that are parties to a regional trade agreement of which at least half of the members are least-devel-

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45 WTO document WT/L/478.

46 WTO document WT/L/540. Insights into the Decision by one of the negotiators are found in Paul Vandoren and Jean Charles Van Eeckhaute, 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) The Journal of World Intellectual Property, 6(6): 779–93.

47 WTO document WT/L/641.

oped countries may export pharmaceutical products, produced or imported under a compulsory license, to other members of the regional trade agreement. The new article also provides that non-violation complaints cannot be brought against any measures taken in conformity with the provisions of Article 31*bis* and the Annex to the TRIPS Agreement.[48] The Annex to the TRIPS Agreement prescribes, among other things, the definition of the eligible importing member and other detailed mechanisms to prevent re-exportation of the imported products produced under such a compulsory license. The 'eligible importing Member' means any least-developed country member and any other member that has made a notification to the Council for TRIPS.[49] When adopting the Protocol, the Chairperson of the General Council read out a statement which indicates shared understanding of the members. Once two-thirds of 150 members accept the Protocol, it will replace the General Council's August 2003 Decision.[50] For the remaining members, the General Council's August 2003 Decision will continue to apply until they accept the amendment.

5 Conclusion

The history of the international development of patent law shows that international harmonization *per se* has never been the ultimate goal or an end in itself. International harmonization has always been a tool to respond to challenges that require international solutions. Since it is a means of addressing a problem rather than an end in itself, the essential questions to ask are: what are the international challenges that need to be addressed collectively, and with this in mind, what should be harmonized and what should be done?

Harmonization of substantive patent law has repeatedly appeared in the international agenda. The last instance was the draft SPLT. Initially, the international challenge addressed was a duplication of search and examination work conducted by a number of patent offices with respect to the same invention. The negotiation on the draft SPLT was initiated with a view to creating an international legal environment that would support better international

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[48] This is necessary since a decision on the applicability of Article 64.2 has not been taken by the TRIPS Council, although a temporary moratorium on non-violation complaints under the TRIPS Agreement is currently in place.

[49] A number of developed countries announced voluntarily that they would not use the system to import. Some other members announced that they would use the system as importers only in the case of national emergency or other circumstances of extreme urgency.

[50] The United States of America, Switzerland, El Salvador, the Republic of Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong-China, China, and the member states of the European Communities have accepted the amendment (updated January 17, 2008) (http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

cooperation in terms of search and examination of patent applications. Although the TRIPS Agreement has harmonized a basic legal framework with respect to patentability requirements, that is, novelty, inventive step (obviousness), industrial applicability (utility) and sufficiency of disclosure (enabling disclosure), it was felt that such harmonization at the level of the basic legal framework was not sufficient for the meaningful utilization of search and examination results prepared in other jurisdictions. It was suggested that not only the harmonization of the legal framework but also the harmonization of search and examination practices (so-called 'deep harmonization') should be achieved.

There is no doubt that the discussions on the draft SPLT have facilitated better understanding of examination practices in other jurisdictions among WIPO member States. For example, when amending the PCT International Search and Preliminary Examination Guidelines, the contents of the draft Guidelines under the SPLT were taken into account. However, during the course of the discussions at the SCP, the Committee failed to maintain the common objective of pursuing the draft SPLT. Why are we negotiating substantive patent law harmonization? Some countries, which are concerned about the cross-cutting implications of patent law for various areas of public policy, saw the SPLT as an instrument that adds new international obligations and stringent standards of protection going beyond the TRIPS Agreement. With a number of countries doubting the direction in which the Committee was heading, it was not possible to make any progress in the Committee. Moreover, we may at least question whether, for the purpose of utilization of examination results prepared in other jurisdictions, the harmonization of patent examination practices at the global level is an absolute necessity. At the level of national legislation, the notions of, for example, novelty and inventive step are to a large extent harmonized. Differences among national legislation, such as the prior art effect of applications which were filed earlier but published later than the application under examination, may result in different examination results among those countries, but only in a small number of cases. Further, the generally accepted interpretation of those notions under national legislation is, in principle, established through national court decisions supplemented by the practices of the patent office. Although non-binding international guidelines may be possible and would facilitate better understanding of highly technical aspects of patent law, it may not be feasible, for the time being, to contemplate an internationally binding instrument concerning examination practices, since national jurisprudence develops constantly through 'real-world' cases reflecting technological and social developments.

While the discussions on substantive patent law harmonization have stalled, the progress made by PCT reform during the same period shows that

patent procedures under the existing international framework can be further improved. Together with its member States, WIPO has been developing a digital access service for priority documents under which offices would be able to have access to priority documents available in digital libraries so that applicants will not need to physically obtain and submit a number of certified copies of the earlier application with each office.[51] The digital access service will improve the practical implementation of priority procedures with the use of information technology under the existing international legal framework for claiming priority, which is found in the Paris Convention, the PCT and the PLT. Similarly, without changing the international legal framework, it may be possible to take further measures to simplify and render more efficient the international patent procedures, taking full advantage of information technology. For example, certain countries allow the public and other offices to consult file wrappers in its office on the Internet. This means that other offices can obtain search and examination information concerning the corresponding applications filed with that office. Such a service could be developed as a network system that facilitates access to search and examination information.

It appears that two opposing forces are present in the international patent discussions. One is a force in the direction of harmonization and integration. An obvious consequence of increasing needs for the international procurement of intellectual property rights is a call for a simpler and more cost-effective international patent system. International harmonization of national/regional patent laws is generally viewed as a supportive measure towards an accessible, transparent and cost-effective international patent system. Harmonization may also create more legal certainty, ensure quality of patents and promote international cooperation. Another force is in the direction of diversity and flexibility. There is greater recognition of the importance of intellectual property rights for technological, cultural and social development. Consequently, participants in the international patent system are more diverse today. Countries do not necessarily share the same policy objectives and priorities. There is an increasing demand for differential treatment taking into account the level of development. With respect to patent applications filed worldwide, from 1995 to 2004, the share of the trilateral offices (Japan Patent Office (JPO), United States Patent and Trademark Office (USPTO) and the European Patent office (EPO)), dropped from 62% to 57%. On the other hand, the share of the top five offices in 2004 (JPO, USPTO, Korean Intellectual Property Office (KIPO), State Intellectual Property Office of China (SIPO) and the

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51 http://www.wipo.int/patentscope/en/pdocforum.

EPO) increased from 71% to 75%.[52] This means that the geographic distribution of patents has been diversified and, more importantly, the language of patent information has been diversified. Further, as has often been observed in conjunction with a reform of national patent system, innovators from different technical fields do not share views on an ideal patent system due to different patent business strategies taken in various sectors.

In the middle of such currents running in opposite directions, finding common ground in terms of operational principles of patent law and practices at the international level is not an easy task. Learning from history, the long-term success of the Paris Convention has been attributed to the concurrence of two factors: vision and modesty.[53] In the post-TRIPS era, vision and modesty still appear to be key to achieving a successful international system. It seems that a multilateral, modestly ambitious approach directed towards a balanced international patent system would better serve the interests of the international community in the long run rather than opening the door to unilateral and bilateral measures which might carry the risk of reducing the ability of less powerful players to defend their legitimate interests. International patent law harmonization has been developed step by step. Although each step may be small in itself, taken together these incremental progressions will, over time, contribute to achieving a patent system that serves society in general and continues to support the cycle of innovation. At the end of the day, it is society at large that should benefit from innovation and technological development.

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52 WIPO Patent Statistics (http://www.wipo.int/ipstats/en/statistics/patents/).

53 François Curchod 'Is the Paris Convention for the Protection of Industrial Property Still Relevant Today?' in Gert Egon Dannemann et al., *Global Perspective of Contemporary Intellectual Property Issues: A Collection of Works Written in Commemoration of the Seventieth Birthday of Peter Dirk Siemsen* (Dannemann, Siemsen, Bigler & Ipanema Moreira, Rio de Janeiro, 1999).

PART 2

INTERNATIONAL AND COMPARATIVE DIMENSIONS: PROCEDURAL ISSUES IN EXAMINATION

6 Examination procedure at the European Patent Office

*Peter Watchorn**

1 Introduction

The European Patent Convention was amended at a Diplomatic Conference held in Munich in November, 2000. The Act revising the EPC was adopted on November 29 and specified in accordance with Article 172(3) of the EPC[1] and EPC 1973 that the text of the revised Convention would enter into force two years after the fifteenth state deposited its instrument of ratification or accession of the revised text with the government of the Federal Republic of Germany under Article 165(2) EPC.[2] Greece deposited its instrument of ratification on the December 13, 2005 meaning that the revised EPC would enter into force at the latest on the December 13, 2007.

The changes to the EPC were made for a number of reasons. First and foremost the EPC was amended to make it compliant with the Patent Law Treaty (PLT). This entailed in particular a number of changes to formal procedures for obtaining a filing date, filing missing application documents, and post-filing formalities, such as claiming priority. The application of legal remedies for failure to meet time limits by further processing and re-establishment of rights was also modified, being extended to cover time limits not previously covered under EPC 1973. Secondly, legal provisions were moved from the articles of the EPC to the implementing regulations. This was done in order to

* The views and opinions expressed in the present chapter are those of the author and do not necessarily reflect the official policy or practice of the European Patent Office.

1 Note that all references to the revised European Patent Convention are denoted 'EPC' and all references to the previous version of the European Patent Convention are denoted 'EPC 1973'.

2 Alternatively, the revised text would have entered into force on the first day of the third month after the last Contracting State deposited its instrument of ratification or accession, if this had been an earlier date (Art.8(1) of the Act revising the EPC of November 29, 2000). However, this did not occur, since the last ratifications/accessions occurred shortly before December 13, 2007. Had any state not ratified the new text in time, it would have ceased to be party to the EPC (Art.172(4) of the EPC and EPC 1973).

make the revised EPC more flexible by allowing changes to the law by a vote in the Administrative Council of the EPO, rather than needing a further Diplomatic Conference.[3] Thirdly, the needs of the user community were also taken into consideration, in particular the new procedure for self-limitation or self-revocation of a European Patent by the proprietor[4] and the petition for review by the Enlarged Board of Appeal of a decision of a Legal or Technical Board of Appeal.[5]

The present chapter is dedicated to explaining those changes to procedural and substantive law which affect the examination procedure at the EPO and comparing the new procedures under the revised EPC with those under EPC 1973.

2 Overlap between formalities and substantive examination

2.1 Filing date requirements

Under the revised EPC, a filing date is accorded to a European Patent application when the following items are received by the EPO[6] (a) an indication that a European Patent is sought, (b) information identifying the applicant or allowing the applicant to be contacted and, most importantly, (c) a description or reference to a previously filed application.[7] Consequently, in contrast to the situation under EPC 1973, a European application under the revised EPC is no longer required to contain claims in order to acquire a filing date. This change was made to align the EPC with the PLT.[8] It is still a requirement that the European application contains claims,[9] but their absence does not prejudice the accordance of the filing date, although they must then be provided later. Where an application is filed without claims, this will be noted by the EPO in the post-filing formality checks[10] and the applicant will be requested to file claims within a period of two months from the invitation.[11] Failure to rectify this deficiency in time (i.e. file claims) will lead to the refusal of the application.[12] Where the applicant does file claims on time, then these late filed claims are treated as amendments to the application as originally filed and so

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3 Art.33(1)(c) and Art.35(2) EPC.
4 Art.105a–c EPC.
5 Art.112a EPC.
6 The application may also be filed at the national offices of those Contracting States which permit it – Art.75(1)(b) EPC.
7 Art.80 EPC and Rule 40(1) EPC.
8 Art.5(1)(a) PLT.
9 Art.78(1)(c) EPC.
10 Rule 57(c) EPC.
11 Rule 58 EPC.
12 Art.90(5) EPC.

must not contain any subject matter going beyond the content of the originally filed[13] application documents, that is, the content of the late filed claims must be directly and unambiguously derivable from the content of the description and any drawings as originally filed.[14]

This means that for the first time for Euro-direct applications, the issue of non-allowable amendments may arise before the European search. This problem already existed under the EPC 1973 for international applications entering the European phase from the PCT and subject to a supplementary search,[15] since these could be amended in the international phase[16] or on entry into the European phase.[17] However, this was previously excluded in respect of Euro-direct applications because amendment of the application was not permitted before the European search.[18] This means that a Euro-direct application with late filed claims directed to non-allowable subject matter may be subject to a limitation of the scope of the European search.[19]

However, the applicant may be able to convince the Examining Division in subsequent examination proceedings that the subject matter of the claims is based on the application documents as originally filed, for example by providing convincing evidence of what was common general knowledge of the skilled person with regard to implicit features. He may then be able to reverse the reasons behind any limitation of the European search.[20] This would then lead to the EPO performing a further search during examination proceedings, which is free of charge.[21] Such a sequence of events could only occur under EPC 1973 for Euro-direct applications where an objection of a lack of clarity or of a lack of support[22] or of insufficiency of the disclosure of the claimed invention[23] led to the scope of the search being limited under Rule 45 EPC 1973, and this was then successfully refuted by the applicant in examination proceedings.

2.2 Priority claim

Under the previous regime a great deal of case law existed on the subject of correction and addition of priority claims after the date of filing. The EPC

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13 EPC Guidelines A-III, 15; B-XII, 2.2 and C-IV, 6.3.
14 Art.123(2) EPC.
15 Art.157(2) EPC 1973 and Art.153(7) EPC.
16 In PCT Chapter I under Art.19 PCT or in PCT Chapter II under Art.34 PCT.
17 Rule 107(1)(b) and 109 EPC 1973; Rule 159(1)(b) and 161 EPC.
18 Rule 86(1) EPC 1973.
19 EPC Guidelines B-XII, 2.2 and Rule 63 EPC.
20 EPC Guidelines C-VI, 5.4.
21 EPC Guidelines B-II, 4.2 and C-VI, 8.2.
22 Art.84 EPC.
23 Art.83 EPC.

1973 did not explicitly provide for the insertion of a priority claim after the date of filing; indeed Rule 38 EPC 1973 was quite unequivocal:

> (1) The declaration of priority referred to in Article 88, paragraph 1, shall state the date of the previous filing and the state in or for which it was made and shall indicate the file number.
> (2) The *date and state* of the previous filing must be stated on filing the European patent application . . . [emphasis added]

As a consequence, two of the three components of the priority claim (the date and state) were, in theory, required on the date of filing of the European application. The file number (the third element of the priority claim) could be provided up to sixteen months after the earliest priority date[24] as could the copy of the priority application.[25] In practice under the old system the Boards of Appeal allowed the addition of new priority claims and the correction of existing priority claims if the addition or correction did not harm the public interest. This meant either that the request for addition or correction of a priority claim had to be made sufficiently early for a warning to be published with the European application[26] or it could be made after publication if this was not detrimental to the public interest because the priority claim as published contained an obvious discrepancy.[27]

The revised EPC now contains explicit provisions which provide statutory time limits for addition of a new priority claim[28] and correction of an existing priority claim,[29] which in both cases is usually sixteen months from the earliest priority date claimed, including the date of the priority being added.[30] In this regard the EPC is now harmonized with the PCT.[31] If the search is carried out on the European application before the priority claim is added (for applications adding a priority claim taking advantage of the full priority year this would have to happen within four months of the European filing date) and the

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24 Rule 38(2) EPC 1973.
25 Rule 38(3) EPC 1973.
26 See decisions of the Legal Board of Appeal J3/82, J4/82 and J14/82. If the applicant wanted to be sure to have a warning published with the application, he had to make his request for addition or correction before the end of the technical preparations for publication (Rule 67 EPC). This is the point in time up to which the EPO can guarantee the ability to change the content of the published application and expires five weeks before the expiry of the eighteenth month after the filing date or, if claimed, earliest priority date (OJ EPO Special Edition 3/2007, Decision of the President D.1).
27 See decisions of the Legal Board of Appeal J3/91, J6/91 and J2/92.
28 Rule 52(2) EPC.
29 Rule 52(3) EPC.
30 EPC Guidelines, A-III, 6.5.1.
31 Rule 26bis PCT.

applicant published his invention in the priority period or other highly relevant publications exist in the priority period, the Search Division will find these relevant documents and stop the search where the likelihood of finding more relevant documents is so low as not to warrant further investigation.[32] If the applicant then subsequently adds a priority claim which pre-dates the publication of that highly relevant document and does so after the search is completed, then that document will cease to be relevant in as far as the priority claimed is substantively valid[33] and the search for relevant documents published prior to the new priority date may be incomplete. This may then require the EPO to perform a free additional search during the examination procedure[34] before substantive examination of the application can continue.

While the above sequence of events could conceivably have occurred under the EPC 1973 in accordance with the established jurisprudence, there was not the statutory right allowing the late addition or correction of a priority claim, which now guarantees the ability to do this after the filing date under the revised EPC.

2.3 Late filing of missing parts

One of the more complex aspects of the new system is the late filing of missing parts of the description or of missing drawings. This is the EPC implementation of filing procedures provided for in the PLT.[35] For example, an applicant files his application by fax and his fax machine pulls two pages through at once causing the description filed at the EPO to be missing one page. In such cases it is now possible for the applicant to file the missing parts of the description or the missing drawings after the filing date. However, this only applies to missing parts of the description or missing drawings and not to claims.[36] The applicant can do this either of his own motion within two months of the filing date[37] or, where the error is noted by the EPO, within two months of an invitation from the EPO Receiving Section to file the missing parts.[38] Usually this late filing of missing parts results in a change in the date of filing to the date of receipt of the missing parts of the description or of the missing drawings.[39] The applicant is informed of the new filing date by the EPO and within one month of this notification he may withdraw the late filed

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32 EPC Guidelines B-IV, 2.6.
33 See decision of the Enlarged Board of Appeal, G2/98 and Art.87(1) EPC.
34 EPC Guidelines C-VI, 8.2.
35 Art.5(6) PLT.
36 Rule 56(1) EPC.
37 Rule 56(2) EPC.
38 Rule 56(1) EPC.
39 Rule 56(2) EPC.

parts of the description or late filed drawings, which causes the original earlier date of filing to be re-instated.[40] Under the EPC 1973 it was only possible to file drawings after the filing date,[41] which also resulted in a change of filing date to the date of receipt of the late filed drawings, but it was not possible to file missing parts of the description.

This issue will in most cases already have been resolved during the filing date checks carried out by the Receiving Section[42] and so will not concern the examination procedure. However, one notable exception exists, which had no equivalent under the EPC 1973. In certain cases, it is possible for the applicant to insert missing parts of the description or missing drawings without changing the filing date, where this can be based on the claimed priority. This can be done where the applicant provides within the time limit specified above, not only the missing part of the description or the missing drawing(s), but also a request to base the late filed missing part of the description or drawing(s) on the claimed priority; a copy of the priority document; a translation of the priority document (if not in English, French or German); and an indication of where in the priority application and in any required translation the late filed missing parts of the description or missing drawings are to be found. If these formal requirements are met and if the late filed missing parts of the description or the late filed drawings are 'completely contained' within the indicated parts of the priority application, then the Receiving Section of the EPO will maintain the original date of filing.[43] The requirement that the late filed missing parts of the description or late filed drawings be 'completely contained' in the claimed priority document means that: for missing parts of the description, the indicated text in the priority or, where applicable, its translation is identical to the text of the missing parts being inserted; and for missing drawings, that the drawings indicated in the priority application are identical to the newly inserted drawings and have the same annotations.[44] The preparatory documents to the PLT make it clear that the check on the 'completely contained' requirement is meant to be no more than a clerical check.[45] This means that this is a stricter requirement than for amendments made in examination or opposition proceedings which are only required to be technically the same, but can use different wording. For example replacing 'H_2O' with 'water' would be an acceptable amendment in examination but would probably not satisfy the 'completely contained' requirement if one appeared in the priority and the other in the late filed missing part of the description.

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40 Rule 56(6) EPC.
41 Rule 43 EPC 1973.
42 Art.90(1) EPC and Rule 56(1) EPC.
43 Rule 56(3) EPC.
44 EPC Guidelines A-II, 5.4.2.
45 PT/DC/5, p. 37, paragraph 2.04.

In cases where a positive decision has been issued by the Receiving Section during the filing date checks, the Examining Division may re-investigate the matter and may review the decision of the Receiving Section that the 'completely contained' requirement was met. The Examining Division may then decide that the filing date changes, unless the applicant withdraws the late filed parts.[46] If the Receiving Section initially finds against the applicant, who then appeals (provided that the interlocutory decision on the 'completely contained' requirement allows separate appeal[47]), then the final decision of the Board of Appeal cannot be contested by the Examining Division.[48]

A change in filing date may cause highly relevant state of the art to be published early enough to be taken into account either by invalidating the claimed priority date by pushing the filing date beyond the twelve month priority period[49] or by pushing the filing date beyond the publication date of that document, where no priority or no valid priority is claimed. In such appealed cases the examination would have to be delayed until the issue is resolved by the Board of Appeal. If on the other hand, a negative decision of the Receiving Section on the 'completely contained' requirement does not allow separate appeal,[50] then the issue of the 'completely contained' requirement in the context of the filing date may have to be part and parcel of the final decision in examination. This only happens in cases where a refusal of the application[51] for lack of novelty[52] and/or lack of inventive step[53] occurs over prior art which becomes relevant due to the change in filing date and any concomitant loss of the priority. In cases where the decision on the 'completely contained' requirement does not allow separate appeal and no prior art arises which could become relevant in the event of a change in filing date and/or loss of the priority right, the applicant would not then be able to appeal the finding of the Receiving Section at all, since there would be no final negative decision ending the examination procedure. There would be no refusal, at least not in connection with the issue of the filing date and the decision to grant the patent, albeit with a later filing date, would not adversely affect the applicant and so an appeal against this decision would not be admissible.[54]

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46 EPC Guidelines C-VI, 3.1.

47 Art.106(2) EPC.

48 EPC Guidelines C-VI, 3.1 – where a decision taken by the Receiving Section is appealed, the *ratio decidendi* of the decision of the Board is binding on the Examining Division, even though this is a first instance department of the EPO different from the one which took the original decision (Art.111(2) EPC).

49 Art.87(1) EPC and Art.4 of the Paris Convention.

50 Art.106(2) EPC.

51 Art.97(2) EPC.

52 Art.52(1) EPC and Art.54 EPC.

53 Art.52(1) EPC and Art.56 EPC.

54 Art.107 EPC.

Previously the Enlarged Board of Appeal held that the priority document could not be used as a basis for the correction or amendment of a European patent application.[55] This principle will continue to apply in examination and opposition proceedings, since the special procedure provided above is only to be applied during the filing date checks carried out by the Receiving Section,[56] although the results can be reviewed in examination, this special procedure will not be initiated by the Examining Division at this later stage. Consequently, the ban on using the priority document for corrections or amendments of the European application established by the Enlarged Board of Appeal will continue to apply and this special procedure before the Receiving Section can be seen as a *lex specialis* to this principle.[57]

2.4 Translation of the priority document

Where the application claims priority, it may be necessary to assess the substantive validity of that priority claim. This happens where documents are published in the priority period or where the validity of the priority becomes relevant in assessing which of two co-pending European applications has the earlier relevant date (*vide infra*). It then becomes necessary to check that the 'same invention'[58] is disclosed in the priority as in the European application. The EPO takes a strict line in this regard, and regards the 'same invention' requirement as not being met in respect of any subject matter of the European application which is not disclosed in the priority. For example:

Priority:	Product A	
	Process 1, for making product A	
EP application	Claim1:	Product A
	Claim 2:	Process 1, for making product A
	Claim 3:	Process 2, for making product A

In this example the invention is product A. Both processes for making product A claimed in the European application are part of the same unitary invention. However, since process 2 is not disclosed in the claimed priority, claim 3 of the European application has no valid priority. This applies because, though the process is closely related to what is disclosed in the priority, this is not enough to satisfy the 'same invention' requirement.[59]

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55 See the decisions of the Enlarged Board of Appeal, G3/89 and G11/91.

56 EPC Guidelines C-VI, 5.3.1.

57 *Lex specialis derogat generali* – specific legal provisions take precedence over more general ones with which they would otherwise conflict.

58 Art.87(1) EPC.

59 See the decision of the Enlarged Board of Appeal, G2/98.

Where it becomes necessary in examination to assess the validity of the priority, but the priority is not in an official language of the EPO,[60] the applicant is requested by the Examining Division to provide a translation of the priority into one such language within a period to be specified[61] (i.e. within a time limit set by the EPO). If the applicant does not provide the translation on time, then the prior art which would have been irrelevant in the event of a valid priority, becomes relevant to the assessment of patentability.[62] Whilst this procedure has not changed, the legal remedy of further processing for rectifying the failure to file the translation on time has become available under the revised EPC,[63] whereas it was excluded under the old regime.[64]

Under the EPC 1973, where the translation of the priority was not required in examination, the applicant had to provide it at the end of the examination proceedings within the time limit for filing his approval of the text proposed for grant by the Examining Division (*vide infra*).[65] If the applicant failed to do this in time, the priority right was lost, although this did not prevent the grant, since if the priority had been relevant to the assessment of patentability the translation would have been requested earlier on in the examination procedure. However, this could have a deleterious effect on subsequent post-grant opposition proceedings in the event of additional prior art published in the priority period or a question arising with regard to the rights arising from a European application which, in the event of an invalid priority, would have an earlier relevant date (*vide infra*). In the new system, if the Examining Division does not request the applicant to file a translation in the examination procedure (pre-grant), the applicant does not have to file it at all in examination. This has the result that it may become necessary to file the translation in post-grant opposition proceedings,[66] which was never possible under EPC 1973. However, in this case further processing no longer applies if the patent propri-

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60 Art.14(1) EPC, the official languages of the EPO are English, French and German.

61 Rule 53(3) EPC.

62 EPC Guidelines C-V, 3.4.

63 Art.121 EPC, Rule 135(1) EPC and EPC Guidelines A-III, 6.8.

64 Art.121(1) EPC 1973 – under EPC 1973 this legal remedy did not apply to a partial loss of rights such as the loss of designations or of the priority right. This is no longer the case under the revised EPC. Although certain time limits in relation to the priority are specifically excluded from further processing by Rule 135(2) EPC (including the time limit for making or correcting the priority claim under Rule 52(2)(3) EPC), the time limit for filing the translation of the priority is not so excluded.

65 Rule 38(5) EPC 1973 – the translation had to be filed by the end of the time limit under Rule 51(4) EPC 1973.

66 EPC Guidelines D-VII, 2.

etor fails to file the translation on time, since this legal remedy only applies in pre-grant proceedings.[67]

2.5 Non-unity and Euro-PCT applications

Where the international search report is prepared by the EPO, no supplementary search report is prepared after the application enters the European phase.[68] The application enters the responsibility of the Examining Division directly as soon as the request for examination is filed on passage into the regional phase, including payment of the examination fee.[69] This situation also applied under the previous regime. The international search report takes the place of the European search report.[70] Cases have occurred where the international search report was incomplete because the EPO, acting as International Searching Authority (ISA), found that the claimed invention lacked unity of invention, invited the applicant to pay additional international search fees, and the applicant did not pay all such additional search fees on time[71] in the international phase. In such cases, under the previous regime, when the application entered the European phase, the applicant was given a second opportunity to pay additional search fees for the inventions which the applicant did not pay for in the international phase.[72] Failure to pay the fee for the unsearched inventions in response to this second invitation in the regional phase meant that the applicant could then no longer pursue them in the examination procedure,[73] although the filing of a divisional for these inventions remained possible.[74] If the applicant paid an additional fee, the invention in question was searched and could be pursued in the examination procedure.

Under the new regime, after the application has entered the European regional phase, the applicant is no longer invited to pay additional search fees for the inventions not searched by the EPO as ISA in the international phase.

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67 Art.121(1) EPC only refers to applicants, not patent proprietors.

68 Art.153(7) EPC and EPC Guidelines B-II, 4.3.

69 See the decision of the legal Board of Appeal, J8/83, reasons for the decision 10.

70 Art.153(6) EPC.

71 Art.17(3)(a) PCT and Rule 40 PCT. The ISA does not then search those inventions in respect of which no additional search fee has been paid.

72 Rule 112 EPC 1973. The applicant was sent an invitation giving the reasons behind the lack of unity and inviting payment within a period of two to six weeks. This was the EPC implementation of Art.17(3)(b) PCT.

73 See the decision of the Enlarged Board of Appeal, G2/92.

74 EPC Guidelines, 2005 version, C-III, 7.11.1 state that the Examining Division must agree with the unity objection and EPC Guidelines C-III, 7.10 also state that if the applicant can convince the Examining Division that the unity requirement is met, the EPO will perform an additional search free of charge.

Instead, the applicant may only pursue an invention which was searched by the EPO in the international phase.[75] The only exception to this is where the applicant can convince the Examining Division that the unity requirement is in fact met.[76] This new procedure is subject to transitional provisions which mean that any pending cases for which no invitation to pay additional search fees was sent by the coming into force of the revised Convention (December 13, 2007), then no such invitation will be sent and the new procedure applies.[77] If an invitation to pay additional fees was sent in the European phase before this date, then the search would be performed on the inventions paid for, even if this occurs after the coming into force of the revised Convention.

In cases where the EPO performs a supplementary search[78] and the EPO finds that the application lacks unity of invention, then the EPO will only search the invention first mentioned in the claims,[79] whereas previously the applicant was invited to pay additional search fees for the claimed inventions other than that first mentioned in the claims.[80] This applies independently of the opinion on unity of invention at the stage of the preparation of the international search report (which for applications filed on or after July 1, 2005 would have been issued by an ISA other than the EPO).[81] The applicant is then not able to pursue any invention other than that first mentioned in the claims which was subject to the supplementary search[82] but may file divisional applications for these inventions. Again in this case, if the applicant can convince the Examining Division that the claimed inventions do indeed comply with the unity requirement, the Examining Division can then extend the examination procedure to cover the other inventions and an additional search may be carried out free of charge in the examination procedure.[83] This new procedure is also subject to transitional provisions whereby it applies to pending cases, for which the supplementary search report has not yet been prepared before the date of coming into force of the revised Convention (December 13, 2007).

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75 Rule 164(2) EPC.

76 EPC Guidelines C-III, 7.11.1(ii).

77 See the EPO publication, 'Implementation of the Decision of the Administrative Council of 28 June 2001 on the Transitional Provisions under Article 7 of the Act Revising the European Patent Convention of 29 November 2000' available at: http://documents.epo.org/projects/babylon/eponet.nsf/0/B06BBB6AE8C22ECCC125735 B0052AD12/$File/EPC_2000_Transitional_Provisions_en.pdf.

78 Art.153(7) EPC and EPC Guidelines B-II, 4.3. This is where the ISA was not the EPO, or where the international application was filed before July 1, 2005 and the ISA was neither the EPO, nor the patent office of Austria, Spain or Sweden.

79 Rule 164(1) EPC.

80 Rule 46(1) EPC 1973 and EPC Guidelines, 2005 version, C-III, 7.11.2.

81 EPC Guidelines B-VII, 2.4.

82 EPC Guidelines E-IX, 5.7.

83 EPC Guidelines C-III, 7.10.

3 The examination procedure

The division of responsibility between various departments of the EPO is important because it determines when certain events can occur. When the application is first filed it is under the responsibility of the EPO Receiving Section, which performs formalities checks in particular for the accordance of a filing date and on other formal requirements.[84] It remains under the responsibility of the Receiving Section while the search is conducted and until the applicant files the request for examination,[85] at which point responsibility passes to the Examining Division,[86] which is responsible for examining the application.[87]

Cases where the applicant files the request for examination before the search report is transmitted to him are an exception to the above. If the applicant does this, he is requesting examination when he does not yet know what kind of prior art he will have to contend with in the examination procedure. As a result, after the search report is transmitted to the applicant, he is invited to indicate if he wishes to proceed with the application.[88] In these cases, it is when the applicant confirms that he wishes to proceed that the application then passes to the responsibility of the Examining Division,[89] since if the applicant does not respond to this invitation in time, the application is deemed to be withdrawn[90] (he may have lost interest due to very pertinent prior art found in the search report). When filing the request for examination before the search report has been transmitted to him, the applicant can waive his right to receive this invitation, in which case the application passes to the responsibility of the Examining Division as soon as the search report is sent to the applicant[91] (the 'waiver case').

Actions which occur in examination and which require actions from the Examining Division, such as the sending of communications to the applicant pointing out deficiencies in the application and to which the applicant must respond,[92] can only occur when the Examining Division has assumed responsibility for the application.

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84 Art.16 EPC.
85 Rule 10(1) EPC.
86 Rule 10(2). EPC.
87 The Examining Division consists of three technically qualified examiners and may be enlarged by a legal member – Art.18(2) EPC. Enlargement occurs in particular in cases where complex legal issues arise which are not addressed in Board of Appeal case law or in the EPC Guidelines – EPC Guidelines C-VI, 7.8.
88 Rule 70(2) EPC.
89 Rule 10(3) EPC.
90 Rule 70(3) EPC.
91 EPC Guidelines, C-VI, 1.1 and Rule 10(4) EPC.
92 Art.94(3) EPC.

This procedure has not been changed in the revised Convention. However, the provisions governing it have been moved from the articles of the EPC to the implementing regulations.

3.1 The European Search Opinion (ESOP) and the First Examination Action

For European patent applications filed as of July 1, 2005, when preparing a European Search Report (ESR), the EPO also prepares a European Search Opinion[93] (ESOP), which gives a detailed and reasoned opinion on the patentability of the invention to which the application relates and the compliance of the application with the provisions of the EPC. The ESR and the ESOP combined form the Extended European Search Report[94] (EESR). Effectively, with the introduction of this system in 2005, the first stage of examination was moved to the search stage.[95] This also harmonised the EPC procedures with those of the PCT, which had introduced the Written Opinion of the International Searching Authority[96] in 2004 (WO-ISA). The applicant can reply to the ESOP, by making amendments,[97] by filing his arguments or both and may do so even before filing his request for examination or payment of the examination fee.[98] However, it is not mandatory to reply to the EESR and if the applicant does not reply to it then, after the application enters the examination phase,[99] the EPO sends him an automated first communication, which simply refers to the contents of the ESOP[100] and sets a time limit for reply. Failure to respond to this automated examination communication in time results in the deemed withdrawal of the application.[101] If the applicant replies to the EESR by amendment or argumentation or both, then no automated reference to the ESOP is sent when the application enters examination. Instead the Examining Division will draft and issue a first communication taking the reply into account.[102]

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93 Rule 44a EPC 1973, Rule 62 EPC, and OJ EPO 1/2005, pp. 5 *et seq.*

94 EPC Guidelines B-XII, 1.

95 EPC Guidelines B-XII, 1.1.

96 Rule 43bis PCT.

97 Rule 137(2) EPC.

98 EPC Guidelines B-XII, 9.

99 However, in the waiver case (*vide supra*) this is not an ESOP, but a communication from the Examining Division under Art.94(3) EPC and Rule 71(1)(2) EPC. The applicant must respond to this within a time limit or the application will be deemed to be withdrawn under Art.94(4) EPC (EPC Guidelines B-XII, 8).

100 EPC Guidelines C-VI, 3.5.

101 Art.94(4) EPC.

102 EPC Guidelines C-VI, 3.5.

This procedure has advantages for applicants over the pre-2005 procedure, where an ESOP was not prepared.[103] Firstly, the applicant has a very good indication early on in the procedure as to the patentability of the invention and the general compliance of his application with the EPC. Secondly, the issuance of the EESR means that the applicant effectively acquires an additional opportunity to amend the application in response to reasoned objections from the EPO. The application is not in the examination procedure when the search report is prepared and sent to him,[104] but the ESOP component of the EESR contains the same reasoned objections which an examination communication would contain.[105] He can amend the application in response to the EESR, in addition to which the Guidelines also allow him to file arguments in response to it. This means that he has two opportunities to amend his application and file counter-argumentation in response to a fully reasoned communication: in response to the EESR[106] (before the examination procedure starts); and in response to the first communication from the Examining Division.[107] Before 2005, the applicant could also amend his application in response to the ESR,[108] but because there was no ESOP he had no reasoned communication from the EPO on which he could base his amendments and argumentation. In this regard it is important to note that after the response to the first communication from the EPO in examination, the Examining Division has the discretion not to admit further amendments.[109] This is usually reserved for cases of abuse, in particular where applicants attempt to re-introduce non patentable[110] or otherwise non-allowable subject matter which they had previously deleted.[111] However, if the applicant replies to the EESR, the EPO cannot invoke this rule in respect of the applicant's response to the first communication in the examination phase, even though this may in effect be the second round of amendments submitted by the applicant in response to a reasoned communication from the EPO, because the discretion not to admit more than one set of amendments only applies in examination and not to the reply to the EESR.

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103 With the exception of European applications not claiming priority, for which an opinion was drafted from 2003 onwards, see OJ EPO 5/2003, pp. 206 *et seq*. However, for these cases, no automated first communication was sent in subsequent examination proceedings.

104 Except in the waiver case (*vide supra*).

105 EPC Guidelines B-XII, 3.

106 Rule 137(2) EPC.

107 Rule 137(3) EPC.

108 Rule 137(2) EPC.

109 Rule 137(3) EPC.

110 Art.52-57 EPC.

111 EPC Guidelines C-VI, 4.7.

3.2 Further communications from the Examining Division

If, after any reply of the applicant to the EESR plus the response to the first examination communication, deficiencies remain in the application, the Examining Division has the discretion to send further communications in the examination procedure 'as often as necessary'.[112] In a number of cases, the Boards of Appeal have found that it is justified to refuse a European application after just one communication from the Examining Division[113] (these decisions were issued before the EESR came into being, but remain applicable because the Examining Division cannot issue a refusal until it has issued at least one communication, which does not include the EESR). In particular, the basic premise of much of the case law is not based on whether the applicant makes a *bona fide* attempt at overcoming the existing deficiencies, but whether or not the response he files results in the deficiencies being overcome or whether the legal and technical background of the deficiencies remains substantially unaltered by the response.[114] If the response changes the legal or technical background of the deficiencies, for example by filing test results in order to demonstrate an unexpected effect in order to overcome an objection of a lack of inventive step, then this means that a further communication becomes necessary in accordance with Article 94(3) EPC.[115] Another yardstick used by the Boards to determine whether a further communication is required by Article 94(3) EPC is whether there is a reasonable prospect of a grant,[116] although this can be somewhat subjective since it depends to some extent on the behaviour of the applicant. In cases where a refusal is issued by the Examining Division and the Board finds in a subsequent appeal that a further communication was required by Article 94(3) EPC, this will be classified as a substantial procedural violation which justifies the reimbursement of the appeal fee[117] due to the failure of the Examining Division to respect the applicant's right to comment on the grounds and/or evidence relied on in the decision to refuse the application.[118]

3.3 Oral proceedings

Under the EPC,[119] applicants have the right to present their case orally before

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112 Art.94(3) EPC and Rule 71(1)(2) EPC.

113 See the decision of the Technical Board of Appeal, T201/98.

114 See the decisions of the Technical Board of Appeal, T201/98, T63/93 and T66/83.

115 See the decision of the Technical Board of Appeal, T921/94.

116 See the decisions of the Technical Board of Appeal, T84/82, T161/82, T243/89, T300/89, T640/91 and T793/92.

117 Rule 103(1) EPC.

118 Art.113(1) EPC.

119 Art.116(1) EPC.

the Examining Division. Oral proceedings in examination at the EPO, often referred to incorrectly in the UK as an 'oral hearing', represent the applicant's 'day in court'.[120] It is his chance to present his case in person or via his professional representative to the Examining Division charged with treating his case at the EPO.[121] This procedure has not been changed under the revised Convention, but it remains one of the main pillars of the EPO examination and opposition procedures. The right to oral proceedings before the Examining Division is absolute and once a request for oral proceedings is made, it must be honoured by the EPO. In practice most applicants and representatives make a conditional request for oral proceedings in their written correspondence with the EPO in examination proceedings, to the effect that if the EPO intends to refuse the application, then oral proceedings are requested.[122] In order to guarantee that this request prevents a refusal from being issued directly, the applicant should make this request in his reply to the first communication of the Examining Division.[123] This then means that where deficiencies persist in the application, the applicant is either sent a further communication from the Examining Division, or is invited to attend oral proceedings.[124] Unconditional requests for oral proceedings irrespective of the intentions of the Examining Division are rare, and if such a request is made but the Examining Division finds that oral proceedings are unnecessary because it intends to grant the patent, then the applicant is contacted and advised of this.[125]

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120 Although an elegant English expression, 'court' is not an accurate description of the first instance departments of the EPO, rather these are administrative instances. The Boards of Appeal as the appellate instances are the true courts of the European patent system. The Boards are also required to hold oral proceedings on request – Art.116(1)(4) EPC.

121 In fact, if the applicant is neither a resident, nor has his principal place of business in an EPC Contracting State, he is required to employ a professional representative, i.e. a European Patent Attorney or possibly a legal practitioner of a Contracting State (Art.134(8) EPC) to present his case both in writing and in any oral proceedings (Art.133(2) EPC). However, parties to the proceedings, including an applicant in examination proceedings, may appear at the oral proceedings in addition to their representative (T621/98) and may also make submissions (see decision of the Enlarged Board of Appeal, G2/94 and EPC Guidelines E-III, 8.5).

122 EPC Guidelines E-III, 2.

123 See decision of the Technical Board of Appeal, T300/89.

124 Where a further communication is sent, the application is not being granted, but since it is also not being refused, the conditions for holding the oral proceedings are not satisfied and the Examining Division need not appoint them. However, if the Examining Division wishes to refuse the application it has to appoint oral proceedings before it can do so. Applicants and representatives make this conditional request in order to delay a potential refusal.

125 EPC Guidelines E-III, 2.

Oral proceedings are a useful tool for the quick resolution of outstanding objections to the grant of a patent, because if the applicant does not resolve all outstanding objections before or during the oral proceedings, then the Examining Division can issue a decision to refuse the application at the end of those oral proceedings[126] after which the decision can only be contested by filing an appeal.[127]

When oral proceedings are appointed, the applicant is sent a summons to attend,[128] which indicates the date set by the Examining Division. The applicant must be given at least two months' notice,[129] but is not consulted with regard to the exact date set and can only change this date if he has good reasons, which do not include problems of workload.[130] The summons also details the points to be discussed and sets a final date for submissions prior to the oral proceedings,[131] which is usually one month before the appointed date.[132] If the applicant does not wish to attend the oral proceedings, he may try to avoid them by filing submissions including argumentation and in particular appropriate amendments[133] to the application documents before the final date set for submissions. However, if these submissions do not overcome all existing objections, then the oral proceedings go ahead, whether the applicant attends or not[134] and a refusal may result.

When filing submissions before the oral proceedings (including facts, evidence and amendments to his application), the applicant should take care that he does so before the final date set for submissions. If he files them after this date, then the Examining Division may reject the submissions as inadmissible.[135]

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126 Rule 111(1) EPC.

127 See the decision of the Enlarged Board of Appeal, G12/91.

128 Rule 115 EPC.

129 Rule 115(1) EPC. According to Rule 126(2) EPC a summons sent by the EPO is deemed notified to the applicant ten days after its date of posting if its actual date of receipt is no later than this date. If it arrives later than ten days after posting, the actual date of receipt constitutes the legally binding date of notification. As a result, if a summons to oral proceedings is posted less than two months and ten days before the date of the oral proceedings, then the two months' notice under Rule 115(1) EPC has not been observed and the summons is not valid. The two months' notice can be curtailed if the applicant consents, but the Examining Division must be able to demonstrate this consent – see the decisions of the Technical Board of Appeal, T772/03 and T111/95.

130 OJ EPO 2000, pp. 456 *et seq.*

131 Rule 116(1) EPC.

132 EPC Guidelines E-III, 5.

133 Rule 116(2) EPC.

134 Rule 115(2) EPC.

135 Rule 116(1) EPC applies to new facts and evidence presented after this date

If the applicant files submissions such as amendments or test results before the oral proceedings and these alter the legal or technical background of the objections and he does not then attend, then any decision to refuse the application issued in those oral proceedings in his absence may infringe his right to be heard.[136] The exceptions to this principle are objections to non-allowable amendments, which introduce new subject matter[137] not present in the originally filed application documents where these amendments were made in response to the summons to oral proceedings. The Board of Appeal has found that in cases where a party has filed amendments in advance of oral proceedings but then chooses not to attend, he cannot be surprised that the allowability of those amendments is examined in those oral proceedings in his absence. A decision based on the amendments' failure to remain within the original disclosure cannot come as a surprise to him and so does not infringe his right to comment.[138]

Non-attendance at oral proceedings is not advised since, even if the Examining Division takes a decision on new facts or evidence such that the applicant's right to comment is at issue, the applicant will still have to appeal in order to recoup his rights. He might be granted interlocutory revision[139] but

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(these do not include amendments; see decisions of the Technical Board of Appeal, T133/92 and T771/92) and allows the Examining Division to refuse to consider them on the grounds that they are late (Art.114(2) EPC). Rule 116(2) EPC provides the same system of discretionary power for acceptance of late filed amendments to the application. EPC Guidelines E-III, 8.6 give further guidance on how this discretionary power of the Examining Division is to be exercised.

136 The right to be heard is a fundamental principle of the EPC and is enshrined in Art.113(1) EPC,which provides that decisions of the EPO can only be based on grounds and evidence on which the parties (in this case the applicant) have had the opportunity to present their comments. If a party does not attend oral proceedings, then G4/92 finds that a decision which adversely affects him, i.e. for an applicant a refusal, cannot be based on facts or evidence on which he has not yet had a chance to present his comments, even though he could have commented had he chosen to attend. See also T951/97, where a new document was used, even when the applicant was in attendance this was considered to violate his right to comment, since he was not given enough time to study it – this is all the more the case when the applicant is not present.

137 Art.123(2) EPC.

138 See the decision of the Technical Board of Appeal T341/92. This case related to non-allowable amendments and non-attendance at oral proceedings by the patent proprietor in opposition, but the same principles should apply to oral proceedings in examination.

139 Art.109 EPC. This is where an applicant appeals against a decision to refuse the application; the grounds of appeal are forwarded first to the Examining Division which may rectify its decision if it finds that the appeal is well founded. If the Examining Division does not find that the grounds of appeal cause it to change its decision, then the case is remitted to the Board of Appeal.

this is not guaranteed and he will in any case have to pay the appeal fee and prepare grounds of appeal in order to achieve this.

Where the applicant does attend, the Examining Division may ask questions and request clarification on outstanding issues. The applicant may propose amendments and provide further explanations or argumentation but is not obliged to add anything new.[140] He can simply reiterate previous argumentation and defend an existing set of application documents.

If when the oral proceedings are concluded agreement has been reached on an acceptable set of amended application documents, which may have already been on file beforehand or may have been submitted in the oral proceedings, the oral proceedings do not end with a decision to grant, but rather with a declaration from the Examining Division that it intends to continue the procedure in writing with a view to issuing a decision to grant a patent based on the agreed text. This is because the grant of a patent is subject to certain formalities which must be performed by the applicant within statutory time limits before the decision can be issued (*vide infra*) and which the Examining Division cannot require the applicant to fulfill during the oral proceedings. If the decision is to refuse the application, this is announced at the end of the proceedings, because there are no further formalities in this case.[141] A detailed written decision detailing the reasons behind the decision is notified later to the applicant[142] from which he may appeal (*vide infra*).

Oral proceedings do not always end with a declaration of intent to grant or a refusal. In certain cases, further clarifications may be required which cannot be provided in the oral proceedings, and the Examining Division may decide to continue the procedure in writing. In this case, the Examining Division will issue the minutes of the oral proceedings to the applicant and set a time limit for him to reply. However, if this happens, the applicant does not have the right to further oral proceedings where the subject of the proceedings is

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140 See the decision of the Technical Board of Appeal, T125/89.

141 Rule 111(1) EPC – The announcement of the decision to refuse in oral proceedings ends the examination procedure – see the decision of the Enlarged Board of Appeal G12/91. The applicant cannot make any further submissions after this point, unless he files an appeal. The author once participated in oral proceedings, where after some hours of debate where the applicant's representative refused to make the necessary amendment to overcome an outstanding objection, the chairman of the Examining Division announced '*The application is r . . .*' at which point the applicant's representative proposed the amendment which the Examining Division had insisted on throughout the entire procedure, since the word '*refused*' was not uttered by the chairman, the submission had to be considered, since although a late submission it was *prima facie* very relevant (it constituted the amendment which the Examining Division had already indicated would overcome the only outstanding objection).

142 Rule 111(2) EPC.

unchanged.[143] A request for oral proceedings in this case, conditional or otherwise, will not delay the issuance of a negative decision.

4 Grant of a patent

When the application is in order for grant, the Examining Division will send the applicant a written communication proposing a text for grant for his approval. The Examining Division will also invite him to translate the claims into the other two official languages of the EPO and pay the grant and printing fees[144] plus any claims fees due.[145] Furthermore, the applicant must pay any renewal or designation fees which fall due in the period before the grant.[146] The applicant must respond within a four month period which is not extendable.[147] Failure to reply to this communication on time results in the application being deemed to be withdrawn.[148]

This communication must be based on a set of application documents submitted by the applicant. The EPO does not have the mandate to make amendments to the application. It is the applicant who always has responsibility for proposing a text which he believes to conform to the EPC.[149] However, where only minor modifications of a text submitted by the applicant are necessary in order to bring the text into conformity with the EPC, then the Examining Division may make such minor amendments and corrections as are necessary in order to bring the text into a state which can be proposed to the applicant for grant. However, such modifications can only be those which the applicant could reasonably be expected to accept.[150]

If the applicant responds on time by filing the translations of the claims and paying the grant and printing fees, he is deemed to have approved the text as proposed for grant. After this has been done, the EPO will then send the applicant the decision to grant the patent. Later the publication of the mention of

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143 Art.116(1) EPC, for example the provision of fresh evidence can change the subject of the proceedings and justify further oral proceedings; see the decision of the Technical Board of Appeal, T731/93.

144 Rule 71(3) EPC.

145 Rule 71(6) EPC – claims fees are due for the sixteenth and subsequent claims (Rule 45(1) EPC); if the applicant did not already pay sufficient claims fees when filing the application, because the application on filing contained fewer claims than when proposed for grant, then the excess of claims fees not paid on filing must be paid at this stage.

146 Rule 71(8), (9) EPC.

147 EPC Guidelines C-VI, 14.1.

148 Rule 71(7) EPC.

149 Art.113(2) EPC.

150 EPC Guidelines C-VI, 14.1.

the grant will occur in the European Patent Bulletin,[151] the latter being the date when the decision to grant takes effect[152] and from which is calculated the nine month period for filing an opposition to the grant of the patent.[153]

In response to this communication the applicant can make his approval conditional on the EPO accepting further amendment or correction of the application documents.[154] If the EPO consents to the proposed changes to the text which it already proposed for grant, then the grant procedure will continue and no further invitation for approval and fee payment will be sent[155] (the applicant is obliged when proposing such amendments to file translations of the claims in the amended form proposed by him and to pay the grant and printing fees within the original four month period).

If the Examining Division does not consent to the amendments proposed by the applicant in response to the proposal for grant, it will send him a communication pointing out the deficiencies and giving him the opportunity to comment on the reasons behind their non-acceptance. The applicant then has a further period to reply which is specified by the EPO. He may propose further amendments, withdraw his request for amendment, or maintain his request for amendment and attempt to convince the Examining Division that his amendments are acceptable. Whichever applies, he must, within the time limit set, provide a translation of the claims which he is proposing for grant where he amends these again.[156] Where the proposal to grant the patent was the first communication from the Examining Division, the applicant has a statutory right to propose amendments at this stage. In such cases the amendments could not be rejected on the grounds of inadmissibility, but could nonetheless be rejected on the grounds that they do not comply with the EPC.[157]

An exception to the above is where the applicant does not approve of a text proposed for grant where he objects to amendments made by the Examining Division. If this is the case, the applicant can respond to the invitation for approval of the text proposed for grant by requesting a grant to be based on the previous set of application documents provided by him, which the Examining Division amended. He is not required to file a translation of the claims or to pay the grant and printing fees. His failure to do so will not result in the sanction of deemed withdrawal,[158] but the examination procedure may

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151 Art.98 EPC.
152 Art.64(1) EPC.
153 Art.99(1) EPC.
154 Rule 71(4) EPC.
155 EPC Guidelines C-VI, 14.4.
156 Rule 71(5) EPC.
157 Rule 137(3) EPC and EPC Guidelines C-VI, 4.9.
158 EPC Guidelines C-VI, 14.4.1 and C-VI, 4.9.

be re-opened if the applicant cannot convince the Examining Division to accept the documents exactly as proposed by him.

Furthermore, the applicant's approval of the text proposed by the Examining Division is not binding[159] and the applicant can propose further amendments to the application documents up until the day before the decision to grant the patent is dispatched by the EPO to its internal postal service.[160] However, changes to the application documents at such a late stage will generally be subject to stringent admissibility requirements, since they could delay the decision to grant.[161]

5 Refusal of the application

In pre-grant proceedings, that is, the post-filing formalities checks and the examination procedure, there are two ways in which the application may be lost. Firstly, the application may be deemed to be withdrawn. This sanction applies where the applicant fails to comply with a number of different time limits in the EPC, for example failure to reply to a communication from the Examining Division in time[162] or failure to pay the examination,[163] search or filing[164] fees in time.

Some requirements of the EPC have no explicit sanction where they are not complied with. For example there is no explicit sanction where the application lacks novelty or inventive step. Failure to comply with these requirements results in the refusal of the application by the Examining Division using a blanket provision covering all deficiencies for which no specific sanction exists in the EPC.[165] As discussed above, the applicant must always be given the chance to present his comments on the grounds and evidence forming the

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159 See the decision of the Enlarged Board of Appeal, G7/93.

160 See the decision of the Enlarged Board of Appeal, G12/91 and the decision of the Technical Board of Appeal, T798/95.

161 The decision of the Enlarged Board of Appeal G7/93 gives some examples of amendments which could be considered admissible at this late stage, in particular corrections which do not appreciably delay the decision to grant and amendments to take account of prior national rights. Prior national rights are national patents or patent applications of EPC Contracting States which have an earlier filing date or valid priority date than the European application – Article 139(2) EPC – which although not causing legal impediments to the grant of a European patent by the EPO, may prejudice the rights of the applicant in the state in question in national nullity proceedings according to Article 138 EPC (see EPC Guidelines C-III, 8.4). Any such changes made at this late stage must also be accompanied by translations of the claims – EPC Guidelines C-VI, 4.10.

162 Art.94(4) EPC.

163 Rule 70(3) EPC.

164 Art.78(2) EPC (the time limit is given in Rule 38 EPC).

165 Art.97(2) EPC.

basis for this negative decision before it can be taken. It is possible for the Examining Division to refuse the application based on grounds and evidence in respect of which the applicant waived his right to comment.[166] However, the waiver of any right under the EPC can never be presumed by any department of the EPO. It must be according to a clear and explicit indication to this effect from the party in question[167] (in this case the applicant).

The application is refused as a whole, it cannot be refused in part,[168] since it either does or does not comply with the EPC, even if only one part of the description or one claim is deficient (e.g. one claim is unclear, not novel, not inventive etc.). If any deficiency in the application is not overcome, the application must be refused *in its entirety*.[169] This decision must be reasoned[170] and the absence of sufficient reasoning is a violation of procedure which justifies the reimbursement of the fee for any subsequent appeal.[171] The decision must be drafted in such a way that the reasons behind the decision are intelligible to the Board of Appeal (and the applicant) in such a way that the Board can establish whether or not the conclusions reached by the first instance department were correct[172] (and so that the applicant may formulate his grounds for appeal). For the purposes of complying with the requirement for a reasoned decision it is only required for one ground prejudicing the grant of the patent to be sufficiently reasoned in the decision to refuse the application.[173] Furthermore, referring to previous communications from the Examining Division for the reasoning in such a decision ('reasoning by reference' as it were) can only satisfy the requirement for a reasoned decision where it is clear which grounds being 'borrowed' from earlier communications from the Examining Division form the basis for the decision.[174]

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166 See decision of the Technical Board of Appeal, T685/98.

167 See the decision of the Enlarged Board of Appeal, G1/88 – *a jure nemo recedere praesumitur*.

168 The same applies when a patent is revoked in opposition proceedings (Art.101 EPC). However, where a European Patent is challenged in proceedings before the courts of the EPC member states, it is possible for it to be revoked in part (see Art.138(2) EPC and the decision of the Technical Board of Appeal, T162/97).

169 See decisions of the Technical Board of Appeal, T5/81 and T162/88 as well as Legal Advice from the EPO 15/05 (OJ EPO 2005, pp. 357 *et seq*).

170 Rule 111(2) EPC.

171 See the decision of the Technical Board of Appeal, T493/88.

172 See the decision of the Technical Board of Appeal, T278/00.

173 See the decision of the Technical Board of Appeal, T859/97.

174 See the decision of the Technical Board of Appeal, T234/86; this was a decision of an Opposition Division, but the same principles apply to the Examining Division.

The applicant himself may request a decision on the state of the file as it stands. This is where he wishes to obtain a speedy decision against which he can appeal.[175] If such a request is granted by the Examining Division, a refusal is issued in a standard form which simply makes reference to previous communications from the Examining Divisions pointing out existing deficiencies in the application. Such a refusal, however, is still subject to the applicant's right to comment and so cannot be based on grounds or evidence on which he has not been given the chance to comment (*vide supra*). For this reason, it is only possible for the EPO to grant this request where the applicant does not simultaneously file any further submissions, in particular amended application documents.[176] This is because, if he changes the legal or factual framework underlying the objections to the application, the request for a decision on the file as it stands does not constitute a waiver of his right to comment on the changed legal or factual framework of the case, and he must be given the chance to comment on this new situation before a refusal may be issued.[177]

6 Changes in substantive patent law

Although concentrated for the most part on procedural changes, which overlap in their consequences with the examination procedure (*vide supra*), the revision of the European Patent Convention also involved some changes to the provisions governing substantive patent law and procedures in the examination procedure. For the most part these are simplifications of procedure, although some are subject to complex transitional provisions.

6.1 Prior rights – Article 54(3) EPC

Article 60(2) EPC states:

> If two or more persons have made an invention independently of each other, the right to a European patent therefor shall belong to the person whose European patent application has the earliest date of filing, provided that this first application has been published.

For the purposes of the above, if priority is claimed, then this is the date to be taken into consideration for the application of the above provision.[178] Consequently, the application which has what the PCT refers to as an earlier 'relevant date'[179] or which the EPC Guidelines refer to as the 'effective date'[180] (filing- or valid priority-date) has the right to the invention.

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175 EPC Guidelines E-X, 4.4.
176 EPC Guidelines C-VI, 4.5.
177 See the decision of the Technical Board of Appeal, T1360/05.
178 Art.89 EPC.
179 Rule 64.1(b) PCT.
180 EPC Guidelines C-IV, 6.3.

This is the very heart of the European 'first to file' system. This is in contrast to the US system of 'first to invent', which requires scientists around the world to maintain diligent records of their research in case they file a US patent application which is subsequently subject to litigation in order to determine who the first person to invent was. The US system represents a purely moral point of view, since it gives the rights to the person who first performed the invention, irrespective of the filing or priority date. The European system forces the applicant to consider very carefully at which point he should file his application, balancing the risks of filing too late or too early. File too late and there is the risk that a competitor files first and so acquires the right to the patent or that another scientist publishes the same subject matter prejudicing the novelty or inventive step of any subsequent application, even where he does not file for a patent.[181] File too early and there is the certainty that the early stages of development of the invention will eat into the 20 year life of the European patent[182] and if the invention requires a lot of development time, the useful life of the patent will be severely curtailed. In addition, there is the risk that the EPO may find that the invention is not sufficiently disclosed,[183] since the development is at too early a stage such that details necessary for executing the invention are missing which the skilled person cannot use his common general knowledge to fill in.[184] The advantage of the European system is that it is very simple to administer. Establishing who has the earlier priority or filing date is considerably easier and a great deal less expensive than determining who the first to invent was. In rare cases a third party challenges the right of the actual applicant to the invention in respect of an existing European application, but this is not based on the 'first to invent' principle, but on other considerations such as employee–employer contracts, breach of confidentiality, theft of the idea behind the invention by the applicant, etc. However, such decisions on the entitlement to the patent are not within the

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181 Unlike in the USA, there is no automatic grace period for disclosures by the inventor or the applicant. Under certain limited circumstances, the applicant or his legal predecessor can display the invention up to six months before the European filing date without prejudicing the novelty of his application (not the priority date – see the decisions of the Enlarged Board of Appeal, G3/98 and G2/99). This is provided that he does so at a recognised international exhibition according to the Convention on International Exhibitions signed at Paris on November 22, 1928 and last revised on November 30, 1972 (Art.55 EPC). He must declare this fact on filing and provide a certificate to this effect within four months of the date of filing (Art.55(2) EPC and Rule 25 EPC). If he fails to fulfil these requirements, then his own disclosure will prejudice his European application.

182 Art.63(1) EPC.

183 Art.83 EPC.

184 EPC Guidelines C-II, 4.1 and 4.9.

jurisdiction of the EPO but are decided by the authorities of the EPC Contracting States.[185]

The 'first to file' system is implemented by the novelty requirement. The claimed subject matter of a European application must be novel over a European application which, although not published before the relevant date, has itself an earlier relevant date. For an example see Table 6.1.

In this example, European patent application EP2 specifies in claim 1 the subject matter A or B which are alternative embodiments of the invention. EP2 has a valid priority date for both of these alternative embodiments of February 1, 2007,[186] which is consequently the *relevant date* for claim 1 of EP2. EP1, filed on November 1, 2007, has a valid priority for embodiment A of November 1, 2006, which is the relevant date for EP1. Since EP1 has an earlier relevant date for embodiment A, then it destroys the novelty of embodiment A in claim 1 of EP2, even though it was not published until after the relevant date of EP2.[187] Note that for EP1 to prejudice the novelty of EP2, it is not necessary for the relevant subject matter which it discloses (subject matter A) to be disclosed in the claims of EP1. It can be disclosed anywhere in the description, claims, or drawings. Much debate occurred on this point in the drawing up of the EPC in its 1973 version, and this was not changed in the revision of the EPC in the year 2000. Finally it was decided on the present 'whole contents approach'. This is a logical conclusion, since even where EP1 does not claim the subject matter A, the applicant in this case could introduce

Table 6.1 Prior rights according to the EPC

Application		Date	Subject matter	Disclosed where?
EP2 published		Aug. 5, 2009	A or B	Claim 1
EP1 published		May 1, 2008	A	Description, claims or drawings
EP2 filed	claims GB2 as priority	Feb. 1, 2008	A or B	Claim 1
EP1 filed	claims GB1 as priority	Nov. 1, 2007	A	Description, claims or drawings
GB2 filed	priority of EP2	Feb. 1, 2007	A or B	Description, claims or drawings
GB1 filed	priority of EP1	Nov. 1, 2006	A	Description, claims or drawings

185 Art.61 EPC and the Protocol on Recognition. The Protocol is an integral part of the EPC (Art.164(1) EPC) and indicates which state has jurisdiction to decide who has the right to the patent.

186 See decision of the Enlarged Board of Appeal, G2/98 and Art.87(1) EPC.

187 Art.54(3) EPC.

this into the claims of EP1, provided that this amendment is admissible.[188] Alternatively, at some point the applicant for EP1 might file a divisional application with claims directed to this subject matter which enjoys both the filing and priority dates of EP1, despite being filed some years later.[189] This means that EP1 has the potential to give rise to patent rights for subject matter A.[190] This special novelty requirement then prevents two applications claiming the same subject matter from being granted and so it implements the first to file system.[191] This novelty requirement is not special in the sense that it is assessed in any way differently from novelty over prior art published before the relevant date, but rather it is special because the document which causes the lack of novelty was not published before the relevant date. While these documents are used to assess novelty in the same way as any other document published before the relevant date, they cannot be used in the assessment of inventive step.[192]

This strict novelty approach for applications with an earlier relevant date is in contrast to the Japanese system where there is the concept of a special 'extended novelty' requirement over co-pending applications with an earlier relevant date. This concept of 'extended novelty' includes anything that can be derived from the application with the earlier relevant date by considering the common general knowledge in the art at its time of filing or information which a skilled person obtains through his general knowledge or with the help of other references mentioned in the earlier application.[193] In using the common general knowledge of the skilled person, some overlap with the inventive step requirement occurs. Consequently, this approach is excluded for the European system by Article 56 EPC, which forbids the use of such documents in assessing inventive step. In the European novelty assessment, common general knowledge can only be used to fill in implicit technical details, for example, the term 'bicycle' implies the presence of two wheels to the skilled person.[194]

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188 Rule 137(4) EPC – to be admissible, unsearched subject matter A introduced from the description or drawings into the claims would have to be unitary with the originally claimed invention.

189 Art.76(1) EPC.

190 See also the comments of the Indian group of the AIPPI relating to opinions on the Substantive Patent Law Treaty, Q170, April 2004, available at: http://www.aippi.org/reports/q170/quest04/q170_india.pdf.

191 See decision of the Enlarged Board of Appeal, G1/03, reasons for the decision 2.1.1.

192 Art.56 EPC.

193 For more details on this topic see Helfgott, Bardehle and Hornickel in WIPR 01/04, pp. 22 *et seq*.

194 See the decisions of the Technical Board of Appeal, T677/91, T465/92 and T511/92.

However, it does not allow the skilled person to seek equivalents to technical features disclosed in the earlier filed application,[195] so the term 'bicycle' would not give rise to the term 'motorcycle' or 'unicycle' being deemed disclosed as would be conceivable in the 'extended novelty' system in Japan.

Under the old system of EPC 1973, this novelty objection only applied in so far as the two applications designated the same states.[196] Where the designation of a Contracting State lapsed in respect of the application with the earlier right (EP1), then the earlier application no longer prejudiced the novelty of the application with the later relevant date in respect of the lapsed designation.[197] This could then lead to the later application having different claims for those states affected and those not affected by the earlier right,[198] where the claims of the later application (EP2) could be different in respect of the states affected by the earlier right disclosed in the application with the earlier relevant date (excluding the subject matter A and directed only to alternative B) whereas those not affected did not (they could claim both A or B). Under the new system, it does not matter if the two applications designate the same states or not.[199] The novelty objection applies in respect of all designated states for the later application (EP2) and consequently this can no longer lead to different claims being filed in respect of different designated Contracting States.[200]

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195 See the decisions of the Technical Board of Appeal, T517/90 and T928/93.

196 Art.54(4) EPC 1973 – The EPC is a multilateral treaty with various Contracting States, whereby the applicant designates those states in respect of which he is interested in obtaining patent protection – Art.79 EPC. In the current system, the applicant is deemed to have designated all EPC Contracting States when filing the request for grant form (Art.79(1) EPC). Since this is a mandatory form (Art.78(1)(a) EPC) then by definition in every case all Contracting States are designated. However, certain designations may lapse for non-payment of fees (Rule 39(2) EPC) or may be actively withdrawn by the applicant (Art.79(3) EPC). Under EPC 1973, the time limit for paying the designation fees expired after the publication date of the application (Art.79(2) EPC 1973) and so applications were published with all states indicated as designated in the application. Any states whose designations subsequently lapsed for non-payment of designation fees then had their effects under Art.54(4) EPC 1973 retroactively removed (Rule 23a EPC 1973). Although the time limit for payment of designation fees is the same under the revised EPC (Rule 39(1) EPC), this is no longer relevant, since common designations are no longer an issue here.

197 Rule 23a EPC 1973.

198 Rule 87 EPC 1973 and EPC Guidelines C-III, 8.1.

199 Art.54(4) EPC 1973 has been deleted.

200 Art.118 EPC provides that, unless otherwise provided, the text of the European application and the European patent must be same in respect of all designated states. Under the previous regime Rule 87 EPC 1973 explicitly provided that earlier rights under Art.54(3) EPC were one such exception where only certain states were affected under Art.54(4) EPC 1973. As an implementation of the deletion of Art.54(4)

This change is a considerable simplification of the system of prior rights under the EPC and also reflects the fact that all EPC Contracting States are automatically deemed to be designated when filing the European application. On a more philosophical level it is a reflection of a greater degree of integration between the EPC Contracting States. The previous system of prior rights under EPC 1973 represented a major difference between the European system and the jurisdictions of individual states, which for the most part had no such territorial differentiations.

The European system is also in contrast to the US system whereby the first to invent system means that the relationship between the earlier right deriving from an earlier filing in the US and giving rise to novelty problems[201] is not a simple implementation of the right to the patent. This is because the earlier application causing the lack of novelty may actually result from research which resulted in the same invention at a later date than the later filed application. Consequently, the relationship between the right to the invention and the sequence of filings is more complex in the first to invent system. Furthermore, the novelty effects of an earlier filing under the European system take into account the priority date of the earlier application[202] regardless of its geographical origin, whereas the Hilmer Doctrine applied in the US ignores foreign priorities in assessing novelty in 'patent interference' cases under the corresponding US provisions. The importance of the Hilmer Doctrine is such that it is even implemented in the PCT reservations.[203]

6.2 Claims to medicinal indications

According to Article 53(c) EPC, European patents shall not be granted in respect of:

> methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

This excludes from patentability claims of the type:

> Use of compound / composition X for the treatment of disease Z'[204]

EPC 1973, the corresponding Rule 138 EPC of the revised Convention no longer specifies this exception.

201 35 USC § 102(e).

202 Art.89 EPC.

203 Art.64(4)(a) PCT.

204 EPC Guidelines C-IV, 4.8.

Under the old regime, these methods were only excluded from an industrial application.[205] Under the revised Convention, these methods are excluded from patentability as a whole. However, the wording defining the excluded matter remained untouched, and a change in EPO practice was not foreseen.[206] A great deal of case law exists explaining what constitutes a method of treatment and what does not. For example a method which results in the death of the laboratory animal in question is not a method of treatment.[207] Treatments for cosmetic weight loss are also not excluded.[208] However, methods for treating animals with both medicinal effects (immunostimulation) and industrial effects (improved meat production) are excluded.[209]

In both the previous and current regimes, the same problem exists: how does one patent a new medical use of a known compound or composition when the inclusion of features relating to medical treatment may result in a claim directed to excluded subject matter? To resolve this problem, the exclusion is mitigated by the provisions of Article 54(4), (5) EPC:

> (4) Paragraphs 2 and 3[[210]] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.
> (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Note the same wording in each of the above provisions. Article 53(c) EPC provides that substances or compositions, 'for use in' methods of therapy are not excluded from patentability. In addition to this, Article 54(4)(5) EPC provides that substances or compositions, 'for use in' methods of therapy are

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205 Art.52(4) EPC 1973 excluded these methods from an industrial application under Art.57 EPC 1973.

206 See CA/100/00 and MR/2/00, Art.53, point 5 – the change in excluding methods of treatment from patentability as a whole rather than from industrial application resulted from a change in philosophical outlook. Art.52(4) EPC 1973 was based on old German case law which found that a doctor does not practice an industrial activity – Beschluss des Bundesgerichtshofs, 26.09.1967, la ZB, 1/65, GRUR 1968, 142 (Glatzenoperation), whereas a more modern understanding is to free medical practitioners from the interference of patent rights in their professional activities – see decision of the Enlarged Board of Appeal, G1/04, reasons for the decision, 4.

207 See the decision of the Technical Board of Appeal, T144/83.

208 See the decision of the Technical Board of Appeal, T780/89.

209 See the decision of the Technical Board of Appeal, T780/89.

210 Art.54(2)(3) EPC defines the state of the art, Art.54(2) EPC defines prior art published before the relevant date, and Art.54(3) EPC is discussed in detail above.

novel, if the use of that compound or composition in the therapeutic method is not known. Article 54(4) EPC refers to the novelty of medicinal indications of compounds not previously known to have any medical use (first medical indication) and Article 54(5) EPC addresses cases where a known medicine is applied in the treatment of a disease which it had not previously been used to treat (second medical indication).

First medical use In the example below, where compound/composition X has never before been used in any medical treatment, Article 54(4) EPC provides novelty to this type of claim:

> Compound/Composition X, for use in medical treatment.

This was also the case under the previous regime.

Second medical use In the example below, where compound/composition X has not been used in the treatment of bacterial infection, Article 54(5) EPC provides novelty to this type of claim:

> Compound/Composition X, for use in the treatment of bacterial infection.

Under EPC 1973, these claims were considered to be the same in scope as the general compound/composition '. . . for use in medical treatment' and so if compound/composition X of the above example were known for a different therapeutic use, this claim would still have lacked novelty[211] even though it specifies a particular condition. Under the revised Convention, such a claim is considered novel if compound/composition X of the above example is known in the state of the art for a different therapeutic use (e.g. as an anti-inflammatory agent).[212]

Under EPC 1973, in order to protect a second medical indication of a known therapeutic agent, the Swiss type claim was used. This claim is of the type:

> Use of compound/composition X for the manufacture of a medicament for the treatment of disease Z

This claim was deemed novel over the use of the compound/composition X in the treatment of different medical conditions.[213] Although the Swiss claim is

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211 EPC Guidelines, 2005 version, C-IV, 4.2.
212 EPC Guidelines, C-IV, 4.8.
213 See decision of the Enlarged Board of Appeal, G5/83.

no longer necessary to render new a claim to a second medical indication of a known therapeutic compound or composition, the EPO will continue to accept such claims as being novel.[214]

7 Conclusion

The procedural law of the EPC has on the whole been made more lenient and flexible in order to harmonize it with the Patent Law Treaty. This has created some new legal overlaps between patent formalities and the work of the Examining Division, which may cause additional complications in the examination procedure. However, these cases will be the exception rather than the rule. Far wider, beneficial effects are derived from the simplification of two important aspects of substantive law of the EPC, namely prior rights under Article 54(3) EPC and medical indications under Article 54(4)(5) EPC. Furthermore, the significant increase in legislative flexibility of the EPC, by having a far greater part of its statutory procedures provided for in the regulatory part of the Convention, will enable the EPC to adapt more rapidly and, if necessary, in a more radical way to developments in the field of Intellectual Property on the international stage.

Appendix

EESR	Extended European Search Report (consisting of a European Search Report and a European Search Opinion)
EPC	European Patent Convention, as revised by the act of November 29, 2000 and the Implementing Regulations thereto as in force on December 13, 2007 (http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/contents.html)
EPC 1973	European Patent Convention, as signed on October 5, 1973, subject to the revision of Article 63 EPC which entered into force on July 4, 1997 and the Implementing Regulations thereto in force on December 12, 2007 (http://www.european-patent-office.org/epo/pubs/oj007/08_07/special_edition_4_epc_2000_synoptic.pdf)
EPO	European Patent Office (http://www.epo.org)
ESOP	European Search Opinion (http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/r62.html)
ESR	European Search Report (http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar92.html)
ISA	International Searching Authority as provided for under Article 16 PCT

214 EPC Guidelines C-IV, 4.8.

PCT	Patent Cooperation Treaty, done at Washington on June 19, 1970; amended on September 28, 1979; modified on February 3, 1984 and on October 3, 2001 and the implementing regulations thereto as in force on December 13, 2007 (http://www.wipo.int/pct/en/texts/index.htm)
PLT	Patent Law Treaty, adopted at Geneva on June 1, 2000 (http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo038.html)
OJ EPO	Official Journal of the EPO (http://www.epo.org/patents/law/legal-texts/journal.html)
WO-ISA	Written Opinion of the International Searching Authority (http://www.wipo.int/pct/en/texts/rules/r43bis.htm#_43bis)

7 Appeal procedure before the European Patent Office

*Andrea Veronese**

Introduction

Parties negatively affected by a decision of a first instance department of the European Patent Office (EPO) have the possibility of appealing and challenging the decision before a Board of Appeal, which is the second and final instance of the EPO. The decisions of the Board of Appeal are final, and may not be made subject to a further appeal. As an exceptional measure, according to Article 112a of the revised European Patent Convention it is possible to challenge a decision of the Board before the Enlarged Board of Appeal on the grounds that intolerable procedural deficiencies occurred during the appeal proceedings or that a criminal act had an impact on the decision. The petition is, however, not a measure to revise the application of substantive law by the Board. Excluding the rare cases where this remedy is applicable, the decision of the Board of Appeal cannot be the subject of any further legal action and has the force of '*res judicata*'. Yet, if a European patent is granted or maintained by the Board, the *res judicata* effect does not rule out further legal actions aimed at revoking the patent before the competent national authorities of the states where a patent has effect.[1,2]

To ensure a uniform application of the law, when the case law of the Boards of Appeal becomes inconsistent, or important points of law arise, the Enlarged Board of Appeal can be requested[3] to make a decision or to give an opinion on the relevant issue. These requests, which can only be triggered by a Board

* The author would like to thank Dr. R. Moufang member of the EPO Board of Appeal, for his useful advice for preparing this chapter. The views and opinions expressed in the present chapter are those of the author and do not necessarily reflect the official policy or practice of the European Patent Office.

1 Art.138 EPC lists the grounds upon which a European patent can be revoked by the national authorities of the states where the patent has effect. Such revocation proceedings are however not centralized, and only have effect in the Contracting States where the decision is made. See also decision of the Board of Appeal T694/01, r.2.12.

2 See decision of the Enlarged Board of Appeal G1/99, r.13.1.

3 Art.22 EPC and Art.112 EPC.

of Appeal or by the President of the EPO, may however not be construed as an additional level of jurisdiction after the Board of Appeal.

Although integrated into the organization of the European Patent Office, the Boards of Appeal act as independent judicial bodies. Their members are appointed for a term of five years[4] and can be removed from office only if there are serious grounds. This requires a decision by the Administrative Council of the Office, upon proposal of the Enlarged Board. To ensure their independence, the members of the Boards may not be members of any first instance department,[5] and have a duty of impartiality.[6] Furthermore, in their decisions, the members of the Boards must comply only with the provisions of the European Patent Convention[7] and are not bound by any instructions, such as the Guidelines of European Patent Office. The Boards adopt their own Rules of Procedure,[8] and are bound to them 'provided that they do not lead to a situation which would be incompatible with the spirit and purpose of the European Patent Convention'.[9]

At the moment there are 24 Technical Boards of Appeal, a Legal Board, the Enlarged Board of Appeal and a Disciplinary Board of Appeal. The Boards receive about 2000 new cases each year and settle around 1600.[10]

There is currently an on-going discussion about possibly detaching the Boards of Appeal from the European Patent Office and creating a new separate organ, the 'European Court of Patent Appeals', responsible for the examination of the appeals. It is believed that this structure would be more commensurate and better reflect the judicial function of the Boards. A diplomatic conference and a change in the European Patent Convention would be required to implement this project.[11]

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4 Art.23(1) EPC.

5 Art.23(2) EPC.

6 Art.24(1) EPC.

7 Art.23(3) EPC.

8 The Rules of Procedure of the Boards of Appeal (RPBOA) are adopted according to Art.23(4) and R.12(3) EPC by the 'Presidium of the Boards of Appeal', an autonomous authority composed by a restricted number of members of the Boards appointed under R.12 EPC, and must be approved by the Administrative Council. The rules were substantially amended in 2003; further amendments were required to take into account the changes in the revised European Patent Convention. The latest version of the revised and renumbered rules entered in force together with the revised European Patent Convention (Official Journal of the EPO, 11/2007, pp. 536 ff.).

9 Art. 23 of the Rules of Procedure of the Boards of Appeal (RPBOA).

10 Information available from the internet site of the European Patent Office: www.epo.org

11 For more information see the EPO site: http://www.epo.org/patents/law/legislative-initiatives/autonomy.html.

Aim and effect of filing an appeal

The appeal, which aims to eliminate the adverse effect of the contested decision, follows a procedure proper to an administrative court. Appeal proceedings are totally separate, and have more of a judicial than an investigative character compared to proceedings before the first instance departments. Once an appeal is filed, and with the exception of interlocutory revision by the instance which made the contested decision, the appeal is referred to the Board of Appeal, and the first instance no longer has responsibility or means to interfere with the decision of the Board ('devolutive effect').[12]

Interlocutory revision,[13] mentioned above, is a procedure applicable to decisions concerning proceedings where there are no opposing parties, known as '*ex-parte* proceedings' (in most cases decisions of the Examining Division to refuse the application). When an appeal is filed, if interlocutory revision is applicable, the department which made the contested decision reconsiders it, taking into account the statement of grounds of appeal, where the appellant explains why the decision should be set aside. If the department is of the opinion that the appeal is admissible and well-founded, it rectifies its decision; otherwise it must remit the case within three months to the Board, without any comment.[14] Since the first instance is familiar with the case, interlocutory decision prevents clear-cut cases from reaching the Board. If the conditions for allowing interlocutory revision are not met, appeals are however always referred to and dealt with by the Boards of Appeal.

The filing of an appeal has suspensive effect,[15] preventing the contested decision from entering into force until the appeal is resolved. For example, if a patent is revoked in opposition and the decision is appealed, the patent is still deemed to confer its protective effects while the appeal is under way until the final decision is issued or the appeal is withdrawn.

The so-called 'principle of party disposition', according to which a public authority or court normally does not continue proceedings if the procedural act which started the proceeding is retracted, carries a heavy weight in appeal proceedings before the EPO. Applying this principle, the Enlarged Board of Appeal[16] decided that appeal proceedings must be terminated, in so far as the substantive issues settled in the appealed decision are concerned, when the sole appellant withdraws his appeal. This applies both in *ex-parte* and in *inter-partes* appeals, and regardless of whether there is evidence that the contested

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12 See decision of the Board of Appeal T473/91.

13 Art.109 EPC.

14 For more information concerning the application of Interlocutory Revision by the first instance departments refer to the EPO Guidelines, E-XI,7.

15 Art.106(1) EPC.

16 See decisions of the Enlarged Board of Appeal G7/91 and G8/91.

decision is flawed. A continuation of the appeal by the Board on its own motion[17] is not possible in this case.

Appealable decisions

The EPO departments issuing decisions[18] that are open to appeal are the Receiving Section, the Examining Divisions, the Opposition Divisions, and the Legal Division. This list is exhaustive, and comprises neither the Boards of Appeal, their decisions being final, nor the Search Divisions which do not issue 'decisions'. Indeed, a finding of non-unity and an invitation to pay additional search fees made by the Search Division at the search stage may not be appealed, and can only be contested before an Examining Division, if the application enters the examination phase; if the Examining Division decides against the applicant by refusing the application, an appeal can be lodged against this decision.

Non-limiting examples of appealable decisions are the refusal of the European patent application by the Receiving Section for failure to comply with formal requirements,[19] refusal of the application by the Examining Division on the ground that the application does not meet the patentability requirements,[20] revocation of the patent[21] or rejection of the opposition[22] by the Opposition Division, and refusal by the Legal Division to register the transfer of an application. After the entry into force of the revised European Patent Convention, an appeal against a refusal from the Examining Division of a request to limit a granted patent[23] also became possible.

Appealable decisions must be reasoned and put in writing, and the parties must be notified of the decision, together with a communication pointing out the possibility of an appeal.[24] They also have to involve a reasoned choice between legally viable alternatives.[25] The EPO departments also have the

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17 According to Art.114(1) EPC in proceedings before it, the EPO examines facts of its own motion, and is not restricted to examining facts, evidence and arguments provided by the parties and the relief sought.

18 Art 106(1) EPC.

19 Refusal according to Art.90(5) EPC.

20 Refusal according to Art.97(2) EPC.

21 Revocation of the patent according to Art.101(2) or Art.101(3)(b) EPC.

22 Rejection of the opposition according to Art.101(2) EPC.

23 According to Art.105b EPC as entered into force with the revised EPC, after grant a proprietor may request at any time that the patent is limited. This request may be refused according to R.95(2) EPC, for example if the text proposed extends beyond the application as originally filed (Art.123(2) EPC), or extends the protection beyond that conferred by the patent as granted (Art.123(3) EPC).

24 R.111(1-2) EPC.

25 See decision of the Board of Appeal T934/91, point r.5.

possibility of making intermediate or 'interlocutory' decisions, which do not terminate the proceedings in regard to one of the parties; such decisions may either allow an appeal together with the final decision only, or allow a separate appeal.[26] For example, it is common practice for the Opposition Divisions to deliver an interlocutory decision open to separate appeal, when a patent is maintained in amended form.[27] This decision terminates the debate on substantive issues, and establishes the text of the amended patent, but does not formally close the Opposition Proceedings. Only after the decision on the substantive issues becomes final because no appeal is filed, or if an appeal is filed after it has been settled by the Board, is the proprietor asked to fulfil other formal requirements (like filing a translation of the amended text) required for a final decision terminating the proceedings to be issued. This practice prevents the proprietor from having to pay fees and file translations before the definitive text is established by a final decision.

Appeals are also possible against decisions of the Opposition Division concerning patents which have been surrendered or lapsed in all designated states.[28] This is allowed because when the proprietor actively surrenders the patent or lets it lapse by not paying the renewal fees, the effect is '*ex-nunc*' (from that moment onwards) and does not affect any pre-existing right before that moment. An opponent who has not been able to achieve revocation of a patent in opposition may thus appeal the decision of the Opposition Division to remove *ab initio* ('*ex tunc*') the residual rights conferred by that patent for the period before the lapse or surrender. Conversely, a patentee whose patent has been revoked in opposition may try to have his rights revived for the period before surrender or lapse, appealing a decision of revocation.

The kind of decision under appeal and the composition of the department which issued the decision determines the composition of the Board of Appeal.[29,30] For example, if an appeal stems from a decision of an Opposition

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[26] Art.106(2) EPC.

[27] See decision of the Enlarged Board of Appeal G1/88 and EPO Guidelines, D-VI, 7.2.1.

[28] R.98 EPC.

[29] The compositions of the different Boards of Appeal are defined in Art.21 EPC. Reference is made to this article for further information.

[30] Note: the decisions of the different Boards of Appeal are identified by different letters. Decisions from a Board comprising technical members (Technical Board) are identified by the letter 'T' (e.g. T473/92). Decisions from a Board composed of legal members only (Legal Board, 'Juristische Kammer') are identified by the letter 'J', e.g. J02/01. Decisions of the Enlarged Board of Appeal ('Große Beschwerdekammer') are identified by the letter 'G', e.g. G01/05. Decisions from the disciplinary Boards are identified by the letter 'D'. All decisions, irrespective of whether they were published in the EPO Official Journal, can be retrieved from the Internet site of the EPO: www.epo.org.

Division composed of three technically qualified members, the Board of Appeal will be composed of two technically qualified members and one legally qualified member, but if the Opposition Division were enlarged by the presence of one legal member, the Board would be composed of three technically qualified members and two legally qualified members. A Board dealing with an appeal concerning a decision of the Receiving Section or of the Legal Division is composed of three legally qualified members.

Right to appeal and to be party to the proceedings

An appeal may only be filed by a person who was party to the proceedings which led to the decision impugned, and who is adversely affected by that decision.[31] If more than one party was present at the proceedings, and one party appeals, any other party who does not appeal becomes 'party as of right' to the appeal. For example, if the patent proprietor and two opponents were parties to opposition proceedings, any of them who is adversely affected by the decision may appeal. If one of them who is adversely affected files an appeal, he acquires 'appellant status' in the ensuing appeal proceedings, while the other two participate as 'parties as of right'.

According to established EPO case law, a party is 'adversely affected' and may appeal only if the decision impugned does not accede to his wishes. To establish whether this condition is met it is necessary to compare the party's objectives with the substance of the decision, and check whether he was adversely affected when the decision was delivered and the appeal filed.[32] A typical example of when these criteria must be considered is when applicants or proprietors file together with a main request one or more auxiliary requests of progressively more limited scope (in the form of separate sets of claims defining progressively more restricted embodiments of the claimed invention). In such cases an applicant or a patentee is negatively affected if the decision of the first instance does not accede to his main request or to auxiliary requests preceding the allowable request.[33] This is further subject to the caveat that, if the party explicitly expressed his approval of a proposed decision based on a lower ranking request during the proceedings before the first instance department, he is not considered adversely affected if that decision is made, even if it does not meet his original higher requests.[34] For this reason, parties to first instance proceedings wishing to preserve their right to appeal and gain appellant status should avoid explicit withdrawal of higher requests. This may be important in some cases which will be considered later.

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31 Art.107 EPC.
32 See decision of the Board of Appeal T244/85, point r.4.
33 See decision of the Board of Appeal T234/86, point r.5.8.
34 See decision of the Board of Appeal T244/85, point r.4.

It is interesting to note that, even if in the majority of the cases the grant of a patent meets the applicant's request, if by mistake the grant is based on a text not previously approved by the applicant,[35] the decision to grant adversely affects him, and can be made the object of an admissible appeal.[36]

In the case of *inter-partes* proceedings (e.g. opposition) if the main request of the opponent was to have the patent revoked in its entirety and that of the proprietor to have the patent maintained as granted (and the opposition rejected), a decision to maintain the patent in limited amended form negatively affects both opposing parties and both may appeal.

Establishing the right to file an appeal can be complicated if a change of entitlement occurred, because of succession, acquisition or merger. In such cases it must be confirmed that the person who files the appeal is the legal successor of the party who participated in the proceedings before the first instance. If the party was an applicant or a patentee the transfer of the application or patent must have been registered at EPO before the appeal is filed[37] by the new entitled person, or it must be proven that the person who files the appeal is the 'universal successor in law' of the original party.[38] Transfer of opponent status before filing an appeal may also be possible, but only in limited circumstances which depend on the status and the relationship between the persons involved in the transfer.[39]

Since the Boards of Appeal act as courts, the principle of equal treatment of parties to court proceedings applies in appeals before the Boards. Accordingly, all parties must be given equal opportunities to defend their interests, and to receive fair treatment. This means that they have the same right to be heard and to oral proceedings. However, some procedural differences exist, which render the status of parties who file an appeal different from that of parties 'as of right'. The first difference is that a party who filed an appeal and paid the appeal fee may decide alone if his appeal has to stand.[40] This is very relevant where the appellant is the sole appellant, because if he withdraws the appeal, the proceedings are terminated irrespective of the stage reached, the possible outcome and the will of the other parties 'as of right'.

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35 According to Art.113(2) EPC, the EPO shall examine and decide upon the EP application or patent only in the text submitted to it, or agreed, by the applicant or proprietor of the patent.

36 See decisions of the Board of Appeal J12/83, J12/85, T1/92.

37 See decision of the Board of Appeal T656/98.

38 See decision of the Board of Appeal T15/01.

39 See decisions of the Enlarged Board of Appeal G4/88, G2/04, and decision of the Board of Appeal T298/97.

40 See decision of the Enlarged Board of Appeal G2/91.

The second difference is that in *inter-partes* appeals ensuing from decisions of the Opposition Division where the patent was maintained in amended (limited) form, the impugned decision may not be amended by the Board to the disadvantage of an appellant being sole appellant.[41] For example, if the proprietor is the sole appellant against a decision maintaining the patent in limited form, the Board may not decide to revoke the patent or to maintain it in an even more limited form. In other words, the non-appealing party is restricted to defending the original decision of the first instance. This follows the principle of prohibition of '*reformatio in pejus*' or '*Verschlechterungsverbot*'. Limited exceptions to this principle exist if the patent was amended in opposition proceedings in an amended but unallowable form, and this was the result of an error committed by the Opposition Division.[42] The principle of prohibition of '*reformatio in pejus*' also does not apply when the patent is maintained in amended form, and both opposing parties file an appeal. Filing an appeal and acquiring appellant status is thus of strategic importance in these cases; it is on this ground that the EPO also decided that if more parties appeal and pay the appeal fee, any fee paid after the first one is not reimbursed.[43]

Procedure for filing an appeal

Three acts are required to validly file an appeal against a decision of the EPO:

(a) filing, within 2 months of the written notification of the decision of a notice of appeal[44] identifying the appellant, the appealed decision and defining the subject of the appeal,[45]
(b) payment, within the same 2 month period, of the appeal fee,[46]
(c) filing, within 4 months of the notification of the decision of a written statement of grounds[47] setting out the reasons why the decision should be

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41 See decisions of the Enlarged Board of Appeal G9/92 and G4/93.

42 See decision of the Enlarged Board of Appeal G1/99.

43 See decision of the Enlarged Board of Appeal G2/91.

44 Art.108 EPC and R.99(1) EPC.

45 The expression 'subject of the appeal' was introduced in new R.99(3) which entered into force with the EPC 2000 on 13.12.2007. The Official Journal of the EPO, 2003, Special Edition No. 1, p. 183, which commented on some changes in the EPC indicated that the subject of the appeal 'defines the framework of appeal proceedings', and that 'as a rule the notice should already clarify whether the decision is contested as a whole or only partially, and define the extent of the issues raised in appeal proceedings'. Future case law will have to clarify the minimum requirements for the 'subject of the appeal' to be sufficiently defined when a notice of appeal is filed.

46 Art.108 EPC; the prescribed amount of the appeal fee is actually 1065 Euro (Rules fees 2(11) EPC).

47 Art.108 EPC and R.99(2) EPC.

set aside or the extent to which it is to be amended, and the facts and evidence on which the appeal is based.

The rationale behind these different time limits is to promptly (within 2 months) inform the affected parties and the public that the decision has been appealed and that its effects are suspended, and to give the appellant enough time (4 months) to formulate his statement of grounds.

If the appellant fails to file the notice of appeal or to pay the appeal fee in due time the appeal is deemed not filed, whereas if the statement of grounds is not filed in time the appeal is rejected as inadmissible. In these cases the only legal remedy is 're-establishment of rights', which may only be granted if the requester can prove that the failure occurred despite all due care required by the case being applied.[48] Furthermore, re-establishment is available only to the applicant or the proprietor and, as an exception, to an opponent who fails to file the statement of grounds in due time.[49]

Deficiencies in the notice of appeal or the statement of grounds may also result in the appeal being deemed inadmissible, if correction is not provided within the prescribed periods.[50] This also occurs when it is found that the decision is not appealable, or that the person is not entitled to appeal. In these cases the proceedings are closed and the appeal is not further examined.

Legal and factual framework of appeal proceedings

In the notice of grounds the appellant has to set out clearly and concisely why he requests that the appealed decision should be reversed or amended, and expressly specify all the facts, arguments and evidence relied upon.[51] For example, an applicant may explain why, in his opinion, the first instance department wrongly interpreted the teaching of the prior art, or did not appreciate certain qualities of the invention. Further arguments or comparative tests proving unexpected technical effects which were not presented in proceedings before the first instance may also be filed. It is important to remark that the impugned decision was not necessarily wrong; for example, an applicant or a proprietor may, instead of disputing the correctness of the decision, file amendments to the application or to the patent which meet the objections which led to the adverse decision, depriving it of its legal basis.[52] It must

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48 Art.122 EPC and R.136 EPC.

49 See decision of the Enlarged Board of Appeal G1/86.

50 R.101(1) EPC and R.102(2) EPC; for a list of deficiencies leading to the appeal being deemed inadmissible and the periods prescribed for correction, reference is made to these regulations.

51 R.99(2) EPC and Art. 12(2) of the Rules of Procedure of the Board of Appeal.

52 See decisions of the Board of Appeal T1197/03, T717/01, T139/87, T729/90.

however always be kept in mind that the appeal may not be considered as an opportunity to start an entirely new case, or as an extension of the proceedings before the first instance department.

The rules of procedure of the Board of Appeal[53] address in depth the issue of admissibility of new submissions in the different stages of appeal proceedings. According to the rules,[54] the statement of grounds, and if there is more than one party, any written reply of the other party/ies to the statement of grounds, has to contain the 'party's complete case' and indicate the reasons why the decision impugned should be reversed, amended or upheld, and specify expressly all facts, arguments and evidence relied upon.

The possibility to submit facts, evidence (e.g. new prior art documents) or requests (e.g. new claims) not presented or not admitted in proceedings before the first instance department is mentioned, and the Boards have the discretion to admit them.[55] The filing by a proprietor of new claims which clearly represent an attempt to overcome the grounds of revocation[56] or the filing by an opponent of new prior art which addresses a missing link in the reasoning of an opposition which was rejected[57] is normally admitted. Often, if reasons to set the decision aside exist but new submissions are put forward which raise fresh issues, the Boards remit the case to the first instance, for it to decide first. This procedure will be discussed later.

Yet it is important that any new submission is made at the very beginning of the appeal when the party's case is defined (with the statement of grounds or in reply to it). According to the rules of procedure,[58] the Boards have the discretion to admit later amendments to the party's case; this discretion is exercised considering, *inter alia*, the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy. The idea behind these rules is that the parties should not be given the freedom to submit relevant pieces of information late, following a strategic plan or taking other parties by surprise, thereby disrupting the smooth conduct of the appeal.

According to established case law issued before the entry in force of the present rules of procedure,[59] *prima-facie* relevance was the most important factor when deciding on the admission of late filed facts, and evidence.

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53 Art.12 RPBOA: 'Basis of the proceedings' and Art.13 RPBOA 'Amendments to a party's case'.

54 Art.12(2) RPBOA: see definition of the 'party's complete case'.

55 Art.12(4) RPBOA.

56 See decision of the Board of Appeal T1197/03, point r.1.3.

57 See decision of the Board of Appeal T1248/03, point r.2.6.

58 Art.13(1) RPBOA.

59 See decision of the Board of Appeal T1002/92.

However, in some recent decisions the Boards applied the new rules of procedure very strictly, and decided not to admit new prior art documents during ongoing appeal proceedings on the ground that they were filed late without justification; relevance was not considered.[60]

The criteria for admitting amendments to the party's case after oral proceedings have been arranged are even more strict. According to the rules of procedure[61] such amendments are not admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings. Relevance of the submissions is not an issue. Also this rule was interpreted very strictly recently; amendments to the application and to the patent and new evidence were not admitted as a result.[62]

Some additional procedural principles developed in the decisions of the Enlarged Board of Appeal further delimit the legal and the factual framework of appeal proceedings and define the limits within which the power of the Board can be exercised.

For example, the extent of the appeal may not extend beyond what is initially requested by the appellant. If his request is to have only a part of the decision set aside (this could be a part concerning a particular embodiment of the claimed invention), he delimits the subject matter under discussion, and requests going beyond this boundary are not admissible. Following the same principle, in an *inter-partes* appeal against a decision of the Opposition Division maintaining the patent in amended form, the Board may neither on its own motion, nor following a request from a non-appealing party amend the decision to the disadvantage of an appellant being the sole appellant (prohibition of *reformatio in pejus*, see above). Doing this would extend the appeal beyond the extent set by the appellant.[63]

Additional limitations apply to appeal proceedings concerning decisions of the Opposition Division: if an opponent, when filing the notice of opposition, limits the extent of the opposition to a part of the patent (e.g. to claims directed to certain embodiments of the invention and not to others) then neither the Opposition Division during opposition proceedings, nor the Board in ensuing appeal proceedings has the power to examine or to decide on subject matter extending beyond that extent.[64] In the case which triggered decision G9/91, the patent related to two types of polymers of different structure. In the notice

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60 See decision of the Board of Appeal T1248/03, points 2.1 to 2.12.

61 Art.13(3) RPBOA.

62 See decisions of the Board of Appeal T764/03, points 6 ff.; T1192/03, see points 3 ff.

63 See decisions of the Enlarged Board of Appeal G9/92 and G4/93.

64 See decisions of the Enlarged Board of Appeal G9/91 and G10/91.

of opposition the opponent requested to have the patent revoked only to the extent that it related to the first type of polymer. In following opposition-appeal proceedings, revocation of the entire patent was requested. Following the rationale of decision G9/91, this request was not considered admissible.

Furthermore, when examining appeals from decisions of the Opposition Division, the Board of Appeal may examine a fresh ground of opposition[65] only with the approval of the patentee.[66] Fresh grounds of opposition are grounds which were neither raised in the notice of opposition nor introduced by the Opposition Division during opposition proceedings.[67] While during the course of the opposition the Opposition Division has the discretion to admit new grounds if they are *prima-facie* relevant, in appeal proceedings raising fresh grounds is severely restricted. For example, if an opposition was filed on the ground of lack of novelty, and no new grounds are raised during opposition proceedings, then in ensuing appeal proceedings, the opponent may not raise a new objection based on the grounds of lack of inventive step or of lack of disclosure unless the patentee agrees to the introduction of this fresh ground.[68] When issuing the decisions which established these criteria, the Enlarged Board commented that it would have caused unforeseeable complications for a proprietor to introduce fresh grounds at a very late stage of the proceedings without his consent. It was however also clarified that if during the opposition or an ensuing appeal the patent is amended, the amendments must be examined for their compliance with all requirements of the European Patent Convention. The examination of the amendments may thus extend even beyond the grounds of opposition.

The powers of the Boards are less restricted if the appeal is against the decision of the Examining Division to refuse a patent application. In this case the Board may extend the examination to patentability requirements that the Examining Division did not consider or regarded as being met during examination proceedings.[69] The appeal is not restricted to the grounds of the decision

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65 According to Art.100 EPC a European Patent can only be opposed on the grounds that: (a) the subject matter is not patentable under Arts.52–7 (i.e. any of the following: it is not new, it does not involve an inventive step, it is not industrially applicable, it may not be regarded as an invention, it concerns subject matter excluded from patentability), (b) it does not disclose the invention in a manner sufficiently clear and complete to be carried out by a skilled person, (c) the subject matter extends beyond the content of the application as originally filed, or if the patent was granted on a divisional application or on a new application filed under Art.61, beyond the content of the earlier application as filed.

66 See decisions of the Enlarged Board of Appeal G9/91 and G10/91.

67 See decision of the Enlarged Board of Appeal G1/95.

68 See decisions of the Enlarged Board of Appeal G1/95 and G7/95.

69 See decision of the Enlarged Board of Appeal G10/93.

or to facts which were considered by the Examining Division. It may then happen that an application which was found by the Examining Division not to comply with the requirement of novelty is found by the Board to fulfil this criterion, but not to meet the requirements of inventive step or sufficiency of disclosure. When the Board has reason to believe that a different patentability requirement is not met, it may decide to further continue examination of this ground and rule on it, or remit the case to the Examining Division for it to decide first on the new issue.

In *ex-parte* proceedings the principle of *ex-officio* examination is therefore exercised more extensively compared to *inter-partes* proceedings. This procedural difference derives from the nature of pre-grant proceedings, which are not contentious, and which are aimed at ensuring that the conditions of patentability are met.

When can a decision on the appeal be made?

The European Patent Convention does not state when the Board may make a decision and close the proceedings, but the Rules of Proceedings of the Boards[70] indicate that a decision may be made at any time, on condition that the decision is made on grounds and evidence on which the parties have had an opportunity to comment,[71] on a text submitted or agreed to by the applicant or proprietor,[72] that the right to oral proceedings has been fulfilled[73] and that the period set for filing the statement of grounds and if there are more parties, for replying to that statement have expired.

The decision is often made in oral proceedings. The right of the parties to oral proceedings before the Board is absolute, which means that if a request for oral proceedings is made by one of the parties it must be honoured. Often the parties file a conditional request, to the effect that oral proceedings are only requested in the event that the Board does not intend to meet their other requests (e.g. on substantive issues). According to the Rules of Procedure of the Boards of Appeal,[74] when oral proceedings have to be arranged, the Board may send a communication drawing the attention of the parties to the matters which appear to be of relevance or to the fact that certain questions no longer appear to be contentious, or containing other observations which could be useful for an efficient conduct of the proceedings. The absence from the oral proceedings of a duly summoned party is not *per se* a sufficient reason to delay any step in the proceedings, including the issuance of a decision. According to

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70 Art.12(3) RPBOA.
71 Art.113(1) EPC.
72 Art.113(2) EPC.
73 Art.116 EPC.
74 Art.15 RPBOA.

the rules, the Boards should ensure that each case is ready for decision at the conclusion of the oral proceedings, so that a decision can be announced at the end of the hearing.[75]

Once all the required conditions are fulfilled, the Board may decide whether to allow the appeal[76] or to dismiss it and uphold the contested decision. If the Board finds that the appeal is allowable it sets the appealed decision aside, totally or in part. For example, when ruling on an appeal against the refusal of a patent application based on a main and an auxiliary request, the Board may find that the decision of the Examining Division was correct in respect of both requests, in which case the decision is upheld; or that the decision on the main request was correct, whereas the decision on the auxiliary request was not, in which case the decision is set aside in part; or that the decision was wrong in respect of both requests, in which case the entire decision is set aside.

Exercise of powers of the first instance or remittal of the case

According to the EPC,[77] when deciding on the appeal the Board may either exercise the powers within the competence of the first instance department responsible for the appealed decision, or remit the case to that department for further prosecution.

In the first case the Board is not limited to acting as a judicial body, and may rule on new matter submitted for the first time in the appeal proceedings. The Boards may, for example, decide to admit and examine new claims[78] filed for the first time with the statement of grounds of appeal or claims which were erroneously not admitted by the first instance department,[79] or new prior art documents filed for the first time during the appeal.[80,81]

In the second case, when the Board decides to remit the case to the first instance for further prosecution, it indicates in an order the course of the following proceedings: the Board may for example admit a new set of claims and order the first instance to continue the proceedings to determine whether they are allowable, or request that a decision on their admissibility is made

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75 Art.15(6) RPBOA.

76 Art.111(1) EPC.

77 Art.111(1) second sentence.

78 See decision of the Board of Appeal T1197/03.

79 See decision of the Board of Appeal T989/99, point r.2 ff.

80 See decision of the Board of Appeal T98/00, points r.9.1 and 9.2.

81 Note however that the admission of new submissions, in particular after the party's case has been defined, is always at the Board's discretion according to the Rules of Procedure discussed above. Submissions not made at an early stage of the appeal, or filed after oral proceedings have been summoned may be considered inadmissible by the Board.

first, and then possibly also on their allowability.[82] Still another case of remittal is that for adaptation of the description. When a Board decides that a patent can be granted (in examination) or maintained (in opposition) on the basis of a particular set of claims, it may order the first instance department to grant or to maintain the patent on that basis, and to continue the proceedings only for adaptation of the description.

Exercise by the Board of the powers of a first instance department may bring the proceedings to a rapid conclusion and lead to the issue of a final decision, but has the drawback that one level of jurisdiction is bypassed. Remittal of the case ensures that any new subject matter is examined at two levels of jurisdiction, and gives the parties more opportunities to consider possible fallback positions and to prepare a proper defence.[83]

Factors which may be balanced in the decision to remit the case are:[84] the need for further investigations, change in the facts upon which the decision was based, the consequences of bypassing one instance, delay of the proceedings. However, when new submissions are made against a party (for example by filing new prior art documents), but the submissions are clearly not prejudicial to that party's position, the Board may decide to admit them and to rule on the case in that party's favour, without remitting the case[85].

According to the rules of procedure of the Boards of Appeal,[86] the case also has to be remitted if it is apparent that fundamental procedural deficiencies occurred in the procedure before the first instance, unless other reasons exist for doing otherwise. Remittal in this case gives the affected party the opportunity to have the case discussed again according to a proper procedural standard, as well as a fair hearing.[87] In these cases, the Boards may also decide that a reimbursement of the appeal fee is equitable.[88]

Binding effect of the decisions of the Board

According to the EPC,[89] when a case is remitted for further prosecution to the first instance department, that department is bound by the *ratio decidendi* of the Board, in so far as the facts are the same. For example, if a case is remitted to the Opposition Division with the order to maintain a patent on the basis of a certain set of claims, and to continue the proceedings only for adaptation

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82 See decisions of the Board of Appeal T63/86 and T746/91.
83 See decisions of the Board of Appeal T361/03, point r.5.3; T592/04, point r.3.
84 See decision of the Enlarged Board of Appeal G10/93, point r.5.
85 See decision of the Board of Appeal T416/87, point r.9.
86 Art.11 RPBOA.
87 See decisions of the Board of Appeal T1065/99, point r.13.
88 R.103(1)(a) EPC.
89 Art.111(2) EPC.

of the description, due to the binding effect, further proceedings do not allow the opponent to challenge the claims as established by the Board, even by adducing new facts, or evidence.[90]

It is, however, important to note that the binding effect applies only to the specific department which issued the contested decision when acting on that individual case.[91,92] For this reason, if a patent is granted on a text established by the Board, in subsequent opposition proceedings an Opposition Division is not bound to the *ratio decidendi* of the Board, even if the facts are the same.[93] The contrary would render meaningless opposition proceedings; the Opposition Division has however to keep the decision of the Board in mind, and not deviate from it unless there are serious reasons for doing so.

The decision of the Board of Appeal on a case is further not binding on any other first instance department or on any other Board dealing with a different case, even if the issues are the same. The Rules of Procedure of the Boards of Appeal[94] take this fact into account, and provide that if a Board considers it necessary to deviate from an interpretation of the EPC given by an earlier decision of the Board, the grounds of deviations must be indicated, unless the grounds follow a previous decision of the Enlarged Board.

Despite not being legally bound by them, the first instance departments and the Boards should still follow earlier decisions of the Boards relating to the same issues, unless they have good grounds not to do so, for the sake of a consistent practice. This is even more important when the case law on a particular issue is already part of established practice in proceedings before the EPO, and has been incorporated in official texts like the EPO Guidelines. Yet, the lack of a binding effect leaves open the possibility, in appropriate cases, of issuing deviating decisions which may contribute to the development of the case law.

Decisions and opinions from the Enlarged Board

When the case law becomes inconsistent, or an important point of law requires clarification, the Enlarged Board of Appeal can be requested to indicate how the law has to be applied. These requests can be triggered either by the Boards or by the EPO President according to the mechanisms described below.

During appeal proceedings, and before deciding on the case, the Board of

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90 See decisions of the Board of Appeal T694/01, point r.2.8 and 2.24; T843/91, point 3.4.2; T153/93, T063/92.

91 See decision of the Board of Appeal J27/94, point r.3.

92 The only exception to this is given by Art.111(2), second sentence which indicates that if a decision emanated from the Receiving Section, the Examining Division (dealing with the case) is also bound by the *ratio decidendi* of the Board.

93 See decision of the Board of Appeal T26/93, point r.2.1.

94 Art.20(1) RPBOA.

Appeal may, if it considers this necessary for the uniform application of the law, or because a point of law of fundamental importance requires clarification, refer a question to the Enlarged Board of Appeal.[95] The referral can be considered by the Board on its own motion or following a request by a party to that appeal. A requesting party has, however, no absolute right to have a question referred; this is at the discretion of the Board. Requests to refer specific technical questions not having general interest, or questions which the Board can answer itself, are refused. Only questions necessary to ensure uniform application of the law or very important points of law are referred. Furthermore, the specific case under appeal remains under the competence of the Board of Appeal, which suspends examination until the Enlarged Board has decided on the relevant point. The parties to the appeal are parties in the proceedings before the Enlarged Board, and have the opportunity to intervene in the proceedings where the point of law relevant for their own case is decided.[96]

Once the important point has been settled, the appeal proceedings are resumed, and the Board decides on the case applying the *ratio decidendi* of the Enlarged Board. Despite having a legally binding effect only on the referring Board in respect to the appeal in question,[97] the decision of the Enlarged Board should be universally applied by all EPO departments where the relevant point of law is applicable. The Rules of Procedure of the Boards of Appeal indicate that when a Board considers it necessary to deviate from an earlier decision of the Enlarged Board, it has to refer the relevant question to the Enlarged Board.[98]

When the EPO case law becomes inconsistent the President of the EPO may also refer points of law to the Enlarged Board.[99] In this case there is no direct binding effect on a specific case under appeal. This alternative mechanism ensures that a point of law can be referred without the need to wait for a triggering case to be pending before the Board.

So far (November 2007) there have been over 70 decisions and opinions from the Enlarged Board of Appeal. Some of them were concerned with the same issues and were dealt with in consolidated proceedings. Only once in the history of the EPO has a decision of the Enlarged Board of Appeal overruled an earlier decision[100] of the Enlarged Board.

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95 Art.112(1)(a) EPC.
96 Art.112(2) EPC.
97 Art.112(3).
98 Art.21 RPBOA.
99 Art.112(1)(b) EPC.
100 In decision G9/93 the Enlarged Board outlawed self-opposition, overruling the *ratio decidendi* of G1/84.

Costs

In principle, in proceedings before the EPO each party has to bear its own costs. However, if the proceedings concern an opposition, a different apportionment of costs can be ordered for reasons of equity,[101] with the result that one party may have to bear costs incurred by another party. The deciding instance determines first who should bear the costs, the percentage of the apportionment and then, upon request, the exact amount is established taking into account a bill of costs and the supportive evidence submitted by the receiving party ('decision fixing of the costs'). The Boards of Appeal have, like the Opposition Divisions, the power to order apportionment of costs concerning opposition proceedings, and also to fix them.[102] The final decision fixing the costs which is issued by the EPO is to be dealt with for the purpose of enforcement in the Contracting States, in the same way as a final decision given by a civil court of the State in which enforcement is to take place.[103]

It is important to note that costs may not be apportioned to a party on the simple ground that he lost the case. Costs can only be apportioned for 'reasons of equity', if they result from the conduct of a party who behaves incorrectly causing additional costs to other parties to the proceedings. This may occur as a result of irresponsible behaviour or a malicious action. For these reasons, even a winning party may be obliged to bear costs incurred by a losing one. Costs incurred by EPO itself for carrying out the proceedings, are in any case not charged to the parties.

According to the Rules of Procedure of the Boards of Appeal,[104] costs may be apportioned by the Boards as the result of filing amendments to a party's case (e.g. by filing new prior art documents at a late stage of the appeal), extensions of time limits, acts or omissions prejudicing the timely and efficient conduct of oral proceedings (e.g. by not providing interpretation as promised, so that oral proceedings must be postponed), failure to comply with the directions of the Board and abuse of procedure. In general any act which disrupts the conduct of the appeal proceedings increasing costs may cause apportionment. The Board may further decide to apportion costs relating to proceedings which occurred before the first instance department which issued the contested decision and even 'future costs' concerning proceedings which are expected to take place after remittal to the first instance.

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101 Art.104(1) EPC and Art.16(1) RPBOA.

102 Art.16(2) RPBOA. Note that the Boards have the power to apportion and to fix costs because under Art.111(1) they may exercise the powers of the department which issued the contested decision (see also decision of the Board of Appeal T323/89).

103 Art.104(3) EPC.

104 Art.16(1) RPBOA; the reasons mentioned not being limitative.

Only expenses 'required to protect the rights involved' incurred by a party can be apportioned.[105] These may include costs charged to a party by its representative, costs of witnesses or experts, or other costs incurred by the party itself[106] (e.g. for travelling to the EPO and for accommodation).

Before the entry into force of the revised EPC, only costs incurred in the taking of evidence and oral proceedings could be apportioned. This restriction has now been lifted and as a result costs must no longer necessarily have to be in connection with these procedures. Any kind of costs incurred to ensure the proper protection of rights could therefore be subject to apportionment. Future development in the case law will clarify to what extent these new far-reaching provisions will be applied. Theoretically, the entire legal costs of a party could be apportioned.

Petition for review

Before the entry in force of the revised European Patent Convention there was no possibility to revise a decision of the Board of Appeal and to overturn the *res judicata* effect of the decision. In decision G1/97 the Enlarged Board decided that even a request based on the alleged violation of a fundamental procedural principle had to be refused as inadmissible.[107] The Enlarged Board nevertheless invited the legislator to provide a mechanism to review final decisions by the Boards in specific cases where intolerable procedural violations were committed during appeal proceedings.

New Article 112a, which entered into force with the revised EPC, fulfils this role and gives adversely affected parties the possibility of filing a petition to have a decision of the Board of Appeal reviewed by the Enlarged Board of Appeal. The applicability of this procedure is however very limited, the only admissible grounds for the petition being substantial procedural violations committed by a Board of Appeal, and criminal acts having an impact on the decision. Substantive issues are not admissible, because the petition is by no means a measure for revision of the application of substantive law by the Boards.

Substantial procedural violations which the parties may invoke are defined in a restrictive list including:[108] the presence on the Board of a member in breach of the prescribed requirement of impartiality, or of a member previously excluded from the Board, or of a person not being a member of the Board; violation of the right to be heard; failure to arrange for oral proceed-

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105 R.88 EPC.
106 Art.16(2)RPBOA.
107 See decision of the Enlarged Board of Appeal G1/97.
108 Art.112a(2) EPC, R.104 EPC, R.105 EPC.

ings as requested by a party; failure to consider a request relevant for the decision.

If the petition is filed on the ground that a criminal act may have had an impact on the decision, the request is only admissible if a competent court or authority has already established by final decision that the crime occurred. A conviction, that is, the passing of a sentence, is not necessary; the contrary would render this remedy inapplicable where for example, the perpetrator of the crime died, or was not legally responsible (e.g. due to mental illness). The EPC does not provide any example of crimes which could have an impact on a decision of the Board, but the Enlarged Board of Appeal in decision G1/97 (see above) mentioned the forging of documents or giving false oral evidence.

Unlike the filing of an appeal, the filing of a petition does not have suspensive effect on the contested decision. However, if the petition is found admissible and allowable by the Enlarged Board, the decision of the Board of Appeal is set aside and the proceedings are reopened before the Board; in this case the suspensive effect of the appeal enters into force again, suspending the effects of the earlier decision of the first instance department.

The time limit for filing the petition depends on the grounds on which it is requested. If it is requested on the grounds of a procedural violation it must be filed within two months of the notification of the decision of the Board; this is also subject to the caveat that the petition is not admissible if the party could, but did not, raise the objection in the course of the appeal proceedings. If the petition is based on the ground that a criminal act occurred, it has to be filed no later than two months from the date on which the crime was established, but in any case no later than 5 years after the decision of the Board was notified.

Two acts are required to validly file a petition for review:

(a) filing, within the prescribed period, of a reasoned statement[109] identifying the petitioner, the decision to be reviewed, the reasons for setting the decision aside and the facts and evidence upon which the petition is based,
(b) payment, within the same period, of the petition fee.[110]

If the petition is duly filed, it is initially examined by an Enlarged Board of Appeal composed of two legal members and one technical member. Any petition which is 'clearly inadmissible or unallowable'[111] is rejected if all the

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109 Art.112a(4) EPC and R.107(1) EPC.

110 Art.112a(4) EPC. Rule fees (Rfees) 2(11): the petition fee amounts to 2500 Euro, the second highest fee charged by EPO.

111 R.109(2)(a) EPC.

members unanimously decide to do so; this decision is made on the basis of the petition and without involvement of other parties.[112] If the Board in this composition does not reject the petition, it submits it to an Enlarged Board of Appeal consisting of four legally qualified members and one technically qualified member.

If the Enlarged Board of Appeal in this new composition finds the petition admissible and allowable, it sets the decision aside and reopens the proceedings before the responsible Board of Appeal.[113] The decision of the Enlarged Board has 'cassatory' effect (*iudicium rescindens*) and overturns the *res judicata* effect of the decision of the Board of Appeal. The petition fee is also reimbursed in this case.[114] The Enlarged Board may further order that members of the Board who participated in the decision which has been set aside are replaced.

The EPC further provides that,[115] a person in a designated EPC State, who has in good faith used or made effective and serious preparations to use an invention which is the subject of a published European patent application or European patent in the period between the decision of the Board of Appeal and publication in the European patent Bulletin of the mention of the decision of the Enlarged Board of Appeal on the petition, may without payment continue such use. These are persons who may have started to use or who have made preparations to use the invention after a decision from the Board refusing an application or revoking a patent, considering the claimed invention free from patent protection. Since a reopening of the proceedings before the Board may reinstate property rights otherwise considered lost, this provision protects third party interests.

Further literature

For more information relating to appeal proceedings before the EPO, reference is made to the additional literature mentioned below. Most of this literature, however, does not take into account the changes in the European Patent Convention which entered into force on December 13, 2007.

B. Günzel, 'The treatment of late submissions in proceedings before the boards of appeal of the European Patent Office'; Official Journal of the EPO, special edition No. 2, 2007 – 13th European Patent Judges' Symposium (pp. 30–47, concerning late submissions in appeal proceedings).

P. Messerli, GRUR 2001, p. 979, 'Die Überprüfung von Entscheidungen der Beschwerdekammern des Europäischen Patentamts nach dem neuen Art.112a EPÜ' (concerning the petition for review by the Enlarged Board of Appeal).

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112 R.109(3)EPC.
113 Art.112a(5) EPC and R.108(3) EPC.
114 R.110 EPC.
115 Art.112(a)(6) EPC.

R. Schulte, *Patentgesetz mit Europäischem Patentübereinkommen* (Carl Heymanns Verlag KG, 2005). See § 73, Art.106–112 EPC (by R. Moufang, concerning appeal proceedings before the EPO).

M. Singer and D. Stauder, *The European Patent Convention* (Carl Heymanns Verlag KG, third edition, 2003). See Part V, Art.106–112 EPC (by U. Joos, concerning appeal proceedings before the EPO).

M. Singer and D. Stauder, *Europäisches Patentübereinkommen* (Carl Heymanns Verlag, 4. Auflage, 2007). See Art.106–112 and Art.112a EPC (by U. Joos, concerning appeal proceedings before the EPO).

A. Veronese and P. Watchorn. *Procedural Law under the EPC 2000: A Practical Guide for Patent Professionals and Candidates for the European Qualifying Examination* (Kastner Verlag, 2008). See Chapters XIX–XXIII concerning appeal proceedings before the EPO.

For more information on our book, please refer to the website: www.epc-compass.com and to the review from Mr Jeremy Phillips: http://ipkitten.blogspot.com/2008/11/no-rumpus-if-you-use-compass.html.

8 Patent Office oppositions and patent invalidation in court: complements or substitutes?

Jay P. Kesan

1 Introduction

A patent can be a powerful tool. It grants its owner exclusive rights over a particular technology by allowing him to exclude others from the use of that technology. It allows the inventor to exploit her unilateral control over the technology by charging other parties for the right to use the invention (i.e. a license). Or the inventor can retain sole access to the technology – charging supra-competitive prices for a good or service that no one else can produce without permission. Either way, the patentee retains sole control over his invention.

From an institutional perspective, the patent system is a two-stage bargain. At the first stage, the U.S. Patent and Trademark Office (hereafter the 'PTO') grants patent rights to inventors after examining the prior art and the patent application to determine whether the requirements for patentability are met. At the next stage, in order to enforce their issued patent rights, patentees have to resort to the federal courts and an action for patent infringement. Alleged infringers may counter by challenging in court the scope, validity, and enforceability of patent rights issued in the first stage. Thus, the patent system itself contemplates a role for the courts that involves reviewing the work of the PTO.

The patent regime is typically justified by the economic argument that the benefits it creates outweigh the costs it imposes. The possibility of high profits and licensing fees accruing to patent holders guarantees that the creator of any valuable invention will be able to recoup his costs, thereby creating incentives to invest in research and new technologies. However, these benefits of the patent system must not only outweigh the direct costs described above, but also the indirect 'social costs' the system creates. For example, other inventors may face higher research and development costs as they take care to avoid the patented invention by 'engineering around' it. Some technological areas may not be exploited or improved at all, as competitors avoid them for fear of running afoul of patented technologies to which they may not have legal access. For the social benefits of patents to exceed their total social costs, it is

important that the fundamental bargain be retained that patents be granted only to inventions that are new, useful, and non-obvious. Moreover, even when it is appropriate to grant a patent, it is essential that the patent rights not be overly broad. For example, a patent should not cover aspects of the technology that are beyond the invention's 'non-obvious' contribution and thereby restrict access to technology that more properly lies in the public domain. Finally, a patent system that grants unwarranted or overly broad patents creates rewards for 'getting some patent claims past the patent examiner' rather than promoting useful research. Thus, a patent regime that grants many 'bad' patents is costly from a social welfare standpoint by imposing indirect and direct costs on the numerous actors affected by the patent system.

For the reasons described above, it is important that a patent be granted only in cases where the conditions for patentability are met. It is the job of the examiners at the PTO to insure that patent rights of appropriate scope are granted. Nonetheless, there is growing concern that the number of overbroad or so-called 'bad' patents may be increasing.

Commentators have long complained about the quality of the patents granted by the PTO. It is widely suggested that the PTO issues patents that are either 'facially' invalid or broader than the actual innovation disclosed in the patent application. Both problems result from the PTO's inability to accurately determine the scope of information that is already in the public domain or is the subject of other patents (i.e. the relevant prior art). By way of illustration only, if an inventor were attempting to patent a bucket with a handle, a lid, and a spout, then the PTO may not be able to determine what aspect of this invention is new and non-obvious – is it the bucket itself or just the spout or the lid? Obviously, the scope of exclusive rights that is granted if the patent applicant is found to have invented the bucket is very different from the situation when the patent applicant is granted exclusive rights to merely the spout or the lid. This is particularly true in areas such as computer software where identifying the relevant prior art is often difficult.[1]

These problems are not necessarily the result of incompetence at the PTO. Several commentators have noted that the PTO is being asked to perform miracles because it operates under significant budgetary constraints. In the patent community, it is well-known that the amount of time the PTO spends examining a patent application, from initial examination to issuance, is approximately the same as the amount of time an attorney may spend searching for relevant prior art in the first week of patent litigation. As a result, even doubling the amount of time spent by a typical patent examiner would still

[1] Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J., 763, 765 (2002).

pale in comparison to the time devoted to studying the prior art in litigation, unless the quality of information made available to the patent examiner is improved.

The problems created by a lack of resources are exacerbated by the localized nature of technical knowledge and the social costs of 'bad' patents. First, we must consider the nature of the technical and specialized knowledge with which the patent examiner must acquaint herself in every application in order to make a patentability determination. The localization of knowledge pertaining to science and technology is well recognized in a number of disciplines, including information science, knowledge management, and information economics. For example, in his book *Information Anxiety*, Richard Saul Wurman[2] categorizes all types of information as a series of concentric circles radiating out from an individual – with internal and conversational information occupying the innermost circles and general cultural information occupying the peripheral ones. Scientific and technological information occupies one of the inner circles because such information is not widely shared; rather, it is available only to persons working in a specific field or sub-field.[3]

Similarly, researchers in information science and knowledge management have demonstrated that within any technical discipline technologists form sub-groups referred to as 'invisible colleges'. These are loose, but effective, communication networks within which technologists share information. Within each sub-group, the members work out a rich set of customs, habits, mechanisms, and traditions to define the protocol for information collection including mechanisms for listening and screening out information. Many of these sub-groups are non-intersecting, and hence, knowledge that is most relevant to their technological activities remains local.

A third example illustrating the wide recognition of technical knowledge's localized nature is found in *The Use of Knowledge in Society*[4], where noted economist Friedrich Hayek recognized that scientific knowledge is not likely to be widely dispersed. Instead, it is most likely to be at the disposal of a few particular individuals, the so-called 'experts' in that field of knowledge. Further, Hayek persuasively contends that any single administrative authority is not likely to possess all of the information dispersed among several individuals about any particular fact.

From these insights, it is clear that information regarding the relevant prior art for any patent application is most likely to be known only to the patentee and his competitors. Hence, the PTO is unlikely to be well informed about the

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2 Richard Saul Wurman, *Information Anxiety* (Bantam Books, 1990).
3 Ibid., 766.
4 AMER. ECON. REV. 519–30 (1945).

relevant prior art, creating an asymmetry between the patentee's information and the information possessed by the PTO. Consequently, in many cases, especially those areas with substantial non-patent prior art, it is simply not a matter of providing the PTO more resources to conduct a more thorough prior art search. Indeed, the patent examiner may not even be aware of where to discover the most relevant prior art once she has exhausted traditional patent databases. Thus, it is not at all surprising that the PTO grants invalid or overly broad patents.

As another preliminary matter, the social costs of improvidently granted patents are numerous. They include the following: (a) opportunistic licensing royalties/fees (including cross-licensing) collected from licensors who may rationally settle for a license instead of resorting to protracted litigation; (b) the disincentive to downstream innovation, that is, the social cost of abandoned research activities by the patentee's competitors who may fear infringement; (c) the cost of wasteful designing-around activities by competitors; (d) the cost of rent-seekers, such as venture capital financiers, who may choose to invest in start-up companies based on bad patents, thereby taking away resources from genuine entrepreneurs; (e) the social cost of supra-competitive pricing, in the absence of non-infringing product substitutes, based on bad patents; and (f) the filing and prosecution costs and the subsequent cost of having the courts fix the PTO's oversights.[5]

Between 1980 and 1996 the number of applications and awarded patents has doubled. These increases have been accompanied by complaints about the level of resources devoted to examining applications and the training, incentives, and procedures facing patent examiners.[6] Patent applications have become more complex over the past twenty years, and patents are being granted in ever broadening areas of technology. Given the growing rate of patent applications and expanding areas of technology being patented, there is some concern that the number of overbroad or 'bad' patents may be increasing too. Consequently, there is a greater need than ever for an efficient mechanism to revoke such overbroad patents.

The U.S. currently has two avenues for challenging a patent's validity: a PTO reexamination or a court's invalidation. The PTO currently has two mechanisms for reexamining patents. The original reexamination procedure was initiated in 1980 as an inexpensive method for reviewing patent validity. However, this procedure suffers from numerous limitations, and it is not

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[5] Ibid., 767–8.

[6] Jay P. Kesan and Gwendolyn G. Ball, *How are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. L. REV. 237 (2006).

widely used. Third parties can request a reexamination of a patent, based on 'new' prior art in the form of a patent or published work that was not considered in the original examination. They are not allowed to present other physical evidence or expert testimony as they could in court. Even if the PTO determines that there is 'a substantial new question of patentability', a third party's role in the patent reexamination process is extremely limited. In effect, the procedure mimics that of the original examination and involves only the examiner and the patentee. If all or part of the patent is revoked, the patentee can appeal as he could after the original examination, while the third party has no forum for an appeal. And, if the reexamination does not revoke any patent rights, any new prior art presented during the reexamination will have diminished value in any subsequent litigation because the court is very likely to presume that the PTO has already found it unpersuasive.

Thus, both the grounds for requesting a reexamination and the nature of the procedure make the system unattractive to interested third parties. As a consequence, the number of reexaminations requested has reached about 20% of the number that was anticipated when the legislation was enacted – running at 200 to 400 cases a year. Thus, while less than 1% of U.S.-issued patents face reexamination, approximately 8% of European patents face oppositions. It stands to reason that unless U.S. patent examiners are more accurate than their European counterparts by a factor of twenty, the U.S. reexamination system is not doing a good job of weeding out overbroad or unwarranted patents.[7]

To alleviate these problems, an alternative mechanism was created. Under the *inter partes* reexamination procedure introduced in 1999, third parties are allowed a much greater role in the examination process. However, they have very limited ability to appeal a ruling under this procedure, and these third parties are hampered by the PTO reexamination process in subsequent infringement litigation in the courts. Unsurprisingly, this system is utilized at an even lesser rate than the original system; only 26 *inter partes* reexaminations were requested in the first five years after its enactment.[8] Therefore, given the limited opportunities for post-issuance patent challenges in the PTO, the burden of revoking overly broad patents will fall on the courts in the context of patent infringement lawsuits (or declaratory judgment actions). In response to the filing of such a case, the alleged infringer may mount a defense that some or all the asserted patent claims should not have been granted in the first place. If the court finds that the PTO erred in granting the patent, it can declare some or all the patent claims to be invalid. Thus, the courts are an integral part of the patent system and serve as an institutional mechanism not only

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7 Ibid.
8 Ibid.

for protecting and enforcing valid patent rights, but also for maintaining the integrity of the process used to grant those rights.

The patent litigation system, however, has its shortcomings as a mechanism for revoking invalid patents. Infringement constitutes the only grounds for launching a patent suit, and the validity of a patent can be challenged as either a counterclaim or as part of a declaratory judgment action in response to the threat of such a suit. However, in the absence of a charge of infringement, a third party has no mechanism for challenging a patent in the courts. Even after a complaint has been filed, the courts require clear and convincing evidence in order to invalidate a patent. Under current law, patents receive a 'presumption of validity' and any challenge to a patent's validity must be proven by 'clear and convincing evidence' rather than a 'preponderance of the evidence'. Importantly, these limitations can all be dealt with through appropriate patent legislation.

There are other more fundamental problems with using the courts as a mechanism for revoking wrongly granted patent rights. There is general agreement that the cost associated with pursuing a patent lawsuit is high. Previous authors have cited legal costs of patent litigation running from half a million dollars to three million dollars per suit or $500,000 per claim at issue per side.[9] These costs create incentives for the parties to settle their dispute rather than seek a final judgment on the merits. Throughout litigation, the parties will receive additional information about the strength of their positions through the results of discovery, the court's construction of the patent claims at issue, rulings on motions for summary judgment, rulings on preliminary injunctions, and the like. Economic theory suggests that when it becomes obvious that a patent is very likely to be invalidated it is in the best interests of the patent holder to offer a cheap license to keep the patent rights intact, and it is in the best interests of the defendant to accept such an offer rather than incur further significant legal costs. Specifically, it is in the interest of the alleged infringer to accept a license if its cost would be less than the cost of continued litigation. Only patents where it is difficult to predict who will win are likely to proceed further to a final determination on the merits.

However, society may have an economic interest in seeing these disputes decided through a formal judgment, which neither the court nor the parties take into account. The parties may settle when both decide that the benefits to doing so exceed their *private* costs of continuing litigation. In short, as other authors have pointed out, pursuit of patent invalidation suffers from a 'free rider' problem. One firm may incur the court costs, but firms incurring no costs will benefit, too. Therefore, everyone has an incentive to allow someone

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9 Ibid.

else to take on the burden. Thus, even if the technology blocked by a 'bad' patent is very useful or valuable, no one firm or even a small group of firms may pursue its invalidation. Stated alternatively, it is not just the value of a patent that is important, but also to whom that value matters.

The courts do little to counter these incentives because they promote settlement to save the public the expense of a trial or lengthy litigation. Trials are expensive and courts have limited resources, so in civil cases it is considerably more efficient to promote a resolution of the dispute without the expense of a lengthy trial. In fact, it is considered a hallmark of efficient court management to encourage parties to resolve their disputes outside the courtroom because litigation costs are also a loss to society. But neither the court nor the parties include the social benefits of revoking a 'bad' patent in making their private decisions about the appropriate use of their resources. Third-party firms simply conclude that it is cheaper to pay for a license or engineer around an erroneously granted patent. When making these decisions, they will not take into account the benefit of appropriately defining the scope of patent protection to other firms or to society as a whole. Consequently, the validity of too few patents will be reviewed on the merits by the courts.

2 Empirical studies of U.S. patent disputes

Our (Kesan and Ball) previous empirical study of patent litigation showed that the current US patent system promotes settlements and offers very limited mechanisms for post-issuance review by courts of validity and infringement.

The first step in our analysis was to construct the dataset. Rather than study a large number of patent cases litigated over a long period of time, we chose to extract the patent cases filed in three recent years. Focusing on a smaller number of cases (about 6300 cases) allowed us to examine the history of each case in greater detail than is possible with a larger dataset. In particular, it allowed us not only to exploit publicly available data on U.S. court cases, but also to examine the docket reports for each individual case. Highly detailed knowledge of each case's history will help us reach the ultimate goal of determining how patent cases are resolved, the costs involved, and how well the courts are fulfilling their role of removing 'bad' patents.[10]

The study tracked the total case history of all patent complaints filed in 1995 and 1997. The years 1995 and 1997 meet two important criteria: first, they are sufficiently lagged for the vast majority of cases to have terminated, and second, they reflect current patent law and civil procedure. Cases litigated in 1995 and 1997 were covered by the most recent developments in patent law. For example, we found that only 23 of the cases filed in 1995 had terminated

[10] Ibid.

before the *Markman* decision. But we also found that only a very few cases from these years had not terminated; only one patent case from 1995 and twelve cases from 1997 were still in litigation as of this writing. Data were also collected on cases filed in 2000, which is even more representative of current patent cases. However, among these cases, 62 (or 2.5% of the original data) had yet to terminate as of this writing.[11]

Once the three years had been selected, we needed to identify the patent cases which would constitute our cohorts and collect information on how they were resolved. To do so, we relied on three sources: (1) case data prepared by the Administrative Office (AO) of the U.S. federal courts, (2) docket reports available online through the PACER system, and (3) U.S. Patents Quarterly. The official statistics show that 1707 patent cases were filed in 1995, 2127 cases were filed in 1997, and 2476 cases were filed in 2000. In each year we eliminated cases which were miscoded or for which data were not available. To avoid double counting, we also eliminated cases that were transferred to other districts or consolidated with other cases. After subtracting those cases, the analysis comprised 1369 cases for 1995, 1756 cases for 1997, and 2081 cases for 2000.[12]

2.1 How many cases are adjudicated on the merits?

Our results show that many more patent cases are adjudicated on the merits (either at the pre-trial stage through a grant of summary judgment or at trial) than is commonly thought. Our results demonstrate that, in addition to the small number of patent cases going to trial (about 5%), another significant percentage of cases (about 6–9%) are resolved on the merits through summary judgment. Thus, the most remarkable conclusion of our analysis is that a much larger share of cases are adjudicated on the merits to a final resolution than has been previously suggested in the literature. Nonetheless, the data still shows that nearly 70% of all patent cases settle. The general conclusion remains that the majority of patent cases terminate in some form of non-adjudicated agreement.[13]

2.2 Rulings of infringement and invalidity

Despite the greater ability of the court system to review all evidence pertaining to the validity of patents, only a very small number appear to be 'weeded out' in a given year. Combined with the small number of reexaminations resulting in total or partial revocation of a patent, it seems that of the order of

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11 Ibid.
12 Ibid.
13 Ibid.

300 patents were invalidated each year in the mid-1990s, while around 300,000 patents were issued each year.[14] It's easy to speculate that in the face of a high probability of losing part of her patent rights, the patentee generally offers the alleged infringer a license that he finds more advantageous than continuing costly litigation proceedings. This situation emphasizes the basic economic calculus at issue here: the probability of being adjudicated an infringer and the subsequent remedy or damage award at issue, the probability of having one's patent rights invalidated (or rendered unenforceable) in whole or in part, the litigation cost that has been incurred by the parties, and the additional cost of litigation that looms ahead.

There is also a substantial difference in the stage of the adjudication process in which rulings of infringement and invalidity occur. Rulings of invalidity tend to occur at an earlier procedural stage compared with rulings of infringement. Most frequently, when a patent is ruled totally or partially invalid, the case terminates with a pre-trial judgment for the alleged infringer although sometimes it settles or litigation continues on other remaining issues. This result might seem encouraging because it implies that invalid patents can be revoked by the courts without resorting to an expensive trial. However, obtaining a pre-trial ruling – particularly pertaining to invalidity – can be very expensive. In short, termination at an early procedural stage does not necessarily mean that the case has been resolved 'cheaply'.

2.3 Expenditure in patent cases in general

We were particularly interested in measuring the costs associated with the case resolutions identified in the previous section. Unfortunately, it is nearly impossible to directly measure litigation costs for the general population of patent cases. To overcome this problem, we have developed three proxies for costs: length of time to termination, number of documents filed in court, and, for the 1997 and 2000 cohorts, whether the cases reached the stage of filing a motion for summary judgment.

These three measures show that the average level of expenditure over all patent cases is relatively modest. However, final rulings by a court after a trial or a grant of summary judgment are expensive. In other words, even cases that do not reach the trial stage but terminate with a successful motion for summary judgment involve a considerable expenditure of resources. As a consequence, our previous finding that rulings of invalidity commonly occur at the summary judgment stage may be somewhat misleading or at least incomplete: terminating early, prior to trial, does not necessarily imply little expenditure of resources.[15]

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14 Ibid.
15 Ibid.

2.4 Level of expenditures in patent cases

The duration of cases filed in 1995, 1997 and 2000 demonstrate that on the average, expenditures in patent cases are not excessively high. In all three years, 50% of cases were resolved within ten months. [16] However, there are a small number of cases with exceedingly long durations. In particular, the 1997 curve has a somewhat longer 'tail'. Sixty-six cases filed in that year had a duration equaling or exceeding five years.

The second measure of expenditure on cases tallied the enumeration of documents filed in the docket reports. The number of documents filed may give a better indication of the number of 'billable hours' paid by the parties and, therefore, direct expenditures. The number of documents filed in patent cases supports the conclusion that expenditure on most cases is not that large. The average number of documents filed was approximately 65 while the median was 25 across all three years.[17] As with the time to termination, the number of documents filed in cases has a long tail of cases with numerous documents. However, by this measure, expenditure on patent cases was strikingly similar for the three cohorts, both in terms of the distributions, and in the summary statistics describing that distribution.

Finally, we determined the number of cases in which a motion for summary judgment had been filed. Certain events such as claim construction or motions for summary judgment indicate that the parties are investing significant resources in the litigation. We found that in 473 cases in the 1997 cohort – that is, approximately 27% of all cases filed that year – a motion for summary judgment was filed. In the 2000 cohort, a summary judgment motion was filed in 490, or 24%, of all cases.[18]

2.5 How do expenditures in patent cases differ across outcomes?

As might be expected, cases which proceed to a final court ruling on the merits entail a greater expenditure of resources than those which settle. The average number of days to termination for cases with a final court ruling was 30–50% larger in cases terminating in rulings than in those that settled over the three years.[19] The contrast was equally stark when the number of documents filed was used as a measure of expenditure. Over three times as many documents were filed in the average case terminating in a ruling than in the average case that settled.[20] This result means that the vast majority of cases terminating

16 Ibid.
17 Ibid.
18 Ibid.
19 Ibid.
20 Ibid.

through rulings had more than 50 documents filed while only a small proportion of those terminating in a settlement fell into this category.

Given the 'long tails' associated with expenditure on patent cases, we compared the distribution of expenditure levels between settled and adjudicated cases. The results show that the relatively low average expenditure observed across all patent cases is biased downward by the low expenditures in the settled cases. In addition, all our measures suggest that the relatively low expenditure on patent cases is, at least in part, due to the propensity to settle these disputes rather than to go to trial.

2.6 Expenditure by type of ruling: trials and summary judgments

In general, it is assumed that the most expensive cases are those that go to trial. Our results verify this assertion. However, it is also obvious that the cases that terminated through successful summary judgments motions nonetheless require a significant level of resources. The average case terminating through a trial endured only two months longer than cases terminating through a summary judgment for the year 1995 and was four months longer for 1997.[21] The decline in the ratio of expenditure on trials to expenditure on summary judgments is even more evident when measured in terms of documents filed. The average number of documents filed in cases that ended with trials was two-and-a-half times the average number filed in cases terminating in successful summary judgments for 1995 (the median was about three times as great), and only about 60% greater for 1997 (the median was about twice as great).[22]

To some extent, these results suggest that there may be a trend in the level of expenditure across the two types of rulings. Whichever measure of expenditure is used, the overall cost of a trial seems to be growing at a relatively slow rate, while that of a summary judgment is increasing rapidly and is only something less costly than a trial in 1997. These results demonstrate somewhat of a shift towards longer trial cases, and a more pronounced shift among summary judgment cases.

The significant difference in duration and number of documents filed in cases resolved through summary judgment for the 1997 cases compared with the 1995 cases are consistent with the changes brought about by the *Markman* decision[23] that established claim construction as a threshold legal issue in patent litigation. The increased importance *Markman* placed on first construing the claims before addressing infringement or invalidity necessitates that significant resources be allotted to the step of claim construction before (or

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21 Ibid.

22 Ibid.

23 Markman v. Westview Instruments, 52 F.3d 967, 977–79 (Fed. Cir.), cert. granted, 116 S. Ct. 40 (1995).

concurrent with) filing motions for summary judgment. Hence, it is not surprising that the cases filed in 1997 expended more resources earlier in the litigation compared with cases filed in 1995.

These results call into question the conventional view that cases which go to trial are much more expensive than those where a final court ruling occurs in the pre-trial stage. For 1995, the majority of cases ending with final rulings that lasted two years or more went to trial. But for 1997, the majority of such cases terminated through a pre-trial final ruling. The results are similar when expenditure is measured by the number of documents.[24] Of course, two years are insufficient to truly diagnose any form of long-term trend. This caveat is especially true given the fact that a significant number of the most expensive cases from the 2000 cohort are unresolved, and the preliminary data from that year provides weaker support for the existence of the trend observed between the 1995 and 1997 cohorts. However, the results suggest that expenditures in patent cases may not be as closely related to the initiation of a trial as is commonly thought.

2.7 Invalidity rulings: the cost of revoking an improvidently granted patent

We can no longer assume that a case which terminates through a pre-trial ruling is necessarily much less expensive than one which goes to trial. This fact is particularly worrisome given the small number of rulings of invalidity observed in the data and the stage at which those rulings are made. We previously noted that such rulings of invalidity tend to occur at an early stage in the litigation. Given the conventional view of the expense of trials, such a result might be considered encouraging by implying that the courts can dispose of the validity issue somewhat early in the process. If this were the case, we would have less cause to worry that the expense of seeking an invalidity ruling is truly prohibitive to defendants. However, given the trend in expenditures for cases terminating in rulings of summary judgment, it is clear that there is still cause for concern. Despite invalidity rulings' tendency to be adjudicated 'early' without a trial, they are not less expensive than rulings on patent infringement which seem to come later.

These results suggest that much of the expense associated with patent litigation occurs long before the parties appear before a jury. The process of filing motions for summary judgment on invalidity involves intensive investigation and study of the relevant prior art, including the activities of third parties, and testimony by expert witnesses. Huge transaction costs are associated with patent litigation because summary judgments, in particular ones based on invalidity, are expensive compared with summary judgments granted on other grounds. As the costs mount, the defendant in an infringement suit is likely to

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24 Ibid.

find an offer of a license more and more attractive. And he will only be taking his own costs – not the potential benefits or costs to society – into account in deciding whether or not to accept such an offer.

Overall, our results show that transaction costs associated with patent litigation loom large, and rulings on the merits by the courts concerning patent validity, patent infringement, and remedies for infringement (i.e. injunctive relief or damages) are rare, expensive, and not pursued to completion by most litigants. Instead most patent cases settle fairly quickly (about 12–15 months) after the filing of the complaint, thereby reducing the actual cost of patent litigation considerably.[25]

Economic theory suggests that the high rate of settlement witnessed in patent cases is a mechanism used by the parties to avoid high litigation costs. If a ruling – especially a ruling of invalidity – turns out to be expensive, the incentive to settle the dispute will be high. Individuals will balance their private benefits against the costs of continuing litigation. However, they will not include in their calculus the public benefits of reduced research costs or cheaper production of goods. Thus, since rulings – particularly rulings of invalidity – are expensive, too few cases are pursued to a final adjudication of validity or infringement to sufficiently weed out 'bad' patents.

3 'Reforming' the Patent Office

Incorrectly issued patents can survive in the market without judicial review even when the invention is neither novel nor non-obvious. A game-theoretic model that studies the interaction between the patentee and an alleged infringer/challenger demonstrates the negative impact of the transaction costs in the patent system at the administrative stage in the U.S. Patent & Trademark Office (PTO) and at the enforcement stage in the courts. In particular, the study highlighted the inability in the current system to mount effective challenges to improperly granted patents in the current system.

When the PTO grants an incorrectly issued patent, the patentee obtains property rights generating private and social costs from the misallocation of resources. The existence of a 'bad' patent, unless challenged successfully, creates a private cost: firms have to pay licensing fees to use the technology, and consumers have to pay higher prices to buy the patentee's products. A 'bad' patent also creates a social cost: the sum of all the private costs plus the externalities over the investment processes of competing firms.

The judicial system has traditionally prevented some incorrectly granted patents from surviving in the market. Court provides competing firms and inventors with an avenue to evaluate and carefully circumscribe the patentee's

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25 Ibid.

rights over her invention. Litigation, however, is expensive. As we demonstrate in our model, the existence of high litigation costs allows many incorrectly granted patents to survive in the market.

Consider the following situation in which the PTO grants a 'bad' patent. We begin with the assumption that the PTO granted a patent to Firm *j*, the patentee, and that a competitor, Firm *i*, was particularly affected by this patent. Once the PTO granted the patent, Firm *i* must decide between taking the case to the courts or letting Firm *j* continue to have patent rights. From our analysis we identify three different outcomes for a challenge of an incorrectly granted patent. First, the patent can survive without any challenge from competitors. This will happen when the benefit lost from the 'bad' patent does not justify the costs of going to court – the challenger is better off leaving the patent in place than undertaking an expensive litigation process. Second, the patent can be challenged directly in court without any private agreement. This will happen when either Firm *i* rejects a private offer from Firm *j*, or Firm *j* never makes an offer to Firm *i*. Finally, a private agreement among the parties will prevent the patent from being fully adjudicated in court. In this case, the 'bad' patent survives but the challenger gets relief from the costs of the 'bad' patent. In general, 'bad' patents will only be challenged when the benefits lost by Firm *i*, the challenger, are large enough to compensate for the high litigation costs and the patentee is not able to generate a private agreement to share some of the benefits.[26]

When the expected benefits from contesting the patent are greater than the expected costs of resorting to litigation, Firm *i* will prefer to take the case to court. Conversely, when the benefits are too small as compared to the expected costs, Firm *i* will prefer to pay licensing fees or change its investment process to avoid illegal use of the newly patented technology. In this latter case, the incorrectly issued patent produces an inefficient economic result: the high transaction costs created by expensive courts and the patent process permit 'bad' patents to survive.

Changes in patent litigation costs and the quality of adjudication in the courts also affect the incentives to challenge patents and thereby affect the probability of securing a patent. Litigation costs have an important role in determining the chances that a patent will be challenged in court. The high transaction costs required to revoke 'bad' patents decrease social welfare. In many cases, patents are not challenged at all because the challenger's litigation costs are prohibitively high. Litigation costs are not limited to the direct costs

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[26] Jay P. Kesan and Andres A. Gallo, *Why 'Bad' Patents Survive in the Market and How Should We Change? – The Private and Social Costs of Patents*, 55 EMORY L.J. 61, 77–80 (2006).

of using the court, but also include indirect costs derived from the externalities of litigation costs, the existence of temporary 'bad' patents, and the opportunity costs incurred by challengers. Accordingly, the granting of 'bad' or unnecessary patents by the PTO generates significant costs for the firms and consumers that want to challenge the patent.[27]

The current patent system in the U.S. relies largely on the judicial system to solve the problem of incorrectly issued patents.[28] Courts, however, are not necessarily well-informed or well-qualified to evaluate the validity of issued patents. In the last few decades, the increase of patents on Internet business methods and software technology has opened new areas of patenting in which judges have little experience. As a consequence, courts do not always eliminate 'bad' patents. Rather, 'bad' patents can survive, even after review by a court.

Contrary to the implicit assumption by the PTO that 'bad' patents can simply be contested in the courts, most incorrectly issued patents are not necessarily going to be contested in the courts. In fact, incorrectly issued patents can survive in the marketplace and impose long-term welfare costs on society. And, the patent system's sole reliance on judicial review is insufficient to correct mistakes in the patenting process. Therefore, there is a need to advance new mechanisms to improve the administrative processes employed by the PTO. Specifically, including administrative challenges, such as patent oppositions, may improve PTO functioning by correcting and limiting the number of improperly granted patents.

The game-theoretic model of strategic interaction between a patentee and an alleged infringer emphasizes the importance of transactional costs and underlines the need for low-cost post-issuance validity challenges. In recent years, the performance problems of the PTO described earlier prompted many scholars and commentators to propose new regimes for granting and managing patents. Many of these proposals included the creation of an opposition system inside the PTO.

In such an opposition system, once a patent is granted, or just before it is granted, there is a limited period of time during which firms or individuals can challenge a patent's validity. If challenged, the PTO will review its own decision concerning the challenged patent or business method. If the patent is not challenged after the legal period, further claims must be brought in court. Even if the PTO declares a challenged patent valid, the firm or individual pursuing the challenge can decide to continue in court. We assume, however, that once the PTO reviews a patent and validates it, the information generated and the

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27 Ibid., 87.
28 Ibid., 90.

decision made will improve the chances for a court to make a more informed decision. As a result, we assume that the PTO's challenge system will be complementary to the court system, rather than merely a substitute.[29]

First, regarding the cost of the opposition system, it is crucial to provide the option of an opposition at costs lower than the court system or typical private agreements.[30] If the cost of resorting to the PTO to challenge an incorrectly issued patent is much lower than the cost of reaching a private agreement, the probability of a challenge will be higher while the probability of 'bad' patents surviving will be lower. In our model, lower costs for the opposition system reduce the number of instances where opposition is unlikely. Lower costs will increase the use of the opposition system and reduce the likelihood of reaching private agreements. As a result, we should expect a higher level of PTO opposition to improperly granted patents than under the current patent system.

Second, the PTO must design the opposition system with the goal of improving information access and efficiency.[31] Under the opposition regime, it is important that the patentee has incentives to conduct more thorough searches of the prior art before applying for the patent. Information gained from a prior art search would be valuable in the event of challenges arising under the opposition regime. This information would allow the PTO to accelerate the process and reduce the amount of work needed to make an informed decision. Another important aspect of the opposition system is its speed. To be efficient, the new regime should provide a limited amount of time for challenges to new patents. After this challenge time, it is the courts that would decide future challenges. Providing a limited time for challenging new patents would minimize the time during which there is uncertainty over the validity of the new patent. In order to provide potential challengers with fair access to the opposition system, the PTO should increase disclosure and make the prior art which was taken into account readily available. The balance between these two factors of improving information access and efficiency is a key element in creating a well-working opposition system.

Third, PTO decisions would ideally reduce the number of challenges in court.[32] For example, if a patent is challenged in the PTO, it might be less vulnerable to future attack if after analyzing the case and gathering information the PTO decides that the patent is valid. With this special protection, courts will have more information about the patent and its quality. Therefore, it should be more difficult to successfully challenge a patent previously rati-

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29 Ibid., 96.
30 Ibid., 108.
31 Ibid., 108.
32 Ibid., 108.

fied by the PTO. Furthermore, the PTO will reduce the work for the courts by providing reliable signals about the quality of a patent that has survived an opposition. In our model, when the PTO validates a challenged patent, the validation decreases the probability of success for the challenger in court. As a result, we should expect that challengers will be discouraged from going to court after the PTO has rejected their claims, unless they have good cause.

Designing an opposition system for the PTO requires considering different issues that might affect the efficiency of the system. One of these issues is choosing between a pre-grant or post-grant system. While both systems have distinct advantages and disadvantages, post-grant systems are in place in most of the international patent offices such as Japan, Germany, and the European Union.

Pre-grant systems have considerable advantages. First, the PTO has more incentive to analyze the opposition claim objectively. Generally, in post-grant systems, it is difficult for organization members to reject a previously granted patent. As a result, claims may be more likely to be treated fairly in pre-grant systems. Second, once the PTO grants the patent, its validity is stronger because it has obtained approval not only from the issuing office, but from the opposition system as well. This increased validity may be helpful for further challenges in court. Third, since the patent is not yet granted, individual inventors or firms have to use the opposition system instead of resorting to the courts. For example, in Japan and Germany, the change from a pre-grant opposition system to a post-grant system produced an increase in the number of court cases and a decrease in the number of oppositions.[33]

Pre-grant systems also have many disadvantages. First, firms with high levels of resources and power will more frequently oppose small inventors in an attempt to block their patents. For the Japanese Patent Office (JPO), the change to a post-grant system was the result of complaints and a strong lobby by American firms that felt Japanese firms were using the pre-grant system to block their inventions. Second, the early information disclosure needed for a pre-grant system may provide otherwise secret information to the patentee's competitors. This disclosure could induce competitors to act strategically and invest in a given technology. Conversely, defenders of early disclosure systems believe that the early disclosure of information encourages technological advances. Third, a pre-grant opposition system may encourage competitors to save costs by holding back potentially invalidating prior art, preferring to wait for the patent to issue.[34]

The disadvantages of the pre-grant system can be ameliorated by: (1) taking

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33 Ibid., 109–10.
34 Ibid., 110.

specific measures to avoid excessive oppositions that attempt to block a new technology, such as limiting the number of oppositions that may be filed by a third party, forbidding repeated oppositions based merely on cumulative evidence, creating pre-grant oppositions only for anticipatory evidence and the like; and (2) publishing the prior art cited by the PTO in its office actions with the patent application.[35]

Post-grant opposition systems also have many advantages. First, because there is no requirement for information disclosure early in the granting process, the inventors' technology remains protected. Second, firms cannot use the opposition system to block the grant of competitors' patents. Challenging a patent is only available after the patent is granted, thus avoiding this problem of pre-grant systems. Third, for some patents, the decision to challenge a patent can change over time. For example, a firm can patent an obvious technology that is not challenged initially because of the small value of the patent. Later, however, this patent could become both valuable and harmful to competing firms. Therefore, having a post-grant system could help provide an inexpensive challenge system for some time after a patent is issued. Nonetheless, for any pre-grant or post-grant system, challengers may still contest a 'bad' patent in court.[36]

Post-grant opposition systems have two distinct disadvantages. First, the Patent Office has an incentive to reject the opposition in order to protect its own initial decision to grant the patent. For post-grant systems, there is an inherent conflict in the management of the system because the same group/office in charge of granting the patent has now to take steps to review its validity. As a result, the examiners will be more willing to reject claims questioning the validity of a patent that they have approved. This problem can be ameliorated by appointing an opposition panel with Administrative Opposition Judges (AOJ) that are independent from the PTO examining corps. Second, once a patent is granted, oppositions may occur less frequently. As a result, it is difficult for the challenger to obtain a successful review of a granted patent.[37]

Based on a careful assessment of the advantages and disadvantages of both systems most observers prefer a post-grant opposition system over a pre-grant system.

Another important characteristic of the opposition system is the scope of estoppel: the extent to which the verdict of an opposition panel would block further action in the courts. At one extreme, a system might permit the presenta-

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35 Ibid., 110–11.
36 Ibid., 111.
37 Ibid., 111–12.

tion of any type of claim in court after the opposition is completed. At the other extreme, a system might prohibit the continued prosecution of any claim in court.

In the first instance, the absence of any estoppel creates a problem for the patentee and for the validity of the opposition system. If the opposition system does not inform court action, or at least improve the chances of the patentee in court after successfully defending her patent, then it is useless as an instrument to assess the validity of patents. In the second case, if the challenger is not able to prosecute his claim in court, then the system is reduced to a one-shot game without further review. Instead of resorting to any extreme estoppel or lack thereof, we suggest using an intermediate solution where the opposition system generates a judicial precedent but does not prohibit the challenger from seeking judicial review.[38]

Another important characteristic of the opposition system is its format: written briefs or live testimony. Making decisions after reviewing written documents allows evidence to be handled and revised more quickly, and the costs of the opposition system are small. Conversely, a system that authorizes full hearings and live testimony for oppositions is more burdensome and can increase the costs of the opposition.

The type of fee schedule utilized can enhance the creation of an opposition system and the incentives that patentees and challengers face. As proposed elsewhere, the incorporation of a system with fee-shifting for patent challenges will increase the number of challenges, changing the incentives for patentees and challengers. In particular, if we wish to induce validity challenges, we might consider a one-way, pro-defendant/challenger, fee-shifting system if a patent is invalidated or revoked in litigation or opposition proceedings. For patentees, the existence of a low-cost opposition system and the possibility of having to pay the full cost of using such a system or the full cost of a court proceeding will increase the incentives for procuring better patents with a lower probability of being challenged. For challengers, the existence of a low-cost opposition system and the possibility of a 'free' opposition procedure for cases when the patent is found to be invalid will increase the willingness to challenge invalid patents.[39]

As we saw in our model, the desirability of using the opposition system depends significantly on the cost savings it offers over the courts. As a consequence, we should design a low-cost revocation system for patents in order to create a successful alternative system to the courts. Otherwise, the increase in the costs of using the opposition system will have a negative impact on the efficiency of the overall examination procedures.

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38 Ibid., 113.
39 Ibid., 115.

4 Patent invalidation processes in the JPO and the Japanese courts

A carefully designed opposition process in the U.S. PTO could increase both the probability of a third-party challenge to an issued patent and the probability of obtaining a decision on the merits regarding validity in the context of such a challenge. In the past five years, Japan has experimented with a dual patent invalidation process that permits issued patents to be challenged in the Japanese Patent Office (JPO) and the Japanese courts. Comparative studies of dual invalidation processes in Japan show that both processes are complementary and necessary.

In Japan prior to 2000, in patent infringement litigation, it was presumed that issued patents should be regarded as valid until such time as the JPO determines invalidity and revokes an issued patent. In April 2000, the Supreme Court of Japan, in the *Kilby* decision, determined that courts can consider the validity of patents in infringement cases in certain circumstances, thereby revoking the teachings of conflicting precedents. In *Kilby*, the Supreme Court of Japan concluded that when the likelihood of a patent being found invalid is quite high, the exercise of that patent constitutes an 'abuse of patent right' and should therefore be prohibited by the court. To clarify, the term 'abuse of patent right' is not similar or related to the patent misuse doctrine in the United States. This term simply refers to patent invalidation in the courts in Japan. In this context, the term 'invalidation' is not used because patent validity is purely a matter for the JPO under Japanese Patent Law. Hence, the Japanese Supreme Court in the *Kilby* decision chose to refer to patent invalidation by the courts as arising from an abuse of the patent right that required correction by the courts. On April 1, 2005, the *Kilby* decision permitting courts to invalidate a patent was codified into the Japanese Patent Law.[40]

Until recently, the Japanese Patent Office had provided two mechanisms for challenging issued patents through a post-grant opposition system and a trial for invalidation system. The two mechanisms have now been merged into a single trial for invalidation procedure in the JPO that provides opportunities for third parties to administratively challenge issued patents.

Table 8.1 presents a comparative assessment of the patent invalidation procedures adopted by the JPO and the 'abuse of patent right' process in the Japanese District Courts by summarizing both key differences and similarities.

The JPO trial for invalidation is a relatively low-cost process. The Japan Patent Attorneys Association's survey in 2003 reported an average cost of ¥377,534 (about $3500) on a per claim basis for a JPO invalidation trial with

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[40] Ibid., 116–17.

Table 8.1 A comparison of patent invalidation procedures in the Japanese Patent Office (JPO) and the district courts in Japan

	Trial for Invalidation in JPO	'Abuse of Patent Right' in District Court
Who Can Raise Invalidation Claims	Anyone and at anytime	Only in an infringement action or declaratory judgment action
Grounds for Invalidation	JPO seen to be better at dealing with patentability standards that are familiar to them	All grounds available
Standard for Invalidation	Basic patentability standards	The invalidation standard may be theoretically higher requiring 'obvious invalidity', but practically, the standard may not be very different from the JPO
Cost of Invalidation Process	Relatively low	Significantly higher
Duration for Invalidation Process	About one year	About 15–16 months, but the time period is diminishing
Evidence Considered	Evidence presented by the parties, but Trial Examiner can uncover their own evidence by conducting own search	What is presented by the parties
Effect of Judgment	Judgment is effective against the public at large, and the scope of protection can be made narrower by issuing newer claims	Judgment binding on the parties only, and narrower claims are not issued by the court
Decision-Maker	3 Trial Examiner panel or 5 Trial Examiner panel	District Court Judge with Technical Assistants
Appeal of Judgment	Can appeal to the High Court	Can appeal to the High Court
Damages	Cannot award damages	Can award damages

over 75% of those responding to the survey reporting an average fee in the range ¥360,000–¥420,000. One can get some insight into what a patent trial is likely to cost in Japan based on the Civil Litigation Lawyers' Fees Guidelines that are put forth by the Japan Federation of Bar Associations (Nichibenren). The guidelines suggest that if the plaintiff's demand for damages is in the ¥30–300 million range, then the starting fee is [3% + ¥690,000] and the success fee is [6% + ¥1,380,000], which amounts to about $325,000 in lawyers' fees for a successful patent lawsuit involving about $3,000,000 in damages. In sum, the typical cost for a patent trial in court can be as much as a hundred times more expensive than a trial for invalidation in the JPO.[41]

The JPO trial for invalidation is open to anyone at anytime; a court process only comes about in the context of an infringement trial or a declaratory judgment action. With respect to the grounds for challenging an issued patent, there is much greater confidence in the JPO's ability to handle issues relating to patentability such as novelty, lack of inventive step, and industrial applicability – matters routinely dealt with by patent examiners – as opposed to other invalidations involving forms of evidence different from prior art patents or publications. In addition, the JPO panel is not limited to evidence presented to it by the parties, as the trial examiners may conduct their own prior art search if they deem it necessary. Hence, the trial for invalidation in the JPO, which is a significantly lower cost process, is favored by third parties, especially if their validity challenges are based on lack of novelty or obviousness.

The duration of a typical patent trial in Japan is currently about fifteen to sixteen months, but the durations are decreasing and heading towards one year. Therefore, these times are comparable to the one year duration for an invalidation trial in the JPO. Thus, in the more recent past, the Japanese courts have had the benefit of rulings on validity by the JPO prior to their own consideration of patent validity in the same dispute.

There are also other procedural differences, such as the effect of the judgment being different in the two cases because the court decision is binding on only the parties, whereas patent invalidation in the JPO is effective against the public at large. In addition, the decision-maker in the JPO may be a panel of trial examiners instead of a single district court judge. The district court judge is assisted in his evaluations by a technical assistant who is typically a former trial examiner in the JPO and who has been sent to the courts by the JPO for a period of about three years. This practice does not appear to pose any separation of powers concerns in Japan since the distinction between public servants and private attorneys in Japan seems to be more important than any institutional

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41 Ibid., 119.

separation between the governmental agencies and the courts. Finally, judgments from both the JPO and the district court can be appealed to the High Court for appellate review.

There is apparently no JPO mechanism in place to prevent repeated filings of trials for invalidation by challengers wishing to simply present repeated claims in the hope of successfully invalidating one or more claims in a patent. In the future, it may be worthwhile to consider mechanisms or schemes to create an incentive for a challenger to present all his claims in one trial for invalidation and to avoid repeated challenges based on 'new' prior art that is merely cumulative compared to what was presented in an earlier challenge.

Tables 8.2 and 8.3 summarize the empirical data resulting from the dual invalidation system in the JPO and the district courts between April 2000 and November 2003.

The empirical data since April 2000 show that in 69% of all patent lawsuits in district court, invalidity was an issue raised in either the JPO or the district court or in both forums. Of this 69%, patent invalidation was raised in only 7% of the cases at the district court level. Therefore, in about 90% of all cases involving patent invalidity, a trial for invalidation was initiated in the JPO. In addition, in about 48% of all cases involving patent invalidity claims, the invalidity issues were presented to both the JPO and the district court. As noted above, in only about 10% of all the cases involving patent invalidity was the invalidation challenge presented exclusively to the district court. These data demonstrate that even with the more recent possibility of court invalidation challenges, the JPO trial for invalidation is seen to be a reliable and efficient way to challenge patents in Japan.[42]

Looking at the consistency in outcomes when the same patents are challenged in both the JPO and the district court over a three year period from April 2000 to November 2003, in the vast majority of cases (about 80%), both the JPO and the district court are in agreement. In about 19.7% of the cases,

Table 8.2 The different categories of actions taken in 270 district court patent cases with respect to invalidation trials in the JPO from April 2000 to November 2003

31% (84 cases)	Infringement action only in District Court
33%	Invalidation Trial in JPO and 'Abuse of Patent Right' claim in District Court
29%	Invalidation Trial only in JPO
7%	'Abuse of Patent Right' only in District Court

[42] Ibid., 120.

Table 8.3 Comparison of 71 JPO and district court decisions regarding patent invalidity from April 2000 to November 2003

		District Court	
		Valid	Invalid
JPO	Valid	18	5
	Invalid	9	39

the JPO and the district court reached different outcomes regarding the validity of the same patent claims. While this difference of opinion may be significant, both decisions can be appealed to the High Court, and hence, the two outcomes can be reconciled at the appellate level. In addition, this difference of opinion is roughly comparable to the percentage of reversals of the JPO in appeals to the High Court (20% to 18% respectively). In short, the different outcomes in about 20% of the cases are understandable and may be attributable to the structural and institutional differences between the Patent Office and a district court in examining the evidence presented. This result also suggests that both institutions are acting quite prudently in resolving patent validity issues.[43]

There is much to be learned from the details of the two patent invalidation processes and from the empirical data presented above. The dual track invalidation system in Japan involving both the JPO and the district courts demonstrates that the two invalidation schemes are complementary and serve to increase the number of issued patents that are challenged by third parties. The specific differences between the two invalidation options that are described above indicate that while in the vast majority of cases a patent may be challenged in both venues there are still sound economic and institutional reasons for maintaining or creating a patent system with the ability to raise patent validity challenges in both the Patent Office and in the courts.

5 Conclusion

The key challenge posed by the patent system continues to remain much the same – how do we reward inventors by granting patent rights commensurate with their innovation? There is significant concern that the PTO grants many overly broad patents because of its inability to accurately determine the scope of information that is already in the public domain or is the subject of other patents. The current patent system permits improvidently granted patents to

[43] Ibid., 120–21.

survive in the marketplace and such patents impose significant social costs. Parties (e.g. alleged infringers and defendants) who are in the best position to challenge an improvidently granted patent in the courts are concerned about private costs, not social costs, so many 'bad' patents go unchallenged in court. Furthermore, prospective challengers to a 'bad' patent often limit their litigation expenses by choosing to settle a case rather than go to trial. This hypothesis is backed by empirical data demonstrating that litigation expenses are low because the vast majority of cases terminate in a settlement. Patent litigation is a settlement mechanism whereby parties sue first, but usually settle their disputes without a trial. Consequently, there are very few rulings on infringement, invalidity, or unenforceability of issued patents. Our current patent system allows 'bad' patents to survive in the market, and the patent system should not rely on just the courts to marshal against low quality patents.

An inter-partes opposition system may increase patent challenges. Designing such a system would increase the likelihood of patent challenges by knowledgeable parties by capturing localized knowledge that would not otherwise be available to the PTO or the courts. Such an opposition system should be low cost, should involve administrative opposition judges in a post-grant system, and should include a limited estoppel effect to disincentivize delay and harassment through repeat filings. The dual invalidation system in Japan shows that patent oppositions and patent litigation in the courts are both complementary and necessary.

9 Trilateral cooperation[1] – mutual exploitation of search and examination results among patent offices with a view to establishing a system of rationalized work-sharing[2]

Shinjiro Ono[3]

Introduction

Each of the Trilateral Offices – USPTO, EPO, and JPO – has been hosting and taking part in annual Trilateral Conferences since 1983 to pursue a cooperative and collaborative approach to solving challenges and issues which each of the offices face in common. Towards the end of the last century, a shared challenge was to establish a 'paperless patent office'. The beginning of the current century has seen an increasing focus on efforts to employ work-sharing with a view to reducing the ever increasing workload brought about by the growth of global patent applications.

Historical background[4]

In the early 1980s, the Trilateral Offices were faced with a dramatic rise in the number of patent application filings. The Japan Patent Office (JPO) received more than 410,000 patent and utility model applications in 1982, which amounted to a 15% annual increase in the number of applications filed. As a result, the JPO projected that unless action was taken, the application examination period would increase from two to seven years, while its archive of 28 million paper documents would expand to 50 million within a decade. Kazuo Wakasugi, then Commissioner of the JPO, later acknowledged that these

[1] The Trilateral Cooperation, the website of the Trilateral Cooperation (2007), at http://www.trilateral.net.

[2] Shinjiro Ono, *Cooperation the Key to Reducing Pendency Times*, INTELLECTUAL ASSET MANAGEMENT MAGAZINE (August/September 2006), at 11.

[3] Shinjiro Ono, INTERVIEWS FOR THE FUTURE 301–6 (European Patent Office, 2006).

[4] Press Release, European Patent Office, '20 Years of Co-operation Between the European-Patent Office and the Patent Offices of the USA and Japan' (2002), at http://www.epo.org/about-us/press/releases/archive/2002/04112002.html.

projections clearly spelled out the future collapse of the entire patent administration system, which at that time was based solely on paper.

Similar issues also confronted the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO). In 1981, the USPTO faced a situation wherein the annual number of patent applications exceeded 100,000. To provide a visual perspective on the volume of paperwork involved, if stacked one on top of another this number of applications would reach a height greater than that of the Empire State Building. However, the issue extended far beyond that of a simple matter of handling a massive volume of paperwork.

In 1981–82, Gerald J. Mossinghoff, the USPTO Commissioner, inspired by a vision of a 'paperless patent office', initiated a series of meetings with Mr Wakasugi and with Mr Van Bentham, President of the EPO, to propose a cooperative approach to solving challenges faced in common by the respective patent offices. As a result of bilateral meetings, it was readily and rapidly understood that the respective patent offices shared the same problems and goals. Accordingly it was reasoned that, if huge amounts of investment were to be made in attaining patent office automation, any resulting systems for automation should be mutually compatible. The result was the creation of a unique and highly effective international cooperation framework: the Trilateral Cooperation. The First Trilateral Conference was held in Washington, DC in 1983. Since then, each of the Trilateral Offices has hosted in turn two expert meetings, one of which is held together as a meeting of the heads of office. The foregoing ideas were expressed in the first Memorandum of Understanding. The meetings envisaged cooperation between the three offices in attaining automation, as well as document classification and indexing, the exchange of documents and electronic data, and a number of joint projects.

Apart from cooperation in automation, patent documentation, and dissemination of patent information, the Trilateral Offices have also cooperated in patent practice. At the first Trilateral Conference, participants were convinced that there existed compelling reasons to cooperate in harmonizing patent laws and procedures. As a result, a large number of projects relating to comparative studies of patent law and practice at the three offices have been carried out since the early stages of Trilateral Cooperation. In 2001, the Trilateral Offices decided to make efforts toward developing possible measures for reducing respective workloads at the Trilateral Meeting for Workload Reduction of Offices and Associated Costs in Tokyo.

Unprecedented protracted pendency and increasing patent application backlog

In fiscal year 2006, a record number of more than 440,000 patent applications

were filed at the USPTO, over and above an existing backlog of more than 700,000 applications awaiting issuance of a first office action. Since 2005, the average pendency has been in excess of 30 months. The JPO and EPO have confronted similar problems. The present crisis faced by the international patent system, with respect to protracted pendency and an increase in patent application backlogs, is unprecedented. Indeed, it has reached a point where it is questionable whether major patent offices will be able to maintain a substantive examination system that satisfies the requirements of applicants in terms of speed and quality, especially those applicants who seek global patent protection. Bruce Lehman, former commissioner of the USPTO, sees in the current situation alarming evidence of a looming crisis in the international patent system.[5]

The Trilateral Offices have implemented strategic plans for addressing their respective circumstances, such as 'The 21st Century Strategic Plan'[6] of the USPTO, the 'Strategic Program'[7] of the JPO, and 'Mastering the Workload' from the EPO. These strategic initiatives have in common a will to train and employ a far greater number of patent examiners, to improve productivity among examiners and other patent office officials, and to invest in equipment and resources for automation and documentation. While these efforts are important, each of the Trilateral Offices recognizes a need to act in a coordinated manner with increased cooperation in order to address and overcome the current workload problem. The concept of work-sharing among offices has already been incorporated into the respective strategic plans of the Trilateral Offices.

Duplication of search and examination

While many patent offices have experienced and continue to experience problems with pendency and backlogs, the Trilateral Offices are particularly affected. This is pressingly apparent when one considers that more than 75% of global patent applications were filed at these offices in 2005. Interestingly however, among the total number of patent applications filed at the Trilateral

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[5] See Bruce Lehman, *Tackling the Shadow Over the International Patent System*, INTELLECTUAL ASSET MANAGEMENT MAGAZINE (August/September 2006), at 8; Ciaran McGinley, *A European Perspective on Global Patent Workload*, INTELLECTUAL ASSET MANAGEMENT MAGAZINE (April/May 2007), at 9. European Patent Office, SCENARIOS FOR THE FUTURE (2007).

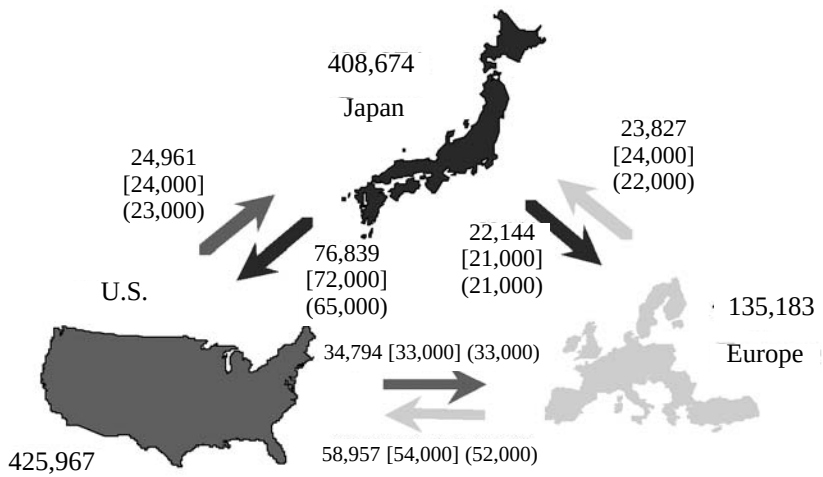
[6] United States Patent and Trademark Office, 'The 21st Century Strategic Plan – Revised' (February 3, 2003), at http://www.uspto.gov/web/offices/com/strat21/stratplan_03feb2003.pdf.

[7] Japanese Patent Office, 'IP Strategic Program 2003–2006' (last visited November 3, 2007), at http://www.ipr.go.jp.

Offices, about 230,000 of these were filed at a minimum of two of the three offices. This indicates the existence of a large number of duplicate applications within the three offices. In total, duplicate patent applications among the Trilateral Offices represent nearly 26% of all applications that these offices received. Taking the USPTO as an example, about 50% of all applications filed at the USPTO were filed at another patent office initially. Furthermore, in 2005, about half of all foreign applications, totaling around 90,000 applications, originated in countries whose official language is not English, such as Japan, South Korea, and China (see Figure 9.1).

Pilot projects for testing mutual exploitation of search and examination results

The overlap in patent applications among the Trilateral Offices clearly presents an opportunity to establish mutual benefit through cooperation. In view of the workload challenges facing the Trilateral Offices, participants at the 20th Trilateral Conference in Vienna agreed to launch bilateral projects for testing the feasibility of Trilateral Cooperation through the establishment of a technical and procedural framework aimed primarily at sharing prior art search and examination results.



Note: Figures for 2006 appear without brackets; figures for 2005 appear in square brackets; figures for 2004 appear in parentheses.

Source: JPO Annual Report, USPTO Annual Report and EPO Annual Report 2004–2006.

Figure 9.1 Patent applications in Trilateral Offices

At the beginning of 2003, the Trilateral Offices commenced Paris-Route (international applications using the Paris Route) bilateral projects, EPO–JPO, EPO–USPTO and JPO–USPTO, in a step-by-step approach, with the emphasis on mutual exploitation of search and examination results. As a first step, 25 pending cases for each of two respective offices (a total of 50 cases) were selected and as a second step, 100 pending cases for each of two respective offices (in total, 200 cases) were selected. These bilateral projects were conducted in a similar manner to that established in the 1999 Paris-Route pilot concurrent search program, in which only 15 cases were selected, but on a larger scale in terms of the number and scope of technical fields. Each of the Trilateral Offices completed their evaluation of the bilateral pilot projects and reported their final results at the May 2004 Trilateral Meeting and Meeting of the Working Group on Strategic Issues and Work Sharing, which was held in September 2004 in Tokyo. The preliminary results reported at the 21st Trilateral Conference in Tokyo in 2003 were substantially the same as the final results. They were sufficient to conclude basic principles for following a new approach, consisting of *three pillars*. It is on this basis that the Trilateral Offices are pursuing their work further.

These test projects demonstrated that if an Office of First Filing (OFF) could provide search results to an Office of Second Filing (OSF) in a timely manner, the workload of the OSF would decrease, while the overall quality of patents would increase. The Trilateral Offices recognized that EPO and USPTO examiners are confronted with significant challenges in performing searches of Japanese language documents that do not have any corresponding patent family members in English. At that time, about 20% of Japanese domestic applications were filed internationally. Stated inversely, a total of around 80% of such applications were available only in Japanese. In this context, conducting a text search is neither feasible nor reliable when searching English translations of entire documents, and such a text search is limited by practical constraints to searching only the English abstracts of such documents (Patent Abstracts of Japan).

Timing issue

Needless to say, to achieve these benefits it is necessary for the OFF to conduct a search in advance of the OSF commencing examination of the corresponding application. Unfortunately, the JPO's request for an examination system that allows applicants to defer patent examination for up to 3 years (prior to 2001, permissible deferment was up to a maximum of 7 years) severely limited the JPO's ability to send search results on to the other patent offices in a timely manner. Findings show that when the JPO was the OFF in the project, only a very small percentage of direct applications (international applications using the Paris Route) had received a prior art search from the

JPO in sufficient time upon commencement of examination in the OSF. Needless to say, this timing problem poses a major obstacle to effective Trilateral Cooperation.

One solution that has been proposed for solving the timing problem is to increase the number of Japanese applicants making use of the PCT Route, the rationale being that when the PCT Route is employed, a search report with an opinion is made available to the OSF at a far earlier date than would be the case had the application been filed directly. To this end, the JPO and Japan Intellectual Property Association (JIPA) have been taking steps to promote the use of the PCT system by Japanese applicants.

Their efforts have resulted in a significant increase (more than double) in Japanese applicants employing the PCT Route; the number rose from 11,700 in 2001 to more than 26,000 in 2006. However, further analysis suggests that, at most, only 50% of Japanese applicants filing internationally would ultimately make use of the PCT system, which is equivalent to approximately the percentage of applicants of major European countries who file applications at the USPTO by using the PCT Route. Therefore, as mentioned, a new approach consisting of three pillars has been developed to resolve the workload issues. The second pillar is directed specifically to this timing issue with special regard for Paris-Route applications (see Figure 9.2).

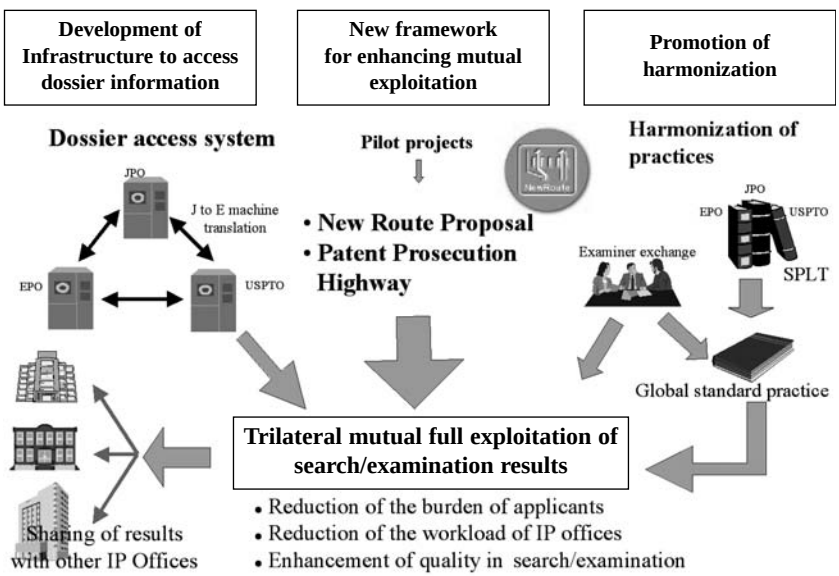


Figure 9.2 Trilateral efforts for mutual exploitation

Pillar one: development of dossier access system with machine translation

The first pillar is the development of an infrastructure used for accessing dossier information of patent applications at the JPO. A dossier access system is an online file-wrapper inspection system that enables each office to obtain examination documents such as office actions issued by other offices. In this regard, the USPTO and EPO provide public web services called PAIR and Epoline file inspection, respectively. In October 2004, the JPO launched its own publicly available Dossier Access System called Advanced Industrial Property Network (AIPN).

The AIPN serves the same functions as PAIR or Epoline, but with one crucial difference; the AIPN also provides machine translation of all dossier documents. Since the JPO employs Japanese as its official working language, it is necessary to translate the contents of a file history, such as the reason for rejection, into English for use by other offices. Thus, the JPO incorporated a machine translation system, already in use in the Intellectual Property Digital Library (IPDL), which provides translations of Japanese patent documents into English. Additionally, the Trilateral Offices are cooperating to improve the functionality of AIPN. These improvements include increasing the quality of translations by creating and improving technology-specific dictionaries and optimizing a system of feedback usable by examiners at the EPO and the USPTO. Such efforts culminated in the launch of an upgraded version of AIPN in March 2006, which has an interface common to that in use at the USPTO and the EPO. Using this common interface, the Trilateral Offices are now able to share data with each other at an unprecedented level.

The success of the machine translation and common interface components of the JPO's new-generation Dossier Access System has sparked interest in its application at other patent offices. For instance, the JPO is working with the Korean Intellectual Property Office (KIPO) to develop a similar Dossier Access System, with a view to sharing and utilizing search/examination results with the Trilateral Offices. Further, the JPO and KIPO have begun sharing information concerning their Dossier Access Systems with China's State Intellectual Property Office (SIPO), also with a view to the future inclusion of SIPO in a similar sharing scheme.

Pillar two: new framework to address the timing issues for enhancing sharing and utilization

At the 19th Trilateral Conference in San Francisco 2001, the Trilateral Offices agreed to create two working groups: one group to focus on medium/long-term strategic issues relating to achieving a reduction in office workloads, and another group to explore possible technical solutions to the workload problems, such as automation, networking, electronic filing, and so on. With

respect to the issue of the new framework, the USPTO and JPO have been taking the initiative, since Japanese applicants file the largest number of applications at the USPTO (72,000 applications in 2005) as non-resident applicants. Moreover, major Japanese applicants in the IT industry tend to employ the Paris Route rather than the PCT Route. Consequently, between the respective offices the issue of timing is of critical importance.

On March 30, 2006, the United States Department of Commerce (DOC) and Japan's Ministry of Economy, Trade and Industry (METI) issued a joint DOC–METI Initiative for Enhanced US–Japan Cooperation on IPR Protection and Enforcement.[8] This joint initiative includes two measures for establishing an effective mechanism to address the timing issue: (1) a Patent Prosecution Highway and (2) a New Legal Framework.

Patent Prosecution Highway (PPH) pilot program

The USPTO and JPO jointly announced the PPH pilot program at the May 22–4, 2006 Trilateral technical meeting held in Japan.[9] The PPH pilot program for applications based on Paris-Route filings began on July 3, 2006, and will last for a period of one year. The PPH pilot program permits an applicant whose claims are determined to be allowable/patentable in the OFF to have the corresponding application advanced ahead of other applications in the OSF, while at the same time allowing the OSF to exploit the search and examination results of the OFF. This scheme also provides Japanese applicants with an added incentive to file a request for examination at a relatively early date, because accelerated examination under PPH will require filing of a statement of correspondence of claims, as opposed to a detailed discussion of how a claimed subject matter is patentable over cited references, as is currently required (see Figure 9.3).

The original notice of the PPH at the USPTO requested an applicant to submit a copy of all office actions from each JPO application containing allowable/patentable claims that serve as the basis for a request, along with an English translation thereof and a statement that the English translation is accurate. The USPTO announced on July 3, 2007, that it will not be necessary for

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[8] Press Release, United States Department of Commerce, 'The U.S. Department of Commerce and Japan's Ministry of Economy, Trade and Industry Announce a Joint Initiative for Enhanced Cooperation on IPR and Other Issues' (March 30, 2006), at http://www.commerce.gov/opa/press/Secretary_Gutierrez/2006_Releases/March/30_DOC-METI-Initiative_FINAL.htm.

[9] United States Department of Commerce, 'Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Japan Patent Office' (last visited Nov. 3, 2007), at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/pph_pp.pdf

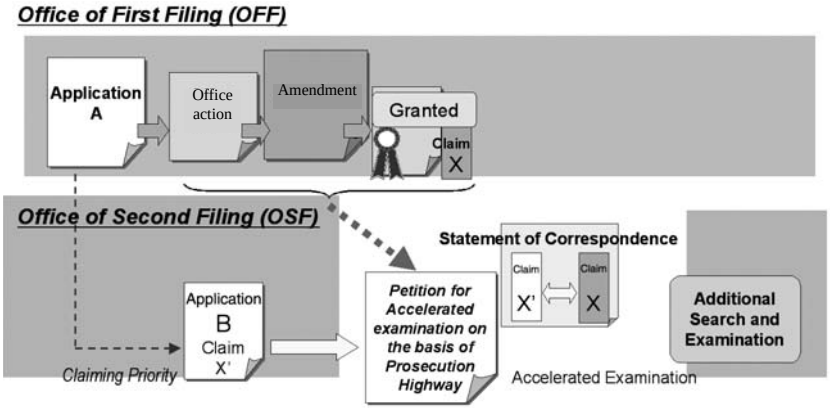

Figure 9.3 Patent prosecution highway (PPH) flow chart

an applicant to submit a copy of the 'Decision to Grant a Patent', an English translation thereof and a statement that the translation is accurate. Rather, the USPTO will obtain a copy of the 'Decision to Grant a Patent' along with a machine translation into English via the Dossier Access System.[10] This revised requirement was made effective immediately on the same day as issuance of notice of the revised requirement.

The requirements of the PPH pilot program, modified on June 12, 2007, are designed to permit certain applications based on PCT filings to qualify for participation in the PPH pilot program. In view of this recent modification, the USPTO and JPO decided to extend the pilot program for an additional 6 months to January 3, 2008.[11] Each office will evaluate the results of the pilot program at the end of the 6 month period to determine whether and how the program should be fully implemented.

According to the JPO[12] with respect to the result of the pilot program from July 3, 2006 to January 3, 2008, the number of applications filed at the JPO by

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[10] United States Patent and Trademark Office, *Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO* 1319 OFF.GAZ.PAT.OFFICE 63 (June 12, 2007).

[11] United States Patent and Trademark Office, 'Extension of the Patent Prosecution Highway Pilot Program between the USPTO and the JPO' (last visited November 3, 2007), at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/pphextension.pdf.

[12] Yukari Terakawa Yukari, Patent Prosecution Highway Program, the Whole New Approaches – The Outline of PPH and Result of the Pilot Program between the JPO and the USPTO, PATENT, 61/2 (February 2008), at 26.

foreign applicants, such as Microsoft, IBM, GE, ASML Netherlands and BOSE (in total 42 applicants), was 189. The corresponding number of applications filed at the JPO by domestic applicants, such as Canon, Matushita Electonic Industry Co., Toshiba, Seiko Epson and Denso (in total 60 applicants), was 276. Pendency for a first action is about 2–3 months from the date of request. (In normal cases, a first action is issued about 26 months from the date of filing of request for examination.) The allowance rate of applications filed at the JPO by foreign applicants was about 64%, which was higher than that of total applications disposed in 2006 (49%). The USPTO and the JPO has implemented the PPH on a full-time basis, beginning January 4, 2008.[13]

The Director of USPTO, Jon Dudas, said, 'The pilot program shows that the PPH offers significant potential for our offices to make inroads in reducing our backlogs, eliminating redundant work, and examining more efficiently'. He further emphasized, 'Implementation of the PPH is an important first step in building up the office to office network of cooperation that will be necessary to make the full vision of work sharing on a global scale reality'.

Implementation of the PPH is a cornerstone of the January 2007 cooperation initiative between the DOC and the MIETI on enhanced intellectual property rights protection. The initiative calls for the USPTO and the JPO to demonstrate leadership by taking a proactive approach to streamlining practices and procedures under the international patent system to promote expeditious, inexpensive and high-quality patent protection throughout the world.

Even though the EPO has not yet participated in the pilot program, the Trilateral Offices continue to evaluate the current status of the pilot program and to consider opinions from users and modification of the PPH framework for improvement. In addition, the Trilateral Offices are considering implementing the PPH in cooperation with patent offices outside the trilateral framework. The JPO started a pilot PPH program with the KIPO in April 2007[14] and with the United Kingdom Intellectual Property Office (UK IPO) in July 2007.[15] In September, 2007, the USPTO also started a pilot program with the UK IPO for a period of 1 year.[16] The Director of the USPTO, Jon Dudas said, 'This pilot project with the UK IPO builds on our work with the JPO and

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[13] Press Release, 'USPTO and JPO to Implement Patent Prosecution Highway on Full-time Basis, at http://www.uspto.gov/web/offices/com/speeches/07-50.htm.

[14] Japanese Patent Office, 'Patent Prosecution Highway' (last visited November 3, 2007) at http://www.jpo.go.jp/cgi/link.cgi?url=/torikumi/t_torikumi/patent_highway.htm.

[15] UK Intellectual Property Office, 'Patent Prosecution Highway' (last visited November 3, 2007) at http://www.ipo.gov.uk/patent/p-applying/p-after/p-after-pph. htm.

[16] Press Release, United States Patent and Trademark Office, 'USPTO and United Kingdom Intellectual Property Office to Pilot Patent Prosecution Highway' (Sepember 4, 2007), at http://www.uspto.gov/web/offices/com/speeches/07-37.htm.

contributes to a more rational international patent system'. In January, 2008, the USPTO expanded the PPH Network to Canadian and Korean Patent Offices.[17] The JPO will expand the PPH Network to the German Patent and Trademark Office (GPTO) as of March, 2008.[18]

Establishing a new legal framework

There have been three proposals put forward to address the establishment of a new legal framework that would take international cooperation well beyond the PPH; two by the USPTO and one by the JPO. While the USPTO proposal is still at an early stage of development, the JPO proposal presents a detailed and significant new route for filing patent applications internationally.

New route proposal The proposed 'New Route' for applications filed abroad is an innovative framework within which search and examination results of the OFF are transmitted to the OSF in accordance with an internationally coordinated timeframe. Under this new framework, comprehensive effective mutual exploitation of an application should be achievable.

The following are the basic concepts of the New Route: (see Figure 9.4)

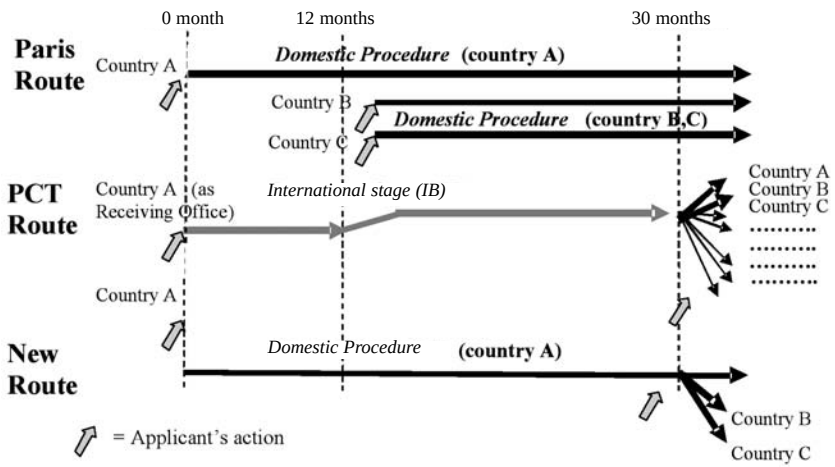

Figure 9.4 Comparison between Paris, PCT and proposed new patent filing route

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[17] Press Release, 'USPTO Expands Patent Prosecution Highway Network to Canadian, Korean Patent Offices: Trial projects will promote efficiency, higher quality', at http://www.uspto.gov/web/offices/com/speeches/08-04.htm.

[18] PPH pilot program between the JPO and the GPTO, at http://www.jpo.go.jp/rireki/index.htm.

(i) An application filed with the OFF through the New Route is deemed to have been filed with the OSF on the filing date in the OFF. A New Route application filed with the OFF has the same status as a regular domestic application in the OSF ('One application').
(ii) Once a New Route application is filed, the national/regional search and examination by OFF is conducted as a first step. No redundancy exists in the international-phase examination and the national/regional-phase examination. (Unlike the PCT, the New Route does not distinguish between the international phase and the national/regional phase.)
(iii) The time limit for an applicant to submit a translation is 30 months from the filing date/priority date. Further, the search and examination result made by the OFF is issued well in advance of the 30-month deadline, so that the applicant can fully examine the necessity of continuing/discontinuing prosecution in the OSF ('30-month moratorium').

The New Route is designed to be a multilateral framework established by an agreement among a number of countries, and is intended to complement currently available filing routes. It can be said that this new route is a combination of the best parts of both the Paris Route and the PCT Route. While the New Route is in many respects similar to the PCT, it may further offer significant advantages to applicants; in particular, lower costs and more targeted filings. Bearing in mind the EPO's reservations, the Trilateral Offices continue to discuss the JPO proposal while recognizing the importance of constructively exploring other options for users. The Japanese IT and automobile industries, which file the majority of global applications originating in Japan at the USPTO, do not employ the PCT route to the same extent as either the chemical industry or the pharmaceutical industry. At the Trilateral Expert Meeting in Alexandria in May 2007, the USPTO and JPO agreed to commence a proposed analogous New Route Pilot Project designed to evaluate the merits of the New Route framework based on the two filing scenarios currently available under existing law (PCT) in both offices, since the New Route framework, as envisioned, would require changes in law in the USPTO.[19] The two filing scenarios eligible to participate in the New Route Pilot Project are:

(1) A priority application is filed with the first office and a PCT application claiming priority to that application is filed with the same first office as

[19] Twenty-fifth Trilateral Conference – Washington, November 7, 2007, 'Summary of the 25th Trilateral Conference Alexandria, Virginia' (November 9, 2007), at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/new_route_pilot_012008.pdf.

the PCT receiving office; if the search and examination results of the priority application are available within about 26 months from its filing date and the corresponding PCT application enters the national stage in the second office, that national stage application would be eligible to participate in the New Route Pilot Project.

(2) A PCT application is filed with the PCT receiving office of the first office (there is no priority application), then the PCT application enters the national stage early in the first office; if the search and examination results of the national stage application are available by about the 26th month from the international filing date, and the PCT application enters the national stage in the second office by the 30th month, that national stage application in the second office would be eligible to participate in the New Route Pilot Project.

The New Route Pilot Project commenced in both offices on January 28, 2008.[20] It will be terminated once 50 applications have been accepted into the pilot project by each office as the OSF or after the expiration of one year (January 28, 2009), whichever occurs first.

Tri-way proposal The USPTO introduced a trilateral search sharing project at the 23rd Trilateral Conference in Munich in 2005, by which the Trilateral Offices will conduct, upon request by an applicant, sequential but closely timed, complementary searches focusing on respectively available documentation. The Trilateral Offices confirmed that the USPTO's proposal would be a useful option for those applicants who wish to obtain high quality search results. Discussion of the Triway continues, particularly from the viewpoint of a reduction of workloads, as well as meeting users' needs.

Strategic handling of applications for rapid examination (SHARE) At the 24th Trilateral Conference in Tokyo in 2006, the USPTO introduced a new work-sharing concept for consideration and discussion in which offices would focus on first-filed applications and take up second-filed applications only when search/examination information is available from the OFF. The 24th Trilateral Conference also decided to set up a 'Working Group on Enhanced Work-Sharing', which will undertake initiatives to further develop sharing and utilization of search and examination results performed by other offices, to the maximum extent possible. They continue to discuss SHARE at the Working Group as well as at the Trilateral Conference.

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[20] New Route Pilot Project between the United States Patent and Trademark Office and the Japan Patent Office, at http://www.uspto.gov/web/offices/pac.dapp/opla/preognotice/new_route_ pilot_012008.pdf.

At the 25th Trilateral Conference in Alexandria in 2007, it was decided to investigate the feasibility of each office of first filing with the intention of coordinating a pilot project beginning in April 2008. In this regard, the JPO introduced a concept of the JP-First (JP-Fast Information Release Strategy). The JPO prioritizes examination of applications, which were filed at the JPO and later filed at the foreign Patent Offices with Japanese priority. Such first filing applications filed after April 1, 2006 with 'examination request within two years' are automatically eligible for the JP-First. (It is not necessary for applicants to take any action.) The JPO intends to commence examination (first action), in principle, within 6 months from (a) the date of filing of a request for examination or (b) the publication of an application, whichever is the latest and not later than 30 months from the filing date. In other words, the second office can receive the result of first action within 18 months from the date of filing at the latest, which is usually in time to commence examination at the second office if the applicant enjoyed a 12-month priority period of the Paris Convention. The JPO will implement the JP-First as of April 1, 2008.

The USPTO and EPO welcomed the JPO's initiative to implement its approach for prioritizing first filed applications. The Trilateral Offices also have a consensus that cooperation of users is indispensable for proceeding with the Trilateral examination work-sharing.

Pillar three: harmonization of patent laws and practices

Urgent need for harmonization of substantive patent law

The effectiveness of work-sharing is limited by differences in national laws and practice. Thus, even though one office may have searched and examined an application, current differences in the international patent system may give rise to circumstances such that one office may consider a document to be relevant as prior art while another office does not. Harmonization of substantive patent law and practices is an urgent goal if there is to be comprehensive effective sharing and utilization of search and examination results among the various patent offices. For instance, the Examiner Exchange Program is already under way (see Figure 9.5), and is of prime importance in attaining harmonization of patent office practices, and developing mutual confidence in examination results provided by other offices.

Another aspect of the urgent need for harmonization of substantive patent law is that some provisions of national laws are considered to be stumbling blocks to resolving the timing problem. For example, US courts (under the Hilmar doctrine) and the provision of 35 USC §102(e) refuse to acknowledge unpublished prior art in a foreign language. This encourages foreign

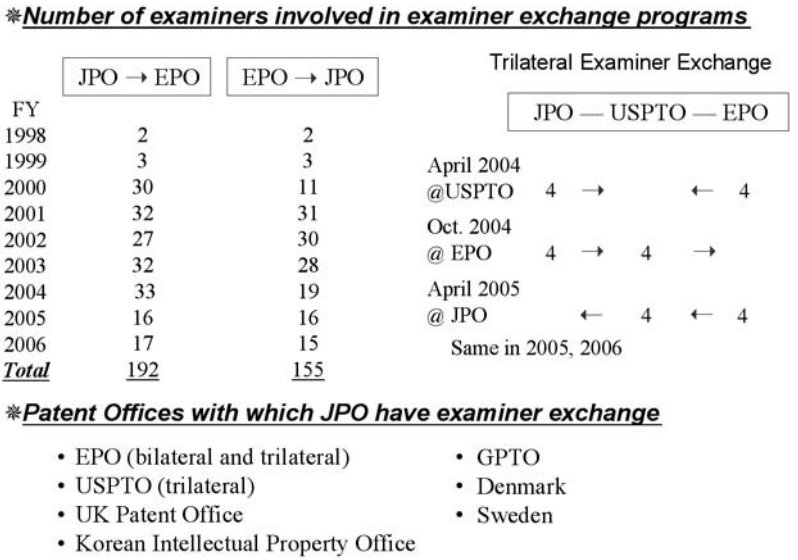


Figure 9.5 Examiner exchange with other patent offices

applicants to file an application as quickly as possible directly at the USPTO. About 20% of Japanese global applications for the USPTO are filed at the USPTO within 8 months from their priority date. To reiterate, this latter issue represents a major obstacle to effective use of the PCT Route by Japanese applicants who seek global patent protection.

Further efforts designed to tackle harmonization of substantive patent law have taken place under the auspices of the World Intellectual Property Organization (WIPO). In an effort to address existing inconsistencies in substantive patent law in the international arena, the US and Japan, on behalf of WIPO's B-Group, submitted a 'Reduced Package' proposal to the Standing Committee on Patent Law and the General Assembly in 2004. The Reduced Package proposal focuses on harmonizing four key areas of substantive patent law – (1) prior art, (2) grace period, (3) novelty, and (4) non-obviousness/inventive step. In other words, the four key areas are highly significant in reaching the objective of rational work-sharing. Unfortunately, the proposal has stalled at WIPO and no consensus has been reached on harmonization based on the Reduced Package. Since 2004, the Trilateral Offices and the EPO member States (Group B+) have been discussing the Reduced Package with a view to arriving at a mutually acceptable text.

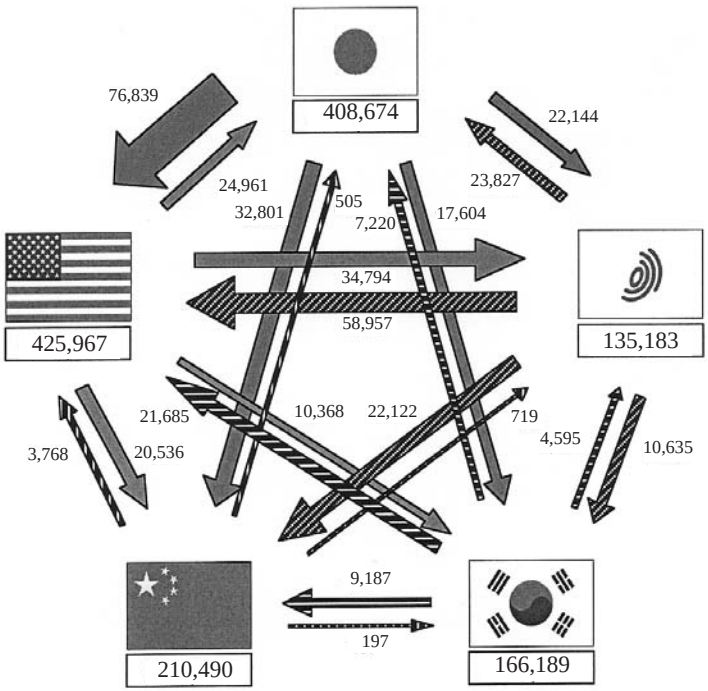
Standard Format Proposal by the Industry Trilateral Comprising the Union of Industrial and Employer's Confederation of Europe (UNICE), American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO) and Japan Intellectual Property Association (JIPA)

In 2005, the Industry Trilateral presented to the Trilateral Offices a suggestion that the offices streamline patent application format standards in such a way as to base them generally on the PCT format. In this way, an applicant would be able to prepare a single application that could be accepted at each office. The Trilateral Offices have reached a common understanding with respect to the draft Standard Format of patent applications in response to a request from users, after holding intensive discussions at three Working Group meetings in 2006. The Trilateral Offices confirmed that they would implement the related pilot project in 2007 in cooperation with users. The Standard Format approach will make patent filing at each of the Trilateral Offices easier, and will improve efficiency not only for patent applicants but also for the Trilateral Offices.

Conclusion

No patent office alone can cope with this crisis, and only international cooperation among the various patent offices with a view to rational work-sharing will provide a resolution. Coupled with the currently stalled negotiations at WIPO and the increasing difficulty in obtaining a consensus with developing nations regarding patent law reforms, it is imperative that the USPTO, JPO and EPO lead the way in developing a multilateral approach to the pending patent office crisis. These three patent offices are in the best position to take the initiative to explore and pursue ambitious solutions with the guidance and support of a majority of users of the patent systems in each of these countries. The heads of the five largest IP offices in the world, which are the USPTO, EPO, JPO, KIPO and SIPO gathered in Hawaii in May 2007 to discuss ways in which the offices could further cooperate to improve efficiency and quality so as to keep pace with the rising tide of global patent filings (see Figure 9.6).

The discussion focused on future opportunities for cooperation to deal with the demands stemming from the increasing globalization of patent protection. The WIPO estimated that between 1985 and 2004 the number of patent applications filed worldwide grew from 884,400 to nearly 1.6 million. The WIPO report further noted that between 1994 and 2004, filings for the KIPO increased by 488%, while those for the SIPO increased by a staggering 643%. Such growth has made cooperation with those countries a priority. The five offices together receive about 75% of all patent applications filed worldwide. The offices agreed to share experiences and the results of



(In 2006)

from \ to	Country/Region where applications were filed				
	Japan	United States	Europe	China	South Korea
Nationality of applicants: Japan	347,060	76,839	22,144	32,801	17,604
United States	24,961	221,784	34,794	20,536	10,368
Europe	23,827	58,957	65,606	22,122	10,635
China	505	3,768	719	122,318	197
South Korea	7,220	21,685	4,595	9,187	125,476

Source: Excerpt from JPO Annual Reports 2008, p. 21.

Figure 9.6 Patent applications filed mutually among the Trilateral Offices, South Korea and China in 2006

Trilateral Cooperation with the KIPO and SIPO and to continue to discuss further cooperation. The foregoing meeting is exemplary of future expansion of Trilateral Cooperation to other offices.

10 'Lost in translation': the legal impact of patent translation errors on claim scope

Donald S. Chisum and Stacey J. Farmer

True art selects and paraphrases, but seldom gives a verbatim translation.
(Thomas Bailey Aldrich, American Poet (1836–1907))

Introduction

For an inventor who has just conceived of a groundbreaking invention, having the potential to impact global markets on a *grand* scale, surely a visit to the patent office ranks high on the 'to-do' list. The inventor will certainly endeavor to fully capture the inventive concept in a well-drafted patent application. Suppose following the grant of the patent in the inventor's most prized foreign market, the inventor realizes that the relevant patent specification contains a fatal translation error, an error so significant that it reduces the scope of the originally disclosed and claimed invention to an utterly meaningless conception.

Unfortunately, this situation occurs with some frequency as a patent application travels across borders between the different national and regional patent offices. An inventor may thus receive vastly different scopes of protection for patents granted in individual countries for the same inventive concept, not necessarily because these patent offices granted the patents under differing patentability criteria – but because the translated patent specification happened to include one or more translation errors that unduly narrowed the patent scope despite all due care exercised by the translator. In other words, the inventive concept became 'lost in translation'.[1]

Alternatively, and probably less common, a translation error may result in a patent claiming a *broader* scope than any of its counterparts to thereby confer more protection than is appropriate, which could lead to partial or complete patent invalidity because the translated specification had subject-matter extending beyond the application as filed (or beyond that described in

[1] The title of this chapter is borrowed from the 2003 motion picture, filmed in Tokyo, Japan. It featured comic actor Bill Murray. Its director and screen writer, Sofia Coppola, received an Oscar award for best original screen play. *See* www.lost-in-translation.com.

a related priority document). Of course, this sort of error could also result in a patent application being refused before a patent grant is even realized.

Before we begin our discussion on the potential impact of translation errors, we must first ask: What is actually meant by the term 'translation'? The translation process foundationally involves interpreting the meaning of a text in a first language (a 'source' text) and producing a new text in a second language (a 'target' text), with the goal of providing two different texts that individually convey the same meaning. This process should ideally involve extrinsic consideration of any cultural, grammatical, and contextual differences that could otherwise make a direct one-to-one correspondence inaccurate or even nonsensical. Therein lies the distinction between an act of *translation*, whereby words are mechanically transferred from one language to another, and the act of *interpretation*, which takes account of other important communication aspects, such as oral inflections or bodily gestures, so that the complete, original meaning of the source text into the target text can be achieved. Only with correct interpretation will the true meaning of the source text translation be accurately captured in the target text.

In drafting a patent application (as a source text), the inventor, through his or her patent attorney, can freely act as his or her own 'lexicographer' to define a known or alternative meaning for any word or phrase – though it may be unclear whether, in a particular application, the drafter has actually exercised this 'lexicographic license'.[2] Even if express definitions are clearly provided, the source text could pose many problems for a patent translator seeking to create a one-to-one target text. Such problems may include the use of idioms (or slang), misspellings, grammatical errors (e.g., sentence fragments, word order) and use of special technical jargon (e.g., flanked, operably engaged, chemically modified). Further complicating a translation effort, a single word can often produce vastly different impressions across cultural lines. For example, 'noodle' will likely be understood differently by a person situated in Italy, Germany, Japan and the United States. Even deceptively simple common words can present profound difficulties to a translator. For example, 'to go', 'to have', 'to play', and 'about'[3] can be effectively translated

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[2] The pitfalls of this practice are highlighted in Justice Rader's dissent in *Merck & Co. v. Teva Pharmaceuticals USA, Inc*., 395 F.3d 1364 (Fed. Cir. 2005) citing *Bell Atlantic Network Services v. Covad Communications Group, Inc*., 262 F.3d 1258, 1268 (Fed. Cir. 2001).

[3] See *Merck & Co. v. Teva Pharmaceuticals USA, Inc*., 395 F.3d 1364 (Fed. Cir. 2005). During *Markman* proceedings, the district court determined that the claim term 'about' had been specifically defined by the patentee in the specification as meaning 'exactly'. The Federal Circuit disagreed, finding that 'about' had not been clearly redefined in the specification and thus should be given its ordinary and accepted mean-

only taking into account the context where such words appear – given the enormous definitional possibilities of these words in isolation.

A source language text may also include expressions referring to concepts that simply do not exist in the target language. As an example, the French pronouns 'tu' and 'vous' are both translated into English as 'you'. However, this particular translation subtly alters an important meaning that is inherent in the French terms: 'vous' is used formally and respectfully to address a new acquaintance or an elder as 'you'. In contrast, 'tu' refers to an informal notion of you, that is, a use more appropriate among family members and close friends. An equivalent of 'tu' in English would be 'thou' – a term that is obsolete in the contemporary English language except for a few regional dialects still spoken in England and Scotland. A comparable translation issue exists in German, wherein the pronoun 'Sie' is used in a manner similar to the French pronoun 'vous' and the German pronoun 'du' mirrors the French pronoun 'tu'. Cultural and other grammatical subtleties associated with, for example, the use of formal versus informal pronouns are apt to be lost when a source text using these pronouns is translated into a target language devoid of an equivalent expression. In a broader sense, when interpreting language in any field, technical or not, it becomes clear that where such differences exist, important semantic nuances (e.g., social status, tone of a situation, levels of intimacy, emotional qualities, and the like) will necessarily become lost in translation.

In short, a translation may be inaccurate, not only because the translator made a simple grammatical error, but also because the translator failed to properly interpret a term in its proper context. We shall explore this theme in some detail, considering the daunting task of the translator who must precisely convert complex technical features forming the basis of an inventive concept from one language to another.

Patent systems worldwide require a patent applicant to specify the metes and bounds of his or her invention. The applicant must not only set forth a technical description of the invention, possibly with examples, but must also include a 'claim', a precise sentence with words and possibly other delimiters, like numbers and formulae, that set the boundaries of the invention as an 'intellectual property' right. (An example: 'I claim a square noodle . . . .'). The claims are analogous, but only roughly so, to a legal description of the extent of a real property right (a parcel of land). Unlike real property and other tangible property, whose boundaries can usually be measured and described with reasonable precision, it is a much more elusive task to define an invention's 'boundaries'. A patent specification will typically provide at least one broad independent claim and one or more associated dependent claims that limit the

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ing of 'approximately'. This conflicting interpretation ultimately led to the finding that the patent was invalid.

invention in a cascading fashion. (For example, 'The noodle of claim 1, wherein said noodle is about 5 cm in length' or 'The noodle of claim 1 or 2, wherein said noodle is selected from the group consisting of spaghetti, udon, and spaetzel'). In essence, the set of claims forms the legal definition of the inventive concept. The text, especially the claims, must withstand initial examination by patent office officials, who determine whether the invention is in fact patentable – and later scrutiny by judges, who determine the scope of the claims both for infringement purposes (i.e., has an accused 'infringer' trespassed on the property?) and for validity assessment purposes (i.e., do the claims, properly interpreted, provide a novel and unobvious distinction over prior art, and meet other legal requirements?).

Most patent systems provide some kind of safeguard designed to assure that an invention's substance is not 'lost in translation'. However, these safeguards are not always perfect and could fail to adequately prevent a loss of claim scope for an invention due to an unintentional translation error. The potential damage to claim scope as a result of a faulty translation can range from (1) a seemingly harmless (but legally significant) mistake in a transition phrase (i.e. 'comprising' becomes 'consisting of'[4]) to (2) the complete omission of a feature that is described as essential in one or more inventive embodiments.[5]

This chapter's discussion of the international patent system's 'lost in translation' problem is preliminary because, as will appear, the problem is complex and in need of further study and analysis from national, regional and global perspectives. But the discussion is based on a clear and simple foundational policy premise: a 'source' document containing the original disclosure of the invention represents the best attempt to capture what the inventor actually invented. Patent systems should endeavor, consistently with other values, such as clear notice to potential competitors of the scope of a patent right, to assure that the actual invention is not 'lost' or distorted because of the imprecise nature of the language translation process.

We also explore how three major patent systems (Europe, United States, and Japan) and the international patent application procedure (Patent Cooperation Treaty or 'PCT') cope with translation errors. Brief, but not

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[4] Because 'comprising' is afforded a broader meaning than 'consisting of', this type of error can produce drastic consequences in European practice – in the chemical field, 'consisting of A, B, and C' means that the presence of any other component is excluded and the total % of A, B, and C must add up to 100%; see EPO Technical Boards of Appeal decisions: T 759/91 and T 711/90.

[5] In Europe, such an omission can be lethal to a claim, which must contain *all essential features* of the invention. If patentability depends on a particularly described technical effect, then the claims must contain those features essential to achieve that technical effect; EPO decision: T 32/82.

exhaustive, comments are directed toward what remedies may be available to an inventor when a translation error unintentionally changes the scope or essence of his claimed invention. For the United States, we indulge in an excursion into a different but instructive patent language translation problem, to wit, whether the United States' 'duty of disclosure' requires an applicant to accurately describe non-English language prior art references, such as one in German or Japanese, to a (typically) mono-lingual US patent examiner.

Europe

The European Patent Convention, which was drafted in 1973 and entered into force in 1977 (the 'EPC 1973'), had only seven original Contracting States. Since then, numerous other European countries have acceded to the EPC, thereby introducing a variety of official state languages into the European patent system.[6]

The drafters of the EPC 1973 strove to adequately address the complex translation issues projected to arise during procedures relating to both acquisition and enforcement of the European patent. This task assumed paramount political importance, as public policy demanded that both individual and corporate interests alike should not be put at risk of infringement simply because European patent claims are published in a 'foreign' language.[7] The European patent system, as governed by the early provisions set forth in the EPC 1973, included a comprehensive, if not somewhat complicated, legal framework regulating translation issues throughout the filing, prosecution, grant, and post-grant procedures relating to the European patent.

Noting that the EPC 1973 could benefit from an update in view of the tremendous expansion in the number of EPC signatory states and the steady rise of European patent grants since the EPC's inception, the Administrative Council of the European Patent Organization initiated a major effort to revise the EPC. The aim of the revision was to modernize the European patent

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[6] The original Contracting States (from 7 October 1977) were: Belgium, Germany, France, Luxembourg, Netherlands, Switzerland and Great Britain. Presently, there are 34 Contracting States and four Extension States who are signatories to the EPC. As of 1 August 2008, the 34 Contracting States include: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom; the four Extension States include: Albania, Bosnia and Herzegovina, Former Yugoslav Republic of Macedonia, and Serbia and Montenegro.

[7] Of course, the assumption of the argument is in many instances dubious. How many Danish or Swedish engineers cannot understand an English technical document in their area of expertise? We submit very few.

system, while maintaining proven foundational principles of substantive and procedural patent law as enshrined in the EPC 1973. The revised EPC 1973 (the 'EPC 2000') was achieved by a delegation of the Contracting States, WIPO (World Intellectual Property Organization), and other parties participating in a Diplomatic Conference taking place at the Munich-based European Patent Office ('EPO') headquarters in November 2000. The EPC 2000 features several prominent revisions governing language and translation requirements, which may have a noticeable practical impact in situations where translation errors have occurred. For completeness, since the EPC 1973 remains applicable to all pending European applications and granted patents at the time the EPC 2000 entered into force (13 December 2007), this chapter will succinctly address the complex European translation issue bearing in mind both EPC versions where differences arise.

Before delving into the translation-related aspects of EPC grant and post-grant procedures, we provide two instructive 'lost in translation' examples to introduce the translation problem in Europe. First, we survey a translation issue appearing in the EPC itself (Article 69(1) EPC 1973). Second, we consider how a seemingly innocent mistake of a translator invoked mass protests and ignited a fierce public debate on the patenting of stem cell technologies that still lingers within Europe's borders.

The EPC (1973 and 2000 versions) is published in all three of the EPO official languages of English, French and German. Article 69 EPC, and its associated Protocol on Interpretation, dictates the extent of protection to be afforded to a European patent claim at the national level, particularly where such patent is involved in national infringement proceedings.[8] Article 69(1) EPC 1973 states that the 'extent of the protection conferred by a European patent or a European patent application shall be determined by the *terms* of the claims . . '[9] (emphasis added). This foundational EPC principle has been

[8] The Protocol to Article 69 EPC states: 'Article 69 is not determined by the strict and literal meaning of the wording used in the claims or that the claims serve only as a guideline (for interpretation) (but) as defining a position between these two extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties'. An aim of the Protocol is to avoid over-emphasizing the literal wording of the claims considered in isolation from the patent specification – and to avoid broadening the general inventive concept over the prior art which inevitably disregards the claims as a fair definition of the disclosed invention.

[9] Article 84 EPC (both versions) complements the wording of Article 69 EPC and provides: 'the claims shall define the matter for which protection is sought (and) shall be clear and concise and supported by the description'. Practically speaking, the expressions 'such as', 'preferably' and 'for example' have no meaningful limiting effect when used in the claim language, EPO Examination Guidelines (2007), C-III, 4.9. Likewise, claims including 'X for use with Y' will normally be construed as 'X

implemented into the national law of most EPC Contracting States through Article 8.3 of the Strasbourg Convention, which provides wording substantially similar to Article 69 EPC 1973. Ironically, the very guidance provided by Article 69(1), which tells us that the extent of protection is determined by the '*terms* of the claims' (English version), was, arguably, itself lost in translation. In the German and French versions of Article 69(1) EPC 1973, the translated equivalent of 'terms of the claims' is '*Inhalt* der Patentansprüche' and '*teneur* des revendications' respectively. Interestingly, both 'Inhalt' and 'teneur' suggest a broader interpretation to a multi-lingual reader that the surrounding content where a term appears must be considered, which could extend the more literal meaning given to an English 'term'. Since Article 177(1) EPC stipulates that all three official versions of the EPC (the English, French, and German text) are equally authentic, the legal guidance available to a reader trying to properly interpret the claims of a European patent could become 'lost' when consulting Article 69(1) EPC 1973. The drafters of the EPC 2000 revision, being keenly aware of this problem, amended Article 69(1) to simply recite: 'The extent of the protection conferred by a European patent . . . shall be determined by the claims', thereby dispensing entirely with the word 'terms' (and 'Inhalt', 'teneur') in the respective translations.

A second example highlighting the European translation problem involves the notorious 'Edinburgh' patent, and illustrates how a seemingly harmless translation oversight quickly captured the attention of not only Greenpeace, but several European governments. In this case, a patent claim involving a relatively straightforward term ('animal') became extremely lost in translation.

In 1999, the EPO granted patent EP 0695351 entitled 'Isolation, Selection and Propagation of Animal Transgenic Stem Cells' to the University of Edinburgh in Scotland. This invention initially claimed methods of isolating and/or enriching and/or selectively propagating *animal* stem cells, genetically modified *animal* cells and *animals* for use in these methods. Observers immediately noted that the granted patent claims (in English) could be reasonably construed to cover human cloning. Greenpeace and the governments of Germany, the Netherlands and Italy quickly lodged formal post-grant oppositions against this patent as violating a potent patentability exclusion under the EPC (in this case, the claims were contrary to 'ordre public' or morality under Article 53(a) EPC 1973). This error appeared because the translator of the

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(merely) suitable for use with Y' – 'Y' is not construed to be a limitation of 'X'. EPO Examination Guidelines (2007), C-III, 4.13. Whether these claim constructions simplify the translator's task is not clear; however, where such nuances are not completely captured in the target text, the meaning of any claim containing such phrasing could be undesirably altered.

patent claims (into the other two official EPO languages, French and German) failed to introduce a crucial qualifier to make clear that the granted patent was restricted to *non-human* animals. The wording of the offending claims (claims 47, 48) in the three official languages was as follows:

(*German*): 'Verfahren zur Herstellung eines transgenen ***Tieres***'
(*French*): 'Procédé de préparation d'un ***animal*** transgénique'
(*English*): 'A method of preparing a transgenic ***animal***'

To guide claim interpretation, the granted patent specification explained: 'In the context of this invention, the term "animal cell" is intended to embrace all animal cells, especially of mammalian species, including human cells' (at [0011]), thereby making it quite clear that the patentee intended for the claimed feature 'animal' to embrace *all animal cells* of the mammalian species, including human unipotential and pluripotential cells and embryonic stem cells derived therefrom (see e.g. [0012]).

Reasonable claim interpretation, at least in the English version of the patent, would lead a reader to fairly construe the patent scope as covering a process for cloning human beings, in direct contravention of not only those patentability requirements specified by the EPC but even in defiance of an EU Directive.[10] Conversely, the use of the term 'Tieres' and 'animal' in the German and French versions of the claims, respectively, is understood as only encompassing a non-human animal. Whether this translation error was an oversight on the part of the participating EPO personnel or the error of an outside translator, the intended (unitary) meaning of the patented transgenic 'animal' was clearly ambiguous. Ultimately, the EPO Opposition Board maintained the patent in an amended form by introducing the term 'non-human' into the offending claims and deleting all disclosure covering human or animal embryonic stem cells – although the patent still validly protects modified human and animal stem cells *other than* embryonic stem cells.

With currently about 30 languages to consider, the EPC provides a framework governing languages and translations throughout the filing, prosecution, and post-grant procedural phases before the European Patent Office. This

[10] The granted patent plainly violated the patentability exceptions under Article 53(a) EPC 1973 *and* Article 6(1) of the European Union Biotechnology Directive (both prohibit the patenting of inventions that are contrary to 'ordre public' or morality – a concept relating to the protection of public health, safety, welfare and the physical integrity of individuals within a society). The EPO eventually upheld a set of amended claims, yet adamantly confirmed the rejection of any disclosed embodiments covering human embryonic stem cells as being contrary to morality (Article 53(a) and Rule 23d(c) EPC 1973).

framework is broadly based on two different categories: (1) the official EPO languages and (2) admissible non-EPO but official language recognized by a particular EPC Contracting State. Under Article 14(1) EPC 1973, a patent applicant, regardless of the country of origin, had to file a European patent application in one of the EPO's three official languages – English, German or French (the 'default' rule). An exception to this rule was found in Article 14(2) EPC 1973, permitting an applicant having a residence or principal place of business within an EPC Contracting State territory (or who is a national of any such State but living abroad) to file a European patent application in any official language *of that State*. This exception also applied to European divisional applications – the translated text was filed in the language used in the proceedings for the earlier 'parent' application (Rule 4 EPC 1973/Rule 36 EPC 2000). An applicant taking advantage of Article 14(2) provisions was required to file a translation in an official EPO language within a prescribed time limit; otherwise risk losing the accorded European filing date.[11]

Article 14 EPC 2000 significantly relaxes the stringent obligations imposed by its EPC 1973 counterpart. Together, Article 14(1) and (2) EPC 2000 make clear that an applicant will be able to file a European patent application in *any* language (such as Japanese). However, a translation into one of the official EPO languages will still be required under certain time constraints in order to avoid a deemed loss of the application.

Thankfully, the EPC affords an applicant the opportunity to bring an erroneous translation into conformity with the original application text throughout pre- and post-grant proceedings before the European Patent Office.[12] As we will examine in more detail below, this correction mechanism applies to situations where errors were introduced when the original application was translated

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[11] Article 14(2) EPC 1973 time limits are stipulated in Rule 6(1) EPC 1973: a translation must be filed within three months from the European patent application's filing date, but no later than 13 months from the earliest priority date. Rule 6(1) EPC 2000 shortens the translation deadline to two months from the date of filing. Most national patent offices of the Contracting States accept a European filing in all recognized Article 14(1) and (2) languages. There are some exceptions, including Greece, which prefers a filing of a European patent application only in Greek; however, the Greek Patent Office will accept an application in English, French or German if the applicant simultaneously provides a Greek translation (for other exceptions, see 'National Law Relating to the EPC' (2006), Table II, Column 3/4).

[12] See Article 14(2) and Article 123 EPC 1973. The EPO will refuse a correction request that would change the overall content of the application, where the skilled person would be presented with information not derivable directly and unambiguously from the application as filed, including any features implicit to a person skilled in the art. The EPO can disregard any non-technical feature when determining the application 'content', since this type of feature does not make a technical contribution to the invention. See Enlarged Board of Appeal decision, G 1/93.

from the filing language (such as Swedish) into one of the three official languages (English, German, French) used in proceedings before the European Patent Office.

The potential impact of Article 14 EPC on the ultimate scope of the European patent application becomes apparent in view of Article 70 EPC, which specifies the authentic text of the European application and resulting patent. Knowing which document is regarded as the authentic text is important for an EPO examiner trying to ascertain the content of the subject-matter of the application as filed (thus, the original scope of the inventive concept). Article 70(1) EPC (both versions) identifies a presumption that the text of a European patent application or a European patent in the official language of the EPC proceedings (English, French or German) is the authentic text for all EPO and any related national proceedings. This presumption applies to not only the published specification of the European patent, but also to each stage of the proceedings where the application is amended or otherwise modified. The EPO further presupposes that a filed translation conforms to the original European application text (Rule 7 EPC 1973/2000), but it can request the applicant to certify the translation's accuracy in the event of any doubt (Rule 5 EPC 1973/2000).

Exceptionally, where a patent applicant has taken advantage of the language provisions of Article 14(2) EPC 1973 by filing the application in a non-EPO language, Article 70(2) EPC 1973 (with parallel provisions in Article 70(2) EPC 2000) specifies that the application in the original language, and *not* the translation, shall constitute the basis for determining whether the subject-matter of the translated patent application or granted patent extends beyond the content of the application as filed (N.B. this does not apply to Euro-PCT applicants, who cannot make use of Article 14(2)). This content assessment is critical, because if the subject-matter of the application has been extended from the original disclosure, this constitutes a valid ground for opposing the granted patent (under Article 100(c) EPC) and/or revoking the validated European patent during national proceedings (under Article 138(1)(c) EPC). The content of the original text of the European patent application is also decisive for determining the state of the art for novelty purposes under Article 54(2) and Article 54(3) EPC (both EPC versions).

Therefore, in certain situations, the EPC affords the applicant a procedural safeguard permitting the recapture of any subject-matter that may have been lost in translation during the course of the pre-grant procedure. Although post-grant amendments to a European patent are *in theory* permissible (i.e. to bring the translated patent in conformity with the original text of the patent application), such amendments will be refused by the Opposition Division or Board of Appeal if the proposed modification would extend the scope of protection

conferred by the European patent *as granted* – despite what was disclosed in the original text of the application.[13]

Conversely, if the content of the translated European application or patent results in a narrower scope, the content of the original document may not automatically be regarded as the authentic text. Under Article 70(3) EPC (both versions), the national patent office of a Contracting State may require a patent applicant to translate the claims (to obtain provisional protection under Article 67 EPC) or a patent proprietor to translate the entire patent specification (Article 65 EPC) into the applicable official State language. If this translation inadvertently narrows the content of the original text, it could actually become the authentic text defining the scope of protection in that particular jurisdiction. Most Contracting States have made use of Article 70(3) EPC 1973, except Belgium and Germany – which both define the authentic text as the one in the language of the EPO proceedings.

Article 70 EPC gains special significance in view of Article 67(1) EPC (both versions), which specifies that a published European patent application will be afforded the same degree of rights and protection as a granted patent in all validly designated Contracting States, although on a 'provisional' basis (applicants usually enjoy broad provisional protection rights, since most applications designate all possible EPC Contracting States – the EPC 2000 makes this a default practice under amended Article 79(1)).

Provisional protection for the European application theoretically takes effect on the date of publication, which is usually 18 months from the date of filing or earliest priority date. However, Article 67(3) EPC (both versions) authorizes a Contracting State (e.g. Greece) having an official language other than the one used during the EPO proceedings (e.g. Greek) to make provisional protection of the claimed invention contingent on whether the patent applicant submits a translation of the claims into an official State language. Currently, all Contracting (and Extension) States require a translation of the pending claims, thus giving fair notice to the public who may not understand the language of the claims as published. Since the EPO communicates the application's publication date in advance, an applicant who is anxious to put potential infringers on notice usually has ample time to file all necessary translations so provisional protection will be immediately effective from the scheduled date of publication.

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[13] Codified in Article 123(3) EPC (both versions): 'The claims of the European patent may not be amended . . . in such a way to extend the protection' it confers. Therefore, a possible extension of the subject-matter is determined from the content of the *granted patent*; A123(2) EPC, by contrast, considers the content of the European patent application *at the filing date*. See EPO Examination Guidelines D-V, 6.2 (2007).

Provisional protection is also available for a published international patent application undergoing PCT procedures pursuant to Article 29 PCT; EPC provisions are only applicable once the PCT application enters into the EPO regional phase. If a PCT application is not published in the official language of an EPC Contracting State where an applicant desires patent protection, provisional protection starts only when the claims are published in that State's language (Article 158(3) EPC 1973, Article 153(4) EPC 2000).

Given the importance of provisional protection, what happens when the translated claims contain a major error and a third party that would otherwise infringe the original patent application does not actually infringe the invention defined by the published claims?

Most EPC Contracting (and Extension) States regard the translated text as the authentic text of the patent application if the conferred protection is *narrower* than that afforded by the language of the EPO proceedings. Where the original text has been 'lost' in translation, the EPC mandates that any Contracting State implementing a translation requirement must provide the applicant with an opportunity to file a corrected translation of the European patent application with the national patent office (Article 70(4)(a) EPC, both versions). Unfortunately, in most cases, the legal effect of this corrected translation is not retroactive to the original date of publication. Only on the date when the corrected claims are published, will provisional protection take effect for that particular State. This principle is paramount for a court attempting to determine the effective date of provisional protection when assessing infringing activities and the applicant's right to damages or reasonable compensation (prescribed by a State's law) in circumstances where an infringer has made unauthorized use of the invention. Once again, we can appreciate how translation errors can alter the legal impact of a claimed invention: not only for how and when infringement activities will be judicially evaluated, but also for an applicant's ability to fruitfully commercialize his or her inventive concept in a particular market.

This notion of 'delayed' provisional protection may actually confer certain advantages on a good faith infringer under the 'Continued Use Doctrine' pursuant to Article 70(4)(b) EPC (both versions), which is recognized in most of the EPC Contracting States. Where the published text of translated European application (claims) reflects a narrower scope compared to the original document, the Doctrine allows any person who is already using (or has made extensive preparations to use) the invention under the narrowed scope to continue such use *without any payment* to the owner of the patent. This situation holds even *after* a corrected translation of the patent application has become effective in that Contracting State. Of course, for this Doctrine to apply, the 'infringer' must not have actually infringed the erroneously translated European application as first published. Moreover, the Continued Use

Doctrine requires that the infringer at all times exercised good faith during the time of infringement. Hence, where a crafty infringer knew of and exploited the translation error, s/he cannot benefit from this defense during an infringement action.

We have surveyed the consequences of a 'lost' translation of a European patent application on provisional rights following publication. Most of these principles also apply to granted European patents per Article 65 EPC, both versions. For example, Article 65(1) EPC authorizes a Contracting State to require a European patentee to file a translation of the entire granted European patent into one of the Contracting State's official languages. This translation process constitutes an important part of national phase procedures for the European patent known as 'validation'. If a Contracting State imposes such a requirement (and most do), this presents yet another opportunity for a potential translation error of an original text that otherwise faithfully describes the claimed invention. Of the currently 34 Contracting States, at least 28,[14] have enacted provisions under Article 65(1) EPC. With the exception of Slovenia and Lithuania (and Iceland, if the European patent is granted in English), which only require the translation of the claims, and Monaco and Luxembourg, who require no translation at all, each Contracting State presently requires a translation of the complete European patent specification. In most cases, failure to file the translation within the prescribed national time limit renders the European patent void *ab initio* (from the beginning). We note that this situation has dramatically changed for States that have acceded to the London Agreement, which entered into force on 1 May 2008 (discussed below).

One clear difference emerges when ascertaining the 'authentic text' under Article 70(3) EPC (both versions) for a European patent versus the European patent application. This EPC provision stipulates that should a nationally validated European patent having a narrowing translation error be the subject of national revocation proceedings, *the language of the EPO proceedings* (and not the restrictive translation) will be decisive for determining the scope of protection conferred. This provision, however, does not apply to the patent scope generally – therefore, a good faith third party infringer can continue an infringing use under an originally published (but erroneous) patent without paying royalties to the patent owner (Article 70(4)(b) EPC). The foregoing provisions are equally applicable to 'amended' European patents, which were

[14] Contracting States presently requiring a full (pre-London) translation of the European patent include: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.

modified during the newly introduced *ex parte* central limitation procedure pursuant to new Articles 105a to 105c EPC 2000.

We noted that the European patent is published in the language of the proceedings, with the claims being published in all three official EPO languages (at grant Articles 14(7), 97(5) EPC 1973; Articles 14(6), Rule 71(3) EPC 2000), and that most Contracting States require a translation of the patent into an official State language (Article 65(1) EPC, both versions). Practically, the expense associated with translating a European patent may be a *monumental* obstacle for an inventor wishing to commercially exploit his invention throughout Europe, since such costs can account for as much as 40% of the entire patent granting process.

Recognizing an increasingly connected European market and Europe's strong position on the global economic stage, several EPC Contracting States concluded the London Agreement ('London') with the objective of substantially reducing the costs associated with validating a European patent. The London Agreement, which entered into force on 1 May 2008,[15] specifies a new translation regime in those states which have ratified or acceded to the London Agreement for all European patents where the mention of grant is published in the European Patent Bulletin on or after the effective date (N.B. Switzerland/Liechtenstein and the United Kingdom have enacted transitional provisions wherein the London Agreement will apply to a European patent where the mention of grant is published on or after 1 February 2008). The Agreement provides that any signatory State having an official language in common with one of the EPO official languages (English, French, German) shall *fully waive* the translation requirements under Article 65(1) EPC (Article 1(1), London).[16] Any State party to this Agreement having no official language in common with one of the EPO official languages may require that the patentee supply a translation of the granted European *patent claims* into one of the States official languages (Article 1(3), London).[17] Alternatively, such a State may require that the *description* of the European patent be

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[15] Presently, there are 14 signatory States: Croatia, Denmark, France, Germany, Iceland, Latvia, Liechtenstein, Luxembourg, Monaco, the Netherlands, Slovenia, Sweden, Switzerland, and the United Kingdom. The Swedish Parliament has approved the London Agreement and amended the Swedish Patents Act accordingly, but has not yet deposited the instrument of ratification.

[16] Currently, this provision applies to the following States: France, Germany, Liechtenstein, Luxembourg, Monaco, Switzerland, and United Kingdom.

[17] The following states require that the claims be supplied in their official language: Croatia (Croatian), Denmark (Danish), Iceland (Icelandic), Latvia (Latvian), Netherlands (Dutch), Sweden, Slovenia (Slovene).

supplied in the official language of the EPO prescribed by that state (Article 1(2), London).[18]

However, Article 65 translation requirements have not completely vanished – in case of a dispute, an accused infringer *or* a national court can request the patentee to provide a full translation of the granted European patent in the official language of the State concerned (Article 2, London).

We consider a final procedural safeguard afforded a European patent applicant or patent proprietor (during *pending* opposition/appeal/limitation proceedings) desiring to correct a translation error in the text of the patent application or granted patent, as provided under Rule 88 EPC 1973 (preserved as Rule 139 EPC 2000). The correction of an error is not a right of a party; rather, the correction is completely at the discretion of the EPO – which balances the competing interests of the parties with those of the public.

The first sentence of Rule 139 EPC 2000 permits the applicant/patentee to correct a 'linguistic error, error of transcription and mistake in any document filed with the EPO'. In practice, a linguistic error is an error in language (such as transposed words); a transcription error is a typing error (like transposed numbers for an experimental parameter); while a mistake is an error that negates the true intention of the person filing the document (such as missing or wrong documents). Corrections of the 'first sentence-type' must be self-evident and would restore the document to the form intended by a party with complete retroactive effect. While correcting translation errors in the European application documents is normally covered by Article 14(2) EPC (both versions), Rule 139 may be invoked for correcting errors in subsequent documents filed during the European patent grant procedure, and applies equally to Euro-PCT applications (as we discuss below).

The second sentence of Rule 139 concerns corrections of errors in the description, claims or drawings of a European patent (application) and requires that the correction is obvious 'in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction'. Corrections of the 'second sentence-type' must be obvious to what a skilled person could derive from the disclosure of the application as filed, and the correction would not alter the scope of such content. Basically, to effect the correction, the applicant must prove: (1) an error is in fact present in a document as filed, and (2) the applicant/patentee plainly intended to express the content of the proposed correction in the original EPO submission.

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[18] The following states have prescribed English: Croatia, Denmark, Iceland, the Netherlands, and Sweden. Furthermore, the following states have not prescribed any language under Article 1(2) of the London Agreement, thus no translation of the description must be provided to the State's Patent Office: Latvia, Slovenia.

In spite of all of the safeguards we have discussed so far, should a translation error somehow render a European patent application withdrawn, deemed to be withdrawn, or refused, or where a translation of the original application was not submitted to the EPO in time, there may be one last hope for the applicant to salvage a right to the claimed invention. This opportunity lies in the 'conversion procedure' provided by Articles 135–7 EPC (both versions), which allows a patent applicant (proprietor) to 'convert' the failed European application (or revoked European patent) into a national patent application in any Contracting State validly designated in the application (patent). An applicant or patentee must submit a conversion request to the EPO (except in a few limited circumstances relating to e.g. national security) within three months after the EPO decision to withdraw the European patent application or revoke the European patent.

The conversion procedure finds legal basis in Article 66 EPC (both versions), which provides that a validly filed European patent application shall be equivalent to a national filing in a Contracting State, meaning that the 'converted' national application will have the same filing (or where applicable, priority) date as the European application. Fortunately for the conversion applicant, the national patent office cannot subject the application to formal requirements different from those provided for in the EPC; however, the national office may require a translation of the original text of the European patent application into the State's official language. Here, special attention should be given to ensure that the provided translation is as accurate as possible, thus avoiding the pitfalls which may have led to the demise of the European patent right in the first place.

The PCT Patent Application

An inventor seeking to obtain patent protection in a large number of jurisdictions worldwide can take advantage of a centralized procedure offered under the Patent Cooperation Treaty or 'PCT', which is administered by the International Bureau ('IB') of the World Intellectual Property Organization ('WIPO') in Geneva, Switzerland. The PCT allows an applicant to file a single 'international' patent application having the potential to mature into multiple national and/or regional patents in countries that have ratified the PCT (presently, there are over 130 signatory Member States).

The PCT process begins when an applicant files a patent application (the 'international application') with an appropriate PCT 'Receiving Office', which is determined according to the residence, place of business or nationality of at least one of the patent applicants. Subsequent to filing, a competent PCT search authority (the 'International Search Authority') that is recognized by the selected Receiving Office will perform a full prior art search of the patent application. These steps occur during the first PCT phase known as 'Chapter I'.

Once the international search is completed, the official 'International Search Report' is sent to the applicant, who can then decide whether to continue the patent proceedings (because no threatening prior art was found) by either: (1) entering the second phase of this process ('Chapter II'), which entails filing a Demand for examination; or (2) skipping the examination process entirely and simply entering the PCT application into the national/regional phase prior to the deadline imposed by the relevant national/regional patent offices (typically 30 or 31 months from the PCT filing date or the earliest priority date, with few exceptions). If the applicant affirmatively elects to enter into Chapter II, the international application is then sent to a PCT 'International Preliminary Examination Authority', which evaluates the application under the patentability requirements set forth in the PCT. By the relevant date, the applicant must then decide to enter the patent application into the regional phase (before the EPO) and/or the national phase (before the Japanese Patent Office, 'JPO' or the United States Patent and Trademark Office, 'US PTO') for each country where patent protection is desired.

A PCT application is usually not a first-filed patent application, but claims priority from an earlier filed application (e.g. through Article 4 provisions of the Paris Convention for the Protection of Industrial Property). If the earlier application was filed with a recognized Receiving Office in a PCT Member State where the applicant has residence or a place of business, no translation is required upon filing. For example, an applicant filing a PCT at the Indian Patent Office in the Hindi language, claiming priority from an earlier Indian (national) patent application, would not have to provide the Indian Patent Office with a translated text where the Office is acting as the PCT Receiving Office. During Chapter I, the PCT application is published about 18 months from the filing or earliest priority date (usually after the International Search is completed). Since the PCT only recognizes eight languages of publication,[19] an applicant may be required to furnish a translation into a language of publication to the Receiving Office (Rule 12.3 PCT). Applicants may also be required to prepare a translated text of the PCT application if the original language text of the application is not accepted by the International Search Authority that is to perform the search.

A flawed translation may finally afford a patent scope that either exceeds or is limited in comparison to the PCT application in the original language. In the international phase, only obvious errors may be corrected (Rule 91.1(a) PCT), and must be approved by one of the PCT authorities, depending on

[19] The languages of PCT publication are: English, French, German, Japanese, Russian, Spanish, Chinese, and Arabic, Rule 48.3(a) PCT (amended in 2006).

where the application is in the PCT process. For example, where the applicant discovers an error in the translated document only after publication, and the application has already proceeded to examination under Chapter II, authorization for correction must be given by the International Preliminary Examination Authority (and ideally before the international preliminary examination report is established).

In PCT practice, 'obvious' mistakes, such as those resulting from a faulty translation, are dealt with under the framework provided by Rule 91 PCT, and are defined as errors where 'something other than what was obviously intended was written in the international application'. The standard for assessing an 'obvious error' is whether 'anyone would immediately realize that nothing else could have been intended than what is offered as (the) rectification' (Rule 91(1)(b) PCT). Perhaps to the detriment of the PCT applicant, no matter how obvious an error may be, no correction is possible if the end result would be extending the subject-matter of the claimed invention beyond the content of the original PCT application as filed. Where the translation of an original application text contains an error exceeding the scope of a translation of any resulting (national or regional) patent down the road, the competent authorities of that PCT Member State can declare the patent retroactively 'null and void' to the extent that the resulting scope exceeds that of the application in its original language (Article 46 PCT).

Where the PCT authority refuses to correct a translation error, the more lenient 'Rule 139' EPO practice (described above) can be requested where the EPO is acting as the Designated or Elected Office for a PCT application that has entered the European regional phase (and becomes a Euro-PCT).

A case highlighting the 'obvious error' principle is EPO Boards of Appeal decision T 353/03, concerning a Euro-PCT application that was filed at the Swedish Patent Office (PCT/SE 98/01477) in Swedish and entered the regional phase before the European Patent Office (as Euro-PCT No. 98 940 729.1). The applicant requested correction of what he considered to be an obvious mistake resulting from a translation error when the original Swedish PCT application was translated into English for publication, that is, substituting 'the cavity space volume shall *not exceed 25% of the cubic root of any wavelength* . . .' (a phrase included in the published PCT pamphlet, WO 99/13688 at page 3, line 2, and claim 3) with the arguably broader phrase 'the cubic root of the cavity space volume shall *not exceed 25% of any wavelength* . . .' (emphasis added). To support his case, the applicant submitted a copy of the corresponding page from the original Swedish PCT application documents and its English translation to the EPO along with an accompanying amended set of claims and description. The Board held that because Swedish is a prescribed official language for a Swedish applicant filing an international application with the Swedish Patent Office acting as the Receiving Office, the

documents as filed constitute the original application documents. Consequently, errors in a subsequently filed translation based on these documents should be correctable. The Board thus held that the wording proposed by the applicant was adequate and importantly, not infringing the added matter prohibition under Article 123(2) EPC (both versions).

Another case that illustrates the complexities of translations of non-English PCT international applications when they become involved in United States priority disputes ('interferences') is *Stevens v. Tamai* (Fed. Cir. 2004). An applicant filed a Japanese priority application, a Japanese Patent Cooperation Treaty (PCT) application, and a US English language application, the last for the purpose of entering into PCT 'national stage' examination. In an interference, the applicant filed a motion seeking the benefit of the Japanese priority application and the PCT application. The court held that the applicant was not entitled to the benefit of the PCT application because the applicant did include with the motion a translation of that application and an affidavit attesting to the accuracy of the translation. It noted that (1) entering the national stage with a US application did not obviate the requirement of filing a proper motion for benefit in an interference, and (2) the applicant was not entitled to the benefit of the Japanese priority application because it was filed more than twelve months before the US application.

United States

The United States patent system, unlike the European patent system, but like the Japanese system, is mono-lingual (English-only). The 'prosecution' (the dialogue between the US PTO examiner and the patent applicant) proceeds exclusively in English based on the English language patent application. With the sheer volume of applications in the US PTO,[20] a large percentage of which are, undoubtedly, based on filings in other countries and non-English languages, translation errors must occur with some regularity. A study discussed in the Japan section below seems to confirm this problem.

Applications based on non-English priority applications in other countries can be filed in the US PTO directly or through the Patent Cooperation Treaty, initially in any language, but an English translation of a 'non-provisional' ('regular utility') application must be provided within prescribed time limits with a 'statement that the translation is accurate'.[21] Recently, the US PTO

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[20] The United States PTO reported that, in 2006, the number of 'total foreign'-based applications was 204,183, compared to US-based applications of 221,784. There were 76,839 applications from Japan.

[21] 37 CFR § 1.52(d)(1) (effective 25 November 2005): 'If a nonprovisional application is filed in a language other than English, an English language translation of the non-English language application, a statement that the translation is accurate, and

amended its rules to require an applicant to file a copy of an English translation of a foreign-language 'provisional' application used as a priority document for a later non-provisional (regular utility) application – else risk losing the priority claim.[22] An interesting question is: what if the English translation of a United States application originally filed in a non-English language is not, in fact, accurate? Can it be corrected by amendment without losing the benefit of the filing date? The question is similar, but not exactly the same, as the one discussed below in which a flawed English translation is filed as the original US application and a certified copy of the original non-English application previously filed in a foreign patent office is filed in the US PTO to support a claim to Paris Convention priority (benefit of the foreign application's filing date up to 12 months prior to the US filing, 35 USC § 119). With a direct filing of a non-English application, it could be argued that the foreign language application is the US application and the English translation merely evidence of what the application in fact says.

A US patent practitioner receiving a patent application text that is drafted in a language other than English should consider a number of questions. For example, what language in the specification, if any, should be and can be altered? (Note that the 'claims' may be freely amended, but only if supported by the descriptive portion of the application's specification.) Are there any direct references to prior art that could have consequences in the United States different from those in the source country? For example, European practice requires a listing of the 'objects of the invention'.[23] Such explicit references to the prior art and 'objectives' in a patent specification may create issues regarding the scope of resulting issued US patent claims.[24]

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the processing fee set forth in § 1.17(i) are required. If these items are not filed with the application, applicant will be notified and given a period of time within which they must be filed in order to avoid abandonment'.

[22] On 21 August 2007 the Patent and Trademark Office published 'Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications' in *Federal Register*, 72(161) – which conforms § 1.52(d)(2) to the provisions in § 1.78 for claiming the benefit of a provisional application (applicable to any patent application filed on or after 25 November 2005).

[23] *See* Implementing Regulations to the European Patent Convention, Rule 27 EPC 1973/Rule 42 EPC 2000, requiring that the 'Description indicate the background art, which as far as known to the applicant can be regarded as useful for the understanding of the invention, for drawing up the European search report and for the examination, and preferably, cite the documents reflecting such art'.

[24] Of course, as held in the landmark 2005 *Phillips* case, ' '[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.' *Phillips v. AWH Corp*., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc) (quoting *Liebel-Flarsheim & Co. v. Medrad, Inc*., 358 F.3d 898, 908 (Fed. Cir. 2004)).

What about deleting other language without expanding the scope of the original disclosure as filed, the language perhaps constituting some kind of admission that could be damaging in future litigation? A translator must always give careful attention to avoid adding any new subject-matter that could jeopardize a priority claim to an earlier filed foreign patent application. To illustrate this point, in *Tronzo* (1998),[25] the Federal Circuit held that a *generically* shaped hip implant structure claimed in a US continuation patent application was not supported (either inherently or via obvious equivalents) and thus could not claim priority to the disclosure of a *conically* shaped structure disclosed in the parent application. This had the unfortunate result that the Federal Circuit invalidated the new claims covering the generically shaped structure due to intervening prior art that was published between the filing date of the parent and the subsequent continuation application.

How can the practitioner be certain that the specification fully satisfies the US requirement that the inventor was 'in possession of the invention as of the filing date sought' or that the application 'particularly points out and distinctly claims' the invention or that the applicant discloses the 'best mode' as currently mandated by 35 USC § 112? A foreign-filed patent application will surely be written in a manner to satisfy all legal requirements in the jurisdiction where it was originally filed. This will undoubtedly present challenges for the translator, who may seek to 'adjust' the specification to comply with the requirements of the US patent law.

Even when a US practitioner receives a patent application that was previously filed in English, such an application may be drafted using words that are customary in other jurisdictions like Britain, South Africa or Australia, but the text may be completely unfamiliar to the American audience (for example, a 'lorry' rather than a 'truck'). To this effect, a claim and/or the applicable patent specification written in 'United States English' may be more persuasive in defining the inventive scope should the patent be subject to judicial proceedings before a US court.

What procedures for correcting translation errors are available under United States patent law? We consider four.

First, if the applicant discovers the error during prosecution, he or she may seek to amend the specification, either directly or by filing a 'continuing' application (although this practice should not be misused to delay prosecution). The primary restraint is the statutory prohibition on the introduction of 'new matter' (35 USC§ 132). 'New matter' cannot be introduced by amendment, and a

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[25] *Tronzo v. Biomet, Inc*., 156 F.3d 1154 (Fed. Cir. 1998). Compare *Lampi Corp. v. American Power Products, Inc*., 228 F.3d 1365, 56 USPQ2d 1445 (Fed. Cir. 2000) (distinguishing *Tronzo*; in another fact pattern involving 'shape').

continuing application is not entitled to the priority filing date benefit of an earlier application with regard to the 'new matter'. An analogous restraint applies to a foreign priority application: if the United States application introduces new matter, it will, to that extent, be deemed not for the same invention and, therefore, not entitled to the benefit of the foreign application's filing date.

Second, after a patent issues, a patent owner may file an application to 'reissue' the patent. The ground for reissue is that the patent is, through error without deceptive intent, wholly or partly inoperative or invalid because the specification is defective, or because the inventors claimed either more or less than they were entitled to claim. At least two limitations on reissue impact the 'lost in translation' question. First, the application must be filed within two years of issuance of the patent if the application seeks to broaden the patent's claims. Second, the reissue application cannot introduce 'new matter'.

One of the few United States cases on the 'lost in translation' problem, as assessed under the no 'new matter' standard, arose in the context of a reissue. In *In re Oda* (1971), the Court of Customs and Patent Appeals allowed a reissue to correct an error occasioned by translation of the specification from Japanese to English. In the section describing how to make the claimed compound, the term 'nitric acid' was mistranslated as 'nitrous acid'. In context, it was clear that a mistake had been made: the acid was at a specific gravity of 1.45, and nitrous acid cannot exist at that specific gravity. The court rejected the argument that the error could have resided equally in either the substance or the number: 'On all the evidence, we conclude that one skilled in the art would appreciate not only the existence of error in the specification but what the error is'.

Third, a patent owner may seek a 'certificate of correction' from the Patent and Trademark Office (35 USC § 254). The certificate is to correct a 'mistake of a clerical or typographical nature, or of minor character', and it must not 'involve such changes in the patent as would constitute new matter or would require reexamination'. Again, the legal standard of no 'new matter' is the primary restricting standard.

Not clearly resolved by the *Oda* decision is whether, in determining that matter is new, the decision maker (patent examiner or judge) can consider directly the foreign language priority document. In *Oda*, the court reasoned primarily that the translation error ('nitrous acid' rather than the proper term 'nitric acid') was evident from the English language document itself and its technological context as a whole. It did discuss the translation mistake in the context of a separate legal requirement for reissue (that there be 'error'). It did *not* consider whether the foreign language priority document, being a matter of record in a foreign government agency (the Japanese Patent Office), a copy of which must be filed in the US PTO in order to perfect the claim of priority

(35 USC § 119(b); 37 CFR § 1.55), should be considered a part of the patent's intrinsic record as a whole, that is, its prosecution history.

Fourth, a patent owner (or potentially anyone) can seek to get a court, in the context of interpreting the patent, to engage in 'judicial correction', that is, simply interpreting the patent, particularly claim language, in context, disregarding any obvious error, just as it would ignore a common, typographical error in any document. In *Novo Industries, L.P. v. Micro Molds Corp.* (2003), the Federal Circuit recognized the power of a court 'to correct an error in a patent by interpretation of the patent'. However, a court 'can do so only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims'. It held that the PTO's statutory authority (35 USC § 254) to issue correction certificates did *not* preclude judicial correction. However, judicial correction is available only under circumstances more limited than those available for a correction certificate. An advantage of 'judicial' correction is that the correction is, in effect, retroactive, whereas a PTO certificate of correction is effective, for purposes of determining infringement and invalidity only, for activity after the correction certification issues.[26]

The *Novo Industries* case did not involve a translation error, but it certainly involved the type of error that could occur during the routine patent translation process. A claim required 'stop means formed on *a rotatable with* said support finger'. A rotatable what? A district court held that 'a' meant 'and', but the Federal Circuit reversed, holding that the claim was fatally ambiguous because, although the error was evident, its proper correction was not.

If a 'correction' is not sought or available under any of the four previous procedures, it can be argued that an apparent discrepancy between the source and target texts should influence the *interpretation* of the English text in the United States. This premise appears to be supported by the Federal Circuit's current trend in constructing claims, that 'a word describing patented technology takes its definition from the context in which it was used by the inventor' and that a patent owner is not entitled to a claim construction 'divorced from the context of the written description'.[27]

In the extensive, on-going process of litigation over the infringement and validity of United States patents, the parties (patent owner and accused infringer) and the courts spend a considerable amount of time posing and

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[26] See *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000) (a 'certificate of correction is only effective for causes of action arising after it was issued.').

[27] *Tap Pharmaceutical Products, Inc. v. Owl Pharmaceuticals, L.L.C.*, 419 F.3d 1346 (Fed. Cir. 2005).

resolving disputes over the meaning of patent claims, attention often focusing on a few words, either technical ones or apparently simple, ordinary English words such as 'a', 'on', 'to', and 'at'. Often, a preliminary hearing, entitled a '*Markman* hearing' is held, which delves solely into claim interpretation disputes.

Exemplary of how much can turn on the meaning of a simple word is *Chef America, Inc. v. LambWeston, Inc*. (2004). The patent claimed a process for producing a dough product. Its claims required, *inter alia*, heating the dough 'to' 400 to 850 degrees. The court refused to read 'to' as 'at' (i.e., meaning heating the dough in an oven 'at' the 400 to 850 degree range) – even though baking dough 'to' those temperatures burns it 'to a crisp', thus defeating the invention's purpose. It noted that the patent owner did not argue that the claim language was a draftsman's mistake and did not seek a certificate of correction by the PTO or by the district court, as was potentially available under *Novo Indus.*

A question about claim interpretation is whether in resolving a dispute a court can take into account a foreign language priority document. In the landmark 2005 *Phillips* decision, the Federal Circuit emphasized the importance of 'intrinsic' evidence in interpreting patent claim language, especially the patent's specification, which describes the invention and how to make and use it (enablement), and, to a lesser extent, the patent's 'prosecution history'. As discussed above in connection with 'new matter', the priority document is arguably 'intrinsic', because it is a public document contemporaneous with the original patenting process. Unlike 'extrinsic' evidence, such as expert testimony, the priority document is fixed and accessible apart from any litigation over the patent. Including the foreign priority document in the arena of intrinsic evidence would impose on competitors of the patent owner and the public the burden of independently translating the priority document to check the accuracy of the English translation. (Under PTO rules, a foreign language priority document is not necessarily translated; it must be translated only if priority becomes an issue during prosecution or interference proceedings.) Yet, if the stakes are high, a prudent potential patent challenger should do that anyway as the basis for disputing the effective status of the foreign language priority document allegedly supporting the claims in the United States patent.

Another facet of 'lost in translation', which is not common to other major patent systems, arises from the duty of candor and disclosure imposed by United States patent law. In the United States, an inventor and his or her representatives are under a duty to disclose to the PTO information that is material to the patentability of claims in a patent application. Much relevant prior art is not in English. Questions have arisen whether an applicant is under an affirmative duty to characterize fairly and objectively to an examiner non-English references of which the applicant was aware. This might be called the '*hidden in translation*' problem.

In *Gambro Lundia AB v. Baxter Healthcare Corp.* (1997), the Federal Circuit agreed that an applicant's statements distinguishing a German language reference were 'at least overstatements'. However, it concluded that 'in the context of [the applicant's] overall effort to show that the German reference does not anticipate its invention, these exaggerations do not rise to the level of gross falsification'. It noted that 'the examiner himself had located and cited the German' reference and 'could consult it while evaluating [Gambro's] comments in response to his office action. The examiner's access to the German [reference] and [an English language reference cited in the applicant's specification that contained a similar disclosure] should have helped place [applicant's] comments in their proper context.' The court further noted that the 'district court . . . overemphasized [the applicant's] in house patent counsel's . . . fluency in German. Although the patent examiner relied on [the applicant's] translations, *the process of moving between languages is not itself sufficient to show that* [the applicant] *exploited its foreign language expertise to deceive the examiner*. The examiner may request translations throughout the examination process. See Manual of Patent Examining Procedure (MPEP), § 901.05(d) (6th ed. 1995)' (emphasis added).

Other recent cases seem to affirm that an 'intent to deceive' requires something more than the applicant's mere failure to disclose a full translation of a pertinent prior art reference. In *Atofina v. Great Lakes Chemical Corporation* (2006), the Federal Circuit reversed a district's court finding of invalidity based on inequitable conduct finding that the applicant's decision to withhold a full English translation of a relevant Japanese reference (in its possession) was not, in and of itself, enough to establish intent – a 'factual basis for a finding of deceptive intent' was required which was not the case here, since: (1) Atofina's comments were consistent with the translated Japanese abstract and the full document, and (2) Atofina did not try to hide information or otherwise mislead the US PTO.

In *Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.* (2000), the Federal Circuit reached a different conclusion about foreign language references and the duty of candor. It held that a patent applicant willfully misrepresented a material prior art reference, a 'laid open' Japanese language patent application, by submitting the full reference and only a partial translation with a concise 'explanation' that focused only on the less relevant portions and omitting its 'key teaching'. The court noted: 'By submitting the entire untranslated . . . reference to the PTO along with a one page, partial translation focusing on less material portions and a concise statement directed to these less material portions, [the applicant] left the examiner with the impression that the examiner did not need to conduct any further translation or investigation'. It stressed that '[t]he duty of candor does not require that the applicant translate every foreign reference'. However, the duty does require

that an 'applicant refrain from submitting partial translations and concise explanations that it knows will misdirect the examiner's attention from the reference's relevant teaching'. The court commented that 'there is no support in the law for a presumption that the examiner will understand foreign languages such as Japanese or will request a costly complete translation of every submitted foreign language document, particularly in the absence of any reason to do so'.

Japan

Since 1995, an applicant filing an application for a Japanese patent before the Japanese Patent Office (JPO) has been afforded the convenient option of filing an original patent application (or a patent application claiming priority to an earlier filing, such as a PCT application) in the English language. However, to preserve an accorded Japanese filing date, an applicant had to provide the JPO with a Japanese translation of the English application not later than two months from the application filing date. Current provisions under Japanese patent law (in force since 1 April 2002) permit an applicant to enter a PCT international application into the Japanese national phase in Japan without a Japanese translation if the PCT is in English; however, it is incumbent upon the applicant to file a Japanese translation of the PCT application with the JPO.

Recently amended Japanese Patent Law (Article 36bis, paragraph 2), applicable to all applications filed with the JPO on or after 1 April 2007, specifies an extended period for filing the Japanese translation of an English language application. An applicant must file a translation within 14 months from the application's 'filing date', which is the date when a first application is filed with the JPO or the earliest priority date of a related PCT or 'Paris Convention' application. For divisional applications, the filing date means that of the parent (but the applicant still has two months for filing the Japanese translation if the 14-month period has already lapsed).

Many non-Japanese patent applicants elect to initially file their Japanese patent in English, perhaps assuming that JPO pre-grant procedure mirrors European practice by allowing an applicant to bring the later-filed Japanese translation into conformity with the original application. However, practically speaking, this strategy may not be strategically prudent. Although translation errors based on the English language application can be corrected, if new matter is introduced into the Japanese translation beyond that disclosed by the English language application, this error could form a sound basis for a JPO refusal of the patent application, or worse – the error could lead to a partial or total invalidation of the subsequently granted patent. In one well-publicized Japanese case, the patentee lost an infringement action because a feature in the claimed rice crackers manufacturing method of '3 to 5 degrees Celsius' had

been mistakenly translated as '3 to 5 degrees Fahrenheit' – an uncorrectable error that rendered the Japanese patent completely worthless (since Japanese law requires a patent examiner to recognize that the language is clearly erroneous in view of the invention's specification).

Most individuals working in the field of translating documents from or into Japanese will recognize that achieving a precise translation between Japanese and English is a laborious undertaking. Inherent difficulties in this task arise from the complexity of the Japanese characters, or 'alphabet systems', as well as dramatic differences in grammatical usage and phrasing compared to most Latin- or Anglo-based languages. The Japanese written language consists of multiple categories of characters, such as 'kana' (of a phonetic nature) and 'kanji' (Chinese-derived characters, of a semantic nature). Even a translation task involving something as simple as an inventor's name (if written in kanji) cannot be readily converted to English, as the actual sound of the name is difficult to formulate given the semantic nature of the kanji character.

Moreover, Japanese characters do not distinguish between singular and plural nouns. Translators are frequently forced to employ a complicated array of modifying words and phrases in order to effectively convert the source text into meaningful English sentences – which can only be accomplished once the translator achieves a complete understanding of the context in which the term appears. The danger of ignoring the use of word- and phrase-modifiers is that the source text could be reduced to an over-simplified target text, which omits the essential meaning of the original construction.[28] As a result, even the most straightforward expressions can become lost in translation.

To underscore the extent of these difficulties, consider the following phrase commonly found in any given invention disclosure: 'We have discovered that (statement of result) . . .' To a native English speaker, this phrase implies that the patent applicant is disclosing a novel result technically linked to the inventive concept of the application. This phrase, however, would *not* conclusively mean that the applicant discovered the (statement of result) and made the result publicly available before the application's filing date. In other words, if this deceptively simple phrase is translated incorrectly, a patent examiner may reject the application by alleging that (statement of result) was known prior to the applicant's asserted date of invention (in Japanese practice, the filing date),

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[28] For illustrative purposes, compare the content of the English translations provided for Japanese patent and utility model documents from the JPO website under the heading 'IPDL' (Industrial Property Digital Library), see: http://www.ipdl.inpit.go.jp/homepg_e.ipdl and click on the link entitled 'Patent & Utility Model Gazette DB' (accessed 1 August 2008) and compare this text with an earlier related priority document available on the EPO database, *see*: http://ep.espacenet.com (accessed 18 September 2007).

therefore leading to the most unfortunate conclusion that the (statement of result) was comprised in the state of the art and therefore destroys the novelty of the claimed invention.

Another problem often confronting the Japanese (to English) translator is the proper use of the indefinite or definite article when translating a feature recited by a dependent claim. Logically, if a claim feature has already appeared in a previously recited claim within the same 'dependency cascade', then the definite article 'the' would be appropriate. By comparison, if there are subtle differences in the claimed feature, or if the feature appears in a new combination with one or more other previously claimed feature(s), these features could be preceded by the indefinite article 'a' since the feature is making an initial appearance in the claim set and is directed to a new embodiment.

Finally, there are major differences between the grammatical structure of the Japanese language and, for example, Indo-European languages, with the seemingly odd exception of German. Surprisingly, many linguistic similarities exist between Japanese and German, most notably in word ordering, which is commonly a subject-object-verb format: 'nihongo o hanas-u' and 'Japanisch sprechen', respectively (compared to the subject-verb-object construction of a typical English sentence: 'speak Japanese'). This Japanese 'word ordering system' may further challenge the translator endeavoring to express the correct relationships between nouns, verbs, adjectives and other modifiers. For example, a patent specification including the phrase: 'There is a need for an advantageous therapeutic compound X useful in chemical process Y, which produces minimal side effects . . .' could be construed as meaning that there is a need (in the prior art) for an advantageous therapeutic compound X that is useful in chemical process Y and that the therapeutic compound X produces minimal side effects. Another reasonable interpretation for a non-native English speaker could be that chemical process Y produces minimal side effects. If these kinds of grammatical constructions figure prominently in the claim language (and they often do), such language may easily fall victim to a serious translation error – with the dangerous consequence of a markedly different (and perhaps narrower) claim scope than originally intended.

The importance of careful and diligent translation for securing a broad (and valid) patent right was recently considered in a study devoted to analyzing the value of English translations of US patents owned by Japanese companies.

This study methodically analyzed 98 United States patents for translator 'vulnerabilities', meaning common Japanese-to-English translation errors that either: (1) restricted the scope of the issued US patent or (2) failed to take into account current US PTO practices or binding legal precedents adopted by the Court of Appeals for the Federal Circuit (and other relevant judicial forums) because the claims were not in a US PTO-acceptable format.

Importantly, the authors observed that in many of the translated US patents, the abstract proved to be narrower in scope than the granted patent claims. Even though the US Code of Federal Regulations explicitly stated, at the time, that a patent abstract is *not* to be considered for interpreting the scope of the claims, Japanese companies were frequently advised by counsel against using a direct Japanese translation of the abstract in view of the *Hill-Rom* decision (2000), which held that a court *could* properly consider an abstract when interpreting features recited by a US patent claim.[29]

The study also revealed that the translated written description typically failed to broadly support the claimed essential technical features – that the invention was often not based on disclosed embodiments; rather, the invention 'would' (prophetically) achieve a certain technical effect. The study also identified a common practice of disclosing only one example in the description to support an otherwise broad claim, and that one-to-one translations of the Japanese specification often failed to comply with numerous requirements of US practice, including best mode and enablement. Finally, the study found that the claims often failed to recite the proper antecedent basis (revisiting the issue of the proper use of definite and indefinite articles).

To summarize, a translator specializing in bi-directional Japanese-English patent translations must constantly unravel highly complex Japanese sentence structures to faithfully express a complex hierarchy of relationships in clear English (and vice versa). In addition to coping with elementary grammatical considerations, the translator must simultaneously incorporate appropriate terms relating to sophisticated new technologies as well as skillfully managing such terminology when translating a patent application for entry into the applicable patent system. This combination of tasks presents the translator with quite a challenge when navigating the often turbulent waters that separate the 'source text' from the 'target text'.

Conclusion

From this preliminary exploration of the 'lost in translation' problem, we reach only one firm conclusion. The 'lost in translation' dilemma for the international patent system should receive much greater study and consideration from both a policy perspective and a practice perspective than it has so far received. We submit that study should extend beyond Europe, the United States and Japan – to China, India and the many other countries with increas-

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[29] See *Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337 (Fed. Cir. 2000), where the CAFC held that an established PTO rule (and long tradition of accepted practice) that the content of a patent abstract *does not contribute* when interpreting the claim scope was in fact *non-binding*. This surprising holding thus infers that a court can properly use a patent abstract to interpret the claims of a granted US patent.

ingly active and developing patent systems, systems dictated in part by the WTO (World Trade Organization) 'TRIPS' Agreement (Trade Related Aspects of Intellectual Property).

In the United States, the problem appears to be generally ignored, except when issues are pressed in specific case matters where such problems arise.

In Europe, correction for errors lost through translation are explicitly provided for – but, apparently, only within the European regional system and in the context of the PCT, that is, not on a truly global basis. Language and translation in the patent system are, for understandable reasons, more frequently and openly debated in Europe than in the United States. (For example, no one seriously suggests that US patents should be translated into Spanish, even though a significant and growing percentage of the US population speaks and reads only Spanish.) But the debate in Europe seems to center more on the tension between national pride (i.e., any property right should be discernible based on a nation's language) and practicality (i.e., reducing costs), and less on fundamental policy considerations inherent in the international patent system – issues such as the desirability of providing early disclosure of technological developments, assuring potential competitors of what is to be covered by an intellectual property right, and appropriately defining patent claim scope uniformly on a multinational basis.

In Japan, the language question appears to be more intensely technical: how indeed can descriptions of complex technologies, especially early, basic inventions in those technologies, be made to flow across radically different languages?

The element openly debated in Europe – the cost of translations – should not be ignored at the global level. Indeed the cost can be an extreme drain on the ability of small- and medium-sized organizations to obtain patent protection for their innovations in all the markets that 21st century transportation and communication technology make available. The lesson from even this preliminary survey of the 'lost in translation' problem is that it would be prudent for any patent applicant to invest a great deal more than is currently typically done in preparing careful and accurate translations, bearing in mind that this cannot be done without a significant increase in cost.

Beyond the practical and financial issues, there linger numerous and fundamental policy questions. Is it not desirable that patent protection for a new technology be available throughout a global market according to uniform standards that encompass global values? How can the 'lost in translation' problem be solved to avoid damaging that ideal? How can the international system be changed to avoid having a critically important invention patented in one set of countries meaning one thing while assuming a completely different meaning in other countries – simply because of the language translation process?

References

International treaties and agreements

Agreement dated 17 October 2000 on the application of Article 65 of the Convention on the Grant of European Patents, concluded in London on 17 October 2000, and entering into force on 1 May 2008.

'Convention on the Unification of Certain Points of Substantive Law on Patents for Invention' or the 'Strasbourg Convention' (27 November 1963) (a multilateral treaty signed by Member States of the Council of Europe in Strasbourg, France, entering into force on 1 August 1980).

The Paris Convention for the Protection of Industrial Property Article 4 (20 March 1883; last amended on 28 September 1979) (a treaty signed in Paris, France; one of the first intellectual property treaties).

The Patent Cooperation Treaty ('PCT') (1970; last amendments entered into force on 1 April 2007) (an international patent law treaty. Parties to the PCT are called Contracting States and together constitute the International Patent Cooperation Union).

European Law and European patent law

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PART 3

CONDITIONS OF PATENTABILITY: ESSENTIAL REQUIREMENTS

11 Patenting software-related inventions in Europe

Stefan Schohe, Christian Appelt and Heinz Goddar

1 Introduction

Software-related patents are a publicly debated issue. As far as Europe is concerned, this issue has a legal side to it. Whereas the public discussion is largely centered on how to best promote the development of the software industry and ultimately debates the usefulness of a patent system in general, rather than specifically software-related patents, the question in Europe is also whether and to what extent software-related patents fit into the legal framework. A few words on the legal framework may therefore be appropriate.

2 Legal provisions and development of the case law

Whereas there is no common patent law in Europe, the substantive legal provisions on patents were harmonized with the introduction of the European Patent Convention (EPC) so that for practical purposes it is sufficient to consider the provisions of the EPC, which are mirrored in the national law of the EPC member states.

The key provision in this regard is Article 52(1) EPC, which reads as follows:[1]

> European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

Article 52(1) EPC is complemented by Article 52(2) EPC, reading as follows:

> The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
> (a) discoveries, scientific theories and mathematical methods;
> (b) aesthetic creations;

[1] As of December 13, 2007; the previous version was missing the words 'in all fields of technology'.

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
(d) presentations of information,

which in turn is subject to the restriction of Article 52(3) EPC, reading

> Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject matter or activities as such.

Thus, the EPC (and the national law of the EPC member states) merely states in a general provision that inventions are to be protected, but does not define what an invention is. There is a general understanding, although not always unquestioned, that patentable inventions have to be technical. This is not exactly the same as being related to a field of technology,[2] but is to be understood as being within the technical arts. In other words, it is not the field the invention relates to that is supposed to be technical, but the invention itself. Apart from this implicit limitation to technical subject matter, Article 52(2) EPC explicitly excludes certain subject matter from patentability and thus defines a line the case law is not allowed to cross. Whereas the list of Article 52(2) EPC comprises abstract, non-tangible subject matter, such as mental schemes, aesthetic creations, business methods and programs for computers, which, by virtue of Article 52(3) EPC are only excluded, if claimed as such, there is a feeling that in order to meet the purpose of this provision, the exclusions should not be construed too narrowly. Furthermore, one frequently finds the notion that programs for computers do not fit in with the other items in the list of Article 52(2) EPC[3] and thus Article 52(2) EPC is not to be considered as a mere list of non-technical subject matter. Thus, European case law is left with the problem of either defining what is technical and/or determining whether the subject matter at issue falls within the list of excluded subject matter according to Article 52(2) EPC or corresponding provisions of national law.

The case law on software-related inventions was largely developed by the German courts and the Boards of Appeal at the EPO, which sometimes take different approaches to accomplishing this task, however, with essentially

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[2] The wording 'in all fields of technology' in Article 52(2) EPC is derived from Art. 27(1) TRIPS, which was frequently asserted to no avail with regard to software-related inventions.

[3] See e.g. United Kingdom, CFPH's Applications [2005] EWHC 1589 (Pat); [2006] RPC 359 and Court of Appeal (Civil Division) – *Aerotel* and *Macrossan* [2006] EWCA Civ 1371; see also EPO T 1173/97 – Computer Program Product, OJ 1999, 609, holding that a computer program is always technical.

similar results. The British courts developed their own line of case law, which steers a course of its own.

Assessing whether an invention is generally amenable to patent protection, the German practice traditionally applied the so-called 'Red Dove Doctrine', named after a case decided by the Federal Court of Justice (Bundesgerichtshof) in 1969. At this time, the court had to decide whether a breeding method for red doves was patentable and coined the definition **'**Amenable to patent protection is an instruction to methodically utilize natural forces for achieving a direct causal result'. This definition implies that a result, which need not have a technical character,[4] is achieved as the result of a process of tangible or measurable events, such as building or operating a machine. The words 'direct causal result' imply that the result is exclusively determined as the result of natural forces, as opposed to a mental process.[5]

Since a computer arrives at a direct causal result, for example, a calculation result, as a result of methodically using natural forces (i.e. following a predetermined program), one might jump to the conclusion that this would settle any discussions on patent protection for software-related inventions. German jurisprudence, however, has traditionally held that a mental process should not be protected using a technical disguise. Considering software from this point of view, a program or a related method of operating a computer is essentially the result of a mental process, the technical implementation of the program on the computer being straightforward. This implies that software protection should be granted only in exceptional cases. The German authorities initially tended to this latter point of view and applied the so-called core doctrine. In a nutshell, the core doctrine provided for an assessment comprising the following steps. First, the so-called 'core' or essence of the invention was determined. In a second step, it was determined whether this core comprised technical subject matter. If so, the further examination proceeded to the issues of novelty and inventive step as usual, if not, the case was rejected because of lack of technical character. Incidentally, the first case rejected by the Federal Court of Justice under this doctrine was a business method case.[6] The practice under the core doctrine even went so far as rejecting applications on software-controlled devices, such as ABS-brakes, and it took a decision by the Federal

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[4] Cf. Federal Court of Justice – *Suppenrezept (Soup Recipe)*, GRUR 1966, 249, holding a recipe for a soup patentable, or Federal Court of Justice – *Garagentor (Garage Door)*, GRUR 1967, 590 holding that it is not a bar to patentability, if the result achieved by the invention is a decorative effect.

[5] The *Red Dove* case was in fact rejected, because the proposed method did not give an explicit rule as to which doves were to be crossbred, but left it to the discretion of the breeder.

[6] Federal Court of Justice – *Disposition Program*, GRUR 1976, 96.

Court of Justice[7] to clarify that such devices are patentable. As a consequence of this decision, the practice has become more liberal over the years. Initially, the list of excluded subject matter in Article 52(2) EPC and of the corresponding German provision never played a large role, as it was mainly considered to contain explicit examples of subject matter not falling under the definition of an invention according to the Red Dove Doctrine. In recent decisions, the Federal Court of Justice has taken the view that the exclusion of protection of software forms a requirement separate from the requirement of technical subject matter, that is, a subject matter may be technical, but nevertheless be excluded from patent protection.[8]

The case law of the EPO initially took a less fundamental approach and rather considered on a case by case basis whether there was a case of excluded subject matter listed in Article 52(2) EPC. In the *Vicom* decision of 1986,[9] the Board of Appeal held that a method of image processing using a mathematical algorithm cannot be considered as being related to a mathematical method as such nor can it be considered as a computer program as such. In clear distinction to the then prevailing practice of the German courts the Board stressed that the invention defined in the claims has to be considered as a whole. In this context the Board said that it is decisive what technical contribution the invention as defined in the claim, when considered as a whole, makes to the known art. Over the years, basically two principles emerged that were frequently cited in decisions by the EPO. The first was that a subject matter is not excluded from patent protection if it comprises or can lead to a further technical effect beyond the normal operation of a computer. The second, essentially derived from the Vicom decision, was that a subject matter is not excluded if there is a technical contribution that the invention makes to the prior art. Both criteria reflected the notion that a method performed on a computer is not patentable merely for the fact that it implies the use of a computer.

In the decision re *Merrill Lynch's Application*[10] the UK Court of Appeal partly took up the technical contribution approach set out in the *Vicom* decision, but with the rider that inventive excluded matter cannot count as a technical contribution. More specifically, the court held that irrespective of whether a new result in the form of a technical contribution to the prior art is produced, if the result is non-patentable subject matter, in the specific case of

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7 Federal Court of Justice – *Anti-blocking system*, GRUR 1980, 849.

8 Federal Court of Justice X ZB 16/00 of October 17, 2001, *Search of Faulty Character Strings*, GRUR 2002, 143.

9 T 208/84 – *Vicom*, OJ 1987, 14.

10 UK Court of Appeal (Civil Division), *Merrill Lynch's Application* [1989] RPC 561.

the production of a trading system, the invention is not patentable. Despite the reference to the *Vicom* decision, this approach was more in line with the core doctrine of the German courts. In fact, it made patentability dependent on the field of application or the result to be achieved, rather than on the claimed subject matter as a whole.

Between about 1999 and 2001 there was a series of decisions both by the EPO and by the German courts, introducing new criteria for technical subject matter and trying to harmonize the case law with the other jurisdiction. This period was characterized by an increasingly liberal approach towards software-related inventions, which development was certainly fuelled by the growth of what was then termed the 'new economy'.

One important issue during this time were program product claims, that is, claims on a storage medium having a computer program stored thereon. In 1999 the EPO decided[11] that such claims were allowable, if the program stored on the storage medium, when executed, exhibits a further technical effect beyond the usual operation of a computer. Thus, the above-mentioned requirement of a further technical effect was relaxed to the criterion of the potential to create a further technical effect. The Board went even further in saying that if there is such a potential for a further technical effect, the program *per se* can be claimed. The basic assumption of the Board was that Article 52(2) EPC does not exclude all computer programs, but only those computer programs not having a technical character. The Board furthermore held that every program has technical character in that it physically modifies the hardware and concluded that, since some programs are excluded and some are not, a program that is not a program as such has to have the potential to create a further technical effect beyond the normal operation of a computer. Whereas this reasoning served its purpose, namely allowing program product claims, for which there was significant pressure at the time, it had intrinsic weaknesses. For instance, it was not considered how specific the potential of creating a technical effect is to be. Following this reasoning, one could patent anything that, after performing additional steps, not the subject matter of the patent, could possibly result in a technical effect, starting from an incomplete process, lacking the final steps necessary to achieve the result, to an abstract technical concept such as plans or concepts for devices and processes. Allowing claims on programs *per se*, the Board did not make any comments on the scope of protection nor require further limitations in the claim to clarify the scope of protection. If, as was probably the intention, the scope of protection was to protect patentable programs in every form, this would not only have protected the source code, but also any abstract representation of a

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11 T 1173/97 – *Computer Program Product*, supra.

program, such as flow diagrams or the like, and thus prohibited the distribution of the content of the program. One may question whether this meets the rationale of Article 52(2) EPC or the wider purpose of the patent system, providing for public dissemination of information about an invention in return for a temporary monopoly of the patentee.[12] Whereas these implications did not become the subject matter of subsequent case law, this decision established a lasting notion that the law distinguishes between technical programs, that is, programs having the potential to create a further technical effect, and other programs. In retrospect one may say that this conception hampered and partly still is hampering the development of the case law towards a consistent and predictable approach.

A different approach to programs or data stored on data carriers was taken in a decision by a different Board of Appeal of the EPO rendered in 2000.[13] The Board held that certain data stored on a data carrier may have a technical function in that they control the operation of a computer-based system.

Interference by a human in a software-related invention, for example, in dialogue methods, was a further issue. In a decision rendered in 2000,[14] the Federal Patent Court discarded a method as non-technical, as it relied on decisions and considerations by a human to be made in a process. According to a further decision by the Federal Patent Court (Bundespatentgericht)[15] and confirmed by the Federal Court of Justice[16] a method involving the interaction of a human is not necessarily excluded from patentability, if the actions to be taken by the human are predetermined by the method and do not involve an interpreting, deciding or evaluating step.

The most important issue during this time was to what extent computer implementations of schemes and methods are patentable, which, taken per se, fall within the scope of the exclusion of Article 52(2) EPC or Section 1(2) Patentgesetz2 (PatG; German Patents Act). This applied primarily to issues of business methods, but also to other pieces of application software.

The German Federal Court of Justice held in late 1999[17] that the technical character necessary for patentable subject matter may reside in technical considerations forming the starting point of the software created and in that the

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12 In fact, it does not become clear from the decision, why the term 'as such', used in Article 52(3) EPC, is to have a meaning different from 'per se'.

13 T1194/97 – *Data Structure Product*, OJ 2000, 525.

14 Federal Patent Court – *Assessment of the Difficulty of Dismounting*, BPatGE 42, 208.

15 Federal Patent Court – *Intercom System*, BPatGE 42, 157.

16 Federal Court of Justice X ZB 3/00 – *Intercom System*, Mitteilungen der deutschen Patentanwälte 2002, 176.

17 Federal Court of Justice – *Logic Verification*, GRUR 2000, 498.

resulting output by the computer can be used in a generally acknowledged field of technology, for example, the manufacture of semiconductor devices.[18] In a way this resembles the concept of a potential to create a technical effect established in T 1173/97 in that no direct and causal technical effect is required. It should, however, be said that this criterion was not applied rigorously in consequence. When it came to deciding on plans for ventilation ducts in a mine, undoubtedly involving technical considerations and suitable for use in the field of mine construction, the Federal Court of Justice flatly denied the technical character.[19]

In a further decision by the Federal Court of Justice,[20] handed down in 2000, the court held that claims directed at a computer generally define patentable subject matter. The EPO adopted this notion in a decision of September 2000,[21] which decision forms the basis of the current practice of the EPO. In subsequent decisions,[22] the EPO considered the issue of non-technical features under the aspect of inventive step and established as a core criterion whether there is a technical solution to a technical problem. Especially, it was confirmed in a decision of 2004 that both a method and an apparatus involving technical means do not fall within the exclusions of Article 52(2) EPC,[23] thus doing away with a reservation still expressed in the *Improved Pension Benefits System* decision where a further technical effect was still required for method claims in order to avoid the exclusions under Article 52(2) EPC. Thus, the criterion of a further technical effect beyond the normal operation of a computer is no longer applied for the purpose of Article 52(2) EPC. It is, however, implicitly still contained in the examination regarding inventive step, as relying on the normal operation of a computer cannot establish an inventive step.

Ironically, at about the same time that the EPO adopted the concept established in the German *Speech Analysis Device* decision the German Federal Court of Justice stepped back from this concept in a decision allowing program product claims of 2001[24] and returned to the ideas developed by the EPO in the decision T 1173/97 and in their previous decision, *Logic*

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18 See also Federal Patent Court – *Computer implemented method for manufacturing a cable harness*, BPatGE 45, 103.

19 Federal Court of Justice – *Wetterführungspläne (Air Supply Plans)*, GRUR 2001, 155.

20 Federal Court of Justice – *Speech Analysis Device*, GRUR 2000, 1007.

21 T 931/95 – Improved Pension Benefits System, OJ 2001, 441.

22 See, especially, T 641/00 – *COMVIK*, OJ 2003,352, and T 258/03 – *Hitachi*, OJ 2004, 575.

23 T 258/03 – *Hitachi*, supra.

24 Federal Court of Justice X ZB 16/00, *Search of Faulty Character Strings*, supra.

Verification. They followed a different reasoning from that of T 1173/97, but similarly came to the conclusion that not all computer programs are excluded and defined the criterion that in order to be patentable, the prominent features of the subject matter of a claim have to serve the solution of a specific technical problem.

Whereas this was stated with regard to a computer program product claim and the concepts of the *Speech Analysis Device* decision were not *expressis verbis* abandoned, this decision was widely understood to overrule the *Speech Analysis Device* decision and to be a partial return to the core doctrine. In consequence, there was a series of decisions by the Federal Patent Court that rejected cases for lack of technical character on the grounds that the prominent feature was non-technical.[25] This attitude was especially adopted by the 17th Division of the Federal Patent Court, which decides most of the software cases. In several decisions of the 17th Division, applications were basically rejected, because the result to be achieved was (also) caused by virtue of a non-technical principle, for example, a business scheme. Technical features regarding the implementation were regularly considered as not prominent, especially if they were generally known in the art.[26] A different practice was pursued by the 20th Division of the Federal Patent Court. The 20th Division emphasized[27] that a subject matter is not excluded because of the mere fact that one prominent feature is non-technical and that it is sufficient if there is a prominent technical feature besides prominent non-technical features. Several of the cases decided by the 17th Division went to appeal at the Federal Court of Justice. In essence, most of them were confirmed, but the Federal Court of Justice shifted its focus. It stepped back from the criterion of technical prominent features or, more precisely, redefined the prominent features as those that define a technical instruction. In a series of decisions[28] the Federal Court of Justice defined the criterion that in order not to be excluded from patentability, the subject matter of a claim has to comprise the solution of a specific technical problem by technical means. If this criterion is fulfilled, it does not

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[25] See, for example, Federal Patent Court 17 w (pat) 28/00 – *Mailing Campaign*, CR 2002, 249.

[26] See, for example, Federal 17 w (pat) 44/02, Mitteilungen 2003, 555; an application to an automated help system evaluating user input was rejected on the grounds that in order to offer help the user input has to be evaluated under psychological considerations and thus use non-technical means.

[27] Federal Patent Court 21 w (pat) 38/00 – *Electronic Monetary Transactions*, BPatGE 45, 133.

[28] Federal Court of Justice – *Electronic Financial Transactions*, GRUR 2004, 667, Federal Court of Justice – *Determination of Profitability (Rentabilitätsermittlung)*, GRUR 2005, 143 and Federal Court of Justice – *Offering Interactive Help (Anbieten interaktiver Hilfe)*, GRUR 2005, 141.

matter whether the claim also relates to a method or device related to subject matter excluded under Article 52(2) EPC or the corresponding provision under German law.[29]

Thus, whereas the approach taken by the Federal Court of Justice and the EPO is still different, the recent case law shows common criteria, namely the requirement for a technical solution to a technical problem. Nevertheless, the differences in approach may have an impact on the outcome of prosecution. The Federal Court of Justice still maintains that the presence of technical features in a claim is not sufficient to avoid the exclusions according to Section 1(2) PatG (corresponding to Article 52(2) EPC) and to this end applies a test as to whether there is a technical solution separate from the test for inventive step. The EPO has completely abandoned the test for an exclusion under Article 52(2) EPC, if technical means are recited in the claim.[30] Like the Federal Court of Justice, the EPO requires that there is a technical solution to a technical problem, but under the aspect of inventive step.

At a time when the case law on the continent seems to be converging, British courts have pursued a course of their own. In a decision of the High Court of Justice of 2005,[31] the approach of the EPO was rejected. Rather, following a detailed analysis of the legal provisions, the decision comes to the conclusion that the order of examination should be reversed. As a first step it has to be identified what is the advance in the art that is said to be new and non-obvious (and susceptible of industrial application). In a second step it is to be determined whether it is both new and not obvious (and susceptible of industrial application) under the description of an invention in the sense of Article 52, that is, whether what establishes novelty and inventive step is patentable subject matter. In a later decision of 2006 by the Court of Appeal,[32] the court essentially reverted to the modified contribution approach of the previous *Merril Lynch* decision,[33] expressly disagreeing with the practice of the Boards of Appeal of the EPO. In a subsequent decision by the High Court,[34] it was clarified that this decision by the Court of Appeal does not imply a prohibition on program product claims.

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29 Federal Court of Justice – *Record Carrier*, GRUR 2005, 749.

30 T 258/03, supra.

31 High Court of Justice (Chancery Division) *CFPH's Applications* [2005] EWHC 1589 (Pat); [2006] RPC 359.

32 Court of Appeal (Civil Division) – *Aerotel and Macrossan*, supra.

33 UK Court of Appeal (Civil Division), *Merrill Lynch's Application* [1989], supra.

34 High Court of Justice (Chancery Division), *Astron Clinica Limited and others*, [2008] EWHC 85 (Pat).

From a practical point of view, the criterion of inventive step is far more important than the exclusions under Article 52(2) EPC. This was, in fact, true even before the EPO turned to consider subject matter comprising technical and non-technical features under the aspect of inventive step. Even under previous case law, most rejections of software-related applications were not based on lack of patentable subject matter, but on lack of inventive step. In many cases, the prior art came so close to the subject matter of the application as to anticipate it or make it obvious. The issue of inventive step becomes complicated, when there are non-technical features which are new with regard to the cited prior article This especially applies to computer-implemented business methods having new business features.[35]

There is a general opinion that the mere implementation of a known or obvious algorithm or business method will not be sufficient to satisfy the requirement of an inventive step. There is a notable tendency by the deciding authorities to invoke the general knowledge of a person skilled in the art or simple common sense in rejecting claims relying on simple algorithms, without relying on specific prior art. In the above-referenced decision by the Federal Patent Court of 2002,[36] the court held, for example, that if the invention is basically a reaction to commonplace desires, the court or the patent office does not have to provide specific evidence for the existence of such desires before the priority date. Case law by the EPO[37] shows a tendency to consider it obvious to apply well-known techniques to a new problem even without a specific hint to this effect in the prior art.

Another ground on which software-related cases are sometimes rejected is insufficient instruction in the claim. This ground is rarely addressed as such. One frequently finds the objection that a mental act is necessary to accomplish the invention, where in fact there is a gap in the instruction leaving it open how a certain step or result is to be accomplished. A typical case is where a result is claimed without setting out how it is to be achieved.

A related issue is that technical features are not clearly defined or only defined by implication through non-technical features. Whereas reference to a non-technical feature should be considered as the specification of a purpose, implying technical means for achieving this purpose,[38] one can notice a tendency to discard related features as non-technical. Frequently enough, there is also little or no technical subject matter associated with such a feature[39]. A variety of cases where the claims were phrased mainly in non-technical

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35 See, for example, T 49/99 or T 1177/97, unpublished.
36 Federal Patent Court 20 w (Pat) 4/00, GRUR 2002, 418.
37 See, for example, T 1081/99 or T 623/97, unpublished.
38 Guidelines for Examination in the European Patent Office, C III 4.13.
39 See, for example, Federal Patent Court 20 w (Pat) 4/00, supra.

language would probably have been decided differently, if a different language had been used.[40]

3 Political developments

In parallel with the judicial developments, economic and political developments have taken place and there is certainly a correlation between them. At the time of what was then called the new economy and later was called the Internet bubble, there was a strong urge to grant patent protection for software-related inventions more liberally. At the time of the diplomatic conference revising the EPC in 2000, serious consideration was given to removing computer programs from the list of excluded subject matter in Article 52(2) EPC and even to abandoning Article 52(2) and (3) EPC completely. In the final act of November 29, 2000, Article 52(2) and (3) EPC were, however, maintained in their previous form, since it was felt that it was still too early to make a binding decision. It was intended to deal with this issue at a further diplomatic conference originally scheduled for 2002, for which, however, no date has been set until today. Another reason why Article 52(2) and (3) EPC were maintained was that at the same time the EU Commission had announced plans for a directive on patent protection for software-related inventions and in view thereof the conference decided to withhold the amendments to these provisions, reportedly following pressure from the European Union. This EU directive was eventually refused by the European Parliament in 2005. The process leading to this decision reflects the change in perception by the public of software-related patents as well as of patents in general that took place between the mid-1990s and the present time. It is worthwhile retracing the twists and turns this process took, as these were to some extent reflected in the case law.

The process started in 1997, when the EU Commission issued a Green Paper on the community patent. In the Green Paper the Commission also addressed the issue of software protection by patents. At this time, the EU Commission was rather inclined to enhance the protection afforded by patents for software-related inventions and indicated that a directive to the member states might issue rather rapidly. The process got delayed due to the parallel work on the community patent. Receiving negative feedback in the meantime, especially from the Open Source movement, the Commission postponed the intended draft directive and instead issued a consultation paper in 2000 inviting the public to comment on whether it was desirable to improve patent protection for software-related inventions and what scope of protection should

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[40] See, for example, Federal Patent Court 17 w (pat) 41/01, relating to the German counterpart of US 2002/0026307 A1.

be awarded to software-related patents. The Commission received approximately 1500 responses. When the draft directive was issued in February 2002, the EU Commission took a rather conservative approach and proposed to preserve the status quo established by the case law of the EPO. The draft by the Commission generally provided that there would not be any special law on software protection but that the general principles of patent law should apply.

In September 2003, the European Parliament passed a resolution[41] on the proposed directive. Whereas the report by the Committee on Legal Affairs and the Internal Market to the Parliament had recommended only moderate amendments to the draft by the Commission, the plenary debate resulted in amendments of the proposal that provided severe restrictions on patent protection, obviously as a result of the massive lobbying of the Open Source community, which went as far as to include personal threats against the rapporteur.

Whereas verbally pretending to make only minor amendments to improve transparency and legal security,[42] the proposal by the Parliament effectively abolished patent protection for software-related inventions in all fields outside production technologies and in all instances where the difference from the prior art resided in (non-technical) software. The amendments included, amongst other things, an explicit provision that data processing is not a field of technology subject to patent protection. According to the amendments made by the Parliament, the technical contribution should be established by the difference between the technical features of a claim and the prior art. It was expressly excluded that an inventive step may reside in the more efficient use of the resources of the computer. Generally, software patents should only be granted for the automated production of material goods. The application had to comprise a well-functioning and well-documented reference implementation without any restricting licensing terms. The use of a patented invention for a significant purpose should not constitute an infringement, the said significant purpose including, but not being limited to, achieving compatibility between different computer systems.

The proposal of the Parliament met severe resistance from the European Commisssion and reservations in the European Council. As the next step in the legislative procedure, the European Council issued a common position on May 18, 2004,[43] which restored most of the Commission's proposal. For formal reasons, the common position was not officially adopted until March 7, 2005. In an unusual manner, several national governments, including the governments of the Netherlands, Hungary, Latvia, Poland, Denmark and Cyprus,

41 Resolution P5_TA(2003)0402 of September 24, 2003.
42 Bulletin of the European Union 9-2003, 1.3.29.
43 Document 9713/04 of May 24, 2004.

although having passed the common position in May 2004, issued declarations expressing reservations regarding the common position and urging further negotiations with the European Parliament.

In preparation for the second reading in Parliament, the rapporteur for the Committee on Legal Affairs made a proposal that was largely along the lines of the resolution passed by the Parliament in the first reading in 2003. In a compromise paper issued later on, some of the restrictions contained in the first proposal were not maintained. Partly due to massive lobbying from both supporters and opponents of software patents, the Parliament was rather divided on the issue which finally resulted in an agenda with a large number of amendments to be voted on that was virtually impossible to deal with in an orderly and feasible manner. Based on the recognition that passing a law with such an agenda would be a rather random process, a majority of members of parliament decided to vote against the directive, which was thus rejected in the plenary session of July 5, 2005.

With the rejection of the directive, the legal provisions remained unchanged, which in turn implied that the practice of the EPO continued as before. Interestingly enough, this was claimed as a victory by the opponents of software patents. In consequence, the discussion about software-related patents lost impetus as such. As a lasting consequence, however, it established a critical perception on the part of the public and of politics towards patents, which pervades the political scene. More frequently than before, potential anti-competitive aspects of patents are discussed and emphasized in the political discussion.[44]

4 Current practice of the courts and Boards of Appeal

4.1 Practice of the EPO

The current practice of the EPO[45] stems from the criteria established in the decisions T 641/00 (*Comvik*)[46] and T 258/03 (*Hitachi*).[47] It basically provides for the following steps.

First, it is examined whether the claim recites technical features, irrespective of whether these are new or not. If technical features are found, the requirements of technical subject matter and of Article 52(2) EPC are considered to be met, even if these features merely relate to the technical environment, for

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[44] See, for example, the opinion on patent protection and innovation by the scientific advisory board of the German Ministry for Economy of March 2007.

[45] An extensive discussion of this approach and the related case law can be found in T 154/04, to be published.

[46] T 641/00 of September 9, 2002 – *Two Identities/COMVIK*, supra.

[47] T 258/03 – *Hitachi*, supra.

example, the presence of a computer, a network or a display. In the subsequent assessment of inventive step only those features contributing to technical character are considered. However, non-technical features may be considered in formulating the problem to be solved according to the problem/solution approach.[48] A distinction is also made between a general underlying non-technical problem, for example, a problem related to the business world, and the technical problem that posed itself to a person skilled in the art in terms of patent law. In the case of a business method implementation, the skilled person is considered to be a software programmer who is not a business expert, but has knowledge of business-related features and aspects of the business method to be implemented by way of a specification of requirement that is provided as the basis for his work.[49]

As an illustrative example, the case decided in T 258/03 related to a remote auctioning method, wherein every bidder provided a desired price and an accepted maximum price. In a first stage the auction prices were successively lowered from an initial price until there were one or more bidders offering a desired price that was equal to or higher than the current auction price. If more than one such bidder were found, the auction price would be raised again in predetermined steps. In each of these steps those bidders are excluded who had indicated an accepted maximum price lower than the current auction price, until one successful bidder remains.

The Board considered the requirements of Article 52 EPC to be met, as the claims at issue recited technical features such as a server computer, client computer and a network. Assessing inventive step it considered the steps of data transmission and storage related to the product to be auctioned and those related to the desired price and maximum price as technical, but known from the prior art. The steps necessary to establish the successful bidder were not considered to have a technical character nor to be specifically related to the implementation of the auction in a computer system and thus were excluded from the consideration of inventive step. The Board especially rejected the argument that the claimed method overcame the problem of delays in the transmission of bids in the prior art on the grounds that the (technical) problem of transmission delays was not solved, but avoided. They acknowledged that the feature of raising the auction price in predetermined steps could be considered as having technical character as it was particularly suitable for being performed on a computer, but considered this as an obvious measure for a person skilled in the art.

Loosely speaking, the EPO considers the invention from the point of view

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48 T 641/00 of September 9, 2002 – *Two Identities/COMVIK*, supra.

49 T 172/03 of November 22, 2003, unpublished.

of a software developer who is presented with the task of implementing a non-technical scheme, for example, a business method, which may be the solution to a non-technical problem.[50] The criterion of inventive step is met if the implementation as claimed comprises non-obvious features. In many instances, this matches the situation of a software developer in the real world.

The approach by the EPO does away with inconsistencies in the prior case law, requiring that the contribution over the prior art has to meet the requirements of Article 52 EPC. Whether or not the claimed subject matter is technical or falls within the list of excluded subject matter requirements of Article 52 EPC does not depend on the prior art or the relevant date for assessing novelty and inventive step. If a subject matter is technical, this will not change if new art is created. Likewise, if the subject matter falls within a generic class of technical and non-excluded subject matter, a specific sample of this class cannot become non-technical or excluded by virtue of the fact that in addition to the technical features of the said generic class it comprises non-technical features or features falling under the exclusions of Article 52(2) EPC, if taken *per se*.

The current practice of the EPO does, however, shift some of the issues of the prior case law to the assessment of inventive step. A central issue of the current approach of the EPO is to determine which technical problem is solved, and more generally, how to define the technical problem and the technical solution. This goes along with the problem of classifying features as technical or non-technical. This approach entails the risk of disregarding technical features implied by non-technical features recited in the claim, for example, by way of purposive wording, and also disregarding the general possibility of non-technical features being introduced as a result of technical considerations.[51] This may result in establishing a technical problem that is too narrow and that may also anticipate parts of the invention.

Another issue that so far has not been addressed in the case law is whether non-technical features are to be considered, if the only prior art is not prepublished (Art. 54(3) EPC). It is, however, likely that such features will be disregarded.[52]

4.2 Practice of the German courts

The initial criterion of prominent features having to serve the solution of a technical problem established by the Federal Court of Justice in 2001[53] was refined to the criterion of the solution of a technical problem with technical

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50 Cf. T 931/95 – *Improved Pension Benefits System*, supra.

51 Cf. T 769/92 – *SOHEI*, OJ 1995, 525.

52 Cf. T 172/03 of November 22, 2003, unpublished.

53 Federal Court of Justice X ZB 16/00, *Search of Faulty Character Strings*, supra.

means. Especially, the court made it clear that the term 'prominent feature' does not imply a standard that is unrelated to the technical context and is not to be understood as a feature establishing the overall character of the claimed subject matter (which may be non-technical). Stating that this criterion is to ensure that inventive step be assessed on the basis of those features that establish a teaching for technical activity,[54] the court made clear that one has to establish the technical teaching implied in the claimed subject matter and subject this to the examination of novelty and inventive step. On the other hand, the court maintained that the exclusion of Article 52 EPC and the corresponding provision of German law cannot be avoided by the mere use of a computer.

In a decision of March 2006,[55] the Federal Court of Justice considered it sufficient that the patent related to the technical problem of allowing prepaid telephone calls without having to use public telephones equipped with card readers, which, according to the court, was to be solved by technical means. The solution in this case was allocating certain amounts of telephone time to a special code and providing this code, concealed on a card, to a customer.

In contrast, the practice of the Federal Patent Court is mixed. In particular, the 17th Division pursues a course that closely resembles the former German practice under the core doctrine. If the claimed subject matter of a computer-implemented invention does not imply a new use or modification of hardware, the Division determines the nature of the processed data. If their content is non-technical, for example, in the case of medical[56] or business data,[57] they deny the presence of a technical problem, if no features related to a modification of the hardware or its operation are contained in the claim. One can also recognize a tendency to focus on the overall purpose, rather than on the specifically claimed subject matter. The Division denied the presence of a technical problem in the case of a device providing a two-dimensional representation of a three-dimensional picture, wherein certain picture elements were moved together in response to a single operation of a user, on the grounds that ergonomics are related to human needs and do not imply a technical problem.[58]

A criterion reiterated in the case law of the 17th Division is whether a person skilled in the art had to consider the structure or the operation of a data-processing device or other hardware[59] or whether there is a non-obvious new

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54 Federal Court of Justice – *Electronic Financial Transactions*, supra.
55 Federal Court of Justice – *Prepaid Telephone Calls*, GRUR 2006, 663.
56 Federal Patent Court 17 w (pat) 15/04, unpublished.
57 Federal Patent Court 17 w (pat) 88/03, unpublished.
58 Federal Patent Court 17 w (pat) 10/04, unpublished.
59 Federal Patent Court 17 w (pat) 82/04, unpublished.

interaction between the components of a data-processing system.[60] One also finds the notion that considerations of a computer scientist are typically not of a technical nature.[61] In particular, the Division held in the case of a system controlled by a computer program capable of multi-tasking, wherein in case of an error a new state of the system was determined to which a transition was made, that maintaining control operation in case of an error involves a technical problem, as it involves considerations beyond the skills of a computer scientist.[62] In contrast, in the case of a method of maintaining inter-task communication in a multi-tasking operating system, wherein inter-task variables were determined and a mechanism for inter-task communication was determined and applied, the Division held that establishing data consistency did not involve a technical problem, since only the software was modified and the method did not involve a new way of operating hardware elements, but only the interaction between tasks.[63] Apparently, the Division was under the impression that in the former case the system was an installation different from a computer, such as a machine tool or an air conditioning system. The claim underlying the decision did, however, not contain any limitation in this regard and the claimed system could very well have been a computer system.

Whereas prior to the *Electronic Financial Transactions* decision of the Federal Court of Justice, the 17th Division based decisions finding that the claimed subject matter was not patentable on the ground that what they considered as prominent features was not technical, the reasoning now goes along the lines that on the basis of what they consider as prominent features, a technical problem cannot be determined. Whereas this formally meets the criterion of the solution of a technical problem, it does not seem to address the requirement of the Federal Court of Justice in *Electronic Financial Transactions* to establish the (entire) technical subject matter that can be subjected to the examination of novelty and inventive step.

Subsequent to the *Electronic Financial Transactions* decision there have only been a few decisions on the issue of excluded subject matter by other divisions of the Federal Patent Court. However, in a decision of the 23rd Division[64] it was held that the evaluation of measurement data with a mathematical method does not fall within the category of excluded subject matter.

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60 Federal Patent Court 17 w (pat) 10/04, supra.
61 Federal Patent Court 17 w (pat) 57/04, unpublished.
62 Federal Patent Court 17 w (pat) 57/04, supra.
63 Federal Patent Court 17 w (pat) 82/04, unpublished.
64 Federal Patent Court 23 w (pat) 55/04, unpublished.

There are few reported decisions on inventive step by German courts, where the claimed subject matter involved a mix of technical and non-technical features.[65] In the case law of the Federal Patent Court, there have been a couple of instances where the issue of an inventive step or the issue of a technical problem and a more general non-technical problem were addressed. In two decisions of 1999 and 2002[66] the 20th Division found that both the technical features and the business method underlying the application had been obvious. Thus, the Division could leave it open whether an inventive step can be based on a business method. In a third decision[67] the Division had to decide this issue. It rejected the approach by the EPO to disregard all non-technical features. Rather, the Division determined the technical content of the claim at issue by establishing the undoubtedly technical features and whether and what technical content was associated with the non-technical features.[68] The Division came to the conclusion that the technical content thus established consisted of techniques well known in computer science and thus rejected the application for lack of inventive step. This approach accounts for the mixed character of features frequently found in business-related applications. It does not, however, take into account whether the application of certain known techniques to the implementation of the underlying business method was obvious. In a decision handed down in November 2004[69] dealing with a case where the new feature, as compared to the prior art, was that the jackpot of a slot machine was increased in a random manner, rather than by predetermined amounts, the court held that the feature of a random increase in the jackpot served the non-technical purpose of making the game more attractive, which was, however, not the technical problem that would present itself to a person skilled in the art. The solution to the technical problem of implementing a random increase in the jackpot was considered obvious.[70]

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65 The situations in which all features of the claim are considered technical or the combination of the technical features in a claim is new and involves an inventive step do not involve particular problems and will be decided according to the usual criteria.

66 Federal Patent Court – *Automated Sales Control*, GRUR 1999, 1078, Federal Patent Court 20 W (Pat) 4/00 – *Self-Service Delivery of Chip Cards*, GRUR 2002, 418.

67 Federal Patent Court 21 w (pat) 38/00 – *Electronic monetary transactions*, BPatGE 45, 133.

68 Essentially, the Board stripped the features of the claim of their (non-technical) meaning, for example, considering data representing monetary units simply as data.

69 20 W (pat) 10/03, Mitteilungen der deutschen Patentanwälte 2005, 119.

70 See also the decision 20 W (pat) 314/02 – *Least Cost Telephone Connection (Preisgünstigste Telefonver- bindung)*, GRUR 2004, 931.

In the practice of the 17th Division, the problem of inventive step did not arise for a long time due to the strict approach with regard to excluded subject matter. However, in a decision handed down in September 2004,[71] the Division held that the mathematical algorithm underlying an image processor relates to a non-technical, namely mathematical problem and that only the implementation of this mathematical algorithm can be considered as patentable. However, the mere fact that the algorithm was implemented in an image processor was not even considered sufficient to establish the technical character of the claimed invention. Assessing auxiliary requests that involved additional hardware features, the Division assessed the question of inventive step only on the basis of technical features. This case shows the difficulties in establishing the borderline between a non-technical overall problem and a technical problem. If the subject matter of a claim is split into a technical and a non-technical part and, accordingly, a technical problem solved by the 'technical features' and a non-technical problem solved by the 'non-technical features' is defined, one will easily arrive at a point where any improvement of an existing device by software or, more generally, algorithmic means will be considered as non-patentable.

There are only a few decisions by the Federal Court of Justice dealing with the issue of inventive step. In one instance,[72] the court emphasized the distinction between a technical problem and a more general problem underlying this technical problem, which is similar to the approach taken by the EPO, for example, in T 172/03. In the previously mentioned decision, *Prepaid Telephone Calls*,[73] the Federal Court of Justice dealt with the issue of inventive step in detail.

The case related to a method of processing telephone calls, wherein certain amounts of telephone time were allocated to identification numbers which were applied in a visible manner on carrier cards such that they could be readily exposed, for example, by rubbing off a cover layer. These carrier cards were offered for sale so that the purchaser of such a card was enabled to place a call for the duration of the allocated time after exposing and entering the respective identification number. As prior art, it was known to have predetermined amounts of telephone time allocated to chip cards. On the other hand, it was also known to issue an identification code in return for the deposit of a certain prepaid amount of money, wherein the prepaid amount and the identification number were stored so that upon entering the

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71 17 W (pat) 31/03 – *Partition Tree (Partitionsbaum)*, Mitteilungen der Deutschen Patentanwälte 2005, 166.

72 Federal Court of Justice – *Electronic Financial Transactions*, supra.

73 Court of Justice – *Prepaid telephone calls*, supra.

identification code, a user could make telephone calls, which were debited from the prepaid amount.

The court held that, starting from this last-mentioned prior art, it was not obvious for a person skilled in the art to introduce a standardization of the prepaid amount, as was usual with chip cards, because, according to the opinion of the court, a simplification of distribution was only possible, if simultaneously there was a solution to the problem of how the identification number could be safely made known to the customer. It was considered relevant that it was necessary to allocate the credit associated with the identification number prior to the purchase and to make the identification code available to the customer.

In this decision the court did not distinguish between technical and non-technical features and apparently also considered non-technical steps, such as the allocation of a certain amount of telephone time to an identification number in a standardized manner as relevant for inventive step. Likewise it was apparently important for the decision that an identification number was allocated prior to the purchase and that the identification number was communicated to the customer. This is in contrast to the practice of the EPO that generally disregards non-technical features. It is not clear from this decision whether the Federal Court of Justice indeed intends to establish criteria different from those of the EPO or whether this was just a decision on an individual case, which will not necessarily allow conclusions for subsequent cases.

4.3 Practice of the British courts

The current practice of the British courts and of the British Intellectual Property Office[74] follows the standards laid down in the *Macrossan* decision[75] mentioned previously, which takes up criteria established in the earlier *Merrill Lynch* decision,[76] simultaneously moving away from criteria established in the *CFPH* decision,[77] and which is explicitly meant to distinguish UK practice from that of the EPO.

In the *Macrossan* decision, the court initially took the view that the various exclusions of Article 52(2) EPC do not fall within a common concept and, accordingly, each of the exclusions has to be treated in its own right. Considering cases where the only new and non-obvious features of the claim

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74 Practice note, 'Patents Act 1977: Patentable subject matter' of November 2, 2006, available at http://www.ipo.gov.uk/patent/p-decisionmaking/p-law/p-law-notice.htm.

75 Court of Appeal (Civil Division) - *Aerotel* and *Macrossan*, supra.

76 UK Court of Appeal (Civil Division), *Merrill Lynch's Application* [1989], supra.

77 High Court of Justice (Chancery Division) *CFPH's Applications*, supra.

are patently non-technical, such as a new music piece on a CD or a book containing a new story, they rejected the approach taken by the Boards of Appeal at the EPO. They essentially reverted to the previous contribution approach, as initiated by the *Vicom* decision,[78] albeit with the modifications made in the *Merril Lynch* decision.[79] The court expressed sympathy for the approach of disregarding non-technical features rejected in the *Merril Lynch* case, but considered itself bound by the precedent.

Based thereon, the court formulated a test consisting of the following four steps:

(1) properly construe the claim;
(2) identify the actual contribution;
(3) ask whether it falls solely within the excluded subject matter;
(4) check whether the actual or alleged contribution is actually technical in nature.

Step (4) was not really considered necessary, but it was required by the precedent of the *Merril Lynch* case.

The first of the two cases decided in this decision (*Aerotel*) related to a telephone system involving prepaid telephone fees, wherein in order to have a call connected, a user had to dial a special exchange that verified that there was a sufficient amount of the prepayment left. If so, the call was connected, the prepayment was monitored and the call was disconnected, when the prepayment was spent.

The court held that the claim implied a new hardware configuration by virtue of the special exchange, and concluded that the claimed system and method were new and that the claims did not relate to excluded subject matter.

The second case to be decided (*Macrossan*) related to a computer-based method of producing documents, wherein a user was posed questions in a number of stages, and the information obtained from the user's answers was used to produce the required documents. The questions posed in subsequent stages were determined by the previous answers provided and the user's answers were stored in a database structure. This process was repeated until the user had provided enough information to allow the documents required to create a corporate entity to be generated. A number of document templates were also stored and the data processor was configured to merge at least one of these templates with the user's answers to generate the required legal

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78 T 208/84 – *Vicom*, supra.

79 UK Court of Appeal (Civil Division), *Merrill Lynch's Application* [1989], supra.

documents. The documents might then have been sent in electronic form to the user for the user to print out and submit, mailed to the user, or submitted to the appropriate registration authority on behalf of the user.

The court considered the claimed subject matter as excluded under both the business method exception and the computer program exception.

Applying the above test, the court noted that the claim did not involve new hardware and that the invention resided in an interactive system that performed a task otherwise done by a solicitor or company formation agent. The court found this contribution to be solely excluded matter under the description of a business method as such. They rejected the notion expressed in the judgement of the lower court that this exclusion related to an abstract concept, invoking the understanding that the exclusions of Article 52(2) EPC do not come under the common concept of abstract ideas. They also rejected the argument of the lower court that the claim did not relate to a business method as such, but to a tool for doing business, on the grounds that the fact that a new tool was created was irrelevant, referring to the previous *Fujitsu* decision.[80]

Applying the test to the exclusion of computer programs, the court found that the contribution consisted in the provision of a computer program, in practice an interactive website, which could be used to carry out the method, whereas the hardware was standard and not part of the contribution. Accordingly the court found that the contribution was just the program and the contribution was not technical.

It is to be noted that the decision does not say how the contribution of the art is to be determined in a different way from the previous High Court decision in the *CFPH* case, which applied the criterion that the claimed subject matter has to be new and non-obvious under the description of an invention, given the case following a prior art search.[81] It is also to be noted that in the *Macrossan* decision the court did not consider prior art, except the standard telephone system in the *Aerotel* matter, and also did not consider the question whether the claimed subject matter was non-obvious due to excluded or non-technical subject matter.

This decision reflects a common law approach to the issue that it may be difficult to follow in jurisdictions with codified law, such as prevail on the European continent. These hold that the requirement of technical subject matter and the exclusions of Article 52(2) and (3) EPC form a separate criterion in addition to those of novelty, inventive step and susceptibility of indus-

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80 *Fujitsu Limited's Application* [1997] EWCA Civ. 1174, [1997] RPC 608.

81 High Court of Justice (Chancery Division) *CFPH's Applications*, supra, sections 93 to 96.

trial applicability. If so, there is a need to construe this criterion independently of the other criteria and especially of the prior art which is the basis for determining novelty and inventive step.[82] In fact, whether certain subject matter is technical and/or falls within one of the exclusions for Article 52(2) and (3) EPC cannot depend on the point of time when this consideration is made, in contrast to the issues of novelty and inventive step, where the EPC itself relates these criteria to a certain point in time, namely the application date or the priority date. Any other approach would lead to the result that only what was created after a certain date could count towards technical character or non-existence of an exclusion, and features known before this date could not. This would mean that if the only new features are non-technical or are exclusively related to excluded subject matter, a patent cannot be granted. In consequence, the improvement of a technical device, such as an ABS brake, by suitable control software would not be patentable. Case law both on the European continent[83] and in the United Kingdom,[84] however, seems to hold the reverse to be the case.

Despite the differences in the approach, there is a striking similarity between the practice of the UK courts and the practice of the 17th Division of the Federal Patent Court, especially in that both seem to require that there be changes to the hardware or its operation.

Following the *Macrossan* decision, the UK Intellectual Property Office issued a practice notice on November 2, 2006, stating that it considers program product claims incompatible with the *Macrossan* decision, even if corresponding method and/or apparatus claims are found to be allowable, and consequently rejected such claims. The reasoning of the Intellectual Property Office was essentially that step (1) of the test of the *Macrossan* decision outlined above implies determining the monopoly awarded by a possible patent, that in case of a program or program product claim this monopoly relates to excluded subject matter and that the contribution to be determined in step (2) of the test cannot go beyond the scope of the monopoly. In a recent decision by the High Court,[85] it was held that program product claims or claims on programs are not excluded *per se* by the law, essentially following the reasoning in decision T 1173/97 by the EPO.[86] Especially, the court found

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82 See T 154/04, supra, sections 10 and 12 of the reasons.

83 Federal Court of Justice – *Anti-Blocking-System*, supra n. 7, T 154/04, supra n. 45, section 13 of the reasons.

84 Court of Appeal (Civil Division) – *Aerotel* and *Macrossan*, supra, sections 78 to 83; note, however, the dissent of Lord Justice Jacob in section 35 of the decision.

85 High Court of Justice (Chancery Division), *Astron Clinica Limited and others*, supra.

86 T 1173/97 – *Computer Program Product*, supra.

that allowing this type of claim is not in contradiction to the *Macrossan* decision, stating that the *Macrossan* decision requires the analysis to be carried out as a matter of substance not form and especially did not doubt decision T 1173/97 of the EPO. In a further practice notice of February 7, 2008,[87] the UK Intellectual Property Office announced that it will adapt its practice accordingly with immediate effect.

4.4 Comparison

Despite the different approaches, there was and still is a common problem in all European jurisdictions, namely to define criteria to exclude certain subject matter that is commonly held unpatentable in a manner that provides legal security in advance of a decision by a patent office or a court. The Court of Appeal in the *Macrossan* decision put its finger on the problem by referring to the case of a book with new content or a CD with a new piece of music, both of which are physically different from books or CDs that existed before. There will be general agreement (and not only in Europe) that a patent cannot be granted by virtue of the mere implementation of new content in a physical device.

Dealing with this problem, one can distinguish essentially two approaches. One approach is to ask what the invention is essentially about. This is the former approach of the German core doctrine and apparently also the approach of the British courts and essentially also of the 17th Division of the German Federal Patent Court. The other approach is to ask what the technical problem underlying the claimed subject matter is. This is the approach of the EPO and of the German Federal Court of Justice.

In the case of the above examples one would say, following the first approach, that the invention is essentially about a new literary work or a new piece of music, which is excluded from being patented. Under the second approach, one would determine the problem underlying the invention as implementing the new content in a carrier medium. As it is well known how to produce a book with any given text or to record a given piece of music, the solution to this problem is usually obvious to a person skilled in the art.[88] The latter is, in fact, the approach already taken by the EPO in the *Vicom* decision,[89] which required consideration of the claimed subject matter as a whole and comparison of this to the prior art. In the context of the *Vicom* decision the

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87 http://www.ipo.gov.uk/patent/p-decisionmaking/p-law/p-law-notice/p-law-notice-subjectmatter-20080207.htm.

88 In certain fields of experimental arts there may be severe difficulties for an ordinary person skilled in the art to implement the content on a carrier medium, in which case, however, the implementation may constitute a patentable invention.

89 T 208/84 – *Vicom*, supra.

term 'technical contribution' cannot be understood except as a technical solution to a technical problem or, in the words of the German Federal Court of Justice, as those features establishing a teaching for a technical activity on the basis of which inventive step is to be assessed.[90]

In both approaches, at some point one has to disregard certain features. In the first approach these are technical features that are thought to be commonplace or a priori not inventive. In the second approach these are non-technical features that are considered as belonging to the conception or motivation phase normally preceding an invention.[91] According to both approaches there is the possibility that a technical effect implied in a seemingly non-technical feature or in the combination of a technical and a non-technical feature may be overlooked. The second approach has the advantage that it more closely resembles the situation in the real world, where, for example, a software developer is asked to implement a business method on a computer, and thus is more accessible to an objective review, whereas the first approach makes an a priori assessment of what can or cannot be considered as inventive under the description of a patentable invention, usually without making a detailed comparison with the prior art.[92]

It should also be noted that there is in fact little difference between the approaches, if one considers the claimed subject matter as a whole. Each of the approaches ultimately aims to establish the technical content of a claim and to subject this technical content to the examination of novelty and inventive step. The problem and hence the source of the differences is rather how this technical content is to be determined. This is a straightforward exercise, if technical and non-technical features are unrelated, at least to such an extent that the combination of both is patently obvious, such as in the case of a printed book or a CD with a piece of music. However, a combination of technical and non-technical features may have a technical character of its own, as is accepted in the case law. Furthermore, quite frequently technical subject matter is described in a non-technical manner, especially in relation to a computer, which is frequently described as acting like a person. It is at this point that the case law may potentially differ. Following a correct approach, one has to examine whether non-technical language implies technical content and whether a combination of technical and non-technical features can serve the solution of a technical problem. This is, however, not always done and quite

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90 Federal Court of Justice – *Electronic Financial Transactions*, supra.

91 Cf. T 1284/04, unpublished, section 3.1. of the reasons.

92 In fact, in the decision of the UK High Court – *CFPH's Applications*, supra, there was an attempt to remedy this by first making a complete assessment of novelty and inventive step and then deciding whether what establishes novelty and inventive step is exclusively non-technical and/or excluded subject matter.

frequently, rightly or not, it is done in a summary manner. The approach by the EPO is more robust in that it relates the issue to an assessment of inventive step, where it is established practice to consider the entirety of features. On the other hand, an approach separating features believed to be essential or prominent features from other features entails the risk that the technical implications of a combination of features is overlooked or disregarded.

Properly construed, all of the above approaches should lead to similar results. It does, however, sometimes seem that the differences in case law are related less to the approach applied, than to the mindset of the decision-makers. In some instances, there seems to be a notion that only modifications to the hardware and its operation can constitute technical subject matter, whereas in other instances[93] it is held that software and data can form technical subject matter as well.[94]

5 Patent Office practice

Whereas legal theory and fine points of case law are exciting topics for discussion, papers and presentations, the examination practice is frequently unaffected by them and rather follows its own, more robust rules. Over the years, certain categories of patentable subject matter have emerged which are generally considered as patentable or largely believed to be non-patentable, respectively. Such categories of patentable or non-patentable subject matter usually have a common type of technical problem to be solved.

Subsequently, an attempt is made to give an overview of some of the more important classes, it being understood that the various categories are mostly established empirically and deviations from the practice as outlined are always possible in the individual case.

5.1 Post-computer process activities

This class relates to cases where software is used to control a machine or a process other than a computer or its peripherals. The classic example is the ABS brake, which is software controlled. Although it is the software that makes the contribution over the prior art, nobody doubts that a brake forms technical subject matter. It is usually accepted that a new and inventive feature can reside in a detail of the control algorithm used. The technical problem may be seen as improving the machine as a whole, with the algorithm being the

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93 Cf., for example, T 1194/97, supra, T 110/90 – *Editable Document Form*, OJ 1994, 575, T 163/85 – *Colour Television Signal*, OJ 1990, 379.

94 In fact, a recurring argument of applicants is the analogy between hardware and software. As early as 1976 the case law holds that it is not pertinent whether the invention is implemented in hardware or software; cf. Federal Court of Justice – *Disposition Program*, supra.

solution to the problem. Problems may arise when the machine or process to be controlled is only vaguely referred to, for example, as a 'physical' or 'industrial process'. This may result in rejection, if there is insufficient support by more specific embodiments in the specification.

5.2 Pre-computer process activities

This class relates to cases where the output of a technical device is delivered and processed by a computer. An important sub-class relates to measurement devices where the software is used to process and evaluate the measurement data.

It is mostly agreed that, for example, a measurement device is technical. Details of a data-processing algorithm are usually accepted as inventive features.[95] As in the case of post-computer process activities, problems may arise when the process or device to which the software is related is not clearly specified. Another problem may arise if the evaluation of data is not directly linked to the measurement, that is, if the subject matter of the claim can be split into a device and/or method of measuring certain quantities and a method or device for evaluating the data. This may be the case where the measurement data are stored and read into a remote computer. There is, however, a tendency to reject applications where the data acquired are related to businesss issues, rather than having a technical content.[96]

5.3 Operation of a computer

It is generally accepted in both German and EPO practice that a new way of operating a computer is patentable. Largely speaking, the technical problem is seen as providing a new and improved computer with additional features over the prior art. A new way of operating a computer may not only be a new configuration of a computer, but may also comprise elements of a computer program not related to information processing but rather to the way a computer manages and processes data. This category of subject matter was sometimes critical in the earlier years, as it was disputed whether the invention related to an improvement of a computer or to an application running on an otherwise unchanged computer (and, in fact, these two cases frequently cannot be distinguished properly). Subsequently, the deciding authorities were more inclined to the former point of view. It should, however, be noted that the British courts and the 17th Division of the German Federal Patent Court seem to require that there be modifications to the hardware or its operation.

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95 Cf. Federal Patent Court 23 w (pat) 55/04, supra.

96 Federal Patent Court, 21 w (pat) 12/02, Federal Court of Justice – *Determination of Profitability*, supra; see also T 641/00 of September 9, 2002 – *Two Identities/COMVIK*, supra.

5.3.1 Operating systems Operating systems are software defining the way the system components and the processing are controlled. As an operating system defines the way a computer works, claims related to operating systems or components thereof usually should not pose problems. The same applies to protocols, especially network protocols, as these define the way two or more systems connected through interfaces cooperate.

5.3.2 Data handling This class is similar to operating systems in that it relates to parts of an application program affecting the operation of the computer, especially the way the data are stored or handled in processing.

Problems arise when the process at issue involves more than one computer, for example, in a network. Claiming one single computer may lead to a claim that is not clear. Claiming two or more interconnected computers may limit the scope of protection.

In order to arrive at a claim allowable under both the aspect of statutory subject matter and inventive step, the related steps or features must go beyond the conventional method of processing or storing data. If, for example, the claim merely states that data are input to and read out from a storage device, this will be considered as the normal operation of a computer. A specific order of storage operations and/or a specific treatment prior to storage, for example, data compression, is, however, potentially patentable. If the new process makes a computer run faster or use less storage space than according to other possible algorithms, this is usually an argument for patentability, although in a number of decisions one can see this argument discarded.[97]

5.3.3 Control data Control data are data that determine the operation of a computer or a computer-controlled device, such as a printer, as opposed to data that merely carry information to be processed. A method involving the manipulation of such control data was therefore held to be patentable.[98]

With the *Data Structure Product* decision,[99] a claim to control data stored on a data carrier to be used in a computer-based system should be allowable, provided it is sufficiently specified which function these control data invoke in the system in which they are to be used. In a decision handed down in 2003,[100] it was held that information that is specifically formatted or represented to reflect the properties of a technical system has a technical character,

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97 See, for example Federal Court of Justice – *Logic Verification*, supra, or Federal Patent Court, 17 w (pat) 69/98 – *Search of Faulty Character Strings II*.

98 EPO T 110/90, OJ 1994, 557.

99 EPO – *Data Structure Product*, supra.

100 T 643/00 – *Canon*, unpublished.

which may be the case for an electronic or a graphical representation of such information, for example, on a graphical user interface.

5.4 User interfaces

Another class of 'technical effects' cited frequently relates to the interaction between the user and the computer. If the input is arranged in a way that makes the computer or the program run on it more easy to handle, this frequently qualifies as a technical effect or the solution to a technical problem. Examples of such human/machine interfaces are the provision of an input mask for simultaneously inputting data for two different processes or the enlargement of a cursor being moved over the screen. In a decision in 2003,[101] the Board of Appeal emphasized that an arrangement of menu items on a screen may be determined by technical considerations and that the mere fact that mental activities are involved does not necessarily qualify subject matter as non-technical, if in the end tools are provided which serve, assist or replace human activity of different kinds, including mental ones. This should, however, be contrasted with the previously mentioned decision by the Federal Patent Court[102] holding that ergonomic improvements do not form technical subject matter.

5.5 Dialog methods

Methods involving the interaction of a human with a computer can be patentable, if the human basically acts like a machine, that is, he gives a predetermined response to a predetermined output. A good criterion is whether in principle the method could be automated. If, however, the claimed method depends on a decision or evaluation by a human as an essential feature, for example, a decision on which data should be stored and processed, the question of technical subject matter will arise.

6 Conclusion

After a period lasting until about 2001 marked by a trend to grant patent protection to software-related inventions in a liberal manner, for some time a tendency to reverse former developments and undo developments in the past which were considered to have gone too far was observable. Despite continuing opposition by circles adverse to any patenting of software-related inventions, the beginning of a return to a less restrictive practice is noticeable. In any case, there is a large field of software-related subject matter, the patentability of which is undisputed. With the current case law of the EPO, but

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101 T 643/00 – *Canon*, supra.

102 Federal Patent Court 17 w (pat) 10/04, supra.

also with the improvements in the search facilities of the patent offices and the increase of prior art created by the large number of software-related applications and the Internet, inventive step is becoming the prominent issue. In many cases, software-related applications are no longer disputed on the grounds of the technical subject matter exclusions of Article 52(2) EPC, but simply rejected because of prior art. A major problem to be resolved by the case law is the relevance of non-technical features for the question of inventive step. However, one can recognize certain criteria emerging in the case law and one can expect that these criteria will become more specific with time. A prevailing problem is still to find proper criteria for establishing the technical content of a claim and to define a technical problem.

12 Utility and industrial applicability

Christopher Wadlow

Introduction

With the WTO TRIPs Agreement[1] in mind, this chapter addresses both utility and industrial applicability. According to TRIPs, Article 27(1):

> [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [Fn].
>
> [Fn]. For the purposes of this Article, . . . 'capable of industrial application' may be deemed by a Member to be synonymous with . . . 'useful' . . . .

Outside TRIPs, and in present-day usage, 'useful' and 'utility' are terms of art in American patent law, whereas 'industrial application' is a term of art in European Law.[2] The Patent Act (1952) of the United States provides:[3]

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.

Conversely, Article 52(1) of the European Patent Convention formerly provided:[4]

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[1] Agreement on Trade Related Aspects of Intellectual Property Rights (Marrakesh, 1994).

[2] It may be assumed that any developed system of patent law will have some kind of requirement corresponding to at least one of these, most probably that of industrial application, but legal systems outside the American and European traditions are not intended to be covered by this chapter. Japanese law uses 'industrial application'. Common law countries (such as Australia, Canada and New Zealand) may retain 'utility' in the former English sense, as well as the old English statutory formula 'manner of new manufacture', resulting in a more restrictive approach to patentability than under current US law.

[3] 35 USC § 101 ('Inventions patentable'). Utility is not further defined in the statute.

[4] Convention on the Grant of European Patents (Munich, 1973). The text quoted being that in force during the negotiations for TRIPs. Article 52(1) has recently been amended expressly to provide for patents to be granted in 'all areas of technology', see below at note 71. See also UK Patents Act 1977 ss 1(1)(c) and 4(1).

> European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.[5]

And in this case 'industrial application' is further defined by Article 57:

> An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

TRIPs itself has nothing further to say about what any of these terms mean, and there is no decision in point under the WTO Dispute Settlement Understanding. From their inclusion as alternatives in TRIPs it may be supposed that the two concepts are related, but not necessarily that they are functionally equivalent, let alone identical. All that can be deduced with certainty is that the deliberate inclusion of these two alternatives precludes any inference that the draftsmen of TRIPs intended to incorporate by reference or implication any single existing standard of patentability, whether national or regional. Whatever 'utility' or 'industrial application' may turn out to mean, members are free to adopt the one or the other.

In the context of this book as a whole, the present chapter is concerned with the two doctrines in the abstract, almost entirely without reference to specific technologies or policy-based exclusions from patentability, from which utility and industrial application are not always easily distinguished. A more fundamental qualification is that the present chapter does not attempt to deal, except in passing, with 'inherent patentability' in the sense of whether there is something which can properly be called an 'invention' at all. The relevance of all these doctrines to factual circumstances of present-day importance is addressed in detail elsewhere: specifically Chapter 11 on computer software. The emphasis of the present chapter is on the origins of these two concepts in national and international law, and on the international treaty regimes which govern their meaning and relevance today.

The concepts in context

The utility of industrial and intellectual property

The whole of intellectual property law (in its broad modern sense, and in so far as it is not based on natural rights) must be assumed to have some kind of social utility, but this does not necessarily depend on the subject matter of any given intellectual property right being 'useful' in any relevant sense, whether as a category or with regard to individual embodiments. Copyright sometimes

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[5] In the (official) French and German texts of the EPC, the corresponding terms are '*susceptibles d'application industrielle*' and '*gewerblich anwendbar*'.

protects works which have some kind of practical or functional utility, such as maps, reference works, instruction manuals and computer programs, but it is not primarily with these in mind that copyright finds its utilitarian justification. On the contrary, there is an equally strong rationale for copyright in so far as it facilitates and encourages the production and dissemination of things of delight: fiction, poetry, films, music and works of art, none of which makes any claim to practical utility. As Oscar Wilde remarked: 'All art is quite useless.'[6]

Within intellectual property law as a whole, 'utility' as such is found as an essential requirement only for patents properly so called, and for the related minor categories of rights which go under the names of 'utility models' and 'petty patents'. At the other extreme, intellectual creations protected by copyright, or by 'neighbouring rights', require neither utility nor industrial applicability. Since the late nineteenth century the world of intellectual property has exhibited a well-established dichotomy between rights subject to the Paris Convention (formerly 'industrial property', though the term was always misleading and is now obsolete); and those exemplified, though not exhaustively, by the Berne Convention (copyright and neighbouring rights, or 'intellectual property' in the original sense). It is implicit that trade marks, geographical indications, industrial designs, and other rights, to the extent that they are covered by the Paris Convention, have some relevant 'industrial' character, but although they may be socially useful, they certainly do not require any kind of utility in the patent sense.

The place of utility in patent law

Within patent law, novelty, non-obviousness and utility (for Americans), or novelty, inventive step and industrial applicability (for Europeans) define an inescapable pair of verbal or conceptual trinities – in each case the bare minimum to which patentability can be reduced. Patent apologists (or propagandists) emphasise the interconnectedness of the three: surely the inventor deserves some return from society for the socially beneficial exercise of his inventive genius, and who could object to giving him short-term exclusive economic rights over something which *ex hypothesi* is both *new* (so that the public are not deprived of anything they already have) and *useful*.

> The patent system . . . secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of *new* and *useful* things.[7]

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[6] Oscar Wilde, *The Picture of Dorian Gray* (London: Ward, Locke & Co., 1891), Preface.

[7] Emphasis added. Abraham Lincoln, 'Lecture on Discoveries and Inventions'

Note that without both novelty and utility, the case collapses. Without the requirement of novelty, the likelihood is that patents would once more degenerate into what they too often were in Tudor England: arbitrary rent-seeking monopolies over everyday essentials. Without utility, the claims of the patent system to promote technical and economic progress would seem to be null and void, with the public being asked to support a system which promised to supply nothing more beneficial than an ever-changing amusement arcade of zombies,[8] flying saucers[9] and perpetual motion machines,[10] beer can umbrellas[11] and Santa Claus detectors.[12] Useless or frivolous patents may individually do little or no harm, but neither do they confer any practical benefit on anyone.

From this brief analysis one might suppose that utility (to concentrate on the American term) is of fully equal importance in patent law with novelty and non-obviousness. Nothing could be further from the truth, whether in legal theory, or in actual practice. Novelty and obviousness are central to the validity of every patent which is examined or litigated, but at a very early stage in American history, utility – a Constitutional requirement no less – was reduced to meaning little more than 'not demonstrably useless or harmful'. Today it is taken for granted that novelty and obviousness are evaluated by reference to the 'state of the art', which advances every day, so that what was new and non-obvious in Benjamin Franklin's time (his eponymous stove, for instance) ceased to be either new or inventive long before his death. But in Anglo-American law utility has never been required to have the same incremental quality. A stove which worked no better than Franklin's (or maybe not so

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(Jacksonville, Illinois; 11 February 1859), quoted in Michael Novak, *The Fire of Invention, the Fuel of Interest: On Intellectual Property* (Washington: The AEI Press, 1996), p. 6.

[8] For fictitious zombies, see Andrew Knight, 'A Potentially New IP: Storyline Patents' (2004) 86 *Journal of the Patent and Trademark Society*, 859. For real zombies: US 6,838,550 (Goeddel and Yingping, 'Suppressors of Death Domains'). Despite its title and inclusion in www.patentlysilly.com, this patent is (probably) genuine. At any rate, the inventors appear to be real, live, scientists; and it was assigned *inter vivos* to Amgen, who presumably knew what they were letting themselves in for.

[9] GB 1,310,990 (Frederick, 'Space Vehicle'); US 6,960,975 (Volfson, 'Space Vehicle Propelled by the Pressure of Inflationary Vacuum State'), the latter also being a flying perpetual motion machine. The former (granted in 1973 to the British Railways Board, who even paid renewal fees until 1976) was more conventionally powered by nuclear fusion.

[10] As well as Christopher Wadlow, 'Patents for Perpetual Motion Machines' (2007) 2 JIPLP 206 (and cases there cited) see *In re Newman*, 782 F.2d 971 (Fed. Cir. 1986) and *Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989). For Joseph Newman's invention at the EPO, see T 5/86 NEWMAN/*Perpetual motion*, [1988] EPOR 301.

[11] US 6,637,447 (McMullin *et al.*).

[12] US 5,523,741 (Cane).

well) would still have sufficient utility to be patentable two centuries and more later. Only in Germany and Switzerland has the law ever required incremental utility, in the sense that a patentable invention should actually be a technical improvement on what was previously known.[13]

Without wishing to anticipate the whole of the present chapter, utility in the American sense seems more relevant to patent mythology than to legal reality. With isolated exceptions,[14] utility in American law is for the most part a minor doctrine of no more than residual importance, invoked in few cases and determinative in fewer still.[15] As and when it recurs in the rest of this chapter, readers may like to ask themselves if utility deserves no better than to be dismissed in the same terms as Nobel prize-winning physicist Richard Feynman reserved for the neutrino: '[it] is almost, but not quite, totally useless – take your son-in-law as a model'.

Historical origins

Venice, Florence and London

By general agreement, the world's first patent in the modern sense was granted in Florence in 1421, the first written patent law was that of the Venetian Republic in 1474, and the longest uninterrupted history of patent legislation is that of the United Kingdom, dating back to the Statute of Monopolies of 1623. Each of these has some bearing on the concepts of utility or industrial applicability, though in no case is the correspondence with modern law exact.

The Venetian statute was enacted in 1474.[16] The effective part of the statute refers to the inventor of 'any new and ingenious device, not previously made within our jurisdiction', but the preamble emphasises that the social and economic utility of this monumental legal innovation both depended on, and corresponded to, the practical utility of the inventions themselves:[17]

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[13] For a plea for Europe to adopt the former German system, see Hanns Ullrich, *Standards of Patentability for European Inventions: Should an Inventive Step Advance the Art*? (Munich: Max Planck Institute, 1977, IIC Studies Vol. 1).

[14] Exceptions (unlike genes) remaining unpatentable, even when isolated.

[15] The modern high point of the utility doctrine in litigation (as opposed to examination) appears to be the decision of the Federal Circuit in *Juicy Whip v. Orange Bang*, 185 F.3d 1364 (Fed. Cir. 1999), holding that the statutory utility requirement was met by a drinks dispenser whose novelty resided in a design feature intended to deceive the public into believing that they were buying fruit juice from a 'pre-mix', rather than a 'post-mix' machine, the pre-mix kind being more popular. The court below had held that the patent lacked utility because its purpose was to increase sales by deception.

[16] See Christopher May, 'The Venetian Moment' (2002) 20 *Prometheus* 159, which includes several translations of the Statute and a review of previous literature.

[17] This translation taken from Jeremy Phillips, 'The English Patent as a Reward

> There are in this city and its neighbourhood, attracted by its excellence and greatness, many men of diverse origins, having most subtle minds and able to devise and discover various ingenious artifices. And, if it should be provided that no-one else might make or take to himself to increase his own honour the works and devices discovered by such men, those same men would exercise their ingenuity, and would discover and make things which would be of no little utility and advantage to our state.

The requirement of individual utility was also implicit from the procedure for examination and grant, as to which Christopher May comments:[18]

> The issue of usefulness (which is one of the three central criteria of modern patent law, alongside novelty and non-obviousness) is clearly articulated in the phrase 'as soon as [the device] has been perfected, so that it will be possible to use and apply it'.

The Venetian statute may be contrasted with what is arguably Europe's oldest patent in the modern sense, which the City of Florence awarded in 1421 to Fillipo Brunelleschi in respect of a boat for carrying heavy loads (such as marble, needed for completion of Brunelleschi's extraordinary Cathedral dome) on the shallow River Arno.[19] The patented boat was built and operated as the *Badalone*, but was not a success. What distinguishes Brunelleschi's patent from earlier monopoly grants in Florence (such as a ten year tax exemption for importing weaving technology) is the beginning of a linkage between invention, disclosure, and reward. It has been called the first modern patent, but the legal innovation it represented sank without trace, like the *Badalone* herself.

The English Statute of Monopolies of 1623 was intended to put an end to previous abuses under which patents granted under the Royal Prerogative had sometimes protected genuine technical innovations (or useful foreign technologies newly copied and imported, which for England in the sixteenth and seventeenth centuries was far more important), but had equally been used to create private monopolies for royal favourites on such everyday items as starch, vinegar and playing cards.[20] The 1623 Act permitted the grant of

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for Invention: The Importation of an Idea' (1982) 3 *Journal of Legal History* 71; quoted in May (2002).

[18] May (2002), 165.

[19] Frank Prager, 'Brunelleschi's Patent' (1946) 28 *Journal of the Patent Office Society* 109.

[20] Described as the 'three worst patents of the [Elizabethan] reign' in E Wyndham Hulme, 'The History of the Patent System under the Prerogative and at Common Law: A Sequel' (1900) 16 LQR 44. The monopoly on playing cards was declared illegal in the famous '*Case of Monopolies*', *Darcy v. Allin (or Allen)* (1602) 1 Web. Pat. Cas. 1; 11 Co. Rep. 84b.

patents for any new 'manner of new manufacture', if not 'contrary to the lawe nor mischievous to the state, by raisinge prices of commodities at home, or hurt of trade, or generallie inconvenient'; and this proviso led in due course to the doctrine of utilty in English, and American, law.

Compared to the positive tone of the Venetian statute, the English statute was more downbeat: it was more an act *against* monopolies in general than in favour of patents.[21] Nonetheless, it acknowledged that patents were not necessarily undesirable, and it provided the basis for English patent law until well into the twentieth century. The formula used in the Act of 1623 continued to be used to define patentability in English law until it was superseded by 'industrial application' in the Patents Act 1977, to conform to the UK's new international obligations.[22] 'Manner of new manufacture' had come to be defined by analogy with established practice, and its meaning was subject to incremental (and occasionally radical) updating.[23] Because 'manner of new manufacture' was defined more by past practice than by principle, and because 'industrial application' had the opposite problem, it was hard to say precisely how the two concepts differed, but the new term was thought to embrace everything within the old, and probably a bit more.[24]

The former English doctrine of inutility is another which was abolished for the sake of European harmonisation. The rationale for the common law doctrine was well stated in the mid-nineteenth century in the classic text by William Hindmarch (citations omitted):[25]

> Utility to the public is, in fact, the consideration for every grant of the sole use of an invention, and letters patent containing such grants always state the public good to be the motive of the Crown in making the grants. It is not every thing invented, therefore, to the sole use of which the inventor can become entitled, for the thing itself (although perfectly new) may be of no value whatsoever to the public. And an

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21 It is instructive to compare the recital to the Venetian statute, with that to the English one.

22 Under the Strasbourg Convention, 1963, and the European Patents Convention, 1973. UK Patents Act 1977 ss 1(1)(c) and 4.

23 See *United Kingdom Patent Law: The Effects of the Strasbourg Convention of 1963* (London: HMSO, 1965, Cmnd. 2835) (the 'Tookey Committee') pp. 10 *et seq.*; and *The British Patent System: Report of the Committee to Examine the Patent System and Patent Law* (London: HMSO, 1970, Cmnd. 4407) pp. 61 *et seq*. (the 'Banks Committee'). It has remained the formal standard for patentability in several common law jurisdictions, such as Australia. See Justine Pila, 'The Common Law Invention in its Original Form' [2001] IPQ 209; Sam Ricketson, 'Business Method Patents: A Matter of Convenience?' [2003] IPQ 97.

24 Tookey Committee, pp. 10 *et seq*., Banks Committee, p. 64.

25 W.M. Hindmarch, *A Treatise on the Law Relating to Patent Privileges for the Sole Use of Inventions* (London: Stevens, 1846), p. 3.

> exclusive right vested in any one to use a thing, which at the time it is given or offered to the public, is of itself of no value, might prevent others from bringing forward useful and profitable inventions, by reason of such otherwise useless thing forming part of their inventions. . . . Still less will the inventor be injured for want of such an exclusive right if the invention is of no utility either to himself or the public, and he cannot have any right by means of his useless invention to anticipate and appropriate to himself any part of the profit to arise from the subsequent invention of any other person who may be able by his ingenuity to confer an actual benefit upon the public.

In modern law, inutility arose not only when an invention was completely useless or unworkable (in the technical, rather than commercial sense), but more importantly, to the extent that a promised benefit relevant to patentability was not produced.[26]

> Inutility, in the sense in which that word is used in modern patent law and practice, is concerned solely with the scope of the claim, and means that the claim covers a mechanism or a process which is useless for the purposes indicated by the patentee i.e. which does not produce the result or one of the results claimed in the specification. A patent would also be void for inutility if the invention was useless for any purpose whatsoever, but this is a circumstance which is unlikely to occur in practice.

Utility in the age of revolutions

According to the Constitution of the United States:[27]

> The Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;

The Constitutional power to grant patents extended only so far as it might be exercised to promote *useful* arts. The early patent acts of the new Republic were not explicit as to what degree or kind of utility was required,[28] but the degree to which an invention needed to demonstrate utility if it was to be patentable was addressed judicially very early in the history of United States patent law:[29]

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[26] Douglas Falconer *et al.*, *Terrell on the Law of Patents* (London: Sweet & Maxwell, 12th ed., 1971) §246.

[27] Constitution of the United States (1787) Article 1, Section 8, Clause 8.

[28] The first US patent acts were those of 1790 and 1793, the latter being amended in 1800. The 1793 Act allowed any US citizen to apply for a patent on 'any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement . . .' which he had invented.

[29] *Lowell v. Lewis*, 15 Fed. Cas. 1018 (Circuit Court, Massachusetts, 1817).

> All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention. But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.

In effect, and apart from these special cases, Justice Story would have delegated the test of utility to the market.

As United States law developed, utility remained a statutory requirement for patents, as it still does.[30] The actual standard required, however, remained very low. Case law and practice throughout the nineteenth century, and well into the twentieth, affirmed that an invention had to be wholly unworkable for the objection of inutility to arise. The period of major legal activity began in 1950 with *In re Bremner*,[31] in which the Court of Customs and Patent Appeals (CCPA) held that to satisfy the statutory patentability requirements, an application had to at least assert some kind of practical utility. What constituted sufficient utility in the case of new chemical compounds of unknown or speculative utility became a bone of contention between the Patent Office and the CCPA – with the Office insisting that the applicant must at least assert some plausible practical use, while in *In re Nelson*[32] the CCPA would have dismissed the requirement even for a bare assertion of utility as a 'mere formality', and a useless one at that. This period in the development of United States law was formally brought to a close in 1968 by the decision of the Supreme Court in *Brenner v. Manson*,[33] under which the *Bremner* test for specific utility was reinstated in the context of an application for a new process for producing a known chemical of suspected but unproven therapeutic value.[34]

In France, there are examples of patent-like grants of monopolies under the Royal Prerogative in the eighteenth century and before, but apparently not on

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Justice Story, an exceptionally learned Supreme Court Justice, was here sitting as a trial judge on circuit. The extract shows very clearly the influence of the English Statute of Monopolies.

30 Present-day discussion of utility in US law is dominated by biotechnology, and no attempt is made here to make this brief summary of the law's origins either complete or up to date.

31 (1950) 82 F.2d 216 (CCPA).

32 (1960) 280 F.2d 172 (CCPA).

33 (1968) 383 U.S. 519, 86 S. Ct. 1033, 16 L. Ed. 2d 69.

34 *Bremner* itself had more than arguably represented a tightening of long-standing Patent Office practice in the chemical field. There is evidence of a previously benign assumption of utility for novel chemical compounds. Compare the dissenting judgment of Justice Harlan in *Brenner v. Manson*.

any systematic basis. The first patent law of the Revolutionary period extended to inventions 'in every type of industry';[35] but patentable subject matter soon came to be restricted, so that protection extended to methods and manufactured articles, but excluding theoretical or scientific discoveries without practical application, financial methods, medicines, and items that could be covered by copyright.[36]

The French Patent Act of 5 July 1844, which remained in force with remarkably few modifications until European harmonisation in the 1960s and 1970s, provided:[37]

> 1. Any new invention or discovery, in any branch of manufacture,[38] entitles its author, upon the conditions and for the terms herein after mentioned, to the exclusive right of putting the said invention into operation, for his own benefit – This right is secured by documents, granted by the government, under the name of Brevets of Invention.
> 2. The following shall be considered as new inventions or discoveries: – The invention of new manufactures;[39] and the invention of new means, or the novel application of known means, for the purpose of obtaining a result, or a manufactured product. . . .
> 3. The following cannot be protected by Brevet: – 1st. Pharmaceutical compositions and remedies of any kind; . . . 2nd. Financial or monetary plans or combinations.

The later nineteenth century: Germany

For present purposes, German patent law may be taken as beginning with the enactment of the first Federal patent law (*Reichspatentgesetz*) in 1877, according to Article 1(1) of which an invention had to be '*gewerblich verwertbar*' ('susceptible of industrial application')[40] if it was to be patentable.

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35 Article 1 of the Law of 7 January 1791 began: '*Toute découverte ou nouvelle invention, dans tous les genres d'industrie, est la propriété de son auteur*; . . .'.

36 B. Zorina Khan, 'Intellectual Property and Economic Development: Lessons from American and European History' (Study Paper 1a for the UK Intellectual Property Commission), (London: HMSO, 2002), 15–16.

37 This translation taken from John L. Kingsley, *Laws and Practice of all Nations and Governments Relating to Patents for Inventions* (New York, 1848), p. 104. Also relevant is Article 30 (Grounds of invalidity), of which para. 3 invalidated patents 'founded upon purely scientific or theoretical principles, methods, systems, discoveries or ideas, without explaining the application thereof to the arts or manufactures'.

38 The translator has rendered the French '*industrie*' in Article 1 as 'manufacture'. The original French text begins: '*Toute nouvelle découverte ou invention dans tous les genres d'industrie . . .*'.

39 In the original, '*produits industrielles*'. The second part of Article 2 (omitted) dealt with novelty.

40 '*Gewerblich anwendbar*' is synonymous.

However, this was not the only relevant factor, because the definition of 'patentable invention' was deliberately left open-ended by this and subsequent acts, with the courts and the Patent Office defining the limits of patentability.[41] In the course of applying the Statute, Germany developed two highly characteristic doctrines which came to have an independent existence despite the absence of any explicit statutory support. In order to be patentable, an invention had to be in a 'technical field' ('*technisches Gebiet*'),[42] and it had to represent a 'technical advance' ('*technischer Fortschritt*') on the state of the art.

The requirement of 'technical advance' developed into an independent and fully-fledged doctrine unique to German (and Swiss) law, and of comparable importance to that of inventive step. In these two systems alone, a patentable invention, at least in theory, had to demonstrate its technical superiority over what was previously known in the art. In this respect, Germany may be regarded as having taken the concept of utility to its logical utilitarian conclusion: what rationale can there be for providing either reward or incentive for supposed inventions which do nothing to improve on what has gone before, and what consideration does even the most ingenious inventor provide by demonstrating that what can already be done, can be done worse or with more difficulty than previously?

International law: Paris, Strasbourg and Marrakesh

The Paris Convention

The Paris Convention for the Protection of Industrial Property[43] (1967) has its entire scope defined in terms of 'industrial property'. So far as relevant, Article 1 currently provides:

> (1) The countries to which this Convention applies constitute a Union for the protection of industrial property. . . .
> (3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive

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41 See Ullrich (1977). Even a doctrine as fundamental as that of inventive step was originally an extra-statutory innovation.

42 This requirement can be stated in other ways, such as that of 'technical character'. By whatever name, this factor went to inherent patentability, and is not further considered here.

43 Paris Convention for the Protection of Industrial Property (Paris, 1883; most recently revised at Stockholm, 1967). See generally G Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (Geneva: BIRPI, 1968); Stephen Ladas, *Patents, Trademarks and Related Rights: National and International Protection* (Cambridge, Massachusetts: Harvard University Press, 1975).

> industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

Article 1 of the original 1883 text of the Convention originally read in its totality:

> Les Gouvernements . . . sont constitues à l'état d'Union pour la protection de la Propriété industrielle.

Instead of what is now Article 1(3), there was originally a *Protocole de Clôture* (Final Protocol) of which Article 1 provided:

> Les mots Propriété industrielle doivent être étendus dans leur acception la plus large, en ce sens qu'ils s'appliquent non seulement aux produits de l'industrie proprement dite, mais également aux produits de l'agriculture (vins, grains, fruits, bestiaux, etc.) et aux produits minéraux livrés au commerce (eaux minérales, etc.).

After minor revisions at intermediate conferences, the text from the Protocol was incorporated into the body of the Convention as Article 1(3) at the 1925 Revision Conference in the Hague, and further modified (to its present form) at the London Conference in 1934.[44]

By its terms, the Paris Convention neither requires nor prohibits the granting of patents in any particular circumstances.[45] However, it has sometimes been argued that the Convention, at least by implication, mandates the granting of patents across the whole range of 'industrial property' as that term is to be understood by reference to Article 1(3). This is certainly wrong. The Paris Convention does not *require* patents to be granted in any circumstances, or indeed at all. Simply as a matter of grammar and common sense, if this were a legitimate interpretation then the same would be true of all the other enumerated industrial property rights of Article 1(2), including some (such as utility models) which are unknown to the majority of the states of the Paris Union, or obviously inappropriate to the subject matter supposed to be protected. Secondly, where the Paris Convention requires a particular kind of right to exist or be available in national law it says so explicitly, for example: trade marks[46]

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[44] Bodenhausen (1968), p. 25.

[45] With the sole exception of Article 4quater which states that a patent may not be refused or invalidated solely because of restrictions on the sale of the patented product in domestic law.

[46] Article 7 (nature of goods not to form an obstacle to registration of the mark) implying that registration of trade marks, if available at all, must be available for goods of all kinds.

and trade names;[47] industrial designs;[48] service marks;[49] and protection against unfair competition.[50] As Bodenhausen observes:[51]

> The meaning of the provision [Article 1(3)] is not that *all* subjects of industrial property indicated in paragraph (2), such as patents, trademarks, etc., shall apply to *all* activities and products mentioned in paragraph (3). There is therefore no obligation for the member states to grant patents for wine, cattle or fruit, or to protect trademarks with respect to minerals.

However, the Paris Convention and its concept of 'industrial property' are certainly relevant for present purposes. First, it will be seen in due course that the expression 'capable of [susceptible to] industrial application' (or 'industrial applicability' for short) in modern European law is expressly and intentionally derived from the corresponding usage of 'industrial' in the Paris Convention. Secondly, the Paris Convention undoubtedly forms an important part of the contextual background to TRIPs. It is therefore apposite to continue to bear in mind what the Paris Convention means by 'industry', and how the latter is defined in Article 1(3).

The Strasbourg Convention

Shortly after the end of World War II, attempts were made to promote the economic revival of the Continent of Europe (and, in a small way, its political integration) by providing for some kind of pan-European patent, to be issued, and possibly enforced, by appropriate European institutions. These proposals immediately ran into the problem that existing national patent laws were far too diverse for any such schemes to be possible without considerable prior harmonisation, and to this end the Council of Europe set up a working party of experts to compare national laws and make proposals, which eventually resulted in the Strasbourg Convention of 1963.[52] Although still in force, the Strasbourg Convention is relatively little known, and very poorly

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47 Article 8, dating from the original 1883 Paris text.

48 Article 5quinquies, dating from the Lisbon Revision of 1958. By necessary implication, there can have been no Convention obligation to protect industrial designs prior to then, although provisions in the body of the Convention relevant to industrial designs have existed since 1883.

49 Article 6sexies, also dating from the Lisbon Revision of 1958.

50 Article 10bis, the original substantive obligation dating from the Washington Revision in 1911.

51 Bodenhausen (1968) p. 25.

52 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg, 1963). The Convention came into force on 1 August 1980.

documented,[53] but it is of central importance in having settled many of the substantive rules of patent validity which were subsequently incorporated into the European Patent Convention, in most cases without further debate or explanation.

As a necessary preliminary exercise, the Experts' Committee compiled a survey of the patent laws of all participating states.[54] So far as 'Industrial Character' was concerned, the Committee noted:[55]

> The industrial characteristic is apart from novelty the only one which is required of a patentable invention by all the notional regulations (inventions 'capable of industrial application' Germany, Austria, Belgium, Denmark, Greece, Netherlands or arising from 'any kind of industry' France, Turkey or of 'manufacture' United Kingdom, Ireland).
>
> But though this fundamental requirement and to a large extent, its content do not vary significantly from one country to the other, the same cannot be said of the nature and the bearing of the very diverse ideas (result, technical effect, utility, etc. . . .) by which the limits of the 'industrial invention' are defined in the national doctrines or jurisprudences. A concept like that of 'utility' may refer to the technical or economic value of the invention ('Nützlichkeit') or to the possibilities of realising the invention (in the French or Belgian terminology), or to one and the other (the 'utility' of the British law) or to the 'technical' character of a product ('useful' as opposed to 'scientific' or 'aesthetic'), etc. It appears therefore to be better not to attempt to group under general headings the various exclusions laid down by the laws or practices but to stick to setting out the common features which an examination of the national replies reveals under the diversity of concepts.

A propos the patentability of all kinds of methods the Committee reported:[56]

> Though the patentability of inventions arising from the techniques of agriculture give rise to a diversity of replies, the same is not true of those which arise not from 'industrial' techniques but from financial, accounting, commercial, publicising, educational, military, touristic, medical, etc., techniques. All national practices

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[53] Fortunately, one of the few systematic treatments of the *travaux préparatoires* to the Strasbourg Convention bears closely, if not quite directly, on the present topic: Justine Pila, 'Article 52(2) of the Convention for the Grant of European Patents: What Did the Framers Intend? A Study of the Travaux Préparatoires', (2005) 36 IIC 755.

[54] Council of Europe, *Comparative Study of Substantive Law in Force in the Countries Represented on the Committee of Experts on Patents*, (Paris, 7 November 1953, unpublished) EXP/Brev (53) 18. National systems surveyed were those of Germany, Austria, Belgium, Denmark, France, Greece, Ireland, Italy, Luxembourg, Norway, the Netherlands, the United Kingdom, Sweden, Switzerland, and Turkey.

[55] *Ibid.*, Section I, p. 3. Subsequent paragraphs dealt with (1) Invention and Discovery; (2) Industry and Agriculture; (3) Systems, Methods, etc.; (4) Scientific Principles and Theories; and (5) Creations of Form.

[56] *Ibid.*, Section I(3), p. 5.

> agree in excluding from the field of application of the law monetary systems or systems of insurance, of accounting, of calculating, of teaching of publicity, etc., as well as rules of games, or methods of medical treatment.

The section concluded:[57]

> Finally, apart from its belonging in a general way to the field of 'industrial techniques' the patentable invention must in a more concrete manner present certain qualities of its own, on the nature of which, furthermore, national agreement ceases as soon as their appreciation passes from the plane of 'reality' to that of 'value'.
>
> It is in this way that the rule according to which the invention must be realisable (in accordance with natural laws; the British (sec. 10(1)(a)) and Irish laws contain an express provision to this effect), capable of repetition, suitable for carrying out in an industrial undertaking or for putting into practice for the needs of such an undertaking can be considered as of general application, although categories as precisely defined as those in the German law are not found everywhere.
>
> On the other hand a notion such as that of utility ('Nützlichkeit' or to some extent 'utility' in the special sense of British patent law) is quite foreign to French and Belgian doctrines, which leave on one side all questions of the technical worth of the invention, and *a fortiori* of its economic worth. Even the decisions which require, in addition to a technical effect (i.e. the immediate efficacy of the invention) a 'result', i.e. the realisation of the ultimate goal sought by the inventor, stop short at least in theory at a subjective enquiry into intentions to the exclusion of all objective estimation.
>
> It is not possible however, to make of this attitude a characteristic common to the 'law of the latins'. The '*incremento alle utilità*' of the Italian doctrine is to some extent akin to the 'utility' of the German doctrine.

Another relevant finding was that *technical progress* was a requirement of patentability only in German and Swiss law (and to some extent Italian, alluded to above), although there were other systems which either recognised technical progress as a makeweight for lack of inventive merit, or denied patentability to inventions which were actually retrogressive.

A draft by Eduard Reimer of what was to become the ancestor of both the Strasbourg Convention itself, and the European Patent Convention,[58] would have provided:[59]

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[57] *Ibid.*, Section I(6), p. 7.

[58] The present draft assumed that creation of a central European Patent Office was premature and instead proposed that national offices should grant European patents according to the (partially) harmonised law of the draft Convention, with a central 'European Court of Justice' to enforce them. A rival proposal (de Haan) proved more prescient: it would have given priority to the creation of a 'European Patent Council' charged with granting patents. For the purposes of the present chapter, the proposed substantive law did not differ significantly between the Reimer and de Haan proposals, except that in de Haan there was no residual role for national law.

[59] *Draft of a European Convention Relating to Patents of Invention* (1953) EXP/Brev (53) 19. Article III Section 1(1).

> The object of the application for a European patent must belong to the domain of technology, must be new, and must have a quantum of invention. . . .[60]

No other provision of that draft is relevant for present purposes, except that Article III, Section 4, reserved 'other grounds for refusal and conditions for granting the patent' to the legislation of the country in which the application was filed. The commentary explained that this meant not only matters of illegality and immorality, but also 'conceptions . . . regarding technical progress, utility, or commercial utilization of the invention, etc.' Reimer's explanatory memorandum for the draft Convention rather cavalierly added:

> The notion of technology is difficult to define completely. It will not be necessary to do it here: the task of dealing with this matter can be left to the practice of each examining office.

In the event, the proposals of 1953/4 were too far ahead of their time to be adopted. However, less ambitious plans for unification of national laws continued, albeit with no urgency. After several more false starts, the Experts' Committee approved what is recognisably a draft of the present Strasbourg Convention in July 1962.[61] This draft provided:

> In the Contracting States, patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. An invention which does not comply with these conditions shall not be the subject of a valid patent. . . .[62]

> An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry including agriculture.[63]

The preparatory documents for this draft are uninformative. The only relevant comment in the explanatory memorandum stated that Article 3:

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[60] Subsections (2) and (3) dealt with novelty and 'quantum of invention', or inventive step.

[61] Council of Europe, *Report of the Committee of Experts to the Committee of Ministers on the Meeting held at Strasbourg from 10th to 13th July 1962*. CM (62) 160 of 8 August 1962 (unpublished). The draft was originally drawn up at a meeting on 2 to 5 May 1962 and circulated as EXP/Brev (61) 4, and further discussed on 7 to 10 December 1962 as EXP/Brev (61) 8.

[62] Draft Article 1. The tailpiece to Article 1, requiring revocation to take effect *ab initio*, is omitted, as is Article 2 (parties not bound to provide for grant of patents contrary to *ordre public* or morality, or for plant or animal varieties or biological processes).

[63] Draft Article 3.

> [I]s concerned with the 'industrial character' of the invention, which is to be understood in the wide sense of Article 1 of the Paris Union Convention.

A preceding memorandum on the work of the Committee[64] suggests that the only live discussion was over specific exclusions which were to be allowed either permanently,[65] or for a limited period of time.[66] Further revisions to the 1962 draft did not affect Articles 1 and 3, which were adopted into the Strasbourg Convention as signed in 1963 without further amendment.

It may be remembered that whereas the Paris Convention defined its entire scope in terms of a broad concept of the 'industrial', it had never required its member states to grant patents across the whole range of Article 1(3), and the majority of its European member states had previously made good use of this freedom. The Strasbourg Convention, on the other hand, expressly *required* the granting of patents for any and all inventions that complied with the patentability requirements of Article 1, thereby bringing to a close the fiction that patents were granted at the discretion of the state, as well as ending the complete freedom the member states had formerly enjoyed in specifying which industries qualified for patent protection. Henceforth, 'inventions' which were new and involved an inventive step could be excluded from patentability only if they fell outside the realm of 'industrial applicability' as that term was to be understood in the light of Article 3, unless they were the subject of the specific exclusions of Articles 2 or 12. Conversely, the Strasbourg contracting states expressly precluded themselves from granting patents for 'inventions' which were not patentable according to Article 1.

The Patent Cooperation Treaty

The Patent Cooperation Treaty,[67] Article 33 provides:

> (1) The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable. …
> (4) For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. 'Industry' shall

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64 Council of Europe, *Committee of Experts on Patents, Memorandum by the Secretariat on the meeting held at Strasbourg from 7th to 10th November 1961*. EXP/Brev (61) 8 of 13 December 1961 (unpublished).

65 Article 2 in the drafts, and in the final Convention.

66 Corresponding to Article 12 of the final Convention.

67 Patent Cooperation Treaty (Washington, 1970). See also Rule 5(1)(a)(vi) of the PCT Regulations.

> be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.

The Records of the Washington Conference have very little to say about Article 33(4), which was adopted in the terms proposed with only one intervention.[68] In the light of TRIPs and subsequent draft treaties, and in view of the express inclusion of language treating inventive step and non-obviousness as alternatives, it may seem surprising that no mention was made of 'utility' as an alternative to 'industrial application', but there are at least two ready explanations. First, the international preliminary examination was entirely non-binding, so countries with a utility requirement, or other non-standard criteria of patentability, were perfectly free to apply those during the national phase. Secondly, United States practice in 1970 and before was not noticeably divergent from the rest of the world. *Brenner v. Manson*[69] had just restated the law of utility in fairly conservative terms, and the surge in what was considered patentable was not to begin for another decade, with *Diamond v. Chakrabarty*.[70]

The European Patent Convention

The original text of Article 52(1) of the European Patent Convention is set out at the start of this chapter. Article 52(1) was subsequently amended,[71] and now reads (with the new text underlined):

> European patents shall be granted for any inventions, <u>in all fields of technology,</u> provided that they are new, involve an inventive step and are susceptible of industrial application.

The meaning of 'industrial application' is further explained in Article 57, which is not changed in the EPC 2000:

> An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

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68 By Argentina, arguing (unsuccessfully) that each state should be allowed to interpret 'industry' according to its domestic law. *Records of the Washington Conference on the Patent Cooperation Treaty, 1970* (Geneva: WIPO, 1972) Main Committee I, paras 1224–6. The fundamental incompatibility of this proposal with the nature of the international preliminary examination was pointed out by the Conference Secretary-General, Arpad Bogsch.

69 Above, note 33.

70 (1980) 447 US 303; 100 S. Ct. 2204; 65 L. Ed. 2d 144.

71 By the Act Revising the Convention on the Grant of European Patents (London, 2000). The EPC 2000 is the European Patent Convention as amended. The amendments took effect from 13 December 2007.

The draftsmen of the European Patent Convention of 1973 drew on two main sources: the Strasbourg Convention of 1963, which, like the EPC itself, had been negotiated and adopted within the Council of Europe; and various draft patent conventions which had been prepared for the European Community.[72] However, in terms of actual legal content there were no relevant differences in the conditions for patentability among any of these, and the *travaux préparatoires* are uninformative except in so far as they express the need for conformity between the Strasbourg Convention, the two draft European treaties, and the Patent Cooperation Treaty. The Records[73] of the conference at which the European Patent Convention was adopted report no discussion of the drafts of what became Articles 52(1) and 57, which were adopted in their present form.

The WTO TRIPs Agreement

The relevant provisions of TRIPs are set out at the beginning of this chapter.[74] By way of background, the negotiators had the benefit of a briefing document from WIPO[75] which acknowledged the definition of 'industrial applicability' in the Patent Cooperation Treaty,[76] and noted that: 'Novelty, inventive step (or non-obviousness) and industrial applicability are patentability criteria commonly applied throughout the world'.

The detailed negotiating history of TRIPs effectively begins, for present purposes, with the almost simultaneous submission of closely similar drafts by the European Communities and the United States in March and May 1990.[77] In the EC draft, the article corresponding to Article 27 of TRIPs (as adopted) began:[78]

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[72] These resulted in the Community Patent Convention (Luxembourg, 1975), which has never come into force.

[73] *Minutes of the Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents* (Munich: Government of the Federal Republic of Germany, 1973).

[74] Agreement on Trade Related Aspects of Intellectual Property Rights (Marrakesh, 1994).

[75] WIPO, *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property*, MTN.GNG/NG11/W/24/Rev.1 of 15 September 1988. This document does not mention 'utility'.

[76] Above, at note 67.

[77] For the drafting history of TRIPs, and the significance of the named drafts which follow, see Daniel Gervais, *The TRIPs Agreement: Drafting History and Analysis*, (London: Sweet & Maxwell, 2nd ed., 2003). For commentary, see Gervais (2003) and Carlos Correa, *Trade Related Intellectual Aspects of Property Rights: A Commentary on the TRIPS Agreement* (Oxford: Oxford University Press, 2007).

[78] *Draft Agreement on Trade Related Intellectual Aspects of Property Rights*, MTN.GNG/NG11/W/68 of 29 March 1990.

> Article 23 Patentable Subject Matter
> (1) Patents shall be granted for any inventions, whether products or processes, which are susceptible of industrial application, which are new and which involve an inventive step. . . .

And in the US draft the corresponding Article read in full:[79]

> Article 23 Patentable Subject Matter
> Patents shall be granted for all products and processes, which are new, useful, and unobvious. [Fn].
> [Fn]. For purposes of this Article, the terms 'useful' and 'unobvious' encompass or are synonymous with the terms 'capable of industrial application' and 'inventive step', respectively. Requirements such as filing of an adequate disclosure in a patent application and payment of reasonable fees shall not be considered inconsistent with the obligation to provide patent protection.

Neither of these drafts was supported by any explanatory memorandum. In each case there was some discussion of the draft in the Negotiating Group,[80] but the records are uninformative and in all cases the relevant debate seems to have concentrated entirely on the lists of specific exclusions, rather than the general words of either draft article.

On the initiative of the Chairman of the TRIPs Negotiating Group, Lars Arnell, a composite draft was prepared and circulated.[81] This contained much bracketed text corresponding to points which had not been agreed, but so far as relevant it began:

> SECTION 5: PATENTS
> 1. Patentable Subject Matter
> 1.1 Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.

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[79] *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights: Communication from the United States*, MTN.GNG/NG11/W/70 of 11 May 1990.

[80] For the EC Draft, *Meeting of Negotiating Group of 2, 4 and 5 April 1990*, MTN.GNG/NG11/20 of 24 April 1990. For the US Draft, *Meeting of Negotiating Group of 14–16 May 1990*, MTN.GNG/NG11/21 of 22 June 1990. The latter meeting also discussed drafts tendered by Switzerland, Japan, and a group of 14 developing countries.

[81] The so-called Chairman's Draft, annexed to *Status of Work in the Negotiating Group: Chairman's Report to the GNG*, MTN.GNG/NG11/W/76 of 23 July 1990.

Further subsections dealt with the first-to-file principle, disclosure and fees, specific exclusions from patentability, general exclusions on grounds of public policy, and plant varieties. The next composite draft to be prepared was the 'Brussels Draft', which would have provided:[82]

> Article 30: Patentable Subject Matter
> 1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [Fn]. [Patents shall be available without discrimination as to where the inventions were made.]
> [Fn]. For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a PARTY to be synonymous with the terms 'non-obvious' and 'useful' respectively.

Finally, the Dunkel draft of December 1991 removed all the options and bracketed text of its predecessors, and adopted wording virtually identical to the present text:[83]

> Article 27: Patentable Subject Matter
> 1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [Fn]. Subject to paragraph 4 of Article 65 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
> [Fn]. For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a PARTY to be synonymous with the terms 'non-obvious' and 'useful' respectively.

It should not be supposed that the TRIPs negotiations reached a genuine consensus with the adoption of the Dunkel draft. Quite apart from the unresolved differences between the European Communities and the United States over choice of wording, a group of developing countries argued as strongly as they could for wide-ranging exclusions from mandatory patentability, but their efforts were unsuccessful, and in any event were focused on lists of specific permitted exceptions relevant to their situation, rather than on the general concepts of utility or industrial applicability as such.

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[82] MTN.TNC/W/35/Rev.1 of 5 December 1990. Provisions dealing with specific exceptions from patentability are omitted.

[83] MTN.TNC/W/FA of 20 December 1991. Articles 27(2) and (3), dealing with exceptions from patentability and also corresponding closely to TRIPs, are omitted.

The draft Substantive Patent Law Treaty

The draft Substantive Patent Law Treaty, Article 12(4), currently under discussion at WIPO,[84] contains 'utility' and 'industrial applicability' as alternatives, with three further alternatives to say what they mean.[85]

TRIPs interpreted

Back to basics

According to the Vienna Convention on the Law of Treaties, whose rules of interpretation are generally taken as declaratory of public international law: [86]

> A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

The Appellate Body of the WTO is strongly attached to giving ordinary words their dictionary definitions, and rather suspicious of arguments based on *travaux préparatoires*. It might therefore do worse than simply adopt the following definitions:[87]

Utility:	The state of being useful, profitable, or beneficial.
Industry:	[1] Economic activity concerned with the processing of raw materials and manufacture of goods in factories. [2] A particular branch of economic or commercial activity.
Industrial:	Of, used in, or characterized by industry.

However, recourse to the dictionary is only the beginning of the exercise, not least when a word is ambiguous, or has a technical meaning. The example above confirms that 'industry' has a wider and a narrower meaning. In the case

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[84] See www.wipo.int/patent-law/en/harmonization.htm. An explanatory memorandum by WIPO, '"Industrial Applicability" and "Utility" Requirements: Commonalities and Differences', SCP/9/5 of 17 March 2003, is most informative, and includes a comparative survey.

[85] Also very relevant as a source of comparative law is the survey conducted by the AIPPI as Q180 under the title 'Content and Relevance of Industrial Applicability and/or Utility as Requirements for Patentability'. The individual country reports, a summary of their conclusions, and the report of the committee, may be found in the AIPPI Yearbooks (2004) to (2006), or at www.aippi.org/reports/q180/gr_q180_index.htm, www.aippi.org/reports/q180/q180_summary_e.pdf, and www.aippi.org/reports/q180/06gothenburg_report_q180.pdf.

[86] Vienna Convention on the Law of Treaties (Vienna, 1969), Article 31(1).

[87] From the *Concise Oxford English Dictionary* (Oxford: Oxford University Press, 11th (revised) ed., 2006). Definitions in French and Spanish (the other two authentic languages of the WTO Agreements) would also be relevant.

of 'utility' as well there is high authority that the word bears more than one meaning, since it was with 'utility' in mind that the Supreme Court of the United States observed: '[A] simple, everyday word can be pregnant with ambiguity when applied to the facts of life'.[88]

There may be more to this dictum of Justice Fortas than a mere *double entendre*, whether intentional or Freudian. One of the patents in *Brenner v. Manson* had been concerned with steroids invented by researchers at Syntex, the Mexican company responsible for one of the first commercially available oral contraceptives, norethindrone.[89] Prior to the decision of the Supreme Court in *Griswold v. Connecticut*,[90] it is very easy to imagine that companies like Syntex were in a kind of Catch-22 situation. *In Re Bremner*[91] had ruled that vague and generalised assertions were inadequate to satisfy the utility requirement for novel chemical compounds; but by the prevailing moral standards of the 1950s (and even the early 1960s) anyone asserting specific utility as a contraceptive might well have found their application rejected even more firmly on the ground of immorality, which in United States practice was subsumed into that of (in)utility.[92] Far better to assert utility in the broadest and least specific terms the Patent Office would accept, and wait for moral standards to change.[93]

Though neither 'utility' nor 'industrial application' is specifically defined for the purposes of TRIPs,[94] it is reasonably clear from the context that in

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[88] *Brenner v. Manson* (above, note 33), *per* Justice Fortas. For an example of the corresponding ambiguity of 'industry' which might appropriately have made reference to this dictum, see T 74/93 BTG/*Contraceptive method* [1995] EPOR 279, in which the Technical Board of Appeal refrained from deciding whether prostitution ('the oldest industry in the world') was an 'industry' for the purposes of EPC Article 57, since on any basis the self-application of the contraceptive by the user to her cervix was not 'industrial'.

[89] The Syntex patent in *Brenner v. Manson* being US 2,908,693, issued in 1959 and claiming priority from a Mexican application of 1956. The inventors were Howard Ringold and George Rosenkranz. The Syntex patent on norethindrone was US 2,744,122 (Carl Djerassi, Luis Miramontes and George Rosenkranz), which issued in 1956 with a 1951 Mexican priority date.

[90] (1965) 381 US 479; 85 S. Ct. 1678; 14 L. Ed. 2d 510. *Griswold* decided that a state statute prohibiting contraception was unconstitutional.

[91] Above, note 31.

[92] See *Lowell v. Lewis*, above, note 29. TRIPs Article 27(2) follows the European Patent Convention Article 53(a) in treating morality as a specific ground of non-patentability in its own right, as opposed to an aspect of utility or industrial applicability.

[93] See Louis Tyrer, 'Introduction of the Pill and its Impact' (1999) 59(1) *Contraception* Supplement 1, January 1999, pp. 11S–16S.

[94] There is an argument that the definition of 'industry' in Paris Convention,

Article 27(1) each of the pair is intended to retain its pre-existing meaning as a term of art in patent law. For 'utility', the single body of law to which its meaning is most likely be referred is that of the United States.[95] However, with 'industrial application' a further ambiguity appears: does 'industrial' refer back to the Paris Convention concept of 'industry', as that term is expansively (re)defined in Article 1(3), or does the composite expression 'industrial application' primarily refer back to the European Patent Convention? The latter would be more consistent with the fact that Article 27(1) demonstrably contemplates a choice between two alternative formulae for patentability, with the European model being the obvious counterpart to that of the United States. Fortunately, the question need not detain us since the end result is almost certainly the same either way: the European Patent Convention, via the Strasbourg Convention, also looks back to the Paris Convention, as does the Patent Cooperation Treaty.

The American and European positions

American law on patentability has to comply with TRIPs, but in practice is under the unfettered control of the United States legislature, acting within the Constitution. Since TRIPs permits patentability to be defined by reference to 'utility', and since the concept of utility in TRIPs (if neither dictionary-defined, nor undefined and open-ended) can only be understood by reference to American law, the practical result is that utility in United States law can hardly fail to conform to TRIPs.

The converse does not necessarily follow, and the situation in Europe is more complicated. First, the Paris Convention has a place of central importance in European law which it lacks in American law. The European concept of 'industrial applicability' is defined by reference to the extended concept of 'industry' as employed in the Paris Convention, rather than the narrower of the two meanings in everyday usage.[96] Next, European law (at least in the states which matter most) must comply simultaneously with the Strasbourg and

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Article 1(3) might be incorporated into TRIPs by Article 2(1) of the latter, but the terminology employed ('Members shall comply with Articles . . . of the Paris Convention') is not free from uncertainty. A definition can be incorporated into one treaty from another, but the language of TRIPs speaks not of incorporation but of compliance with a treaty which retains a separate existence, and one cannot *comply* with a definition.

[95] Although one should acknowledge that 'utility' (in what may be a rather different sense) remains an express requirement of the law in at least Australia, Canada, and New Zealand.

[96] Though the United States is also a Paris Union member, its concept of 'utility' antedates the Paris Convention by nearly a century, and makes no explicit or implicit reference to the latter.

European Patent Conventions.[97] Finally, as for the United States, there is TRIPs, but once again this proves to be a false alarm, since the TRIPs formula 'capable of industrial application' is a mere reformulation of the European position.[98]

There is one further conclusion, which is that European states, or at least those which are parties to the Strasbourg Convention, cannot, consistently with their existing international obligations, purport to grant patents for so-called inventions which may satisfy the TRIPs concept of 'utility' but are not 'susceptible of industrial application'. This is because the Strasbourg Convention expressly provides that 'an invention which does not comply with these conditions [novelty, inventive step, industrial applicability] shall not be the subject of a valid patent'. The European Patent Convention contains no such prohibition, and neither does TRIPs. In the case of the European Patent Convention, a likely explanation is that the European Patent Office is entirely a creature of the Convention, and has no power to grant patents except pursuant to Article 52, so that an express prohibition would have been otiose.

The role of utility, revisited

With these considerations in mind, some attempt may be made to say what TRIPs means. Article 27(1) most probably requires members to adhere either to the European concept of 'industrial application', or to the American one of 'utility'. Alternative interpretations might be that either or both of these terms bear their respective dictionary definitions; or that these two expressions (whatever their individual meaning) define the acceptable end points of a range, so that members have free choice where to position themselves between them. While the latter would be a convenient interpretation for those countries which formally subscribe to neither the European nor the American doctrine, it is difficult to reconcile such freedom with the precise words of Article 27(1): 'industrial application' (whatever that may mean) is the norm, and 'utility' is the only permitted alternative.

On any interpretation, the irreducible minimum of any such requirement is that patent protection may be denied to the irredeemably inoperative or dysfunctional, so that members may deny patent protection to the likes of

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[97] The European Patent Convention has just over 30 member states. The Strasbourg Convention has only 13, but these include Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom.

[98] It is impossible to attribute any significance to the change from 'susceptible' in the European and Strasbourg Conventions, to 'capable' in TRIPs. The latter is more idiomatic, the former is probably attributable to excessively close tracking of the French text of the Strasbourg Convention.

perpetual motion machines,[99] and 'inventions' of other kinds which contravene the laws of nature, or which are otherwise wholly unworkable. British Rail's fusion-powered flying saucer may serve as an example of an invention which, though not actually contravening any physical laws, was quite impossible to realize with the technology of the 1970s.[100] A perhaps over-subtle example is *Eastman Kodak v. American Photo Booths*,[101] deciding that it was physically impossible for the folded optical path of the patent to achieve the claimed narrowing of depth of field. The patent therefore lacked industrial applicability, as well as sufficiency of description.

'Inventions' in the private and personal realm also seem to lack industrial applicability, though perhaps not utility,[102] but personal and private use is better addressed in terms of immunity from infringement.[103] Aesthetic creations, mental acts, and abstract or unrealized discoveries may also be considered to lack industrial applicability,[104] but it is preferable to treat them under inherent patentability. For the rest, and in so far as the differences between the American and European systems are real, and attributable to the difference between 'utility' and 'industrial applicability', there is much to be said for the conclusion of one American commentator:[105]

> There is much to commend the adoption of the standard of industrial application in the United States patent law. For our patent law should comport with our percep-

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[99] See Wadlow (2007). Even for perpetual motion machines, though, the objection of lack of utility or industrial applicability is not really indispensable, since much the same effect can be achieved through the objection of insufficiency, which seems to be the preferred ground of rejection in the EPO.

[100] GB 1,310,990, above, note 9. Although inutility and insufficiency were grounds of revocation once a patent had been granted (UK Patents Act, 1949, s. 32(1)(g) and (h)), on examination the Patent Office had no power to refuse an application on either of these grounds.

[101] UK Patent Office decision BL O/457/02 of 8 November 2002 (GB 2,314,719).

[102] WIPO Memo (2003), at paras 29 and 56. The example given is that of a contraceptive method rejected on this ground by the EPO: T74/93 BTG/*Contraceptive method* [1995] EPOR 279; but compare T1165/97 ULTRAFEM/*Feminine hygiene device* [2002] EPOR 35.

[103] As under the UK Patents Act 1977, s. 60(5)(a), corresponding to the Community Patent Convention, 1975, Article 31(a). In BTG/*Contraceptive method* (*supra*) it was acknowledged that the real reason for the disputed claim was to impose liability for contributory infringement on BTG's competitors.

[104] WIPO Memo (2003), paras 13 and 28.

[105] John R. Thomas, 'An Epistemology of Appropriation: Patentable Subject-Matter after Statestreet' [2000] IPQ 27 at 65. Though it is welcome to see the European approach commended by Professor Thomas, he arguably conflates questions of industrial application with ones of inherent patentability.

> tion of what technology is, not defy it. By restoring a patentability standard firmly grounded in industrial applicability, rather than equating technology with anything artificial, we would not only maintain the patent system in its proven paths. We would recognise our own humanity by refusing to identify our entire universe as technological in character. However central to contemporary life and worthy of nurturing through the patent system, technology is but one manifestation of the human experience, not the only one.

Conclusion

Once the flying saucers and the perpetual motion machines have been seen off, and when all due account has been taken of inherent patentability, and the effect of the specific exclusions, it is difficult to see that there is really anything of much practical importance left for either utility or industrial applicability to do. The real work of keeping inappropriate 'inventions' out of the patent system seems to be done under the doctrine of inherent patentability, or by *ad hoc* policy-based exclusions. At the end of the day, the choice between 'utility' and 'industrial applicability' appears to be symbolic, rather than real. The concept counts for little, under whatever name, and the words ought to count for rather less.

Protagonists of the two rival systems, American and European, presumably hope that the exclusive or preferential incorporation of their choice of wording into a global treaty (if not TRIPs, then the future Substantive Patent Law Treaty) will not only import with it all the accumulated values and prejudices of the system they represent, but will somehow implant in it enough of their own system's legal DNA to predetermine its future course of development.[106]

If there be more to the debate than that, it is because the choice between 'utility' and 'industrial applicability' is one of the few occasions on which the pervasive differences between the American and European systems can be reduced to a single word or phrase.[107] Compare 'novelty', in which the same word in both systems conceals unbridgeable differences between them as to what constitutes the state of the art – differences which are of far

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[106] Compare the Australia–United States Free Trade Agreement (Washington, 2004), which repeats the first sentence of TRIPs Article 27(1), but also provides at Article 17.1.13: 'Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility'. This formulation corresponds to the US Patent and Trade Mark Office, *Manual of Examining Practice*, § 2107(2)(A)(3), and the associated USPTO *Utility Guidelines* (2001). Rightly or wrongly, it has been suggested on the basis of Article 17.1.13 that '[i]n effect, Australia has tied itself to a US standard of utility and its subsequent interpretation'. Peter Drahos *et al.*, 'Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US-Australia Free Trade Agreement' (2004) 22 *Prometheus* 243.

[107] Another being the equally elusive difference between 'inventive step' and 'non-obviousness', see Chapter 14.

greater practical importance.[108] So the argument between 'utility' and 'industrial applicability' turns out to be symbolic at a second and perhaps more significant level: the choice of words symbolises or determines who controls the concept, unimportant though the concept may be – but control of the concept symbolises who is to control adjacent bodies of law of far greater practical importance, in particular that of inherent patentability. It is like raising the Union Jack on the island of Rockall, to claim that worthless blade of rock for the United Kingdom, and with it all the economic rights in the Atlantic Ocean and on the continental shelf surrounding it; or like the recent occasion on which a Russian flag was planted by submarine on the seabed at the North Pole. In themselves these actions were perfectly useless, but even purely symbolic acts may have legal significance: the flag is the universal symbol of sovereignty, and the island (or the Pole) may serve to symbolise the ocean and the seabed around it, with all its resources.[109]

If that is all there is to the debate over 'industrial applicability' and 'utility', then it would be better to settle on some neutral terminology acceptable to all sides, and concentrate on individual categories of invention, and whether they are appropriate for patentable status.

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108 For novelty see Chapter 13.

109 See C.R.. Symmons, 'Legal Aspects of the Anglo-Irish Dispute over Rockall' (1975) 26 *Northern Ireland Legal Quarterly* 65, although much of the analysis is superseded by the United Nations Convention on the Law of the Sea (Montego Bay, 1982), especially Article 121(3). The Russian action at the North Pole has no known effect in international law.

13 The novelty and priority provision under the United States first-to-file principle: a comparative law perspective

*Toshiko Takenaka**

1 Introduction

Patent professionals trained in first-to-file countries wonder why the novelty and priority provisions set forth in 35 USC § 102 are so complex and difficult to understand because the novelty and priority provisions of first-to-file countries are short and simple. Only after studying the historical backgrounds of each provision and the policy considerations related to the terms used in those provisions, can they hope to understand the complex structure of defining prior art and the unique interpretation given to the terms. However, the more familiar they become with US case law and the policies emphasized by US judges, the more they question whether the United States actually follows the first-to-invent system, which US patent scholars and professionals claim to follow.[1] The policies US judges emphasize are similar to the policies emphasized by first-to-file patent systems. Furthermore, the examination practices followed by the United States Patent and Trademark Office (USPTO) are very similar to that of patent offices in first-to-file countries.

On its face, the § 102 novelty and priority provisions under the US first-to-invent policy are very different from novelty and priority provisions under the first-to-file principle. The first provision defining novelty in § 102(a) sets forth a determination of novelty as of the invention date, and § 102(g) provides a rule that determines priority based on the date of first invention rather than the date of the first application.[2] However, are these differences in fact real? And,

* This chapter was revised from Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure §102 Novelty and Priority Provisions*, 39 HOUS. L. REV. 621 (2002).

1 Many commentators compare the first-to-invent and first-to-file systems with a presumption that they are very different. *See, e.g.*, Stephanie Gore, Comment, *'Eureka! But I Filed too Late . . .': The Harm/Benefit Dichotomy of a First-to-File Patent System*, 1993 U CHI. L. SCH. ROUNDTABLE 293, 305–9 (1993) (comparing and contrasting the first-to-invent and first-to-file systems in terms of the harms and benefits of each defined from a natural rights baseline).

2 35 USC § 102(a) (1994); 35 USC§ 102(g) (1994 & Supp. 2000).

are these differences so fundamental as to be irreconcilable with concepts of novelty and priority under the first-to-file principle?

2 Review of novelty and priority provisions

2.1 The simple structure of first-to-file novelty and priority

2.1.1 Novelty The novelty provisions of major first-to-file countries, namely those of the European Patent Convention (EPC)[3] and Japanese Patent Law (JPL),[4] have a simple and short definition of prior art – any form of disclosure gives rise to the prior art, regardless of the actor of such disclosure. For example, the EPC provides the following definition of novelty:

(1) An invention shall be considered to be new if it does not form part of the state of art.
(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.[5]

The novelty definition of Japanese Patent Law is similar to the EPC definition, except the Japanese definition also lists items that constitute the prior art, including information available via the Internet.[6] Unlike the United States, neither the European nor Japanese provisions distinguish the definition of prior art by actors and thus do not have separate provisions for the inventor's

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[3] Convention on the Grant of European Patents, October 5, 1973, art. 54, 1065 UNTS 255, 272 [hereinafter European Patent Convention] (entered into force on October 7, 1977). The Convention represents the substantive patent law for seven European nations: Germany, Netherlands, United Kingdom, Switzerland, France, Luxembourg, and Belgium.

[4] Tokkyo Ho [Japanese Patent Law], Law No. 121 of 1959 arts. 29–30 [hereinafter Japanese Patent Law].

[5] European Patent Convention, *supra* note 3, art. 54 at 272.

[6] Japanese Patent Law, art. 29 reads:

(1) Any person who has made an invention which is industrially applicable may obtain a patent therefor, except in the case of the following inventions:
(i) inventions which were publicly known in Japan or elsewhere prior to the filing of the patent application;
(ii) inventions which were publicly worked in Japan or elsewhere prior to the filing of the patent application;
(iii) inventions which were described in a distributed publication or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the patent application.

and others' actions. The terms used to define the prior art are given ordinary meaning. Thus, the simple, key concept that makes information give rise to prior art is public accessibility.[7] Under the European and Japanese novelty approaches, any information made publicly available in any form of publication anywhere in the world, as of the date of application, constitutes prior art.[8] In other words, European and Japanese novelty does not discriminate disclosures by form or the place of disclosure.

Although technically not available as of the application date of the subject matter under examination, first-to-file countries also view subject matter described in an application pending in their own patent office as prior art, provided that the application is later published through an eighteen-month publication rule, thus becoming publicly available.[9] This is because the subject will soon become publicly available, and has already become available at least to the patent office. Both the EPC and JPL adopted the 'whole contents' approach, making the whole contents of European and Japanese applications the prior art as of the filing date.[10] With respect to applications claiming priority right under the Paris Convention, the whole contents of applications become the prior art as of the priority date.[11]

As an exception to this simple novelty principle, most first-to-file countries provide a grace period provision.[12] A commentator of a first-to-file country defines the grace period as a specific period of time prior to the filing of a patent application by the inventor or his or her successor in title, during which time disclosures of an invention do not forfeit a right to patent the invention.[13] Under the first-to-file system, the grace period provisions are provided as an exception to the principle that novelty is determined as of the application date. Because the grace periods are an exception and not a rule, conditions that allow one to take advantage of the grace period are very restrictive. Among those countries that provide a grace period, the majority, 57%, adopted a six-month period and only

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7 ROMUALD SINGER & MARGARETE SINGER: THE EUROPEAN PATENT CONVENTION, 221 (Ralph Lunzer trans., London, Sweet & Maxwell rev. ed.) (1995).

8 *See, e.g.*, European Patent Convention, *supra* note 3, art. 54; Japanese Patent Law, *supra* note 6, art. 29(1)(iii).

9 European Patent Convention, *supra* note 3, art. 54(3) & (4).

10 Singer & Singer, *supra* note 7, at 165.

11 *Id.*

12 According to the survey conducted by AIPPI Japan Group, 87% of 121 national and regional patent systems provide for some type of grace period system. Japanese Group of AIPPI, *A Study of Grace Period and other Conditions of Patentability in National and Regional Patent Systems* (summary report), 1 (March, 2000) [hereinafter AIPPI Study].

13 Joseph Straus, *Grace Period and the European and International Patent Law: Analysis of Key Legal and Socio-Economic Aspects*, 20 IIC STUDIES 3 (2001).

30% adopted a one-year grace period.[14] To limit the scope of subject matter that can take advantage of the exception, the vast majority of countries have adopted a disclosure-specific grace period, in which only certain categories of disclosure are qualified to take advantage of the grace period.[15] The most common disclosure-qualified categories include: experimental use, disclosure by an applicant, disclosure by a third party, abuse of right, display at an international exhibition, and presentation at a scientific meeting.[16] Furthermore, applicants cannot take advantage of the system unless they invoke the grace period at the date of application and submit evidence of the claimed subject matter.

One extreme example of a first-to-file grace period is the system under the EPC. The scope of disclosure that can take advantage of the EPC grace period is very limited and applicants must meet procedural requirements to invoke the system.[17] In contrast, the scope of the Japanese grace period is more generous than that of the European system and includes a broad range of inventors' activities to take advantage of the system including presentations at science meetings and document publications.[18] Under the Japanese system, an applicant can take advantage of the grace period with not only subject matter that is identical to the subject matter disclosed prior to the date of application, but also obvious subject matter.[19]

2.1.2 Priority The priority provisions of major first-to-file countries are predicated on a simple rule: a patent should be granted to the first applicant. For example, EPC Article 60, paragraph 2 provides:

> If two or more persons have made an invention independently of each other, the right to the European patent shall belong to the person whose European patent application has the earliest date of filing; however, this provision shall apply only if this first application has been published under Article 93 and shall only have effect in respect of the Contracting States designated in that application as published.[20]

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14 AIPPI Study, *supra* note 12, at 2.
15 *Id*. at 3–4.
16 *Id*. at 2.
17 *E.g*., European Patent Convention, art. 55.
18 Japanese Patent Law, art. 30.
19 Japanese Patent Law, art. 30.
20 European Patent Convention, art. 60(2). The JPL similarly provides:

> (1) Where two or more patent applications relating to the same invention are filed on different dates, only the first applicant may obtain a patent for the invention. Japanese Patent Law, art. 39(1).

Because priority is granted based on the date an applicant files an application to be examined by the European Patent Office (EPO),[21] a procedure to decide the priority among more than one application is unnecessary as long as the date is clear. When more than two applicants file applications for the same invention on the same date, the EPO gives patents to both applicants.[22] The Japanese rule is very similar to the European rule, except for when handling more than one application with the same application date.[23] The JPL requires applicants who filed for the same invention on the same date to negotiate for an agreement to identify one applicant who will obtain the patent.[24] If applicants cannot reach an agreement, the Japan Patent Office (JPO)[25] refuses to give a patent to either party.[26] This practice avoids expensive proceedings to award priority.

This rule also applies to the determination of priority during the grace period. Under the grace period provisions of first-to-file countries, if a third party files prior to the date of application by the inventor who disclosed the same invention during the grace period, the inventor's application is rejected for being the second to file.[27] If the third party's date of application is after the inventor's date of disclosure, the disclosure destroys the novelty of the third party application and thus a patent is granted to neither party.[28]

2.2 Complex and confusing: US first-to-invent novelty and priority

In contrast to the European and Japanese systems, the novelty and priority provisions under 35 USC § 102 adopt a complex structure to define the prior art and use confusing terms that lack a clear definition. Courts give terms used to define the prior art an interpretation that is vastly different from their ordinary meanings. As a result, these terms are very difficult for inventors to understand without extensive knowledge of US case law, which clarifies the meaning of terms used in § 102.

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21 The European Patent Office was established under Article 4 of the Convention on the Grant of European Patents. European Patent Convention, *supra* note 3, art. 4. News, updates, and general information concerning the European Patent Office can be found at http://www.european-patent-office.org.

22 Singer and Singer, *supra* note 7, at 221.

23 Japanese Patent Law, art. 39(1).

24 Japanese Patent Law, art. 39(4).

25 Information about the JPO is available at http://www.jpo.go.jp/homee.htm.

26 Japanese Patent Law, *supra* note 6, art. 39(2).

27 *See, e.g.*, European Patent Convention, art. 60(2); Japanese Patent Law, art. 29b.

28 *See, e.g.*, European Patent Convention, art. 54(2); Japanese Patent Law, art. 29.

2.2.1 Novelty a. § 102(a) and (b). The United States novelty provisions, § 102(a) and (e), determine the novelty of the invention as of the date of invention, thus making the first-to-invent novelty rule clear.[29] The approach adopted by § 102(a) and (e) is very different from the first-to-file approach of the EPC and JPL, both of which determine the novelty of invention as of the filing date.[30]

However, like the novelty definition of first-to-file countries, § 102(b) defines the prior art as of the date one year prior to the date of application.[31] The substance of the condition provided in § 102(b) in removing pre-filing disclosures during a specific period, one year, from the filing date, seems to fit the definition of a grace period.[32] However, the significance of a grace period is very different between the first-to-invent and first-to-file systems. Under a true first-to-invent rule, a grace period is not an exception, but a principle because the novelty is determined as of the date of invention.[33] A true first-to-invent rule requires that a patent office grant a patent on subject matter that was published and has become old prior to the date of application as long as the subject matter is new and non-obvious as of the invention date. Under such a rule, the subject matter's condition as of the date of filing has nothing to do with its patentability.

However, the United States patent system does not follow a true first-to-invent rule because it has an exception to the rule – statutory bars – which prevents inventors from obtaining a patent after the expiration of the grace period once inventors engage in one of the activities listed in § 102(b), (c), and (d).[34] Thus, under the current United States first-to-invent rule, granting a patent on subject matter which is disclosed prior to the date of application is a principle, and a statutory bar that prevents the patent office from granting a patent on subject matter that is disclosed prior to the grace period is an exception.

As a result, the conditions for taking advantage of the grace period under § 102(b) are much more generous than the conditions under the first-to-file principle. There is no restriction on the type of disclosures that can take advantage

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29 35 USC § 102(a) (1994); 35 USC§ 102(e) (1994, Supp. 2000).

30 *E.g.*, European Patent Convention, art. 54(2); Japanese Patent Law, art. 29(1).

31 35 USC § 102(b) (1994).

32 For the definition of grace period, *see* Straus, *supra* note 13, at 3. US legal scholars also see a similarity between § 102(b) and first-to-file novelty provisions. *See* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 206 (1998).

33 Canadian patent law long followed this true type of first-to-invent rule until it was revised to adopt a first-to-file rule. *Christiana v. Rice*, [1931] AC 770, 777–9, 782–3 (appeal taken from Can.) *See generally*, Adelman et al., *supra* note 32, at 318.

34 *See, e.g.*, *Pennock v. Dialogue*, 27 US 1, 23–4 (1829).

of the grace period and that are thereby automatically removed from the prior art for examination of both novelty and non-obviousness under § 102.[35] Further, the grace period is one year from the actual US filing date, instead of the six months adopted by the majority of first-to-file countries.[36]

Compared with the novelty provisions of first-to-file countries, such as the EPC and JPL, 35 USC § 102 is much more complex and difficult to understand. This complexity results not only from the types of disclosures listed in 102(a) and (b), but also from the fact that many such disclosures may overlap. For example, both § 102(a) and (b) list subject matter that can be patented and described in a printed publication.[37] With respect to these disclosures, only the actor distinguishes § 102(a) from § 102(b).[38] If subject matter is patented or described in a printed publication more than one year prior to a third party's date of invention for the same subject matter, an examiner can cite both § 102(a) and (b) to reject the third party's claim for the subject matter.[39] Because the substance of the conditions for § 102(b) is essentially the same as first-to-file novelty in excluding inventors' activities during the grace period, patent professionals wonder why the US patent statute avoids defining the prior art by actors separately, which would remove redundant items of disclosures from the prior art definition.[40] Only after reading early court decisions and finding out the historical reason for separating the definition of prior art by actors of disclosure, could they understand these complex provisions.

The origin of separate provisions by actors can be found in the 1829 *Pennock* case.[41] In *Pennock*, a major flaw of a true first-to-invent system was highlighted because the first inventor publicly used his invention and filed an application only after a competitor started to sell the invention.[42] In interpreting the novelty provision of the 1793 Patent Act, Justice Story excluded from the definition of first inventors persons who publicly used the invention prior to the date of invention.[43] With respect to acts of inventors, reflecting the policy of promoting an early disclosure through patent application, he held that inventors were prevented from commercial exploitation of their inventions prior to the date of application to avoid an extension of a statutorily limited patent

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35 35 USC§ 102(b).
36 *Id*.
37 *Id*. § 102(a); Id. §102(b).
38 *Id*.
39 *Id*.
40 *Id*.
41 *Pennock v. Dialogue*, 27 US 1 (1829).
42 *Id*. at 7–8.
43 *Id*. at 18–20.

term.[44] Later, § 102(b) was added to codify Justice Story's holding regarding inventors' activity.[45] Following the rationale adopted by Justice Story that the policy of early disclosure only relates to acts of inventors, the US novelty rule provides novelty for inventors and for third parties separately.

Another confusing aspect regarding the definition of the prior art under § 102(a) and (b) is the unclear distinction among the listed subject matter. Although § 102(a) and (b) list 'being patented' and 'described in a printed publication' separately, both subject matters become the prior art when the subject is made available to the public even in a minimal way.[46] Even though courts limit the scope of what is patented to claimed subject matter and try to distinguish it from being described in a printed publication,[47] as long as the content of a patent is made available to the public, both claimed and unclaimed subject matter become the prior art under § 102(a) and (b) as a printed publication. Further, the narrow view adopted by the majority of US courts is criticized for failing to find a sound justification for distinguishing claimed and unclaimed subject matter in a single document.[48] Therefore, first-to-file patent professionals wonder why US novelty does not adopt a simple definition of public accessibility, instead of listing redundant subject matter definitions.

Moreover, a variety of foreign patents, which are vastly different from US patents, present serious problems.[49] Parties dispute whether foreign patents, the term and scope of exclusive right of which are not as extensive as US patents, fall within the meaning of 'being patented' in § 102(a) and (b).[50] Parties also dispute the date that a foreign patent has become 'patented' because the content of a foreign patent does not necessarily become available to the public on the same day that an exclusive right is vested.[51]

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44 *Id.* at 6–8.

45 DONALD S. CHISUM, CHISUM ON PATENTS § 6.02[1][b] (1978, supp. 2007) [hereinafter CHISUM ON PATENTS].

46 *In re Hall*, 781 F.2d 897, 899–900 (Fed. Cir. 1986). *See also* CHISUM ON PATENTS, *supra* note 45, § 3.04[2].

47 *Carter Prods., Inc. v. Colgate-Palmolive, Co.*, 130 F. Supp. 557, 566 (D. Md. 1955); CHISUM ON PATENTS, *supra* note 45, § 3.06[3].

48 CHISUM ON PATENTS, *supra* note 45, § 3.06[3].

49 *Id.* § 3.06.

50 *See, e.g.*, *Atlas Glass Co. v. Simonds Mfg.* Co., 102 F. 643, 646–7 (3d Cir. 1900); *In re Carlson*, 983 F.2d 1032, 1034, 1038 (Fed. Cir. 1992); *Reeves Bros., Inc. v. U.S. Laminating Corp.*, 282 F. Supp. 118, 134–6 (EDNY 1968), *aff'd* 417 F.2d 869 (2d Cir. 1969).

51 *In re* Monks, 588 F.2d 308, 308–10 (CCPA 1978); *In re Ekenstam*, 256 F.2d 321, 322–5 (CCPA 1958); *Trico Prods. Corp. v. Delman, Corp.*, 180 F.2d 529, 533 (8th Cir. 1950); *Duplan Corp. v. Deering Milliken, Inc.*, 353 F. Supp. 826, 829–31

Literally interpreted, subject matter 'being known or used' in § 102(a) and subject matter in 'public use or on sale' in § 102(b) seem to overlap each other. Although § 102(a) and (b) use distinct terms, courts interpret each the same way by requiring public access to the subject matter information when an act of a third party is concerned.[52] However, when the terms are interpreted with respect to an act of an inventor, courts distinguish 'being known or used' from 'public use or on sale' because they do not require public access for determining 'public use or on sale'.[53]

Even worse, although the language of § 102(b) does not define an 'actor', courts apply this peculiar interpretation of 'public use or on sale', including confidential use, only with respect to acts of inventors.[54] One can understand this distinction only when he or she investigates US case law and finds that this interpretation is included to prevent inventors from extending the limited patent term by secretly exploiting their inventions.[55] Because third party activities have nothing to do with the policy of encouraging inventors to disclose early, courts give ordinary meaning to 'public use or on sale' and require public accessibility and knowledge.[56]

Additionally, US courts have introduced another difficulty in interpreting 'public use' by developing the experimental-use exception doctrine. The doctrine originates from the 1877 Supreme Court decision *City of Elizabeth* in which the court failed to find a public use when the inventor installed his street pavement on the public road to check the durability of the pavement.[57] When US courts find a public use of an invention by the inventor to be experimental, such public use does not fall under the meaning of 'public use' in § 102(b).[58] However, nothing in the patent statute mentions exclusion of public experimentation. Thus, only those who are familiar with US case law understand that the term 'public use' includes a secret use, but excludes public experimental use when an inventor's act is concerned.

(DSC 1973) *aff'd* 487 F.2d 459 (4th Cir. 1973); *Ex Parte Fuji*, 13 USPQ 2d 1073, 1074–5, (Bd. Pat. App. & Int'f 1989).

52 For an interpretation of 'being known or used', see *Conn. Valley Enters., Inc. v. United States*, 348 F.2d 949, 951–2 (Ct. Cl. 1965), which recognized that '[t]he prior knowledge or use in order to negative novelty must also be accessible to the public'. For an interpretation of 'public use or on sale', see *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1549–50 (Fed. Cir. 1983), which refused to find 'public use' with respect to subject matter that a third party used secretly.

53 *See Egbert v. Lippmann*, 104 US 333, 336–7 (1881); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 517–18 (2d Cir. 1946).

54 *Metallizing Eng'g*, 153 F.2d at 520.

55 *Pennock v. Dialogue*, 27 US 1, 19–20 (1829).

56 *W.L. Gore*, 721 F.2d at 1549.

57 *City of Elizabeth v. American Nicholson Pavement Co.*, 97 US 126, 134–5 (1877).

58 *See generally* CHISUM ON PATENTS, *supra* note 45, § 6.02[7] .

These doctrines relating to the interpretation of 'public use or on sale' introduce uncertainty to the validity of US patents. First, inclusion of secret commercial use within the meaning of 'public use or on sale' introduces a significant uncertainty into US patent validity. This is because the patent office is unable to find out that the inventor secretly used the invention more than one year from the date of application. The duty of candor requires the inventor to disclose such use.[59] However, if the inventor violates the duty and fails to disclose the use, such use is only revealed through discovery when the inventor tries to enforce his patent.

Another difficulty results from simply trying to apply the doctrine. Common sense requires that an invention must be complete to make an offer to sell.[60] However, US courts struggle to clarify the degree of an invention's completeness required to find commercial activity with respect to the invention, which will give rise to 'on sale'.[61] Both courts and parties are confused by similar concepts used to determine the completion of invention: the concepts which are used for determining the priority in interference practice – the conception and reduction to practice; and the concept which is used for applying on sale bar – the invention being on hand for sale. Despite the similarity in these concepts, interference practice and on sale bar relate to different policies.[62] Although the Supreme Court announced a 'ready for patenting' standard to replace the Federal Circuit's 'substantial completion' standard, supposedly to bring more certainty,[63] parties still dispute the definition of 'ready for patenting' in relation to the conception and reduction to practice. The Federal Circuit's inconsistent application of the 'ready for patenting' standard further confuses whether subject matter is on sale if a commercial offer is made. In some cases, the court has found the subject matter ready for patenting when all claim elements existed in the subject matter.[64] In other cases the court found on sale even if some claim elements are missing from offered subject matter as long as the missing elements are inherent or obvious from the subject.[65] Another factor

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59 37 CFR § 1.56 (2007).

60 This requirement is known as the 'on hand' doctrine. CHISUM ON PATENTS, *supra* note 45, § 6.02[6][a].

61 For a discussion of US courts' attempt to clarify the on sale bar doctrine, see Daniel J. Whitman, Note, *The 'On-Sale' Bar to Patentability: Actual Reduction to Practice Not Required in Pfaff v. Wells Electronics, Inc*., 32 AKRON L. REV. 397, 410–19 (1999); Vincent J. Allen, Comment, *The On Sale Bar: When Will Inventors Receive Some Guidance?*, 51 BAYLOR L. REV. 125, 131–46 (1999).

62 *See UMC Elecs. Co. v. United States*, 816 F.2d 647, 656 (Fed. Cir. 1987).

63 *Pfaff v. Wells Elecs. Inc.*, 525 US 55, 65–6 (1998).

64 *Robotic Vision Sys. v. View Eng. Inc.* 249 F.3d 1307 (Fed. Cir. 2001).

65 *Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 156 F.3d 1193 (Fed. Cir. 1998); *Tec Air Inc. v. Denso Mfg Michigan Inc.*, 192 F. 3d 1353 (Fed. Cir. 1999).

that causes difficulty in the application of the doctrines associated with 'public use or on sale', is the requirement of a commercial nature in the inventors' acts.[66] To give rise to 'on sale', courts only require an offer to sell and not an acceptance or delivery.[67] However, even if the subject matter was delivered to others, courts may find the offer to be a sham.[68] The same degree of difficulty exists in establishing a standard to determine 'experimental use'.

Another complexity in the current § 102(a) and (b) results from a distinction between foreign and domestic prior art depending on the place of disclosure.[69] Under the current US patent statute, only information described in a published patent or printed publication constitutes the prior art.[70] If information is merely 'known or used' or 'in public use or on sale', such information must be available in the United States to constitute the prior art under § 102(a) and (b).[71] However, the progress of technology has made electronic publication easy and, in turn, has made it difficult to determine if such publication meets the definition of 'printed publication' in the patent statute. If information falls within the meaning of 'printed publication', the USPTO does not need to distinguish foreign from domestic information. Thus, the USPTO clarified that the meaning of 'printed publication' includes electronic publications with a condition that such publication is available to those who relate to the field of subject matter disclosed in the publication.[72] First-to-file countries also addressed this difficulty and removed the distinction between foreign and domestic prior art, and between written and unwritten form, making prior art information that has become available in any form anywhere.[73]

b. § 102(c) and (d). The novelty rule, under the US first-to-invent system, includes additional grounds for preventing an inventor from obtaining a patent – § 102(c) and § 102(d) statutory bars.[74] These bars do not exist under the first-to-file principle and make the novelty provision lengthier.

Section 102(c) provides that an inventor's abandonment of an invention prevents the inventor from obtaining a patent on that invention.[75] This act of

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66 *See Mahurkar v. Impra, Inc.*, 71 F.3d 1573, 1577 (Fed. Cir. 1995).

67 *See, e.g.*, *In re Theis*, 610 F.2d 786, 791–2 (CCP 1979).

68 *See, e.g.*, *Mahurkar*, 71 F.3d at 1577.

69 35 USC§ 102(a), (b).

70 *Id*. § 102(a), (b).

71 *See, e.g.*, *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426, 434-35 (9th Cir. 1973).

72 35 USC § 102(a), (b); Manual for Patent Examining Procedure § 2128 (8th ed. 2001) [hereinafter Patent Manual], *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm.

73 *E.g.*, European Patent Convention, *supra* note 3, art. 54(2); Japanese Patent Law, *supra* note 4, art. 29(1).

74 35 USC § 102(c), (d) (1994).

75 *Id*. § 102(c).

abandonment should be read as distinct from the abandonment outlined in § 102(g) because once § 102(c) abandonment is found, an inventor loses his right to obtain a patent forever and is unable to recover the right.[76] In contrast, § 102(g) abandonment does not result in a loss of right to obtain a patent.[77] When an inventor resumes her work before the second person, to reduce the invention to practice, conceives the same invention, the inventor can rely on the date of resuming the activity to file an application and obtain a patent.[78] This distinction is only visible through investigating court interpretations of § 102(c) and (g).[79]

An even more confusing aspect of § 102(c) abandonment is its relationship with 'public use or on sale' under § 102(b). The leading Supreme Court case, *Kendall*, suggests that an inventor can abandon the right to obtain a patent not only by an express declaration of abandonment, but also by actions indicating an intent to abandon the right.[80] Such acts include acquiescence in the use of his invention by others, delay in enforcing rights, or an attempt to withhold the benefit of his invention.[81] However, the acts the *Kendall* Court listed to constitute abandonment are now subsumed by § 102(b).[82] Courts interpret § 102(b) to include within the meaning of 'public use and on sale' a delay in filing an application while commercially exploiting an invention, which delay is comparable to the acts to indicate an intent of abandonment under Kendall.[83] It is not clear whether any act that does not give rise to a 'public use or on sale' falls within the meaning of § 102(c). No court has found an abandonment relying on an act during the grace period.[84] An early Supreme Court decision suggests that a delay in filing an application while keeping the invention secret does not constitute abandonment.[85] As a result, § 102(c) abandonment is seldom relied on to reject or invalidate a patent.[86]

Another statutory bar provision that does not exist under the first-to-file principle is foreign patenting under § 102(d). This bar shares the same problem as § 102(a) and (b) regarding the question of when and whether a foreign patent falls within the meaning of § 102(d).[87] This section was originally

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76 CHISUM ON PATENTS, *supra* note 45, § 6.03[2].
77 35 USC § 102(g).
78 *Paulik v. Rizkalla*, 760 F.2d 1270, 1275–6 (Fed. Cir. 1985).
79 *See, e.g., Kendall v. Winsor*, 62 US 322, 329 (1858).
80 *Kendall*, 62 US at 329.
81 *Id.* at 328–31.
82 *See* CHISUM ON PATENTS, *supra* note 45, § 6.03[1][c][i].
83 *See, e.g., Mahurkar v. Impra, Inc.*, 71 F.3d 1573, 1577 (Fed. Cir. 1995).
84 CHISUM ON PATENTS, *supra* note 45, § 6.03[1][c][i].
85 *Bates v. Coe*, 98 US 31, 46 (1878).
86 CHISUM ON PATENTS, *supra* note 45, § 6.03.
87 Refer to notes 41–3 *supra* and accompanying text.

added to encourage foreign applicants who obtain patent protection abroad to promptly file with the USPTO.[88] When the United States joined the Paris Convention, this goal was already well-served by the priority system under the Convention, which requires applicants who filed an application in one of the Paris Union member states to file in another country within one year of the application date of the early filing (priority date).[89] Meeting the requirement under the Paris Convention automatically satisfies the one-year filing requirement under § 102(d). Therefore, § 102(d) is seldom relied upon for rejecting claims or invalidating patents.

Additionally, § 102(d) has a serious flaw in that it unfairly discriminates against inventions made outside the United States by imposing an additional bar to foreign-originated inventions. Thus, it is arguable that § 102(d) may violate the non-discrimination provision in the WTO-TRIPS agreement with respect to the place of invention.[90] Not only is § 102(d) unnecessary and confusing because of the interpretation of a foreign patent, it also provides a source of criticism from US trade partners.[91] Although there is very little justification, this provision presents another hurdle for US inventors and further complicates the novelty provision.

c. § 102 (e). The distinct policies related to novelty with respect to actors of disclosures introduce another complexity in determining novelty under § 102(e). The US first-to-invent principle introduces two separate concepts by distinguishing a priority right or a senior right in obtaining a patent from a defensive effect of preventing a third party from obtaining a patent, which relates to the statutory bar events under § 102(b), (c), and (d).[92] In interpreting the effect of priority right under the Paris Convention, Article 4B, US scholars read the article to bind only a defensive patent-defeating effect.[93] Applying this interpretation to the definition of the prior art in § 102(e), the USPTO and the US courts give the effect of the priority only with respect to subject matter claimed in an application if the applicant claims the priority for the application based on a foreign application under the Paris Convention. However, they refuse to give the same effect to subject matter which is not claimed but disclosed in the application. The latter subject matter does not relate to a priority or senior

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88 CHISUM ON PATENTS, *supra* note 45, § 6.04[1].

89 Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 UST 1583 [hereinafter Paris Convention], art. 4A.

90 WTO-TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, para. 1.

91 *See* Kim Taylor, Note, *Patent Harmonization Treaty Negotiations on Hold: 'The First to File' Debate Continues*, 20 J. CONTEMP. L. 521, 521–2 (1994)

92 Adelman et al., *supra* note 32, at 824.

93 *Id.*

right and only relates to a defensive effect because the applicant does not claim the priority to obtain a patent.[94] In contrast, to avoid this complexity, most first-to-file countries give the effect of priority under the Paris Convention to both claimed and unclaimed subject matter.[95]

However, the language of § 102(e) does not make clear the different timings required to become prior art with respect to claimed and unclaimed subject matter.[96] Literally interpreted, it requires the invention to be described in an application for a patent by another filed in the United States before the invention, and it does not specify in which part of the application the invention must be described.[97] When one interprets the language in the context of the benefit given to an early application in the operation of § 119, he or she might reasonably conclude that the same prior art effect would be given to both claimed and unclaimed subject matter.

In fact, this interpretation was adopted by the USPTO until the *Hilmer* court instructed it to adopt the more complex interpretation of limiting the effect to only claimed subject matter.[98] The *Hilmer* court upheld this complex interpretation only after extensively reviewing the legislative history and emphasizing the necessity of limiting secret prior art.[99] This practice of distinguishing a priority or senior right from a patent-defeating right confuses both US and foreign inventors and makes it difficult to determine if their inventions are patentable with respect to an application filed earlier by a third party under § 102(e). This difficulty is enhanced when the USPTO discriminates against non-English international applications under the Patent Convention Treaty.[100]

d. §102(g). Finally, § 102(g) provides another category of secret prior art: an invention by the first inventor that has become known only after the date of invention by the second inventor.[101] Secret prior inventions under § 102(g)

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94 *See, e.g., In re Hilmer*, 359 F.2d 859, 863 (CCPA 1966) (applying the *Milburn* rule, which proclaims '[t]hat a complete description of an invention in a U.S. patent application, filed before the date of invention of another, if it matures into a patent, may be used to show that the other was not the first inventor,' and acknowledging that '[t]his was a patent-defeating judge-made rule and now is section 102(e)').

95 Reinhard Wieczorek, *Convention Applications as Patent-Defeating Prior Rights*, 6 IIC 135, 156–65 (1975).

96 35 USC § 102(e) (1994 & Supp. 2000).

97 *Id.* § 102(e).

98 *Hilmer*, 359 F.2d at 877 (reasoning that to give effect to both claimed and unclaimed subject matter 'has the practical potential effect of pushing back the date of unpublished, secret disclosures, which ultimately have effect as prior art references in the form of US patents, by the full one-year priority period of § 119').

99 *Id.* at 878.

100 35 USC § 102(e), *supra* note 72, Patent Manual § 2136.03.

101 Adelman et al., *supra* note 32, at 312.

introduce a significant uncertainty into US patent validity because the USPTO cannot find such inventions during the examination. The inventor of the prior invention can challenge the validity of a patent only after it issues.

To reduce this uncertainty, the US patent system introduced a series of limitations to challenge patents based on secret prior inventions. First, the US patent system introduced the concepts of abandonment, concealment, and suppression to prevent first inventors from challenging the validity of a patent issued to the second inventor.[102] When an inventor unreasonably delays in filing an application, courts find abandonment, concealment, or suppression, thus the first inventors are precluded from challenging the validity.[103] Second, the US patent system introduced a procedure that precludes the first inventor from challenging the patent's validity, unless such claim is raised within one year from the date of issuance of a US patent or of publication of a US patent application.[104]

Despite court attempts to limit such challenges, § 102(g) secret prior inventions still bring significant uncertainty into the validity of US patents. This is because courts refuse to adopt a strict test to determine the time necessary to give rise to abandonment, suppression, and concealment.[105] Moreover, courts may let first inventors rely on their initial conception as long as they can establish their continuous diligence up to the date of reduction to practice.[106] As a result, current practice allows inventors to predate the second invention beyond the grace period, and to date back to the conception without limitation as long as the first inventors continue to work on the invention's reduction to practice.[107]

In short, the US first-to-invent novelty provision is very complex and lengthy. Some terms are redundant and unnecessary and others are confusing. This combination makes it difficult for US inventors to show the novelty of their inventions. Moreover, the interpretations US courts give to some of the terms depart from the ordinary meaning, thereby confusing inventors not familiar with US case law.

2.2.2 Priority Sections 102(f) and (g) codify the rule developed by US courts to determine the 'first and true inventor'.[108] However, US courts give

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102 35 USC § 102(g).

103 *See, e.g., Dunlop Holdings Ltd. v. RAM Golf Corp*., 524 F.2d 33, 35–7 (7th Cir. 1975).

104 35 USC § 135(b) (1994).

105 *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1568 (Fed. Cir. 1996) .

106 *See, e.g., Keizer v. Bradley*, 270 F.2d 396, 399-400 (CCPA1959).

107 *See* CHISUM ON PATENTS, *supra* note 45, § 10.03[1].

108 35 USC § 102(f), (g) (1994 & Supp. 2000).

special interpretation to the terms used in § 102(g) and, therefore, the rule is almost impossible to understand without knowledge of US court decisions. For example, § 102(g) prevents an inventor from obtaining a patent even if the inventor is the first-to-invent when the inventor abandoned, suppressed, or concealed the invention.[109] Although the patent statute lists three separate acts – abandonment, suppression, and concealment – US courts do not distinguish one from the other.[110] Instead, the three acts connote one concept: an unreasonable delay in disclosing the invention though filing a patent application[111] and/or commercializing the invention. Such delay gives rise to the possibility of 'abandonment, suppression, or concealment' regardless of the inventor's intent.[112] This interpretation departs from the ordinary meaning of the terms used in § 102(g) and misleads inventors not familiar with court interpretations.

In addition, although § 102(g) clearly articulated a rule that considers both the dates of conception and reduction to practice to determine the priority of invention, courts give priority to the first person who reduces the invention to practice.[113] Giving priority to the first person who conceived the invention is not a rule but an exception. The first exception applies only if the first-to-conceive exercised reasonable diligence in reducing the invention to practice from a time just prior to when the first person who reduces the invention to practice enters the field.[114] The second exception to the rule giving priority to a person who reduces the invention to practice is when the person has abandoned, suppressed, and concealed the invention.[115] However, the sentence of § 102(g) providing this exception uses the term 'the invention was made'.[116] Obvious questions from first-to-file patent professionals are 'what constitutes an act of invention and how can one establish the date of invention'? The answer is not easily derived from the statute because, although § 102(g) requires an invention to be made in this country, it does not define the meaning of 'made in this country'. It simply describes the rule of priority using the terms such as 'reduction to practice' and 'conception' without explaining the relationship between the invention made and these terms.[117] Without reading

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109 35 USC § 102(g)(2).

110 CHISUM ON PATENTS, *supra* note 45, § 10.08[1].

111 *See, e.g., Lutzker v. Plet*, 843 F.2d 1364, 1367 (Fed. Cir. 1988).

112 *See* CHISUM ON PATENTS, *supra* note 45, § 10.08[1]

113 *See Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993) For a general discussion of the priority rules, see CHISUM ON PATENTS, *supra* note 45, § 10.03[1].

114 *See* CHISUM ON PATENTS, *supra* note 45, § 10.03[1].

115 35 USC § 102(g)(2).

116 *Id.* § 102(g).

117 *Id.* § 102(g).

US case law, it is impossible to understand how the act of the invention 'being made' relates to an act of reducing the invention to practice and conception.

Further, § 102(g) does not define the term of reducing an invention to practice. Nonetheless, this term is highly technical and only used by patent specialists. Courts interpret the term to include two types of activity: (1) constructive reduction to practice by filing an application for a patent with a disclosure complying with § 112 requirements;[118] and (2) actual reduction to practice by constructing a product or performing a process that is read on the claims and confirming the suitability of the product or process for its intended purpose.[119] Accordingly, the US priority provision is also difficult for U.S. inventors to understand without fully appreciating US case law on the priority rule under § 102(g) because the most important concept 'invention being made', is not clearly defined. The rule and its exceptions also are unclear from the language of § 102(g). The statute is simply user-unfriendly and written only for patent lawyers.

2.3 Discrepancy between statutory language and practice

A more serious problem of the novelty and priority provisions under 35 USC § 102 is a discrepancy between the statutory language and practice. Although § 102(a) and (e) make clear that novelty is determined as of the date of invention, the USPTO determines the novelty for the vast majority of applications as of the date of application.[120] In interference proceedings, the USPTO also follows a first-to-file principle by imposing on second-to-file inventors the ultimate burden of showing the priority.[121] Due to the difficulty in meeting the burden, the US priority rule grants the priority to first-to-file inventors far more frequently than to second-to-file inventors.[122] Labeling the current US practice

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118 *See, e.g., Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998).

119 *See, e.g., Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994).

120 *See* CHISUM ON PATENTS, *supra*, note 45, § 10.03[c][*i*].

121 37 CFR § 41.207(a) (2007).

122 *See* Charles R.B. Macedo, *First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 18 AM. INTELL. PROP. L. Q.J. 193, 217 (1989) (observing that senior parties win 75% of the interferences). *Edwards v. Strazzabosco*, 58 USPQ 2d 1836 (Pat. & Trademark Office Bd. App. 2001) (a panel of the trial section at the USPTO Board noted a 75% success rate for senior parties over junior parties); Gerald J. Mossinghoff, *The U.S. First-To-Invent System Has Provided No Advantage to Small Entities*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 425 (2002) (during the period between 1983 and 2000, of the total of 2,858 interference cases, 1,917 were favorable to the first-to-file inventors). *But see*, Charles L. Cholz, *A Critique of Recent Opinions in Patent Interference*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 163, 181 (2002) (the author points out a conflict between the assessment of the Edwards panel and the last interference statistics published by the USPTO); Mark Lemley & Colleen Chien, *Draft Submitted for Address at 2002 CASRIP High*

as a first-to-invent is misleading. Many US inventors may have lost their rights for patents, believing that United States follows first-to-invent and delayed an application.

2.3.1 Novelty a. §102(a) and (e). The language of § 102(a) and (e) requiring novelty as of the date of invention is misleading because it departs from the USPTO examination practice.[123] To avoid the necessity of showing an invention date for every application, the USPTO examines the novelty of a vast majority of applications under § 102(a) and (e) as of the application date,[124] because the filing date of a US patent application with an adequate disclosure of the invention is presumed to be the invention date.[125] Only if an examiner finds a reference published earlier than the filing date is an inventor given a chance to eliminate the prior art reference by showing that his invention date is earlier than the effective date of the reference or that the reference is the inventor's own work, unless the subject matter is claimed in a US patent.[126] However, unsophisticated inventors often fail to take advantage of this practice because they do not keep records of the activities which resulted in the invention and cannot establish an earlier invention with corroborative evidence.[127]

The language of § 102(a) and (e) indicates that the date of invention is the critical date at which novelty must be demonstrated and does not accurately reflect the USPTO practice of examining, on an ad hoc basis, the novelty as of the invention date.[128] The language of the statute would more accurately coincide with practice if it made clear that the novelty of applications are examined as of the date of application, unless an inventor can establish an earlier date of invention with corroborative evidence. Because the current language of § 102(a) and (e) does not make clear that novelty pertains to the date of application, many US inventors may have lost their right to a patent by innocently failing to produce corroborative evidence showing an earlier date of invention.

b. §102(b) Grace Period. The view that the United States effectively has a first-to file system is also supported by the fact that § 102(b) functions like the priority and novelty provisions in countries using a true first-to-file system.[129]

Technology Summit Conference, Are the U.S. Priority Rules Really Necessary? (July 20, 2002) (the authors' survey indicates that 43% of junior parties won in the cases that are litigated to judgment and actually resolved on priority grounds).

123 *See* 35 USC § 102(a), (e).

124 CHISUM ON PATENTS, *supra* note 45, at § 10.03[1][c][*i*].

125 *Bates v. Coe*, 98 US 31, 34 (1878).

126 37 CFR § 1.130 and 131 (2007).

127 *Gould v. Schawlow*, 363 F.2d 908, 920 (CCPA 1966).

128 35 USC § 102(a), (e).

129 *See* Adelman et al., *supra* note 32, at 206. However, these provisions serve a

This is because when the USPTO relies on § 102(b), it determines the patentability of inventions based on the date of application, instead of the date of invention, because certain activities occurring more than one year prior to the filing date serve as an absolute bar to patentability.[130] Since the Supreme Court's *Pennock* decision in 1829, inventions have been excluded from the definition of first inventions if they were publicly used or on sale prior to the filing date.[131] The 1836 Patent Act, which codified *Pennock*'s holding, required novelty as of the date of application. The statutory bar provision in the Act thus functioned exactly like the novelty provision of first-to-file countries, although the underlying policy relating to the statutory bar provision differed from that of the first-to-file novelty provision.[132] The introduction of a grace period by the Patent Act of 1839 made it possible for inventors to obtain patents on publicly known inventions as of the filing date only if an application was filed within the grace period.[133] This means that the US patent system awards patents to inventions that are new and non-obvious as of the filing date, with a one-year grace period during which inventors are allowed to exploit their inventions to find commercial value.

The US patent system frequently fails to award first inventors when the inventors delay in filing an application and more than one year has passed from the time the invention was in 'public use' or 'on sale' in this country.[134] A good example is the invention in *Lough v. Brunswick Corp*.[135] In *Lough*, the inventor, Mr Lough, constructed six prototypes of his invention – a marine propulsion device for boats – and gave them to his friends to allegedly conduct testing of the invention's performance more than one year prior to filing a patent application for the invention.[136] Unfortunately, he failed to keep records on his testing.[137] Mr Lough's device functioned well and he did not receive complaints from friends who used his device in their boats. Thereby, he obviously did not need to inspect or repair his device on his friends' boats.[138] A jury found Brunswick Corporation guilty of infringing Mr Lough's

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philosophically different role in the first-to-invent system from the first-to-file system as their functions are keyed with the patent-defeating activity, which removes the priority.

130 35 USC §102(b).

131 *Pennock v. Dialogue*, 27 US 1, 23 (1829) .

132 Patent Act of 1836, ch. 357, 5 Stat. 117, § 6 *reprinted in* CHISUM ON PATENTS, *supra* note 45, Appendix 11.

133 Patent Act of 1839, ch. 88, 5 Stat. 353, § 7 *reprinted in* CHISUM ON PATENTS, *supra* note 45, Appendix 13.

134 35 USC § 102(b).

135 *Lough v. Brunswick Corp*., 86 F.3d 1113 (Fed. Cir. 1996).

136 *Id*. at 1116.

137 *Id*. at 1121.

138 *Id*.

patent, and the US District Court for the Middle District of Florida denied Brunswick's motion for a judgment as a matter of law, claiming the patent invalid under § 102(b).[139] A panel of the Federal Circuit found that the court erred in denying Brunswick's motion, noting that the inventor did not produce any objective evidence of experimentation such as a record of testing or inspection on the devices installed in his friends' boats.[140] In examining a request for en banc consideration of *Lough*, the dissent showed great sympathy for the inventor.[141] Nevertheless, the court declined to hear the case en banc.[142]

Had the inventor known that he should file an application within one year from the date he publicly disclosed the invention to his friends, he likely would have filed an application sooner and retained the right for a patent on his invention. Labeling the US novelty requirement as following a first-to-invent system with the presence of a provision determining novelty as of the date of application, even with a one-year grace period, misleads US inventors and may cause inventors, such as Mr Lough, to lose their patent rights.

2.3.2 Priority provision The heart of the US first-to-invent system, the priority rule under § 102(g), also primarily follows, in practice, the first-to-file principle favoring inventors who file their application first.[143] This is because the procedural rule gives preference to inventors who file an application first.[144] In an interference procedure, the person who filed an application first for a particular subject matter in question is referred to as a senior party and all other applicants filing later than the first applicant are called junior parties.[145] When an inventor is a senior party, she may simply rely on her application date as the date of invention. She is very likely to be awarded with priority because junior parties bear a series of burdens of proof to establish the priority over the first applicant's date of invention.[146]

First, the USPTO declares an interference only when (1) there is interfering subject matter in the applications or in the application and the patent, and (2) the subject matter is patentable to the applicant.[147] An interference can be

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139 *Id*. at 1118.

140 *Id*. at 1122.

141 *Lough v. Brunswick Corp.*, 103 F.3d 1517, 1528 (Fed. Cir. 1997) (Rader, J., dissenting).

142 *Id*. at 1518.

143 35 USC § 102(g).

144 37 CFR § 41.207 (a) (2007).

145 37 CFR § 41.201 (2007).

146 For a short discussion of interference proceedings, see Adelman et al., *supra* note 32, at 322–4.

147 CHISUM ON PATENTS, *supra* note 45, § 10.09[2][a].

declared among applications and among applicants and patentees. Before an early publication system was introduced, an interference among applications was declared only if an examiner happened to know the claims in the other applications and initiated an interference – US patent applications were kept secret until issuance.[148] Now, applications are published eighteen months after the effective filing date, and consequently, it has become more common for applicants to provoke an interference.[149]

When an applicant junior party tries to invoke an interference, she must demonstrate a *prima facie* case for the entitlement of priority over the patentee and when her earliest constructive reduction date is later than the filing date of the senior party, she must explain why she would prevail on priority.[150] This practice may present a high hurdle to overcome for unsophisticated inventors.[151] When an applicant junior party fails to make a claim to substantially the same subject matter prior to one year from the issuance date of the patent, the junior party's attempts to challenge her claim for an interference are precluded by a procedural bar.[152] Even having the USPTO declare an interference is a difficult task for those who did not file first because they bear the burden of demonstrating that they are *prima facie* entitled to an earlier filing date.[153]

Even if a junior party succeeds in having the USPTO declare an interference, the party will bear the burden of going forward with evidence as to the date of actual reduction to practice or early conception.[154] Since the date of application, with a disclosure to meet the § 112 requirements, is presumed to be the date of invention,[155] a senior party has the initial burden only if he chooses to show an actual reduction to practice or an early conception with diligence.[156] A senior party may otherwise choose a strategy concentrating on disproving the junior party's purported date of invention.

Throughout an interference proceeding, a junior party bears the ultimate burden of persuasion with respect to all issues of fact in establishing priority.[157] If the junior party filed an application before issuance of a patent to the first-to-file, the burden of persuasion is to show an earlier invention with proof

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148 35 USC § 122(a) (1994 & Supp. 2000).
149 35 USC § 122(b) (1994 & Supp. 2000).
150 37 CFR § 41.202 (2007).
151 *See, e.g., Hahn v. Wong*, 892 F.2d 1028, 1035 (Fed. Cir. 1989).
152 35 USC § 135(b); *see also In re Sasse*, 629 F.2d 675, 680 (CCPA 1980).
153 37 CFR §41.207(b) (2007).
154 CHISUM ON PATENTS, *supra* note 45, § 10.03[1][c][ii], [iii].
155 *E.g., Bates v. Coe*, 98 US 31, 34 (1878).
156 CHISUM ON PATENTS, *supra* note 45, § 10.03[1][c][ii].
157 *See, e.g., Bosies v. Benedict*, 27 F.3d 539, 541 (Fed. Cir. 1994).

by a preponderance of the evidence.[158] If a patent had been issued to the first-to-file by the time the junior party filed an application, the junior party must show an earlier invention with proof by clear and convincing evidence.[159] Further, US case law requires applicants to produce corroborative evidence regarding the complex legal concepts required to show priority.[160] Due to this heavy burden, in three-out-of-four cases junior parties lose in interference proceedings.[161] Taking into account inventors who fail to establish a *prima facie* priority and thus are unable to have the USPTO declare an interference, the chance for second-to-file inventors being awarded with priority is slim.[162]

In addition to this difficulty of showing an early invention, the high cost associated with an interference proceeding discourages second-to-file inventors from taking advantage of the first-to-invent priority rule.[163] As a result, only a very small portion of US applications (less than 0.1%) engage in a priority contest in an interference proceeding.[164] It thus follows that under the current USPTO interference practice the scope of the first-to-invent exception is very narrow.

The first-to-invent system is often viewed as being more favorable to small inventors than the first-to-file system.[165] However, this assertion is a myth.[166]

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158 *Id.* at 541–2.

159 *See, e.g.*, *Price v. Symsek*, 988 F.2d 1187, 1190–9 (Fed. Cir. 1993).

160 *See, e.g.*, *Hahn v. Wang*, 892 F.2d 1028, 1032–3 (Fed. Cir. 1989).

161 *See, e.g.*, Macedo, *supra* note 123 at 217 (indicating that senior parties win 75% of the interferences).

162 A conflict exists between the assessment of the *Edwards* panel and the last interference statistics published by the USPTO. *Compare, Edwards v. Strazzabosco*, 58 USPQ 2d 1836, 1840 (Bd. Pat. App. & Interf. 2001) (recognizing that a panel of the trial section at the USPTO Board noted a 75% success rate for senior parties over junior parties); Gerald J. Mossinghoff, *The U.S. First-to-Invent System Has Provided No Advantage to Small Entities*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 425, 427 (2002) (noting that during the period between 1983 and 2000, of the total of 2,858 interference cases, 1,917 were favorable to the first-to-file inventors), *with* Charles L. Gholz, *A Critique of Recent Opinions in Patent Interference*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 163, 181 (2002) (contending that the board's last statistics reveal that the senior party prevailed 52.5% of the time and the junior party prevailed 31.7% of the time).

163 *See, e.g.*, Macedo, *supra* note 123, at 218–19 (estimating that conducting interferences costs patent applicants approximately $15,000,000 per year). According to a survey conducted by American Intellectual Property Association (AIPLA) in 2006, the median of the estimated cost inclusive in a two-party interference is $450,000. AIPLA, Report of Economic Survey 2007, 90 (2007)

164 Mossinghoff, *supra* note 162, at 427.

165 *See* Ned L. Conley, *First-to-Invent: A Superior System for the United States*, 22 ST MARY'S L.J. 779, 782–3, 792–3 (1991).

166 Mossinghoff, *supra* note 162 at 428 (analyzing USPTO data and concluding that the first-to-invent system provides no advantage to small entities). Lemley &

It is doubtful that inventors with limited budgets can afford to take advantage of the expensive interference regime. Small inventors believe the first-to-invent principle favors them in that they can rely on a mere conception of an invention and avoid the financial burden of filing an application.[167] However, mere conception is never sufficient to show a date of invention under the current US first-to-file priority rule.[168] The priority rule requires either an actual or constructive reduction of the invention to practice. The US first-to-invent principle may in fact disfavor small inventors because constructing and testing a prototype is often even more expensive than filing an application. It follows that, in many cases, a first-to-file system in fact favors small inventors by saving costs for constructing and testing a prototype and attorney fees for establishing the priority.

The priority rule provides an exception to the first to reduce to practice principle by allowing inventors to rely on the date of conception.[169] However, unless an inventor reduces the invention to practice, he or she cannot rely on the conception date.[170] Moreover, an inventor must continuously work to reduce the invention to practice because an inventor's inactivity gives rise to a lack of diligence and prevents the inventor from relying on the date of conception.[171] Even if an inventor reduces the invention to practice, an unreasonable delay in filing an application with the USPTO gives rise to abandonment and prevents an award of priority.[172] Unfortunately, lack of funding seldom justifies a delay caused by lack of diligence or abandonment.[173]

In short, the current US first-to-file priority rule disfavors inventors who stop working on an invention before filing an application with the USPTO. To establish the priority, he or she must show continuous work by corroborative

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Chien, *supra* note 122 (the authors concluded their empirical data do not support the view that first-to-invent favors small inventors over large companies).

167 First-to-invent advocates focus solely on the cost of application but pay no attention to the cost of reducing the invention to practice, which is necessary for establishing the priority under the US first-to-invent system. *See, e.g.*, Conley, *supra* note 165, at 783.

168 35 USC § 102(g)(2).

169 35 USC §102(g)(2); *See, e.g.*, *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1378 (Fed. Cir. 1986); CHISUM ON PATENTS, *supra* note 45, § 10.03[1].

170 See 35 USC § 102(g)(2); *Edwards v. Strazzabosco*, 58 USPQ 2d 1836, 1841–2 (Bd. Pat. App. & Interf. 2001).

171 35 USC § 102(g)(2); *Gould v. Schawlow*, 363 F.2d 908, 919-21 (CCPA 1966).

172 35 USC § 102(g)(2); *See, e.g.*, *Lutzker v. Plet*, 843 F.2d 1364, 1366–7 (Fed. Cir. 1988). *But see* CHISUM ON PATENTS, *supra* note 45, § 10.07[4][b].

173 *See, e.g.*, *Griffith v. Kanamaru*, 231 USPQ 892, 893 (Bd. Pat. App. & Int'f 1986).

evidence.[174] It is very likely that a practice of maintaining records on continuous work is more expensive than the practice of filing an application early. Moreover, taking into account the hardships that a first-to-conceive but second-to-reduce-to-practice inventor encounters under the current priority rule, the belief that the US first-to-invent system favors small inventors is not only false but misleading. Many unsophisticated inventors may lose a chance to obtain a patent because they are misled by the labeling of the US patent system as being 'first-to-invent', thus believing their early conception of an invention establishes priority under § 102(g).

3 Proposed first-inventor-to-file

A review of the language in § 102 has revealed that the complexity of defining the prior art and confusing interpretations given to the terms 'public use' or 'on sale' have resulted from the need to abrogate the problems inherent in a true first-to-invent principle. This review has revealed that some categories of the prior art in § 102 are simply outdated or redundant and thus unnecessary. It also has revealed categories of the prior art that are unique to the first-to-invent principle and that introduce a significant uncertainty into US validity. The perception that the first-to-invent principle favors small inventors also misleads US inventors. In essence, the worst problem of the US first-to-invent principle is not that it differs from patent systems from other countries, but that it is user-unfriendly due to its difficulty to understand, which accordingly harms US inventors.

Furthermore, the examination and interference practices at the USPTO follow the first-to-file principle, with first-to-invent acting more as a narrow exception. Inventors are only permitted on a limited ad hoc basis to show priority by establishing an early invention date. Reflecting the reality of US practice, US Congress is currently examining a proposal to rename the priority principle as 'the first-inventor-to-file' system. A bill that passed the House defines novelty and priority:

> §102 Conditions for Patentability; novelty
> (a) Novelty; Prior Art – A patent for a claimed invention may not be obtained if –
> (1) the claimed invention was patented, described in a printed publication, in public use or on sale –
>
> (A) more than one year before the effective filing date of the claimed invention; or
>
> (B) one year or less before the effective filing date of the claimed invention, other than through disclosures made by the inventor or a joint inventor or by others who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

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174 *See, e.g.*, *Gould*, 363 F.2d at 919–20.

(2) the claimed invention was described in a patent issued under section 151 or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.[175]

In principle the proposed revision is in line with a priority and novelty provision proposed by the author in clarifying the adoption of the first-to-invent principle and in reforming the first-to-file provision by restating the current § 102(b) grace period as an exception to the novelty.[176] The language in this provision allowing the determination of novelty as of the date of application with a one-year grace period will protect inventors from losing a patent right for failure to file an application within the grace period.

The proposed revision is also in line with the author's proposal in maintaining a limited exception to the first-to-invent principle. However, the revision goes beyond the author's proposal because it prevents first inventors from relying on their early inventions, unless the inventions are disclosed to the public. Thus, the revision eliminates the complexity involved in conception and reduction of invention to practice.

(b) Exceptions. –
(1) Prior Inventor Disclosure Exception – Subject matter that would otherwise qualify as prior art based upon a disclosure under subparagraph (b) of subsection (a)(1) shall not be prior art to a claimed invention under that subparagraph if the subject matter had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or others who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.[177]

3.1 Novelty

3.1.1 Merge § 102(a) and (b) The proposed revision of § 102(a) merges the current § 102(a) and (b). The new § 102(1)(A) provides separately for the one-year grace period under § 102(b) and makes clear that inventors must file an application during this period once they either make the invention being patented, describe it in a printed publication, or put it in 'public use or on sale'. The new § 102(1)(B) adds an ad hoc exception to the first-to-invent principle under Rule 131 by showing that the early invention during the one-year grace period is the inventor's own work.

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175 H.R. 1908, 110th Cong. (Patent Reform Act of 2007), Section 3, (b) §102(a). (http://www.govtrack.us/congress/bill.xpd?bill=h110-1908).

176 Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure §102 Novelty and Priority Provisions*, Hous. L. Rev. 621, at 654 (2002) [Hereunder, Rethinking the First-To-File].

177 *Supra* at n. 175.

However, the proposed revision maintains the confusing definition of 'being patented'. Acts of 'being described in a printed publication' subsume acts of 'being patented'. It is not necessary to list both acts in the novelty provision. Further, the proposed revision still associates the definitions 'being in public use or on sale' with the secret-commercial-use bar and experimental-use exception doctrines.[178] It would be much better if the revision replaced the 'public use or on sale' definition with the 'publicly known or used' definition that US courts have interpreted as the ordinary meaning of public accessibility. The 'public use or on sale' definition in the proposed revision not only preserves the complexity of the novelty provision but also decreases the credibility of US patent validity by maintaining the uncertainty arising from obscure interpretation in the relevant case law.

Further, to address the complexity resulting from the geographical limitation on unwritten forms of prior art information,[179] the proposed revision does not distinguish foreign prior art information from domestic prior art information. The sole reason for including the categories of the prior art 'described in a patent or printed publication' in the current § 102(a) and (b) is to distinguish written from unwritten forms of prior art information. This is because only former information becomes the prior art if the information is made available outside the United States. The removal of the geographical limitation would make it unnecessary to list these categories in addition to 'being in public use or on sale'. Nevertheless, the proposed revision maintains these categories which may introduce confusion.

3.1.2 Removal of § 102(c) and § 102(d) The proposed § 102 revision eliminates the current § 102(c) from the novelty provision. Even under the current novelty provision, § 102(c) offers very little justification for providing the bar separately from § 102(b) and introduces only confusion with respect to § 102(g) abandonment. Thus, a removal of § 102(c) will not only contribute to the simplification of the US novelty provision, but will also clarify the statutory interpretation of the novelty provision. The proposed § 102 revision also removes § 102(d), which the Paris Convention has already made useless and which may also violate the TRIPS provision.

3.1.3 Revision of § 102(e) The proposed § 102(a)(2) is comparable to the current § 102(e) in defining an early application pending in the USPTO as the

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178 An early version of patent reform bill included a provision to require public accessibility for defeating the novelty. H.R. 2795, 109th Cong. (Patent Act of 2005) (http://www.govtrack.us/congress/billtext.xpd?bill=h109-2795) [hereunder, H.R. 2795].

179 *See* 35 USC § 102(a), (b).

prior art. However, despite making clear a determination of novelty as of the application date, the proposed § 102 provides an exception which maintains the current practice of providing an ad hoc opportunity to establish an early invention under Rule 131. This practice will be used to establish that subject matter disclosed in an early application is the inventor's own work.[180] Further, the proposed § 102 provides another exception which maintains the current practice of removing § 102(e) prior art where (1) the claimed invention was owned by the same person or subject to an obligation of assignment to the same person as of the effective filing date or (2) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect or before the effective filing date.[181]

The proposed revision includes a provision which expressly gives the same effect as a domestic application to both the benefit of priority under the Paris Convention and an international application filed under the Patent Cooperation Treaty.[182] Thus, it overrules the *Hilmer* doctrine.[183] A removal of the *Hilmer* doctrine will better serve US inventors by removing the complex interpretation of the discriminating effect regarding claimed and unclaimed subject matter.[184] It also eliminates the illogical problems caused by the doctrine that US legal commentators extensively criticize.[185] The *Hilmer* doctrine is also heavily criticized by foreign legal commentators for violating the priority right provision under the Paris Convention, as well as the non-discrimination policy provision regarding the place of invention under WTO-TRIPS.[186]

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180 H.R. 2795, Section 3, (b), § 102(b)(2)(A)(B).

181 H.R. 2795, Section 3, (b), § 102(b)(2)(C); § 102(b)(3).

182 H.R. 2795, Section 3, (b), § 102(b)(4)(B).

183 *In re Hilmer*, 424 F.2d 1108 (CCPA 1970). The Fifth Circuit summarized the *Hilmer* doctrine thus, 'under the *Hilmer I* doctrine, a prior art reference patent is effective only as of its U.S. filing date'. *Studiengeselleschaft Kohle mbH v. Eastman Kodak Co.*, 616 F.2d 1315, 1337–8 (5th Cir. 1980).

184 Richard A. Neifeld, *Viability of the Hilmer Doctrine*, 81 J. PAT. & TRADEMARK OFF. SOC'Y, 544 (1999).

185 *See* DONALD S. CHISUM, ELEMENTS OF UNITED STATES PATENT LAW 104 (2000); Kevin L. Leffel, Comment, *Hilmer Doctrine and Patent System Harmonization: What Does A Foreign Inventor have at Stake?*, 26 AKRON L. REV. 355, 357 (1992) (providing a historical analysis of the *Hilmer* doctrine and its effects); Harold C. Wegner, *TRIPS Boomerang-Obligations for Domestic Reform*, 29 VAND. J. TRANSNAT'L L. 535, 558 (1996) (describing the *Hilmer* opinion as 'a low point in judicial understanding of international patent practice and treaties').

186 Paris Convention, *supra* note 89, art. 4; TRIPS Agreement, *supra* note 90, art. 27(1). Professor Chisum also pointed out this problem, see, DONALD S. CHISUM, ELEMENTS OF UNITED STATES PATENT LAW 104 (2000) [hereinafter CHISUM, ELEMENTS].

A worse problem is that the application of the *Hilmer* doctrine results in a double patenting problem through the issuance of separate multiple patents to obvious inventions.[187] The double patenting problem was somewhat remedied by the *Deckler* case in which the court applied the interference estoppel doctrine broadly and prevented the applicant from seeking a second chance to request a priority contest with respect to obvious inventions through an interference proceeding.[188] This expansive use of the estoppel doctrine effectively prevents multiple patents from being issued on obvious inventions as long as claims are contested through an interference proceeding.[189] Accordingly, some commentators view the *Deckler* case as essentially overruling *Hilmer*.[190]

There are no justifiable reasons to keep this doctrine due to these serious problems. First, disclosure of patentably indistinguishable inventions brings no benefits to the public.[191] Second, the *Hilmer* court's major concern in using the foreign priority date for a patent-defeating effect was to prevent the expansion of secret prior art.[192] This concern over secret prior art has been significantly remedied by the introduction of an early publication system under the 1999 American Inventors Protection Act.[193] The content of all applications is now automatically published after eighteen months from the filing date.[194]

In essence, the proposed § 102(b) simply clarifies the holding of *Deckler* and removes any suspicion of violating the Paris Convention and the TRIPS Agreement. The revision will result in very little impact on USPTO practice under § 102(e) because the *Hilmer* doctrine has seldom been raised in the USPTO and court proceedings since its adoption. However, it will help the USPTO greatly by removing the complex novelty determination of international applications.

3.1.4 Secret prior invention The proposed revision removes secret prior inventions under the current § 102(g). Because secret prior inventions introduce uncertainty in patent validity, this removal significantly improves the US patent system.[195] This removal also greatly simplifies the novelty rule by

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187 *See* Leffel, *supra* note 184, at 357.

188 *See In re Deckler*, 977 F.2d 1449, 1452 (Fed. Cir. 1992).

189 *See id*.

190 Charles E. Van Horn, *Effects of GATT and NAFTA on PTO Practice*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 231, 234 (1995) (noting that the doctrine of interference estoppel 'precludes two patents from issuing on patentable indistinct inventions').

191 DONALD CHISUM, ELEMENTS OF UNITED STATES PATENT LAW 104 (2000).

192 *In re Hilmer*, 359 F.2d 859, 877 (CCPA 1966).

193 PL 106-113, §§4001–4808, 113 Stat. 1501 (November 29, 1999).

194 35 USC § 122(b)(1) (2000).

195 F. Andrew Ubel, *Who's on First? – The Trade Secret Prior Use or a Subsequent Patentee*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 401, 405 (1994).

making the prior art only publicly available information, except for unpublished applications pending in the USPTO under current § 102(e).

3.1.5 Inventorship Although patent systems of first-to-file countries do not require inventors to file an application under their names, they do provide a recourse designed to prevent applicants from obtaining a patent if the applicant did not legally obtain a right for patent from the true inventor; this is common to first-to-file countries.[196] Thus, the proposed revision keeps the current § 102(f) and maintains the interference procedure so that a true inventor can request a procedure to decide whether the applicant derived the invention from the true inventor.[197]

3.2 Priority

3.2.1 First invention by disclosure The proposed revision provides an exception to establish the priority based on a disclosure made by the first inventor.[198] Thus, a first inventor can rely on his or her early invention only if the invention is disclosed by the inventor or a joint inventor. Since a significant problem of the current first-to-invent principle is that a first inventor can rely on an early invention which was kept secret and thus the USPTO was unable to examine such invention, a removal of secret invention from the priority dispute substantially improves the credibility of US patent validity.

Further, the revision removed the confusing concepts of 'conception' and 'reduction of the invention to practice' from the new derivation proceeding. Instead, a first inventor simply establishes that the invention under the examination was invented and disclosed to the public by the inventor or a person who obtained information on the invention from the inventor. Although uncertainty may remain in determining the effective date of publication and whether the information was in fact derived from the inventor, the determination is simpler than the determination of the first inventor under the complex priority rule used in the current interference procedure. For example if a person other than the inventor disclosed the invention, it is relatively easy for the USPTO examiners to determine whether an early disclosure which is publicly accessible enabled one skilled in the art to enable the invention under the examination and thus the inventor of the invention in the early disclosure is the first inventor. The new priority system removes the complexity in applying the

196 *See* European Patent Convention, art. 61; Japanese Patent Law, *supra* note 4, art. 113(1)(ii).

197 H.R. 2795, Section 3, (b), § 102(a)(1)(A).

198 H.R. 2795, Section 3, (b), § 102(a)(2)(1).

priority rule and limits the use of interference procedure only to find whether the invention is directly or indirectly derived from a third party inventor.

Giving the priority to the first disclosure promotes the progress of useful arts and thus attains the goal of the patent system by encouraging early disclosures. Disclosing an invention is much less expensive than constructing a prototype or filing an application with a patent office – acts currently required for establishing the priority. Thus, the practice is more friendly to the small inventor than the current first-to-file principle.

3.2.2 Modest proposal As a modest option of revision, the author once proposed to keep the current first-to-file rule while preventing inventors from establishing the date of invention beyond one year prior to the application date.[199] Because an inventor's own disclosure bars inventors from obtaining a patent unless an application is filed within one year from the disclosure, they cannot establish the priority beyond the grace period. Thus, this proposed revision effectively adopts the goal of the author's modest proposal.

The author also proposed a more ambitious option to limit the exception of first-to-invent by applicants.[200] This option proposed to expand the current exception to early publication for domestic inventors to include first-to-invent priority. Under this exception, only applicants who do not wish to file an application outside the United States will be allowed to take advantage of the first-to-invent exception and establish an earlier invention date under the § 102(g) priority rule. However, the proposed revision which passed the House does not include this limitation even though limiting the first-to-invent exception to domestic applicants will greatly reduce the number of cases taken to an interference proceeding, thereby reducing administration costs.

3.3 Condition for revision

The proposed revision includes a provision that the amendment to the novelty and priority will not become effective unless major patenting authorities, including at least the European Patent Office and Japan Patent Office, adopt a grace period having substantially the same effect as that under the revised US patent system.[201] Such a grace period is defined as the one-year period ending on the effective filing date of a claimed invention.[202] During this period, direct or indirect disclosure of the invention by the inventor, a joint inventor, or by others who obtained the invention must not qualify as prior art to the invention under examination.

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199 Rethinking the First-To-File, *supra* note 178 at 661.
200 Rethinking the First-To-File, *supra* note 178 at 662.
201 H.R. 2795, Section 3(k)(1)(A).
202 H.R. 2795, Section 3(k)(2)(B).

This condition to trigger the amendment did not exist when the original bill was introduced in 2007. However, USPTO and the Bush administration were concerned that giving up on the first-to-invent principle might lessen their bargaining chips when negotiating with their trade partners about harmonization. However, this inclusion may present an impossible hurdle to the revision because European countries have long resisted the idea of a grace period due to the uncertainty introduced by the determination of derivation of the invention from an early disclosure.

4 Conclusion

A review of the current first-to-invent novelty and priority provisions in 35 USC § 102 has revealed serious problems resulting from a complex structure for defining the prior art and inclusion of confusing terms without definition. A review of the examination and interference practice at the USPTO has also revealed that a serious discrepancy between the language of the current novelty and priority provisions very likely misleads US inventors. The well-established perception of first-to-invent favoring small inventors does not reflect the USPTO practice. It is necessary to revise § 102 to make the novelty and priority rule simple and user-friendly. The proposed revision which passed the House can meet this requirement and move the US novelty and priority provision more in line with those of the first-to-file countries.

However, it is unlikely that the proposed revision will in fact take effect because the revision is conditional upon the adoption of a one-year grace period by the European Patent Office. It does not make sense to delay the effective date of the revision because the revision should be made more user-friendly for US applicants to the US patent system, and to reduce the administrative burden upon USPTO. Industry has already expressed its dissatisfaction with the inclusion of the new condition. Thus, the introduction of the corresponding reform bill to the Senate has been significantly delayed. At worst, both bills may end up failing to become law. In failure, all efforts over the last three years will have been in vain.

14 Back to the *Graham* factors: nonobviousness after *KSR v. Teleflex*

*Elizabeth A. Richardson**

Introduction

To be patentable, an invention must have utility, it must be new, and it must be different enough from what has come before such that it is not merely an obvious advance. Nonobviousness is thus a central part of the bargain between the inventor and society; an invention that is simply obvious over the prior art is not worthy of the limited monopoly a patent provides, because such an invention contributes less to society than an invention that represents a greater (nonobvious) advance. Akin to the 'inventive step' in many other jurisdictions, nonobviousness is in some respects the heart and soul of patentability, separating the truly innovative wheat from the chaff of unpatentable minor improvements. In the United States, nonobviousness as a requirement for patentability is codified at 35 U.S.C. § 103(a), which provides in relevant part:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [novelty], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[1]

This fairly straightforward statutory language belies a far more complex tapestry of case law, from both the United States Supreme Court and the United States Court of Appeals for the Federal Circuit, which provides significantly more guidance for both patent applicants and litigants alike as to what

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1 35 U.S.C. § 103(a) (2000).

obviousness really means in the patent context. The Supreme Court's recent *KSR Int'l Co. v. Teleflex, Inc.*[2] opinion, which rejected what it considered an overly rigid application of the 'teaching-suggestion-motivation' (TSM) test[3] by the Federal Circuit, favors a case-by-case approach to nonobviousness, rooted in the *Graham* factors.

After the Supreme Court granted *certiorari* in *KSR* but before it handed down its decision, the Federal Circuit issued a handful of opinions that in many ways foreshadowed *KSR*, taking a more flexible approach to the TSM test. These cases, including *DyStar Textilfarben GmbH v. C.H. Patrick Co.*[4] and *Alza Corp. v. Mylan Laboratories, Inc.*,[5] were of course not before the Supreme Court in *KSR*, and the Court did not comment on them except to say that it was not commenting on them.[6] From the perspective of cases like *DyStar* and *Alza*, *KSR* tempered, rather than truly altered, nonobviousness jurisprudence in the United States. But, some things have changed and will continue to evolve as the United States Patent & Trademark Office, the district courts, and the Federal Circuit digest *KSR*. The goal of this chapter is to discuss *KSR* and some of the earliest post-*KSR* Federal Circuit decisions, so as to begin to explore what has changed, and what has not, in approaching nonobviousness in the United States since *KSR*. Instead of focusing on the TSM test alone, however, this chapter will explore the obviousness inquiry overall, by considering, as the Supreme Court did in *KSR*, the factors articulated in *Graham v. John Deere Co.*[7]

Graham and *KSR*

After over forty years, the Supreme Court's opinion in *Graham* remains the cornerstone of nonobviousness jurisprudence, its dominance only reinforced by *KSR*. While the ultimate question of whether a patent is obvious is one of law, *Graham* articulated several subsidiary factual inquiries undergirding this determination:

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2 *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007).

3 Basically, the TSM test asks whether there is some teaching, suggestion or motivation in the prior art that would have lead a person of ordinary skill in the art to combine the prior art in the manner claimed by the patentee/patent applicant. Some, but not by any means all, courts before *KSR* had required a level of specificity in this showing, namely an explicit motivation in the prior art, prior to *KSR*, an approach the Supreme Court rejected.

4 *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

5 *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006).

6 *KSR*, 127 S.Ct. at 1743.

7 *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

> Under 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.[8]

In other words, to judge whether a claimed invention is obvious or nonobvious, the analysis begins with three factors:

1. the scope and content of the prior art;
2. the differences between the prior art and the claims at issue; and
3. the level of ordinary skill in the pertinent art.

Then, a fourth factor comes into play: the secondary considerations, which may provide circumstantial evidence to guide the ultimate conclusion of obviousness.

Over the years since *Graham*, the Court of Customs and Patent Appeals and its successor, the Federal Circuit, have applied the *Graham* factors and have developed from them a number of additional inquiries to evaluate obviousness without falling prey to hindsight, including the TSM test and the analogous art test. Also, technology-specific considerations as well as the varying levels of predictability among different fields (chemistry and biotechnology being less predictable, in general, than the mechanical arts, for example) have played roles in the development of the case law; for example, structural similarity as a basis for a *prima facie* case of obviousness is understandably unique to the chemical arts, but this approach is nonetheless still rooted in the *Graham* factors and is consistent with the application of § 103 to patents in other technological fields.

In *KSR*, the Supreme Court underscored the central role of the four *Graham* factors as 'a framework for applying the statutory language of § 103'.[9] Before undertaking a further exploration of the *Graham* factors in the context of *KSR*, however, a review of *KSR* is helpful to provide some context.

The patent at issue in *KSR*, entitled 'Adjustable Pedal Assembly With Electronic Throttle Control',[10] presented an opportunity for the Supreme Court to consider obviousness issues in the context of a straightforward tech-

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8 *Id.* at 17–18.
9 *KSR*, 127 S.Ct. at 1734.
10 United States Patent No. 6,237,565 (filed Aug. 22, 2000).

nology (at least as compared with many electrical, chemical, software-related and even other mechanical patents). Referred to in the litigation as the 'Engelgau patent', after the inventor's name, the claimed invention involved an improved accelerator pedal for use in cars and particularly trucks. The Supreme Court agreed with the district court's synopsis of claim 4, the claim at issue, as disclosing 'a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal.'[11] In other words, claim 4 claimed a pedal assembly including a mechanism for combining an electronic sensor with an adjustable pedal, allowing the pedal's position (which moves about a pivot axis with the force applied by the driver's foot) to be transmitted to a computer, which in turn controls the throttle in the vehicle's engine.[12]

During prosecution, a claim similar to but broader than claim 4 had been rejected as an obvious combination of two prior art references (Redding,[13] which taught an example of an adjustable pedal, and Smith,[14] which described how a sensor could be mounted on the support structure of a pedal).[15] The broader claim was amended to include a limitation of a fixed pivot point, which distinguished it over the teachings of Redding and Smith.[16] Claim 4 was born, and the Engelgau patent issued. Later, Teleflex, the assignee of the patent, sued KSR, one of its competitors, for infringement of the Engelgau patent, after KSR refused to license the Engelgau patent and pay royalties to

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11 *KSR*, 127 S.Ct. at 1737 (quoting *Teleflex Inc. v. KSR Int'l Co.*, 298 F. Supp. 2d 581, 586–7 (E.D. Mich. 2003)).

12 *KSR*, 127 S.Ct. at 1734. Specifically, claim 4 provided:

> A vehicle control pedal apparatus comprising:
> a support adapted to be mounted to a vehicle structure;
> an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support;
> a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and
> an electronic control attached to said support for controlling a vehicle system;
> said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot. (U.S. Patent No. 6,237,565 (filed Aug. 22, 2000) (diagram numbers omitted)).

13 U.S. Patent No. 5,460,061 (filed Sept. 17, 1993).

14 U.S. Patent No. 5,063,811 (filed July 9, 1990).

15 *KSR*, 127 S.Ct. at 1737.

16 *Id.*

Teleflex.[17] KSR had taken its own patented adjustable pedal system and added a modular sensor to it for use in a pedal system that would be compatible with some of General Motors' light trucks, which utilized computer-controlled throttles.[18]

The district court concluded on summary judgment that claim 4 of the Engelgau patent was invalid for obviousness.[19] In making this determination, the district court considered one prior art reference, Asano,[20] that had not been before the patent examiner during prosecution of the Engelgau patent.[21] Asano taught a supportive structure for housing the pedal so that the pedal's pivot point would remain fixed even when the pedal's location was changed relative to the driver.[22] Also, Asano's structure allowed for the force needed to depress the pedal to remain constant regardless of the pedal's location.[23] As with other advances in the field, Asano's invention aimed in part to make driving both safer and more comfortable for drivers, regardless of adjustments to the seat location relative to the pedals and steering wheel made to accommodate the individual driver's height.[24] Applying the *Graham* factors, the district court found 'little difference'[25] between Asano and the Engelgau patent, as 'Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle'.[26] But the feature missing from Asano was taught by other references. The district court went on to apply the TSM test, concluding that combining Asano with the other references to arrive at the claimed invention was taught or motivated by the prior art or the state of the industry, which the district court saw as inexorably leading to the combination of electric sensors and adjustable pedals.[27] Also, the district court reasoned that, had the Asano reference been available to the patent examiner, claim 4 would have been rejected during prosecution over Asano in combination with Smith.[28]

The Federal Circuit, in a non-precedential opinion, vacated the district court's summary judgment of invalidity and remanded for further proceedings because the district court had failed, in its application of the TSM test, to make

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17 *Id.*
18 *Id.* at 1736.
19 *Id.* at 1737.
20 U.S. Patent No. 5,010,782 (filed July 28, 1989).
21 *KSR*, 127 S.Ct. at 1738.
22 *Id.* at 1735.
23 *Id.*
24 '782 patent, col. 1 ll.14–60.
25 *KSR*, 127 S.Ct. at 1738 (quoting *Teleflex*, 298 F. Supp. 2d at 590).
26 *KSR*, 127 S.Ct. at 1738.
27 *Id.*
28 *Id.*

'specific findings showing a teaching, suggestion, or motivation to combine prior art teachings in the particular manner claimed by the patent at issue'.[29] In this case, that meant making ' "finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention" . . . to attach an electronic control to the support bracket of the Asano assembly'.[30]

The Supreme Court reversed the Federal Circuit in a unanimous opinion authored by Justice Kennedy, explicitly rejecting the Federal Circuit's 'rigid approach' under the TSM test and described its own cases as 'set[ting] forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here'.[31] The Supreme Court emphasized that the granting of combination patents, like the Engelgau patent, requires a degree of caution, because 'a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men" '.[32] While the Court noted that the TSM test 'captured a helpful insight',[33] it could not be applied so formulaically:

> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.[34]

By returning the central focus of the nonobviousness inquiry to the *Graham* factors, the Supreme Court made it clear that the TSM test could be properly applied in many cases, but that 'the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a

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29 *Teleflex Inc. v. KSR Int'l Co.*, 119 Fed. Appx. 282 (Fed. Cir. 2005), *rev'd*, 127 S.Ct. 1727 (2007).

30 *KSR*, 127 S.Ct. at 1738 (quoting *Teleflex*, 119 Fed. Appx. at 288 (brackets in original)) (quoting *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000)).

31 *KSR*, 127 S.Ct. at 1739.

32 *Id.* (quoting *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950)).

33 *KSR*, 127 S.Ct. at 1741.

34 *Id.*

person of ordinary skill in the art would employ'.[35] Thus, in exploring what nonobviousness means post-*KSR*, it seems important to examine how the Federal Circuit has approached each *Graham* factor both before *KSR*, and, where available, since *KSR*.

The scope and content of the prior art

From the first *Graham* factor, the scope and content of the prior art, the Federal Circuit developed the 'analogous art' test: 'to rely on a reference as a basis for rejection of the applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned'.[36] Under this test, art is not analogous to the extent that the art 'merely . . . relate[s] to the [same] industry' as the invention.[37] Also, because the analogous art test focuses on 'the applicant's field of endeavor', the *purposes* of both the prior art and the invention are relevant to this analysis. Where the prior art shares the same purpose as the invention, both are directed to the same problem, and it is more likely that the inventor would have been motivated to consider the reference during the inventive process. The opposite is true where the prior art and the invention are aimed at different purposes.[38]

The Federal Circuit's pre-*KSR* cases also recognized that in some cases, references from a 'related field', as opposed to the inventor's particular field of endeavor, can be part of the analogous art.[39] In *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, the claimed invention was a capillary electrophoresis device. The trial court concluded that liquid chromatography references were properly part of the obviousness analysis. The Federal Circuit agreed because the evidence indicated that liquid chromatography (the subject of the prior art) and capillary electrophoresis (the subject of the invention) were related fields.[40] In making this determination, the court looked to a vari-

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35 *Id.*

36 *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

37 *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992).

38 *Id.* 'Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.'

39 *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1339 (Fed. Cir. 2005).

40 *Id.*

ety of sources, including the patent examiner's statements during prosecution and expert testimony presented at trial.[41] The analogous art test is based, in large measure, on the attempt to avoid impermissible hindsight bias. This is, of course, also the goal of the TSM test.[42] The Federal Circuit has acknowledged that there are 'subjective aspects' involved in this inquiry, and that generally common sense is needed 'in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor'.[43] Even the Patent Office, speaking through the Manual of Patent Examining Procedure, has recognized that determining the analogous art may, in some cases, present a difficult challenge.[44]

The Federal Circuit has described the TSM test as 'pick[ing] up where the analogous art test leaves off'.[45] Thus, the Supreme Court's discussion of the closely related TSM test in *KSR* likely has implications for the Federal Circuit's approach to analogous art. For example, the Supreme Court rejected, in the context of the TSM test, the Federal Circuit's focus on the problem that motivated the inventor:

> The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.[46]

This statement, as applied to the analogous art test, appears to endorse the 'field of endeavor' prong of the analogous art test articulated by the Federal Circuit in *Oetiker* discussed above, but seems to dispense with the 'reasonably pertinent to the particular problem' prong. Ironically, considering only this statement from *KSR* in the context of *Oetiker*, one might conclude that the universe of analogous art is *smaller* after *KSR* rather than larger, but this conflicts with the overarching flexible approach to nonobviousness that seems to be the primary lesson of *KSR.* And, indeed, other passages from *KSR* point in this more flexible direction. In particular, the Supreme Court seemed less disturbed by the risks of hindsight bias in *KSR* than the Federal Circuit has been in the past, noting that while one should be 'aware' of the 'distortion'

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41 *Id.*
42 *See In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006).
43 *Oetiker*, 977 F.2d at 1447.
44 *See* M.P.E.P. § 904.01(c).
45 *Kahn*, 441 F.3d at 987.
46 *KSR*, 127 S.Ct. at 1742.

caused by hindsight bias, the problem is not so serious as to justify 'rigid preventative rules that deny factfinders recourse to common sense'.[47]

Post-*KSR*, the Federal Circuit has continued to use its analogous art test, albeit with a nod to *KSR*. In *In re Icon Health & Fitness, Inc.*, the reexamined patent application at issue claimed a treadmill with a folding base, where the base could swivel into an upright position for storage.[48] The examiner rejected claim 1 as obvious during the reexamination, based on an advertisement for a folding treadmill and another patent (Teague), which taught a folding bed employing a novel dual-action spring as a counterbalancing mechanism.[49] There was no dispute that the treadmill advertisement disclosed all of the claimed elements except for a gas spring, so the issues 'focuse[d] on Teague's disclosure of gas springs and the applicability of Teague to Icon's invention'.[50] The Board of Patent Appeals and Interferences concluded that Teague disclosed analogous art: because both Teague and the reexamined patent application 'address[ed] the need to stably retain a folding mechanism', Teague was reasonably pertinent to the application, even though Teague was not part of the treadmill art.[51] While reiterating the analogous art test used pre-*KSR*,[52] the Federal Circuit also acknowledged *KSR* in explaining the 'reasonably pertinent' prong of the analogous art test, for the proposition that 'familiar items may have obvious uses beyond their primary purposes'.[53] The court reviewed the Board's factual determination of analogous art for substantial evidence,[54] and noted that '[n]othing about Icon's folding mechanism requires any particular focus on treadmills; it generally addresses problems of supporting the weight of such a mechanism and providing a stable resting position'.[55] Thus, analogous art to Icon's application, 'when considering the folding mechanism and gas spring limitation, may come from any area describing hinges, springs, latches, counterweights, or other similar mechanisms – such as the folding bed in Teague'.[56] Overall, the Federal Circuit's

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47 *Id.*

48 *In re Icon Health & Fitness, Inc.*, 496 F.3d 1374, 1377 (Fed. Cir. 2007).

49 *Id.*

50 *Id.*

51 *Id.* at 1378.

52 *Id.* at 1379–80. The Federal Circuit defined analogous art in *Icon* by quoting *In re Clay*, 966 F.2d at 659: 'A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.'

53 *Id.* at 1380 (quoting *KSR*, 127 S.Ct. at 1742).

54 *Id.* at 1378.

55 *Id.* at 1380.

56 *Id.*

continued and consistent use of the analogous art test in *Icon* suggests that the analogous art test as an approach to the first *Graham* factor was unchanged by *KSR*.

The differences between the prior art and the claims at issue

The second *Graham* factor, the differences between the prior art and the claims at issue, is arguably the central inquiry under § 103. Once the universe of applicable prior art is defined (see discussion above), and the level of ordinary skill in the art (see discussion below), the real issue is how a person of ordinary skill would approach that prior art, and whether it is different enough from the claimed invention to render the claim nonobvious. But, how different must the prior art and the invention be? Does this factor in some ways just collapse into the whole notion of what is 'obvious' under § 103, without providing much additional guidance? The Federal Circuit has explained that 'minor' differences and those 'achievable by simple modification' are insufficient,[57] but the inquiry is decidedly context- and technology-specific. But, more broadly, in approaching this issue, the Federal Circuit (and the CCPA before it) have utilized other benchmarks, including the TSM test, to determine whether one of ordinary skill in the art would have a reasonable expectation of success in combining the prior art references, and whether a prior art reference teaches away from the claimed invention.

In *KSR*, the Supreme Court explained simply that '[w]hat matters is the objective reach of the claim'.[58] How does this statement help to specifically analyze whether a given claim of a particular patent application or issued patent is really obvious, or not, over the prior art? Depending on the complexity of the claim at issue, the number and type of references involved, and the accessibility of the technological field of the invention, among other factors, knowing what this means could be extremely difficult. Fortunately, the Court signaled its understanding of this predicament, and provided the following guidance:

> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.[59]

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57 *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993).
58 *KSR*, 127 S.Ct. at 1742.
59 *Id.* at 1741–2 (internal citation omitted).

This statement actually does provide some clarity, and in discussing the need, at least 'often', to determine if there was an 'apparent reason to combine' the known elements, suggests that a non-rigid TSM test is still of central importance, at least where more complex combination patents are concerned.

The continued vitality of the TSM test, tempered by *KSR*, is reflected in some of the Federal Circuit's post-*KSR* decisions. In *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*,[60] the patent at issue claimed the 5(S) stereoisomer of ramipril, a pharmaceutical compound used to treat high blood pressure, in a formulation 'substantially free of other isomers'.[61] One compound is an isomer of another if it contains the same atoms, but arranged differently. Stereoisomers differ from one another not by which atoms are bound to each other, but in their three-dimensional configurations. Without getting any deeper into the chemistry than absolutely necessary,[62] each 'stereocenter' of a molecule is an atom around which other atoms may be attached in two different three-dimensional configurations, which can be labeled 'R' and 'S'. Because ramipril has five such stereocenters, it has 2^5, or 32, stereoisomers.[63] As claimed, each stereocenter was in the 'S' configuration, or in other words is the 'SSSSS' or '5(S)' stereoisomer of ramipril, as discussed above.[64] The prior art to ramipril included enalapril, a closely related compound[65] with only three stereocenters. It was known that the SSS stereoisomer of enalapril was 700 times more potent than the SSR stereoisomer.[66] Also known in the prior art, and not abandoned, suppressed, or concealed, was a mixture of 5(S) ramipril with its SSSSR stereoisomer.[67] The district court determined that the scientist who created this mixture appreci-

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60 *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007).

61 U.S. Patent No. 5,061,722 (filed Jan. 12, 1989).

62 For additional discussion of the similarities between the prior art and the claimed invention, including a discussion of the configuration of 'bridgehead' carbons, the chemically inclined reader is referred to the Federal Circuit's opinion, which provides a thorough and accessible explanation.

63 *Aventis*, 499 F.3d at 1295.

64 *Id.*

65 Enalapril and ramipril are both angiotensin-converting enzyme (ACE) inhibitors, a family of compounds that inhibit a biochemical pathway responsible for constriction of blood vessels. Hence their use in treating high blood pressure. ACE inhibitors were first derived in the 1960s from the venom of the Brazilian viper. The active ingredient in the venom, BPP5a, has six stereocenters, and is in the 6(S) configuration. *Id.* at 1296. Unlike BPP5a, which occurs naturally, enalapril, ramipril, and other similar compounds are synthetic.

66 *Aventis*, 499 F.3d at 1297.

67 *Id.* at 1297–8.

ated which stereoisomers were present in the mixture, but had not attempted or conceived of purifying the 5(S) stereoisomer.[68]

Thus, the primary[69] § 103 issue presented in the *Aventis* case was whether a claim to the 5(S) stereoisomer of ramipril 'substantially free of other isomers' was obvious to one of ordinary skill in the art, at the time of the priority date of the patent at issue, in light of the prior art teachings of the very same compound, though not in a substantially purified form, combined with the prior art teachings that, in general, as between S and R stereoisomers of closely related compounds, S stereoisomers were more potent. The district court concluded after a bench trial on validity that the claim was neither anticipated nor obvious because there was no reason that one of ordinary skill in the art would 'necessarily [have] been motivated to isolate Ramipril in the 5(S) configuration substantially free of other isomers'.[70] But, the district court acknowledged that it reached its decision 'reluctantly', and that '[i]f the standard . . . had been by a preponderance of the evidence rather than by clear and convincing evidence, the Court might have determined this case in Lupin's favor'.[71]

The Federal Circuit reversed the district court's judgment of nonobviousness. Noting that the district court had reached its decision prior to the publication of the Supreme Court's opinion in *KSR*, the Federal Circuit explained that the district court had applied just the kind of rigid TSM test criticized by *KSR*.[72] Of some importance to understanding the Federal Circuit's interpretation of *KSR* in this case, perhaps, is the passage it selected to quote from *KSR* as part of this discussion, which in turn quoted one of the Federal Circuit's own cases: '[i]t remains necessary to show "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," but such reasoning "need not seek out precise teachings directed to the specific subject matter of the challenged claim" '.[73] In the chemical arts, structural similarity combined with some motivation to combine the prior art has long

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68 *Id.*

69 Actually there were technically four claims at issue on appeal, but the Federal Circuit, like the district court before it, considered all of the claims at issue to 'rise or fall' with claim 1, the only independent claim at issue, as the added limitations in the dependent claims were well known in the art. *Aventis*, 499 F.3d at 1303 (quoting *Aventis Pharma Deutschland GmbH v. King Pharms., Inc.*, No. 2:05-CV-421, slip op. at 17 (E.D.Va. July 17, 2006) (*Aventis* Invalidity Opinion)). While obviousness is a claim-by-claim evaluation, in this case neither party contested the district court's central focus on claim 1 in the obviousness analysis.

70 *Aventis*, 499 F.3d at 1299 (quoting *Aventis* Invalidity Opinion at 75).

71 *Id.* (quoting *Aventis* Invalidity Opinion at 1–2) (ellipsis in original).

72 *Aventis*, 499 F.3d at 1300–01.

73 *Id.* at 1301 (quoting *KSR*, 127 S.Ct. at 1741 (quoting *Kahn*, 441 F.3d at 988)).

been recognized by the Federal Circuit as creating a *prima facie* case of obviousness.[74] Again echoing *KSR*, the Federal Circuit explained that this motivation needs not be explicit in the prior art: 'it is sufficient to show that the claimed and prior art compounds possess a "sufficiently close relationship . . . to create an expectation," in light of the totality of the prior art, that the new compound will have "similar properties" to the old'.[75] Meanwhile the court pointed out that a purified compound is not necessarily *prima facie* obvious over a mixture containing that compound, such as where the presence of the compound is not known in the mixture, or where the purification step itself would represent a patentable advance over the prior art.[76] On the other hand:

> [I]f it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified. Ordinarily, one expects a concentrated or purified ingredient to retain the same properties it exhibited in a mixture, and for those properties to be amplified when the ingredient is concentrated or purified; isolation of interesting compounds is a mainstay of the chemist's art. If it is known how to perform such an isolation, doing so 'is likely the product not of innovation but of ordinary skill and common sense.'[77]

The Federal Circuit concluded that the claims at issue fell into this latter category. First, because of the structural similarities between ramipril and enalapril as well as other prior art compounds in the same family, and the known trend in these compounds that stereoisomers having all their stereocenters in the S configuration are more potent than when some stereocenters are in the R configuration, a person of ordinary skill in the art would have expected 5(S) ramipril to be similarly more potent than the SSSSR form.[78] Also, there was no evidence that separating 5(S) ramipril from the SSSSR form required anything more than ordinary skill in the art.[79] Aventis attempted to rebut this *prima facie* case of obviousness by arguing that 5(S) ramipril's increased potency over the next-most-potent RRSSS stereoisomer constituted unexpected results because 5(S) ramipril was eighteen times as potent as the RRSSS stereoisomer.[80] But the court pointed out that the appropriate compar-

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74 *Aventis*, 499 F.3d at 1301.

75 *Id.* (quoting *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir.1990) (en banc)) (ellipsis in original).

76 *Id.*

77 *Id.* (quoting *KSR*, 127 S.Ct. at 1742) (other internal citations omitted).

78 *Aventis*, 499 F.3d at 1302.

79 *Id.*

80 *Id.*

ison was between pure (or substantially pure) 5(S) ramipril and the mixture of 5(S) and SSSSR ramipril known in the prior art, because this mixture formed part of the basis of the *prima facie* case of obviousness.[81] Engaging in the correct comparison, the court concluded that 'the potency of pure 5(S) ramipril is precisely what one would expect, as compared to a mixture containing other, inert or near-inert stereoisomers', and as a result held that the asserted claims were invalid for obviousness.[82]

In *Omegaflex Inc. v. Parker-Hannifin Corp.*, a non-precedential opinion, the Federal Circuit essentially began its obviousness analysis with the following quotation from *KSR:* 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art'.[83] From there, the court launched into a discussion of motivation to combine. The patents at issue in *Omegaflex* related to pipe fittings for use with corrugated stainless steel tubing (CSST). CSST is often used to carry natural gas, so a leak-free design is critical.[84] As a leak-free seal requires proper alignment of the piping, the patents at issue accomplished this task by using a locating sleeve as a pipe guide to ensure proper alignment even where problems like poor-quality piping or tight spaces make proper alignment difficult.[85] The case came to the Federal Circuit after the district court granted the patentee's motions with respect to both validity and infringement, and only the validity ruling was appealed, with the appellant arguing that the patents were obvious in light of the prior art.[86] The prior art consisted of the Sweeny patent, which undisputedly disclosed each claimed element except for the locating sleeve, and a product, called the Parker Compression Fitting (PCF). The PCF was not sold with an integrated locating sleeve, but could be fitted with a locating sleeve if necessary to aid alignment. The PCF was not used with CSST, but rather with other types of metal tubing.[87]

The Federal Circuit found that there were genuine issues of material fact with respect to obviousness, rendering summary judgment inappropriate.[88] With respect to motivation to combine, the court quoted a second passage from *KSR*. Rather than looking for an explicit motivation to combine, courts must also 'look to interrelated teachings of multiple patents; the effects of

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81 *Id.*
82 *Id.*
83 *Omegaflex Inc. v. Parker-Hannifin Corp.*, 2007 WL 1733228, at *2 (Fed. Cir. June 18, 2007) (unpublished opinion) (quoting *KSR*, 127 S.Ct. at 1741).
84 *Omegaflex*, 2007 WL 1733228, at *1.
85 *Id.*
86 *Id.* at *2.
87 *Id.* at *1.
88 *Id.* at *4.

demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art'.[89] In this case, the alleged infringer had proffered an expert witness who opined that one of skill in the art would have recognized the importance of proper alignment, and would have thought to add a locating sleeve to the Sweeny patent.[90] But, the district court gave this witness's testimony no probative value, which was an error in the summary judgment context.[91] The district court likewise disregarded this witness's testimony regarding reasonable expectation of success. This was also erroneous for the same reason.[92] Also, the district court took a too narrow approach to the prior art teachings, focusing on the problem to be solved, thus failing to account for the capabilities of one of ordinary skill in the art.[93] The Federal Circuit further found that there were triable issues with respect to secondary indicia of nonobviousness.[94] Thus, the court reversed and remanded the case for further proceedings, and vacated the district court's grant of a permanent injunction.[95]

The *Omegaflex* case, while non-precedential, may offer an important procedural lesson about nonobviousness after *KSR:* many § 103 issues, including and perhaps especially the differences between the prior art and the claims at issue, may be more difficult to resolve on summary judgment, at least in the patentee's favor. Although the Federal Circuit remained true to the TSM test, the highly fact-specific nature of the subsidiary inquiries of obviousness in *Omegaflex*, namely the *Graham* factors and the tests that have sprung forth from them, may require development at trial in many cases. In other circumstances, summary judgment may be appropriate. In *KSR*, the Supreme Court rejected the Federal Circuit's alternative basis for its reversal of the district court's summary judgment of obviousness, which was that there were genuine issues of material fact on the § 103 issue that required a trial.[96] Instead, the Supreme Court reminded the Federal Circuit that while expert testimony that may raise factual issues may be considered, obviousness is ultimately a legal question, so '[w]here, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors,

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89 *Id.* at *2 (quoting *KSR*, 127 S.Ct. at 1740–41).
90 *Id.* at *2.
91 *Id.* at *3.
92 *Id.*
93 *Id.*
94 *Id.* at *4.
95 *Id.*
96 *KSR*, 127 S.Ct. at 1745.

summary judgment is appropriate'.[97] Such a conclusion may seem less 'obvious' in cases with more complex technologies. Overall, whether summary judgments of validity or invalidity under § 103 by district courts post-*KSR* will increase or decrease, whether any changes will favor patentees or alleged infringers, and how the Federal Circuit will respond, are all questions that may provide interesting insight into the procedural ramifications (or lack thereof) of *KSR* at the trial court level. At this early date, not enough time has elapsed since *KSR* for meaningful trends to emerge or for any completely post-*KSR* cases to work their way through the courts.

Taken together, *Aventis* and *Omegaflex*, two cases that could hardly be more different in terms of the technologies involved, suggest that the Federal Circuit is applying *KSR* and its own prior jurisprudence regarding the necessary differences between the prior art and the claims at issue consistently across various fields of art. Like the Supreme Court, the Federal Circuit appears to be taking a broad-based approach to the types of evidence that may be relevant to rebut the presumption of validity that attaches to issued patents in litigation.

The level of ordinary skill in the pertinent art

In *Daiichi Sankyo Co. v. Apotex, Inc.*,[98] another post-*KSR* obviousness opinion from the Federal Circuit, setting the level of ordinary skill in the art, essentially controlled the outcome of the § 103 issue. Also another pharmaceutical case, the patent at issue *Daiichi Sankyo* claimed '[a] method for treating otopathy which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otopathy in a pharmaceutically acceptable carrier to the area affected with otopathy'.[99] In other words, the patent claimed a method for treating bacterial ear infections by administering ofloxacin, an antibiotic, into the ear.[100] Based on its construction of the phrase 'effective to treat' to mean 'efficacious and safe', and following a bench trial, the district court concluded that the patent at issue (the '741 patent) was not invalid.[101] The district court determined that one of skill in the art of the '741 patent would be a doctor with experience in treating ear infections, and a knowledge of pharmacology (by virtue of their medical training) and the use of antibiotics, such as a general practitioner or pediatrician, someone on the front lines

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97 *Id.* at 1745–6.
98 *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007).
99 *Id.* at 1255–6 (quoting U.S. Patent No. 5,401,741 (filed Apr. 12, 1993)).
100 *Id.* at 1255.
101 *Id.* at 1256.

of defense against ear infections.[102] Apotex, in contrast, argued that one of ordinary skill in the art of the '741 patent would have far more specific expertise, namely 'a person engaged in developing new pharmaceuticals, formulations and treatment methods, or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations'.[103] The dispute over the ordinary level of skill in the art was critical to the adjudication of the obviousness issue in this case, because a higher (or at least more specialized) level of skill would mean that the ordinary artisan would consider more to be obvious than a person of lesser skill.

To determine the level of ordinary skill in the art, the Federal Circuit offered six factors, long considered to be a helpful, though not exclusive, list: '(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field'.[104] The court then described the field of art of the '741 patent as 'the creation of a compound to treat ear infections without damaging a patient's hearing', and noted that the inventors, like others working in that field, were 'specialists in drug and ear treatments – not general practitioners or pediatricians'.[105] Also, the problem in the prior art, namely the side effect of ear damage that was a risk with many antibiotics used to treat ear infections, necessitated animal testing to determine whether ofloxacin would suffer the same deficiencies. Such animal testing would have been outside the experience of an average pediatrician or family doctor.[106] Moreover, while a pediatrician or family doctor would likely prescribe ofloxacin for ear infections, they would not have the specialization or expertise necessary to develop the claimed compound absent additional training.[107] Thus, the Federal Circuit concluded that the district court had erred in its assessment of the ordinary level of skill in the pertinent art, and instead found that the appropriate skill level was that of 'a person engaged in developing pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in

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102 *Id.* (quoting *Daiichi Pharm. Co. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 485 (D.N.J. 2005)).

103 *Id.*

104 *Daiichi Sankyo*, 501 F.3d at 1256 (quoting *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)).

105 *Daiichi Sankyo*, 501 F.3d at 1257.

106 *Id.*

107 *Id.*

pharmaceutical formulations', [108] almost wholly adopting the standard advocated by Apotex.

With the level of ordinary skill in the pertinent art established, the Federal Circuit then turned to the teachings of the prior art, focusing on a single article, the Ganz reference. The Ganz reference taught the use of ciprofloxacin in ear drops to successfully treat middle ear infections, without damaging the ear, but also noted that administration of ciprofloxacin was appropriate only in difficult cases and, even then, only by an otologist.[109] As ciprofloxacin is in the same family of compounds as ofloxacin (both are gyrase inhibitors), Apotex's expert testified that, given the Ganz reference, ofloxacin would also be effective in safely treating ear infections.[110] But the district court disregarded the Ganz reference because the district court considered an otologist to be outside the ordinary level of skill in the art.[111] Since the Federal Circuit had found a higher level of skill to be appropriate, and indeed, one that encompassed otologists, the Federal Circuit considered the Ganz reference to be within the relevant prior art, leading it to conclude that the Ganz reference made using ofloxacin to treat ear infections in the manner claimed would have been obvious to one of ordinary skill in the art at the time of the invention (or, more specifically, to conclude that no reasonable jury could have concluded that the '741 patent was nonobvious in light of the Ganz reference).[112]

Although the level of ordinary skill in the art is frequently not disputed by the parties in litigation, this *Graham* factor plays a very important background role in determining the size of the universe of relevant prior art for any given invention. As demonstrated by *Daiichi Sankyo*, this factor can sometimes be dispositive of the obviousness inquiry, at least where the prior art in question is very close to the claimed invention.

As for changes post-*KSR* to how the Federal Circuit views the level of ordinary skill in the art, it seems that there has been no change, especially since the Federal Circuit apparently did not feel compelled to cite *KSR* in the *Daiichi Sankyo* case. Since *KSR* focused on the TSM test and how references are considered, rather than on setting the level of ordinary skill *per se*, perhaps this should come as no surprise. And indeed, the Federal Circuit took a very similar approach to the level of ordinary skill in *Daiichi Sankyo* as it did in *DyStar*, one of its opinions issued after the Supreme Court had granted *certiorari* in *KSR* but before that case had been decided. In *DyStar*, the patent claimed a

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108 *Id.*
109 *Id.* at 1258.
110 *Id.*
111 *Id.*
112 *Id.* at 1258–9.

process for dyeing textiles with indigo,[113] and the parties disputed whether the person of ordinary skill in the art would be a dyer with a high school education and no knowledge of chemistry whose job involved operation of the dyeing machines, or rather an individual who designed the dyeing processes, performing calculations as necessary to achieve the desired result.[114] The Federal Circuit found that substantial evidence did not support the jury's assumed finding that the level of ordinary skill in the art was that of a 'mere dyer', based on the sophisticated nature of the problem the invention was trying to solve:

> Designing an optimal dyeing process requires knowledge of chemistry and systems engineering, for example, and by no means can be undertaken by a person of only high school education whose skill set is limited to 'flipping the switches'. This is especially true when one considers that only in the last century have improvements in indigo reduction chemistry enabled outsourcing of the indigo reduction step from dyehouses to chemical manufacturers; prior to that simplification, there would have been no question that a dyer would also require knowledge of indigo reduction. Because, for this patent, the only finding supported by substantial evidence is that an ordinary artisan is not a dyer but a person designing an optimal dyeing process, the jury's implicit finding of a mere dyer cannot withstand scrutiny on JMOL.[115]

Thus, the Federal Circuit concluded that it was inappropriate for the jury to have discounted certain prior art references because a person of ordinary skill in the relevant art, that is, a dyeing process designer, would indeed have considered those references.[116] Ultimately, after considering all of the *Graham* factors including a flexible version of the TSM test, the Federal Circuit concluded that all four claims at issue were invalid for obviousness.[117]

Although not directly on point with determining the level of ordinary skill in the art, at least as it relates to *technical* skill, it is worth mentioning at this point in the discussion that *KSR* did mention something about the *creativity* of the ordinarily skilled artisan. Again, this comes back to the decidedly non-rigid approach to the TSM test, and to obviousness overall, emphasized by the Supreme Court. *KSR* noted that '[a] person of ordinary skill is also a person of ordinary creativity, not an automaton'.[118] So, to the extent that prior cases did not adequately account for this creativity in their overly rigid application of the TSM test, perhaps *KSR* has affected the third *Graham* factor after all, at

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113 *DyStar*, 464 F.3d at 1356.
114 *Id.* at 1362.
115 *Id.* at 1362–3.
116 *Id.* at 1363.
117 *Id.* at 1372.
118 *KSR*, 127 S.Ct. at 1742.

least indirectly, as a more creative artisan is presumptively more likely to see connections between prior art references that might seem unrelated or obscure to a less insightful artisan with equal technical prowess.

Secondary considerations

Also known as objective indicia of nonobviousness, secondary considerations like those specifically identified in *Graham* may weigh against a determination of obviousness even where the other *Graham* factors might suggest otherwise. In the prosecution context, secondary considerations may be proffered by the applicant to rebut the examiner's *prima facie* case of obviousness. In litigation, secondary considerations may help the patentee in defending the presumption of validity in its asserted patent against the alleged infringer's attempts to defeat it. Notably, the secondary considerations enumerated by the Supreme Court in *Graham* are not exhaustive; the Federal Circuit and district courts routinely consider other factors, too, where relevant. One district court put together the following list of secondary considerations, the first three of which come from *Graham*:

(1) a long-felt and unmet need in the art for the invention;
(2) failure of others to achieve the results of the invention;
(3) commercial success of the invention;
(4) copying of the invention by others in the field;
(5) whether the invention was contrary to accepted wisdom of the prior art;
(6) expression of disbelief or skepticism by those skilled in the art upon learning of the invention;
(7) unexpected results;
(8) praise of the invention by those in the field; and
(9) independent invention by others.[119]

In *KSR*, after considering the first three *Graham* factors, the Supreme Court concluded that Teleflex, the patentee, had 'shown no secondary factors to dislodge the determination that claim 4 is obvious'.[120] Since secondary factors were thus not really an issue in *KSR*, presumptively the consideration of secondary factors remains unchanged post-*KSR*. Thus, insofar as *KSR* weakened the TSM test and made it easier overall for patent examiners (during prosecution) and alleged infringers (during litigation) to establish a *prima facie* case of obviousness, secondary factors are *comparatively* more important than they were before *KSR* because the patent applicant or patentee will

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[119] *Rhenalu v. Alcoa, Inc.*, 224 F. Supp. 2d 773, 800 (D. Del. 2002) (citing *Graham*, 383 U.S. at 17–19; *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667–8 (Fed. Cir. 2000)).

[120] *KSR*, 127 S.Ct. at 1745.

need to rely more heavily upon them in the absence of arguments either foreclosed (*e.g.* focusing on the problem the inventor was trying to solve as a way to narrow the prior art; explicit motivation to combine) or attenuated (*e.g.* obvious to try; vigilance against hindsight bias; *etc.*) by *KSR*.

In *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*,[121] a pre-*KSR* case, the Federal Circuit affirmed the district court's judgment, after holding a bench trial, that the patent at issue was valid and infringed. The patent in *Eli Lilly* claimed the compound olanzapine and its use in treating schizophrenia.[122] Although the Federal Circuit concluded that the defendants had not proven a *prima facie* case of obviousness, the court also suggested that the secondary considerations proffered by the patentee, Eli Lilly, would have overcome a *prima facie* case of obviousness anyway, having established a long-felt, unmet need in the art, failure of others to achieve a solution, industry acclaim, and unexpected results:[123]

> The record shows a long-felt need for a safer, less toxic, and more effective clozapine-like drug; a decade (or more) of failure to find a replacement for clozapine; a reasonable amount of commercial success for olanzapine; and a number of awards for olanzapine as indicators of industry acclaim. . . . The trial court also discussed the unexpected differences between the closest analog, Compound 222 and olanzapine, most of which focused on olanzapine not raising cholesterol levels in dogs, and a comparison of some humans tests with other similar drugs that raised CPK.[124]

Post-*KSR*, in affirming a district court's judgment of nonobviousness after a bench trial in *Takeda Chemical Industries, Ltd. v. Alphaharm Pty. Ltd.*, the Federal Circuit likewise did not need to reach whether secondary considerations rebutted a *prima facie* case of obviousness or not, because the alleged infringer had failed to prove one.[125] But, in *Takeda*, unlike *Eli Lilly*, the Federal Circuit did not discuss the evidence of secondary considerations relied upon by the district court.

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121 *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006).

122 *Id.* at 1373.

123 *Id.* at 1380 ('Furthermore, Lilly overcame any prima facie case of obviousness.').

124 *Id.* 'CPK' is short for creatine phosphokinase, a muscle enzyme, the unwanted increased production of which was a side effect associated with related prior art compounds. *Id.* at 1375.

125 *Takeda Chem. Indus., Ltd. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1363 (Fed. Cir. 2007).

Is it obvious what isn't obvious anymore?

Responding to *KSR*, the United States Patent & Trademark Office issued Examination Guidelines for Determining Obviousness on October 10, 2007.[126] These guidelines were not issued as part of a substantive rulemaking process and do not, therefore, have the force of law.[127] Even still, patent examiners will follow them, and the guidelines supersede the Manual of Patent Examining Procedure (MPEP) insofar as the two are inconsistent, so they are tremendously important.[128] In addition to discussing *KSR* generally and reviewing the *Graham* factors, the Guidelines list seven rationales for examiners to use to support obviousness rejections under § 103:

[A] Combining prior art elements according to known methods to yield predictable results;
[B] Simple substitution of one known element for another to obtain predictable results;
[C] Use of known technique to improve similar devices (methods, or products) in the same way;
[D] Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
[E] 'Obvious to try' – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
[F] Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
[G] Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference teachings to arrive at the claimed invention.[129]

These Guidelines provide a nice summary of the seemingly myriad ways to conclude that a patent application or a patent is obvious, but how can patent applicants establish that their claimed inventions are nonobvious? Likewise, how can patentees rebut *prima facie* cases of obviousness during litigation? The Guidelines note that an applicant can reply to a § 103 rejection by traversing, that is by submitting evidence to challenge the examiner's factual findings underpinning the conclusion of obviousness.[130] The applicant may also try to

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126 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007).
127 *Id.* at 57,526.
128 *Id.*
129 *Id.* at 57,529.
130 *Id.* at 27,534.

rebut the examiner's case, through evidence of secondary factors/objective indicia of nonobviousness (*see* discussion above).[131]

So what does it all mean? At first glance, *KSR* might seem rather grim for patentees. The TSM test is no longer a source of refuge, given that a motivation to combine may be implicit or derived from common knowledge. To the extent that a more explicit motivation was expected in the past, this regime at least represented a more reliable means of avoiding hindsight bias. 'Obvious to try' is now a *bona fide* reason to conclude that a claim is obvious rather than a critique of an insufficient basis for a conclusion of obviousness, insofar as there are a small number of predictable solutions. The prior art is no longer bound by the specific problem the patentee was trying to solve, making patent applicants and patentees more vulnerable to a wider array of prior art. Finally, while a patentee in litigation is still entitled to a presumption of validity for an issued patent, the Supreme Court in *KSR* cast doubt upon this privilege where the reference at issue was not before the patent examiner during prosecution, noting (without deciding the issue) that the rationale supporting the presumption of validity is undermined in such cases.[132]

On the other hand, there are ways in which *KSR* is not so bad for patentees. The Supreme Court did not reject the TSM test entirely, and as discussed above, the Federal Circuit continues to apply it in much the same way as it did pre-*KSR*, in cases like *DyStar*. Post-*KSR*, the Federal Circuit has characterized the Supreme Court's opinion as follows: 'the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination'.[133] 'Identifying a reason' that would 'prompt' combination of the prior art is effectively the same old TSM test, albeit without the rigid approach erroneously taken at some points by the district courts and the Federal Circuit before *KSR*. Patentees should also remember that examiners are *required* to consider evidence of secondary considerations;[134] this is a mandatory part of the § 103 analysis in litigation as well. Also, examiners and courts alike cannot rely on a generalized conclusion of obviousness; under *KSR*, 'this analysis should be made explicit'.[135] As

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131 *Id.*

132 *See KSR*, 127 S.Ct. at 1745 ('We nevertheless think it appropriate to note that the rationale underlying the presumption – that the PTO, in its expertise, has approved the claim – seems much diminished here.').

133 *Takeda*, 492 F.3d at 1356–7 (quoting *KSR*, 127 S.Ct. at 1731).

134 72 Fed. Regs. 57,526, 57,527 ('Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel.' (citing *Graham*, 383 U.S. at 17–18)).

135 *KSR*, 127 S.Ct. at 1741.

patentees and patent applicants learn to become more comfortable with *KSR*, and as the courts and the Patent Office issue more guidance, the system seems likely to balance itself.

Also, while many of the cases discussed in this chapter have ultimately concluded that the claims at issue were obvious and thus invalid, a judgment of obviousness is not foreordained in the post-*KSR* world. As discussed briefly above with respect to secondary considerations, the *Takeda* case decided after *KSR* by the Federal Circuit was one in which the court affirmed the district court's judgment of nonobviousness. In *Takeda*, the patent at issue was drawn to pioglitazone, which belonged to a family of compounds known as thiazolidinediones (TZDs) used to treat type II diabetes.[136] Alphapharm's obviousness argument relied on a single prior art compound, compound b, which differed from pioglitazone insofar as compound b had a methyl substituent at the 6-position on a carbon ring, whereas pioglitazone had an ethyl substituent at the 5-position.[137] Agreeing with the district court, the Federal Circuit rejected Alphapharm's claim that a person of ordinary skill in the art would have selected compound b as a lead compound (it was one of hundreds of millions of similar prior art compounds) because there was no indication that compound b would be a good target for further development of antidiabetic drugs.[138] Also, while one prior art reference described compound b as 'especially important', another reference taught away from using compound b because its use was associated with increased body weight, making it a poor candidate for long-term treatment of a chronic condition associated with obesity like type II diabetes.[139] The Federal Circuit also expressly rejected that it would have been 'obvious to try' under the *KSR* standard:

> Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was 'obvious to try.' The evidence showed that it was not obvious to try.[140]

Thus, as the Federal Circuit noted in *Takeda*, the 'test for prima facie obviousness for chemical compounds is consistent with the legal principles enunciated

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136 *Takeda*, 492 F.3d at 1352–3.
137 *Id*. at 1357.
138 *Id.*
139 *Id*. at 1358.
140 *Id*. at 1359.

in *KSR*'.[141] Alphapharm's reliance on a single prior art compound could not supply such a case, and the court concluded that compound b did not render the asserted claims obvious. Thus, while 'obvious to try' may be a basis for obviousness in some cases with a finite number of solutions, the Federal Circuit has made it clear that this argument is not a catchall method for alleged infringers to invalidate patents with ease. To the contrary, it appears that by and large, the analysis under § 103 remains much the same as it did before *KSR*, with some slight alterations, of course.

Technology-specific considerations

KSR was in some ways an anomalous case on the facts, insofar as the technology involved was a relatively simple device, mostly mechanical in nature. Reading *KSR* as radically altering § 103 jurisprudence, especially in more complex, less predictable arts, and indeed, the Federal Circuit has pointed out that in *KSR*, would probably be a mistake. For example, after discussing *KSR* in *Takeda v. Alphapharm* (*see* discussion above), the Federal Circuit remarked on the pre- and post-*KSR* continuity in its approach to § 103 in the chemical arts: 'in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound'.[142] And indeed, the Supreme Court itself recognized that the nonobviousness analysis may be less straightforward where other technologies or more complex combinations are concerned, as noted above in the discussion of the differences between the prior art and the claims at issue:

> Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement.[143]

This statement, combined with the Federal Circuit's retention of a technology-sensitive approach to § 103, as evidenced by *Takeda* and other cases, suggests that all is not lost, from any perspective, and that in the grand scheme of things, relatively little has changed in the overall approach to obviousness in the post-*KSR* world.

Conclusion

More than anything, *KSR* can be considered to be a course correction rather

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141 *Id.* at 1356.
142 *Takeda*, 492 F.3d at 1357.
143 *KSR*, 127 S.Ct. at 1740.

than a dramatic change of direction in determining whether a claimed invention is nonobvious or obvious over the prior art. In reemphasizing *Graham*, and in recognizing that the Federal Circuit may indeed apply the TSM test in a non-rigid way, the Supreme Court declined to impose a new multi-factor analysis on top of the statutory scheme and the existing case law. Thus, the Federal Circuit still has ample room to adjust its own obviousness jurisprudence in light of *KSR*, without straying from *KSR*'s general principles of flexibility. Of course, it will take time for sufficient numbers of post-*KSR* cases to work their way through the courts, but in the meantime, preliminary indications suggest a continuing stability overall in the approach to nonobviousness in the United States.

PART 4

PATENT ENFORCEMENT ISSUES: EXTENT OF PATENT PROTECTION AND INFRINGEMENT REMEDIES

15 Extent of patent protection in the United States, Germany, the United Kingdom and Japan: examination through the concept of 'person having ordinary skill in the art of the invention'

Toshiko Takenaka

1 Introduction

The Interpretation Protocol of European Patent Convention Article 69 emphasizes a balance between the competing policies for fair protection with respect to the patentee's interests and legal certainty with respect to public interests in determining the extent of protection offered by European patents.[1] This protocol for determining the extent of patent protection is common in the United States and Japan.[2] The rule that claim terms determine the extent of patent protection is also common to four important jurisdictions, namely the United States, Germany, the United Kingdom and Japan. However, the courts in these four jurisdictions do not literally interpret the claim terms to decide the extent of patent protection, although these courts adopt the same rule that claim terms determine the extent of protection. Reflecting the balance, the extent of protection defined by these courts can be narrower or broader than the literal scope supported by the claim terms.

This flexible claim interpretation results from the adoption of a statutory hypothetical person having ordinary skill in the art (PHOSITA). Although

[1] Convention on the Grant of European Patents, October 5, 1973, art. 54, 1065 UNTS 255, 272 [hereinafter European Patent Convention] (entered into force on October 7, 1977), The Protocol on the Interpretation of Article 69 of the Convention, art. 1.

[2] For the US, *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 37, 137 L. Ed. 2d 146, 166 (1997); For Japan, see Judgment of Supreme Court of Japan, February 24, 1998, 52 Minshu (No. 1) 113, 1630 Hanrei Jiho 32 (1998). An English translation of the decision by the author is published in Toshiko Takenaka, 'The Supreme Court Affirmed the Presence of the Doctrine of Equivalents Under Japanese Patent System', 5 CASRIP Newsletter (1998) 12, available at <http://www.law.washington.edu/Casrip/Newsletter/Vol5/newsv5i1jp1.html> accessed March 3, 2008.

courts in these jurisdictions use very similar definitions of PHOSITA, they use PHOSITA in different ways, which results in significant differences in the extent of patent protection in different jurisdictions.

2 PHOSITA under US Law

2.1 Definition of PHOSITA in assessment of patentability

In the United States, numerous court decisions recite that claim terms are interpreted as having the meaning that a PHOSITA would understand them to have.[3] The perspective of a PHOSITA enables US courts to make an objective assessment of the meaning of claim terms by providing a starting point for claim construction.[4] It also enables US courts to define and limit the concept of equivalents.[5] Despite its key role in determining the extent of patent protection, the courts do not give detailed definitions with respect to who is a PHOSITA, although the courts often define PHOSITA in determining non-obviousness under §103.[6] In determining the meaning of claim terms, the courts use a singular form, 'a person' or 'one', and alternatively a plural form, 'persons' or 'those', to describe a PHOSITA.

US courts justified using the perspective of a PHOSITA as the starting point for claim construction because inventors are typically PHOSITAs and patents are addressed to and intended to be read by PHOSITAs.[7] However, if PHOSITA in the assessment of protection scope is the same as that of §103 non-obviousness, neither a fictional inventor nor a real inventor is part of the PHOSITA because the enactment of the 1952 revision replaced the fictional inventor standard with the current statutory PHOSITA standard for assessments of non-obviousness.[8] US courts interpret the §103 language to distinguish a PHOSITA from real inventors in that the latter have a creative quality while the former are not innovative and thus merely exercise conventional wisdom in the

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[3] *E.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 US 722, 123 S. Ct. 70 (2002); *Phillips v. AWH Corp., reh'g denied, reh'g, en banc, granted, vacated*, 376 F.3d 1382, 71 USPQ2d 1765 (Fed. Cir. 2004), Chisum on Patents, 18.03 [2][b] (1978, Supp. 2005).

[4] *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

[5] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 37, 137 L. Ed. 2d 146, 166 (1997).

[6] Joseph P. Meara, 'Just Who Is The Person Having Ordinary Skill in the Art? Patent Law's Mysterious Personage', 77 Wash. L. Rev. 267 (2002).

[7] *Phillips v. AWH Corp.*,415 F.3d 1303, 75 USPQ. 2d 1321 (Fed. Cir. 2005).

[8] *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 223 USPQ 603 (1984).

art.[9] The courts often note that a PHOSITA is not a real human being but a hypothetical person who is presumed to have the knowledge of all relevant prior art in the field of invention and any art analogous to the art of invention.[10] Thus the knowledge or skill of a particular individual such as an inventor who drafted claims is irrelevant for the non-obviousness determination.[11]

Although US courts emphasize the importance of identifying the skill level of a PHOSITA for making an objective assessment of non-obviousness,[12] they often fail to do so. In the seminal *Graham* decision,[13] the Supreme Court required a step to identify the skill level of a PHOSITA for non-obviousness determinations. However, when it made the determination following the framework, the Court did not make any reference to the skill level of a PHOSITA. The US Court of Appeals for the Federal Circuit, which has exclusive jurisdiction over appeals arising from US patents, also often refuses to find reversible errors for district courts' failure to make an explicit finding regarding the skill level of a PHOSITA. Although the Federal Circuit listed five factors in determining the skill level of a PHOSITA: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which inventions are made; (5) sophistication of the technology and (6) educational level of active workers in the field,[14] it did not give any detailed instructions regarding how to use these factors.[15] As a result, district courts frequently cite these factors, but these factors are not helpful to the courts for addressing the non-obviousness question.[16]

Responding to criticisms that the skill level of §103 PHOSITA employed by the Federal Circuit is very low and does not properly reflect the real perspective of actual practitioners in the art of the invention[17] the US Supreme

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9 *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

10 *Standard Oil*, 774 F.2d at 454.

11 *Endless + Hauser, Inc. v. Hawk Measurement Systems Pty. Ltd.*, 122 F.3d 1040, 43 USPQ2d 1840 (Fed. Cir. 1997); *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 225 USPQ 20 (Fed. Cir. 1985).

12 *Ryco Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 21 USPQ 1053 (Fed. Cir. 1991).

13 *Graham v. John Deere Co.*, 383 US 1, 17 (1965).

14 *Environmental Designs, Ltd. v. Union Oil Co.*, 713 2d 693 (Fed. Cir. 1983).

15 *Supra* note 6, Meara, Part II, B4.

16 *Id.*

17 Rebecca S. Eisenberg, *'Implementing Reform of the Patent System: Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA'*, (2004) 19 Berkeley Tech. L.J. 885 (2004); Briefs of Twenty-Four Intellectual Property Law Professors as Amici Curiae, *KSR Int'l Co. v. Teleflex Inc.*, 119 Fed. Appx. 282; 2005 US App. LEXIS 176 (2005) (No. 04-1350) <http://patentlaw.typepad.com/patent/ksramicus.pdf> accessed March 8, 2008.

Court, in *KSR*, clarified the common sense held by PHOSITA.[18] Emphasizing that PHOSITA is a person of ordinary creativity, not an automaton, the Court explained that the common sense of PHOSITA enables them to conceive of obvious uses of familiar items in the art in addition to the main purpose and to combine teachings of multiple patents and publications.[19] Common sense makes it possible for PHOSITA to solve a problem or meet a design need if only a finite number of identified, predictable solutions are available. The USPTO interprets the level of PHOSITA to be high because it finds obvious with respect to a combination of elements which are individually disclosed in the prior art unless the combination produces unexpected results.[20]

US courts define a person skilled in the art (PSITA) under §112¶1 as having an ordinary skill which is the same level of skill as that of a PHOSITA under §103.[21] However, the knowledge presumed for a PSITA under §112¶1 is different from PHOSITA because only well-known information can be omitted from the disclosure[22] but nascent technologies should be disclosed to meet the enablement requirement.[23] The knowledge of §112¶1 PSITA does not include information which is not publicly accessible such as the disclosure in the pending application under §102(e) which is included in the knowledge of §103 PHOSITA.[24]

2.2 PHOSITA in assessment of extent of protection

US courts seldom discuss the skill level of a PHOSITA in assessing the extent of patent protection. Instead, their analysis focuses on which sources to rely on to find the meaning understood by PHOSITA.[25] In claim construction, a PHOSITA is deemed to have knowledge of any special meaning and usage in the art of the invention and to have read the patent documents, that is, the

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18 *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 82 USPQ2d 1385, (US 2007).

19 *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. at 1742.

20 Department of Commerce, United States Patent Office, Examination Guidelines for Determining Obviousness Under 35 USC 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* <http://www.uspto.gov/web/offices/com/sol/og/2007/week45/patgide.htm> accessed March 3, 2008.

21 *Johns Hopkins University v. CellPro Inc.*, 152 F.3d 1342, 1360, 47 USPQ2d 1705, 1718 (Fed. Cir. 1998).

22 *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

23 *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 US 963 (1997); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 70 USPQ2d 1321 (Fed. Cir. 2004) , *cert. denied*, 543 US 1050 (2005).

24 *In re* Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

25 *Innova/Pure Water, Inc.*, 381 F.3d 1111 at 1116.

patent specification and prosecution history, with such understanding.[26] Emphasizing the ordinary meaning to a PHOSITA, the *en banc* Federal Circuit requires US courts to use the perspective of a PHOSITA for claim construction while using patent documents as a primary source for clarifying claim terms.

In determining the extent of patent protection, US courts do not discuss whether the PHOSITA for claim interpretation is the same PHOSITA as for non-obviousness. However, the knowledge of the former PHOSITA should be different from that of the latter PHOSITA. Because claim terms' function is to give notice to the public with respect to the scope of the exclusive right, information which is not available to the public should be excluded from the knowledge of PHOSITA in determining the extent of protection. Such information must be available at the time of invention, that is, the effective filing date for construing claims.[27] For applying the doctrine of equivalents, the information must be available at the time of infringement.[28] Thus, the PHOSITA should read claim terms as excluding technologies which were developed after the effective filing date.[29] However, it sometimes reads claim terms to include such later-arising technologies.[30]

The level of skill in PHOSITA for claim interpretation should be the same as the level of §103 PHOSITA as well as §112 PSITA because the PHOSITA has an ordinary skill and should have the same common sense for combining and replacing old elements in the art. Contrary to the definition, US courts do not always presume the same skill level of a PHOSITA when they construe claim terms for literal infringement. The same PHOSITA does not foresee variations of the embodiments disclosed in the specification and read claims to cover them even if claim terms can be construed to cover the variations. Claim terms, the coverage of which includes such variations, may be found invalid for a violation of the written description requirement.[31] Although US courts emphasize the rule to ban importing limitations into claim terms and the limiting of protection to disclosed embodiments is emphasized,[32] there is no

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[26] *Phillips v. AWH Corp.*, 415 3d at 1313. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 45 USPQ2d 1429 (Fed. Cir. 1998).

[27] *Phillips v. AWH Corp.*, 415 3d at 1313.

[28] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 37 (1997).

[29] *Shering Corp. v. Amgen Inc.*, 222 F.3d 1347, 55 USPQ2d 1650 (Fed. Cir. 2000).

[30] *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 2004 US App. LEXIS 5830, 70 USPQ2d 1321 (Fed. Cir. 2004).

[31] 35 USC §112¶1. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 133676 USPQ2d 1724 (Fed. Cir. 2005).

[32] *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 76 USPQ2d 1641 (Fed. Cir. 2005).

bright line to distinguish the rule from another important rule to permit US courts to clarify the meaning of claim terms in light of the specification and drawings.

An emphasis on the claim construction with a heavy reliance on the written description in the specification often leads the PHOSITA to read claim terms as covering only disclosed embodiments. First, a PHOSITA often finds in the specification a definition of the disputed claim terms which was set forth by an inventor who acted as his or her own lexicographer.[33] Since the written description in the specification describes embodiments rather than the invention, the adoption of the special meaning results in a meaning which excludes the accused embodiment which is different from those disclosed in the specification. Second, the PHOSITA finds a disclaimer of the accused embodiment (1) when the patentee distinguishes claimed subject matter from the prior art which is similar to the accused embodiment or (2) when he or she describes a particular disclosed embodiment as important to the invention but the accused embodiment is different from the particular embodiment.[34] Third, although the USPTO found the patent terms to meet the definiteness requirement under §112¶6 and issued a patent, US courts may find that the claim terms chosen by the patentee so deprives the claim of clarity to a PHOSITA.[35] This will also allow the courts to resort to the specification and restrict the claim terms to cover only the disclosed embodiments. Finally, if a PHOSITA found that the terms did not include sufficient structural limitations regardless of the claims being drafted in means-plus-function format, courts can limit the claim terms to cover only the disclosed embodiments and their equivalents.[36]

In practice, it is very difficult for courts to decide if these circumstances apply to a given case. This difficulty in permitting claim interpretation while banning importation of limitation is highlighted in a recent Federal Circuit *en banc* decision, *Phillips*.[37] *Phillips* was selected to resolve this split because its technology was simple, the disputed term being 'baffle', a single ordinary term. *Phillips* involved a simple mechanical invention: modular steel-shell

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[33] *Johnson Worldwide Assocs. v. Zebco Corp*., 175 F.3d 985, 50 USPQ2d 1607 (Fed. Cir. 1999); *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 60 USPQ2d1851 (Fed. Cir. 2001).

[34] *Spectrum Int'l v. Sterilite Corp.*, 164 F.3d 1372, 49 USPQ2d 1065 (Fed. Cir. 1998); *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 58 USPQ2d 1059 (Fed. Cir. 2001).

[35] *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 50 USPQ2d (BNA) 1607 (Fed. Cir. 1999).

[36] *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

[37] *Phillips v. AWH Corp.*, 415 3d at 1313. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 45 USPQ2d 1429 (Fed. Cir. 1998).

panels which can be welded together to form vandalism-resistant walls. The term 'baffle' was used to describe an element extending inwardly from the steel shell panels, but the specification did not include any detailed description of its structure. Because the district court concluded that 'load bearing means', of which 'baffle' was a part, was drafted in a means-plus-function format, it applied §112¶ 6[38] and interpreted 'baffle' to require extending at an angle other than 90 degrees to the wall.[39]

On appeal, a three-judge panel of the Federal Circuit found that 'baffle' was a structural limitation and thus found error in the district court's application of §112¶ 6 to the disputed term.[40] Nevertheless, two judges of the panel upheld the district court's claim construction to limit 'baffle' by the angle because the specification repeatedly referred to the projectile deflection ability. Since only structures extending at acute or obtuse angles could deflect projectiles, and because the specification did not include any structure extending at 90 degrees, the panel concluded that 'baffle' was limited to structures extending at angles other than 90 degrees. One judge dissented, arguing that the majority improperly limited the term 'baffle' to the embodiments disclosed in the specification instead of adopting the plain meaning of 'baffle' found in a dictionary.[41]

In relying on the specification and records of prosecution, the majority of the *en banc* court nevertheless found it wrong to exclude from the term 'baffle' a structure oriented at a right angle, thus reversing the district court's claim construction ruling. Instead, the *en banc* court adopted a construction such that a 'baffle' must be a load-bearing object that serves to check, impede or obstruct flow.[42] The court relied on the claim differentiation doctrine, explaining that the district court's interpretation, which limited 'baffle' based on projectile deflection, made redundant the other claims which included specific limitations of the projectile deflection function. This interpretation is also supported by the specification which recites multiple functions of the baffles other than the projectile deflection.

Two judges dissented from the reversal of claim interpretation ruling although they followed exactly the same methodology.[43] For the two judges,

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38 35 USC §112¶ 6.

39 *Phillips v. AWH Corp.*, 2002 US Dist. LEXIS 27298 (D. Colo. November 20, 2002).

40 *Phillips v. AWH Corp.*, 363 F.3d 1207, 70 USPQ2d 1417 (Fed. Cir. 2004). This opinion was withdrawn by the court when the court granted rehearing the case *en banc*.

41 *Phillips v. AWH Corp.*, 363 F.3d at 1216 (Dyk, J. dissenting).

42 *Phillips*, 415 F.3d at 1324.

43 *Phillips*, 415 F.3d at 1328 (Lourie, J., dissenting).

a PHOSITA should have acknowledged the presence of the inherent angle limitation within the term 'baffle' in light of the specification, which contains no disclosure of baffles at right angles and repeatedly refers to the projectile deflection function of the baffles. Ironically, this disagreement on the inherent limitation highlighted the difficulty in setting the line between impermissible importation of limitations and permissible claim construction.

US courts use a PHOSITA for denying a claim of infringement under the doctrine of equivalents. Despite the ordinary skill and common sense which enables a PHOSITA to foresee variations, they impose a duty on patent drafters to foresee such variations of the disclosed embodiments and draft claims to literally cover them when original claims are drafted and amendments are made.[44] US courts use a PHOSITA to exclude accused embodiments which are not literally covered by claim terms from protection and punish patent drafters if the embodiments were foreseeable at the effective filing time and thus the drafters failed to meet the duty.[45] Accordingly, a PHOSITA finds a disclaimer or surrender with respect to such embodiments under the doctrine of prosecution history estoppel if the embodiments are excluded from the literal scope of claims when an amendment or argument is made during the prosecution.[46] The PHOSITA finds a disclaimer under the doctrine of the all elements rule if claim terms include a limitation which excludes the accused embodiments.[47] In particular, if the accused embodiments are not only foreseeable but also disclosed in the specification, the PHOSITA views the exclusion of the embodiments indicating the inventor's intent to dedicate the embodiments.[48]

US courts find infringement under the doctrine of equivalents only if inclusion of the accused embodiment in the literal scope was impossible at the filing date and thus the drafter did not fail to meet the duty.[49] A good example of such an impossible situation is where a varied element involves a technology which was developed after the filing date. Only when the patentee establishes such an impossible situation, does the PHOSITA need to determine if the accused embodiment involves only an insubstantial difference from the

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[44] *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., Inc*., 285 F.3d 1046, 1056, 62 USPQ2d 1225 (Rader, J, concurring) (Fed. Cir. 2002).

[45] *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 44 USPQ2d 1103 (Fed. Cir. 1997).

[46] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 US 722, 62 USPQ2d 1705 (2002).

[47] *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 44 USPQ2d 1103 (Fed. Cir. 1997).

[48] *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., Inc*., 285 F.3d 1046, 1056, 62 USPQ2d 1225 (Rader, J., concurring) (Fed. Cir. 2002).

[49] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 US 740.

claim terms and thus infringes claim terms under the doctrine of equivalents. The PHOSITA finds the difference insubstantial if it would have known the interchangeability between missing limitations of claim terms and the corresponding elements of the accused embodiments or it finds substantial similarity of function, way and result with respect to the accused embodiment and the invention defined by the claim terms on an element-by-element basis.[50]

3 PHOSITA from the comparative law perspective

3.1 Germany

The role played by the PHOSITA in determining the extent of patent protection in Germany, the United Kingdom and Japan is as important as in the United States. Like the United States, none of the courts in these jurisdictions clearly defines the PHOSITA in comparison with the skilled person for the assessment of inventive step and sufficiency of disclosure.

In Germany, Bundesgerichtshof (BGH, German Federal Supreme Court) emphasized in *Formstein* that the scope of the invention as recognized by a PHOSITA is decisive in claim construction and the application of the doctrine of equivalents in the era of European Patent Convention (EPC) Article 69.[51] The German PHOSITA is presumed to have the capability of making references to embodiments in the specification and exercising his or her general knowledge to readily come up with variations which function in the same way to produce the result of the invention.

Although US courts use the PHOSITA to impose a duty on claim drafters and to find a disclaimer, German courts use the PHOSITA to stretch the meaning of claim terms to read on variations of the disclosed embodiment.[52] In contrast, it is relatively rare for German courts to use the PHOSITA to restrict the claim terms to exclude variations which may otherwise fall into the claim terms.[53] Although BGH's approach to claim construction after joining the EPC has not been uniform, the BGH's expansive claim construction sometimes goes beyond the literal meaning of claim terms with an attempt to include such variations.[54] Assuming that a PHOSITA should be able to derive a generic concept from a particular structure recited in the claim terms, the

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50 *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17 at 37.

51 Judgment of Bundesgerichtshof (BGH, German Federal Supreme Court), April 29, 1986, (Moulded Curbstone or Formstein), 18 IIC 795.

52 Judgment of BGH, June 14, 1988, (Ion Analysis) 22 IIC 249 (1991).

53 Judgment of BGH, March 2, 1999, 30 IIC 932 (1999).

54 Judgment of BGH, 22 IIC 261 (1995); Friedrich-Wilhelm Engel, 'The "Wortsinn" of Patent Claims in German Case Law on Patent Infringement Dispute' (2003) 34 IIC 233.

court adopted a high level of abstraction and found literal infringement with respect to the accused structure which does not fall within the meaning of the disputed claim term.[55] Further, the perspective of a PHOSITA also justifies the application of the doctrine of equivalents. If the PHOSITA should have found at the effective filing date that the varied element in the accused embodiment is equivalent to the claimed element in solving the problem of the invention because the replacement of the claimed element with the varied element does not affect on the result of the invention, courts find infringement under the doctrine of equivalents. They find such infringement even if they found no literal infringement through the expansive claim construction.[56]

This expansive construction and the application of the doctrine of equivalents has been highlighted in multiple BGH decisions involving construction of numerical range limitations: *Cutting Blade I*,[57] *Cutting Blade II*,[58] *Plastic Pipe*,[59] *Custodiol I*[60] *and Custodiol II*.[61] In these decisions, BGH examined whether a PHOSITA should read claim terms to include a tolerance when construing the numerical range limitation before applying the doctrine of equivalents. The flexible nature of claim construction undertaken by BGH is particularly clear in *Cutting Blade I* because the court affirmed the Court of Appeal's finding of infringement under the doctrine of equivalents although the Court of Appeal refused to take account of any tolerance with respect to a numerical range limitation.[62] German patent scholars also propose a variety of approaches to construe claim terms and stretch the scope of such terms beyond their literal meaning.[63] In short, German courts employ a highly skilled PHOSITA and use this standard to impose on competitors, instead of patent drafters, a duty to foresee equivalent variations and avoid infringement.

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55 Judgment of BGH (Mine-Sweeping Shield), 33 IIC 525 (2002).

56 Judgment of BGH, April 29, 1986, (Moulded Curbstone or Formstein), 18 IIC 795.

57 Judgment of BGH, March 12, (Cutting Blade I or Schneidmesser I) 2002 GRUR, 2002 IIC 873.

58 Judgment of BGH, March 12, 2002, GRUR 519 (Schneidmesser II).

59 Judgment of BGH, March 12, 2002, GRUR 511 (Kunststoffrohrteil) 2003 IIC 302 (Plastic Pipe).

60 Judgment of BGH, March 12, 2002, GRUR 523 (Custodiol I).

61 Judgment of BGH, March 12, 2002 GRUR 527 (Custodiol II); 2003 IIC 197 (Custodiol II).

62 For a discussion of claim construction for numerical limitations, see Toshiko Takenaka, 'Protection Scope for Claim Including Numerical Limitations: Range of Equivalents and Prosecution History Estoppel', 11 CASRIP Newsletter (2004) available at <http://www.law.washington.edu/Casrip/Newsletter/Vol11/newsv11i1Takenaka.pdf> accessed March 3, 2008.

63 *Supra* note 54, Engel, at 238.

3.2 The United Kingdom

In the purposive claim construction in which UK courts engage to determine the extent of patent protection, the perspective of a PHOSITA is used to decide what the inventor intended to mean when he or she chose the disputed claim terms.[64] The House of Lords justifies the use of a PHOSITA for claim construction because the patent documents are addressed to PHOSITAs to describe the invention.[65] Although UK courts use the perspective of a PHOSITA, they use it in a very different way from German courts. This is highlighted by the *Kirin-Amgen* court in which Lord Hoffmann used the perspective of a PHOSITA to endorse a narrow claim construction for excluding subject matter which is in the prior art or is not enabled by the disclosure in the specification.

In *Kirin-Amgen*, the dispute centered on the term 'host cell' regarding the question of whether an inherent limitation exists with respect to the type of DNA sequence which is host to the cell to exclude endogenous DNA. The claims at issue did not appear to include any limitation as to the type of DNA. Nevertheless, the court found such a limitation in light of the specification and expert testimony, with the result that the erythropoietin (EPO) produced by an endogenous DNA did not infringe. Because the process of using an endogenous DNA was developed after the effective filing date of the patent, the court addressed the question of whether claim terms can be interpreted to cover later-arising technologies. The House of Lords answered in the negative, focusing on the perspective of a PHOSITA as of the effective filing date, with respect to what the inventor meant to say by adopting the claim terms because one should construe those terms so as to exclude subject matter in the prior art as well as subject matter which was insufficiently disclosed in the specification and drawings.[66] This use of the PHOSITA is a stark contrast to the use of the German PHOSITA, which supports the expansive claim construction which covers variations of the disclosed embodiments if the variations are known to the PHOSITA to produce the result of the invention.

However, the extent of UK patent protection is not completely limited by the scope enabled by the disclosure in the specification. Responding to Kirin-Amgen's argument that such restrictive construction makes the patent meaningless as soon as a new technology is developed, the House of Lords acknowledged the possibility of a claim covering an after-arising technology if a PHOSITA would understand it in a way that was sufficiently general to

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64 *Catnic Components Ltd v. Hill & Smith Ltd* [1982] RPC 183; *Kirin-Amgen Inc. v. Hoechst Marion Roussel Limited*, 2004 UKHL 46 (House of Lords, 2004).

65 *Kirin-Amgen*, 2004 UKHL 46, at para. 33.

66 *Id.*

include the technology.[67] When the Court applied the perspective of a PHOSITA, it concluded to exclude from the claim term 'host cell' endogenous DNA prepared by the gene activation method which was unknown as of the effective filing date. Thus the perspective of a PHOSITA effectively limits the claim construction to existing technologies.

The perspective of a PHOSITA also limits the conditions that trigger the UK doctrine of equivalents and its content. Unlike German courts, UK courts use the concept of equivalents as a means for claim construction.[68] Although the UK doctrine of equivalents allows an expansive claim construction covering an accused embodiment which does not necessarily fall within the meaning of claim terms, the application of the doctrine is not as a matter of right. Where the court has already used the perspective of a PHOSITA and concluded that the claim term should not be read to cover the accused embodiment, the court no longer needs to apply the concept of equivalents and explore the possibility if the claim can be read to cover the accused embodiment.[69] In contrast, where the court did not conclude with the coverage of the claim terms, the court can apply the protocol questions: (1) Does the varied element have a material effect upon the way the invention works?; (2) Would the fact that the replacement with the varied element has no material effect have been obvious to a PHOSITA as of the date of publication of the patent?; and (3) Would a PHOSITA have understood from the claim terms that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention?[70]

In the protocol questions, the perspective of a PHOSITA is decisive as to whether the courts can extend patent protection to the accused embodiment because no infringement is found if the third question is affirmatively answered. To address the second question, courts assume a relatively low skill level on the part of the PHOSITA, requiring that a PHOSITA should have known at the date of publication that the varied element is a good candidate but also that it should work as the invention works,[71] which seems parallel to the 'would have' versus 'could have' test under the EPO inventive step standard.[72]

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67 *Kirin-Amgen*, 2004 UKHL 46, at paras. 78–85.

68 Toshiko Takenaka, 'A Person of Ordinary Skill in the Art and the Extent of Patent Protection' in Dietrich Beier, Laurence Broening-Petit and Christopher Heath (eds), *Festschrift for Jochen Pagenberg* (Carl Heymanns Verlag, Munich, 2006) 81.

69 *Kirin-Amgen*, 2004 UKHL 46, at para. 71.

70 *Improver Corporation v. Remington Consumer Products Ltd* [1990] FSR 181, cited in *Kirin-Amgen*, 2004 UKHL 46, at para. 51.

71 *American Home Products v. Novartis* [2001] FSR 599.

72 EPO Board of Appeals T/83, OJ 1984, 265. Margarete Singer and Dieter Stauder, *The European Patent Convention*, 155 (2nd edn, Sweet & Maxwell, London, 2003).

This provides a high hurdle to meet the requirement of an equivalent and thus the perspective of the UK PHOSITA effectively prevents the substitution of a claim element with a varied element.[73]

3.3 Japan

The significance of the PHOSITA has recently increased in Japanese claim construction and the doctrine of equivalents. In the early era of the Japanese patent system, scholars and courts developed a rule that the inventor was entitled to protection only for what he or she recognized as his or her invention regardless of the claim terms (the inventor's recognition theory).[74] Under this theory, the disclosure in the specification and drawings constitutes the scope which was recognized by the inventor. Some scholars advocate the view that an assessment of the scope should be made objectively from the perspective of a PHOSITA. Others support the view that an assessment of scope should be made on the basis of the subjective state of mind of the particular inventor. Older court decisions indicate Japanese courts' heavy reliance on the disclosure in the specification, which led to a restrictive claim construction to import limitations from the specification and exclude accused embodiments which are not disclosed in the specification.[75] In addition, Japanese courts' claim construction in older decisions was very similar to UK courts' purposive construction in excluding from the claim terms subject matter in the prior art.[76]

Japanese doctrine of equivalents was also similar to the UK courts' doctrine of equivalents. Like the UK House of Lords, Japanese courts did not acknowledge the extra-textual protection, but, under an exceptional circumstance, adopted an expansive construction to include equivalents which involve a replacement of the element where the interchangeability between the claimed element and the varied element in the accused embodiment was well known to

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[73] Hugh Dunlop, 'Court of Appeals Gets to Grips with the Protocol' EPIR 342 (2003).

[74] Nobuhiro Nakayama, *Patent Law Annotated* 705 (3rd edn, Seirin Shoin, Tokyo, 2000).

[75] Testuya Obuchi, 'A Study of Claim Construction and Validity of Patent, in Patent Litigation in the Era of the Intellectual Property Based Nation', Japan Patent Attorneys Association Intellectual Property Study Center (ed.), *Claim Construction* (Hanrei Taimuzu, Tokyo, 2005) 2.

[76] Judgment of Supreme Court of Japan, August 4, 1964 (Crude Petroleum Rotation Combustor), 18 Minshu (No. 7) 1319; Judgment of Supreme Court of Japan, June 28, 1974 (Single Lens Reflex Camera), Saibanshu Minji (No. 112) 155. *Supra* note 75, Obuchi; Toshiko Takenaka, 'Technical Scope of Patent Claims and the Prior Art', *Issues Relating to Intellectual Property: Festschrift for 70th Birthday of Judge Takura Osamu* (Hatsumei Kyokai, Tokyo, 1996).

the PHOSITA.[77] However, courts seldom allowed such an expansive construction. Thus, the Japanese PHOSITA was a non-creative hypothetical person who had no capability of foreseeing variations in the disclosed embodiments and covering them within the claim terms.

A change was made to this restrictive claim construction by the Japanese government's adoption of a national strategy to become an IP-based nation in order to recover from the prolonged recession. Since the Commission on Intellectual Property Rights in the 21st Century published a report that recognizes intellectual property rights as a driving force in activating the intellectual creation cycle in 1997, METI and its agency JPO have led an extensive campaign for the pro-patent policy.[78] Responding to the needs of domestic industry for prompt and strong patent protection, the Supreme Court of Japan handed down the *Ball Spline* decision,[79] and expressly adopted the doctrine of equivalents as an extra-textual infringement. The Court stressed the impossible nature of the patent drafters' task of foreseeing equivalent variations and drafting claims to cover them. To remedy this impossible situation, the extent of patent protection should extend to a variation which a third party would have readily conceived of as subject matter that is substantially the same as the claimed invention. Accordingly, as part of the five questions examined by lower courts to apply the doctrine of equivalents, the court requires that a PHOSITA would have readily conceived the replacement between the claim element and the varied element to produce the result of invention.

In current practice, Japanese courts try to read broadly drafted claim terms as they are while avoiding importing limitations into claims from the specification.[80] To clarify the meaning of the claim terms at issue, Japanese courts

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[77] Judgment of Supreme Court of Japan, May 29, 1987 (Pulpwood Barking Machine), Juristo (No. 903) 85 (1988). For a discussion of this decision, see Toshiko Takenaka, 'Interpreting Patent Claims: The United States, Germany and Japan', 17 IIC Studies, 261 (VCH, Munich, 1995).

[78] For a discussion of Japan's national strategy on IP, see Toshiko Takenaka and Ichiro Nakayama, 'Will Intellectual Property Policy Save Japan from Recession? Japan's Basic Intellectual Property Law and its Implementation through the Strategic Program' (2004) 35 IIC 877.

[79] Judgment of Supreme Court of Japan, February 24, 1998, 52 Minshu (No. 1) 113, 1630 Hanrei Jiho 32 (1998). An English translation of the decision by the author is published in Toshiko Takenaka, *The Supreme Court Affirmed the Presence of the Doctrine of Equivalents Under Japanese Patent System*, 5 CASRIP Newsletter. (1998) 12 <http://www.law.washington.edu/Casrip/Newsletter/Vol5/newsv5i1jp1.html> accessed March 3, 2008.

[80] Hideo Ozaki, 'How Should Courts Engage Claim Construction in Patent Litigation in the Era of the Intellectual Property Based Nation?', Japan Patent Attorneys Association Intellectual Property Study Center (ed.), *Claim Construction* (Hanrei Taimuzu, Tokyo, 2005) 176.

examine what the claim terms would have meant to a PHOSITA in light of the specification.[81] However, the courts and scholars did not completely eliminate the inventor recognition theory. Although Japanese Patent Law does not provide §112¶6 equivalents, some courts limited the extent of functional claims to disclosed embodiments and their equivalents.[82] A leading patent scholar defines the proper extent of protection to include only disclosed embodiments and their equivalents.[83] This view is perfectly in line with the purposive claim construction in the *Kirin-Amgen* decision in giving flexibility to the courts to expand or limit the literal meaning of the claim terms through construction if the terms are narrower or broader than the proper scope supported by the disclosure. Japanese courts also retained the claim construction to exclude subject matter in the prior art,[84] although the main reason for justifying the restrictive construction, the court's inability to entertain the defense of patent invalidity in infringement proceedings, was eliminated by the Kilby Supreme Court decision[85] and the addition of Patent Law Article 104-3.[86]

In addition, even after the Ball Spline decision, Japanese courts seldom find infringement under the doctrine of equivalents because the courts often find one or more requirements are not met by the accused embodiments.[87] As a result, the Japanese PHOSITA remains relatively non-creative even after the adoption of the pro-patent policy and seldom finds variations in the disclosed embodiments as either literal infringement or infringement under the doctrine of equivalents.

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81 Judgment of Tokyo High Court, April 17, 2001.

82 Judgment of Tokyo High Court, December 20, 1978 (Ball Bearing), Hanrei Taimuzu No. 381, 165; Judgment of Tokyo District Court, Dec. 22, 1998 (Magnetic Medium Reader), Hanrei Jiho No. 1674, 152.

83 Ryu Takabayashi, *Standard Patent Law*, 128 (2nd edn, Yuhikaku, Tokyo 2005).

84 Naoki Matsumoto, 'The Relationship between the Possibility of Patent Invalidity and Finding of Non Infringement at Infringement Proceeding', Japan Patent Attorneys Association Intellectual Property Study Center, Claim Construction (Hanrei Taimuzu, Tokyo, 2005) 49.

85 Judgment of Supreme Court of Japan, April 11, 2000 (Kilby), 54 Minshu (No. 4) 1368.

86 Law for Revising Part of Law of Courts, Law No. 120, 2004.

87 Makoto Endo, 'Application of the Doctrine of Equivalents after the Ball Spline Supreme Court Decision' [Hereunder, 'Endo, Application of the Doctrine of Equivalents'] Part 1, Hanrei Taimuzu No. 1051 (2001) 60; Part 2, Hanrei Taimuzu No. 1108 (2003) 92. During the period between February 24, 1998 (the date of the Ball Spline decision) and July 31, 2002, courts found infringement under the doctrine of equivalents in ten cases out of 120 cases where a party claimed infringement under the doctrine of equivalents.

4 Analysis

A review of case law revealed the different manner in which PHOSITAs are used by the courts in the four jurisdictions to support their claim construction and reject or apply the doctrine of equivalents.[88] The levels of knowledge attributed to the PHOSITA in these jurisdictions are not exactly the same. In determining non-obviousness, the content of relevant prior art which a PHOSITA is presumed to know is different because the United States follows the first-to-invent system, in contrast to the other three jurisdictions which use first-to-file systems.[89] However, because of exclusion of publicly unavailable information in determining the literal scope of claim terms, the knowledge of US PHOSITA is more in line with that of PHOSITAs in the other three jurisdictions, who are presumed to know only publicly available information.[90] Further, PHOSITAs in the US, Germany and Japan read claim terms based on the knowledge available at the time of the effective filing date in contrast to the UK PHOSITA, who reads claim terms based on the knowledge, including the prior art, which has become available at the publication date of the patent.

In applying the doctrine of equivalents, Japanese and US PHOSITAs are presumed to know the prior art which has become publicly available as of the time of infringement,[91] in contrast to UK and German PHOSITAs who are presumed to know the prior art as of the filing date.[92] In claim construction and the doctrine of equivalents, German and UK PHOSITAs are presumed not to read records of prosecution but to read the specification and drawings before construing claims.[93] In contrast, US and Japanese PHOSITAs are

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88 For the difference in the extent of patent protection among EPC member states, see Jochan Pagenberg and William Cornish, *Interpretation of Patents in Europe: Application of Article 69 EPC* 251 (Carl Heymanns Verlag, Munich, 2006).

89 For a general discussion of the comparison of the prior art under 35 USC, European Patent Convention and Japanese Patent Law, see Toshiko Takenaka, 'The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal For a "First-To-Invent" Exception for Domestic Applicants' (2003) 11 Texas Intellectual Property L.J. 259.

90 There are some differences, such as public use, outside the United States. For details of the comparison between the prior art in the US and first-to-file countries, *see* Chapter 13.

91 *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 37, 137 L. Ed. 2d 146, 166 (1997); Judgment of Supreme Court of Japan, February 24, 1998, 52 Minshu (No. 1) 113, 1630 Hanrei Jiho 32 (1998).

92 *Kirin-Amgen*, 2004 UKHL 46; Judgment of BGH, April 29, 1986 (Moulded Curbstone or Formstein), 18 IIC 795.

93 *Kirin-Amgen*, 2004 UKHL 46, at paras. 36–44; Judgment of BGH, March 12, 2002, GRUR 511 (Kunststoffrohrteil) [2003] IIC 302 (Plastic Pipe).

supposed to read not only the specification and drawings but also records of prosecution.[94]

Thus, some may argue that the difference comes from the difference in the knowledge that PHOSITAs are presumed to have. However, although the German and UK PHOSITAs should be the same person under the EPC, in determining the extent of patent protection, a German PHOSITA is very different from a UK PHOSITA with respect to what a PHOSITA would have understood as part of the claim terms. Instead, US and Japanese PHOSITAs are much more similar to the UK PHOSITA than the German PHOSITA in being non-creative and excluding variations of the disclosed embodiments from the claim terms.

It is possible that these differences have resulted from the procedural differences in patent litigation. A US legal scholar pointed out the gap between the skill of ordinary practitioners in the art and the written record of prior art and thus argued that the US PHOSITA for non-obviousness assessment does not properly represent the level of real practitioners. She urged courts to rely on USPTO expertise because examiners and board members are at least one-time practitioners in the field, and proposes to establish a mechanism for consulting with the current practitioners.[95] US courts face the same challenge in construing the claim terms from the perspective of a PHOSITA. The problem of lack of access to the perspective of actual practitioners is worse for infringement litigation because judges construe the claim terms. Judges have no training in the art of invention and are not PHOSITAs.[96] Expert reports and testimony once were used to provide a mechanism to provide judges with access to the perspective of a PHOSITA.[97] However, since the *en banc Markman* court restricted the use of such evidence, noting a risk of bias, US courts have become very reluctant to rely on expert testimony.[98] Characterizing extrinsic evidence in general as less reliable,[99] the *en banc Phillips* court effectively eliminated from litigation a mechanism to get access to the perspective of a PHOSITA in claim construction.

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94 *Phillips v. AWH Corp*., 381 F.3d at 1317; Judgment of Nagoya District Court, May 27, 1998, Hanrei Taimuzu No. 682, 219. *Supra* note 83, Takabayashi 113.

95 *Supra* note 17, Eisenberg at 898.

96 *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.,* 807 F.2d 955, 1 USPQ2d 1196 (Fed. Cir. 1986). (Obviousness is determined by reference to a person of ordinary skill in the art – not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art.)

97 *McGill, Inc. v. John Sink Co.*, 736 F.2d 666, 221 USPQ944 (Fed. Cir. 1996).

98 *Markman v. Westview,* 52 F.3d 967, 34 USPQ2d 1321 (Fed. Cir. 1995).

99 *Phillips*, 415 3d at 1318.

In contrast, Japanese judges and UK judges have more access to the perspective of actual practitioners through technical experts. In UK litigation, expert evidence is prepared by party technical experts.[100] In *Kirin-Amgen*, the House of Lords gave due deference to the district court's claim construction based on expert testimony. Japanese judges are assisted by judicial research officials, 'chosa-kan', who are experienced examiners dispatched by the Japan Patent Office and experienced patent attorneys who are full-time court employees appointed by the Supreme Court of Japan.[101] In cases where the art of invention is not within any of the research officials' expertise, judges can seek assistance from expert commissioners.[102] Nevertheless, both UK and Japanese PHOSITAs remain as non-creative as the US PHOSITA in construing claim terms to cover only the disclosed embodiments. Further, German judges do not necessarily have more access to the perspective of actual practitioners, although their claim construction seems to reflect such a perspective in including variations within the claim terms. At the Dusseldorf district court, where patent cases are most frequently litigated, technical expert evidence is rarely introduced.[103]

A more plausible source of the difference is different preferences held by the judges in these jurisdictions with respect to the competing patent policies of fair protection and legal certainty.[104] The US Supreme Court often draws parallels between the PHOSITA in patent law and the reasonable person in tort negligence law.[105] In Japan and Germany, tort negligence rules apply to patent infringement and negligence of infringement is presumed by imposing on competitors a duty of care to read patent documents and avoid infringe-

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[100] The Supreme Court of Japan, *General Affair Office, Report on Patent Litigation in the United States, the United Kingdom, Germany and Netherlands* [Hereunder, 'Patent Litigation Report'], (The Supreme Court of Japan, Tokyo 2000) 123.

[101] General information about judicial research officials is available at <http://www.ip.courts.go.jp/eng/aboutus/organization.html> accessed March 3, 2008.

[102] Expert commissioners are part-time court employees appointed by the Supreme Court of Japan.

[103] *Supra* note 100, Patent Litigation Report, 199. Opinions by court-appointed experts are introduced in only 5% of all cases.

[104] Toshiko Takenaka, 'Extent of Patent Protection in the United States, Germany and Japan: Analysis of Two Types of Equivalents and their Policy Implications' in Annette Kur, Stefan Luginboehl and Eskil Waage (eds), *Patent Law on the Move: Festschrift for Gert Kolle and Dieter Stauder* (Carl Hymanns Verlag, Munich, 2005) 115; Toshiko Takenaka, 'Claim Construction and the Extent of Patent Protection: A Comparative Analysis of the *Phillips en banc* Federal Circuit Decision' (2005) 1 Journal of Intellectual Property & Law 119 (2005).

[105] For the non-obviousness PHOSITA, *Graham v. John Deere Co.*, 383 US 1, 18 (1966); for the extent of patent protection, 527 US 17, 37 (1997).

ment.[106] In tort negligence, US legal scholars and courts identify the function of a reasonable person as a vehicle for making concealed choices among political preferences.[107] The patent law PHOSITA functions in the same way as the reasonable person as a vehicle to implement a political choice.[108] German judges follow their tradition to reflect their preference for the fair protection policy and use the PHOSITA to achieve generous patent protection. In contrast, UK and Japanese judges follow their traditions to reflect their preference for legal certainty and limit its scope to disclosure in the specification. In response to the increased significance of legal certainty policy after *Warner-Jenkinson*,[109] US courts use the PHOSITA more frequently in the same manner as UK and Japanese courts, to restrict the scope of patent protection rather than expand it.

It seems impossible to remove political preferences and achieve perfect harmonization. Even in the same jurisdiction, the United States, under the same patent statute and case law, judges in the *Phillips* court agreed on the methodology to use different sources to clarify the meaning of claim terms but disagreed as to whether an inherent limitation exists in the claim terms in light of the patent document.[110] A conclusion to support the presence of the inherent limitation clearly reflects dissenting judges' preferences to give more weight to the legal certainty policy and to limit the patent scope to what is disclosed in the specification. It follows that even the establishment of a uniform patent court may not be able to remove the different manner in which PHOSITA is used to determine the extent of patent protection.

5 Conclusion

An examination of cases and the manner in which PHOSITA is used has revealed a difficulty in bringing about uniformity in the extent of patent protection through an adoption of the same rules and protocols as well as the methodology for interpreting claim terms. Because PHOSITA is used to support a preference between two competing policies for fair protection and legal certainty, which was also closely connected to the traditional perception

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106 Japanese Patent Law Article 103; German Patent Law Article 139.

107 Michael H. Davis, 'Patent Politics', 56 S.C.L. Rev. 337, 356 (2004).

108 *Id.*

109 *Warner-Jenkinson.*, 520 US 17. For a discussion of the impact of *Warner-Jenkinson*, *see* Timothy R. Holbrook, 'The Supreme Court's Complicity in Federal Circuit Formalism' (2003) 20 Santa Clara Computer & High Tech. L.J. 1; John R. Thomas, 'Formalism at the Federal Circuit' (2003) 52 Am. U.L. Rev. 771; Christina Y. Lai, 'Comments, A Dysfunctional Formalism: How Modern Courts Are Undermining the Doctrine of Equivalents' (1997) 44 UCLA L. Rev. 2031.

110 *Phillips v. AWH Corp.*, 415 F.3d, at 1328 (Lourie, J., dissenting).

of the patent system, it is impossible to bring about perfect harmonization. As suggested by the US Supreme Court with respect to the test of equivalents,[111] only through case-by-case development, by giving due attention to case law developments in different jurisdictions, can the manner in which PHOSITA is used be made uniform.

[111] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 US 17, 37, 137 L. Ed. 2d 146, 166 (1997).

16 Direct and indirect patent infringement

Alison Firth

Introduction

Patent infringement

Proving patent infringement involves two distinct aspects. First, it must be shown that a defendant is using the patented invention, whether a product or a process. This will involve comparison of the defendant's product or process with the patent claims. Very often, the claimed invention will involve a combination of features. For infringement to occur, all these features need to be present,[1] exactly as claimed ('literal infringement'), in the form of functional equivalents under a doctrine of equivalents,[2] or at least in spirit under a theory of purposive construction ('non-literal infringement'). These tests give a narrow scope of protection compared with, say, copyright infringement[3] and its concepts of 'substantial taking'.

Secondly, it must be shown that the defendant is using the invention in a way reserved exclusively to the patentee. Classically,[4] the patentee is given the right to 'make' (product), 'use' (product or process) or 'vend' (product or process) the invention in the territory for which the patent is in force. The World Trade Organisation's agreement on Trade Related aspects of Intellectual Property Rights (WTO TRIPs) now provides an international minimum standard:

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1 See, eg, *MacLennan v Gilbert Technology Inc.* (2004) 41 CPR (4th) 131 (Beaudry J) (Federal Court of Canada). Here the patent claimed a combination of saw teeth and holder. Supply of replacement teeth did not infringe, though some were sold with adaptors to achieve fit with the holder. Section 1358(3) of Russia's new intellectual law, codified as Part IV of her Civil Code, states that an 'invention . . . is deemed to have been used in a product if that product contains every single characteristic of the invention set out in the independent clause [claim] . . . or a characteristic that is equivalent to it . . .' L Haworth and P Haworth, 'Codifying Russia's Intellectual Property Law' (2007) 30(2) EIPR 50, 54.

2 See Chapter 15, Toshiko Takenaka.

3 L Gimeno, PhD thesis (University of London 2002). Gimeno's thesis compares patent infringement with copyright infringement in the UK, Spain, and other jurisdictions.

4 See Chapter 3, John Adams.

> Article 28 Rights Conferred
> 1. A patent shall confer on its owner the following exclusive rights:
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
> 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.[5]

There is no requirement that these acts involve copying or derivation from the patent or from the patentee's activities. Nor does a patent claimant have to establish an intention to infringe[6] or knowledge of the patent on the part of the defendant, although innocence may be a defence to a claim for damages (as opposed to an injunction). In this respect the scope of protection conferred by a patent is wide and absolute, although usually tempered by defences such as private/non-commercial use, or experimental use.[7]

As well as 'direct' forms of infringement,[8] it is recognised that a number of 'indirect' forms may be needed adequately to protect the interests of a patentee in the patent territory. An important example is the right to prevent import of the direct products of a patented process which has been used beyond the jurisdiction.[9] If admitted to the market where the patent is in force, these imports could undermine the market for the patentee's or licensee's local output. Other aspects of infringement proceedings, such as the award of consequential or 'parasitic' damages for losses on non-patented items or business,

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[5] World Trade Organization, 'Uruguay Round Agreement: TRIPs' <http://www.wto.org/English/docs_e/legal_e/27-trips_04c_e.htm#5> accessed 9 February 2008 (footnote omitted). These rights may be subject to exhaustion according to national law. TRIPs art 6.

[6] Nor, conversely, does an intention to infringe establish infringement. *Halford v. Seed Hawk Inc.* (2004) 31 CPR (4th) 434 [322] (Pelletier J) (Federal Court of Canada).

[7] See Chapter 19, Sean O'Connor; Trevor Cook, 'Responding to Concerns about the Scope of the Defence from Patent Infringement for Acts Done for Experimental Purposes Relating to the Subject Matter of the Invention' (2006) 3 IPQ 193.

[8] For a reference table for direct forms of infringement under TRIPs, the Community Patent Convention, German, British, French, Dutch and Swiss law, see Ian Muir, Matthias Brandi-Dohrn, and Stephan Gruber, *European Patent Law: Law and Procedure Under the EPC and PCT* (OUP, Oxford 1999) 249.

[9] Recognized in TRIPs art 28(1)(b).

may address similar concerns.[10] The use of 'reach-through' claims in biotechnology, whereby an attempt is made to extend infringement rights to embrace downstream inventions achieved by using the patented technology, have been discussed by Lim and Christie.[11] The EC Biotechnology Directive[12] extends the infringement rights relating to biological material to downstream products produced by propagation or multiplication.

There is interplay between claim drafting, the activities which infringe and of course the validity of a patent. Infringement of process or method claims tends to be more difficult to prove than infringement of product claims and Park has commented in the context of software patents:

> Inadequate claim drafting may not permit the effective enforcement of the patent by confining it only to indirect (contributory) infringement and allowing the competitor to be able to assert a substantial non-infringing use of the patent . . .
>
> In anticipation of those issues above, patent drafters should examine whether each claim component can be viewed from the perspective of its separate location in a country protected by the patent. In addition, claims should be crafted so that the step(s) performed by the competitor's server, located at one extraterritorial station, may constitute indirect infringement, once direct infringement of the competitor's customer is established in the country where the patent is enforced. These strategies will enhance the enforceability of a claim against any potential infringers.[13]

If an element of the invention as claimed is absent from the defendant's activity, a court minded to find in favour of the patentee might do so by way of a beneficial construction of the claims, by a favourable construction of the law characterising infringing activities, or by applying/adopting rules on indirect infringement. An example of these possibilities in action is the Israeli case of *Rav-Bariah v. Havshush*,[14] where the Supreme Court of Israel held that the

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[10] *Gerber Garment Technology, Inc. v. Lectra Systems Ltd.* [1997] RPC 443 (Court of Appeal, England); *Rite-Hite v. Kelly* and other cases discussed in Chapter 21, Toshiko Takenaka.

[11] Amanda SY Lim and Andrew F Christie, 'Reach-through Patent Claims in Biotechnology: An Analysis of the Examination Practices of the United States, European and Japanese Patent Offices' [2005] 3 IPQ 236.

[12] Council Directive (EC) 98/44 on the legal protection of biotechnological inventions [1998] OJ L213/13 art 8.

[13] Jinseok Park, 'Think before You Write: Considerations for Drafting Claims of Software Patents', paper at 19th BILETA Annual Conference 2004, available from www.bileta.ac.uk, click on 'conference papers' (last visited 5 January 2008) (footnotes omitted). See also Jinseok Park, 'Interpretation of Patent Claims in the EPO, USPTO and JPO – In the Context of the Doctrine of Equivalents and Functional Claims' (2005) 27(7) EIPR 237.

[14] Case 1636/98 reported at 55(5) PD 337 (Supreme Court of Israel). The case concerned import of two of three components of a patented lock to prevent car theft.

Israeli legislation, which had recently been amended to narrow the scope of infringement, should nonetheless be interpreted to cover contributory infringement.

The three unities

The respective roles of direct and indirect (or 'contributory') infringement may be appreciated by considering the dramatic doctrine of unity, which has been applied in copyright cases like *Green v. Broadcasting Corp. of New Zealand*.[15] The unity which renders a drama capable of performance may be subdivided into three aspects – unity of space, unity of time and unity of action (under which heading we shall include unity of actor).[16] Unity of space is represented by the territorial nature of a patent. The concept of unity of time can be used to analyse activities which precede or follow on from the main forms of infringement. Unity of action relates to the forms of infringement and the possibility that several different actors may contribute to a single instance of infringement.

Contributory infringement tends to come into play when one or more of the unities is lacking, so that direct infringement may not be proven. For example:

- Can individual infringements be pre-empted before they occur, by restraining the supplier of essential components or raw materials rather than suing numerous direct infringers?
- What if different actors provide different stages of an infringing process?
- Can successful suit be brought if some elements of infringement occur off-shore?
- A non-injuncted party supplies an injuncted party with the means to infringe and thereby to act in breach of an injunction.[17] Is the supplier liable in contempt of court as well as the party under restraint?

See A Benyamini, 'Indirect Infringement of Patents in Israel: Judge-made Law' in D Vaver and L Bently (eds), *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish* (Cambridge University Press, Cambridge, 2004) 116–17; KL Elburg, 'Israel: Patents: Doctrine of Contributory Infringement of a Patent Applies in Israeli Law' (2002) 24(7) EIPR N112. Reinhold Cohn & Partners have described the decision as 'judicial legislation'. 'Israel: Patents: Contributory Infringement', article available at http://www.mondaq.co.uk/article.asp?articleid=18747.

15 [1989] 2 All ER 1056, [1989] RPC 700 (Privy Council, from New Zealand). (The Privy Council sits in the UK, hearing appeals from certain Commonwealth countries).

16 The concept of the three unities is also helpful in analysing passing off. See Jeremy Phillips and Alison Firth, *Introduction to Intellectual Property Law* (4th edn, London, Butterworths, 2001) at para 20.18.

17 See Chapter 20, Christopher Cotropia.

This chapter will analyse patent infringement by reference to the concept of unities, illustrated with examples from international conventions,[18] regional or national legislation[19] and case law.

What this chapter does not deal with

Because patent infringement is not usually pursued as a criminal offence, even in countries where the offence exists technically,[20] we shall not consider criminal infringement of patents, or the related and fascinating issue of participation in such offences. The English Law Commission has been wrestling for several years with the law on participation in crime.[21]

Neither shall we engage in a comparative analysis of general principles of vicarious liability, whereby the liability of one person, such as an employee or agent, is imputed to another, such as the employer or principal. In *Perfect 10 v. Visa Int'l Service Assoc.*[22] a US court recently considered whether a claim for vicarious copyright liability had been made, in that the plaintiff had to 'allege that the defendant has the right and ability to supervise the infringing conduct, as well as a direct financial interest in the infringing activity'.[23]

We shall not consider the question of 'parallel imports' or 'gray goods', whereby products placed in free circulation in one territory are imported for distribution in another; these are the subject of another chapter in this volume.[24]

From time to time, patent concepts and cases are referred to in deciding cases on other intellectual property rights[25] and vice versa. As far as possible this chapter will concentrate on patent jurisprudence.

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[18] See, also Chapter 5, Tomoko Miyamoto.

[19] Many European countries follow the approach of the draft Community Patent Convention/Agreement, which has never made it to being a concluded agreement. See A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993), especially Chapter 2, 'Historical Development, Objectives and Fundamentals of the Community Patent'.

[20] Such as France or Denmark. See AIPPI, 'Summary Report on AIPPI Question Q169 – Criminal Law Sanctions with regard to the Infringement of Intellectual Property Rights' <http://www.aippi.org/reports/q169/q169_Summary_e.html> accessed 9 February 2008.

[21] See [2008] 1 Crim LR, especially editorial summary. (This is a special issue devoted to the Law Commission papers.)

[22] 494 F.3d 788 (9th Cir. 2007) (D Smith Jr, J, Kozinski, J, dissenting).

[23] See Paul Devinsky, 'United States: Credit Card Processor Not Liable For Infringement' McDermott Will & Emery United States: Intellectual Property Quarterly Newsletter, Winter 2007.

[24] Thomas Hays, Chapter 18.

[25] Such as copyright. See, eg, *CBS Songs v Amstrad Consumer Electronics*

Direct and indirect forms of patent infringement

Indirect or contributory infringement

In a given jurisdiction, the concept of indirect or contributory infringement may be recognised in statutory form, or it may result from the application of general common law or civil law concepts of participation in tort or delict. In some jurisdictions, such as the federal patent law of the USA, contributory infringement is a highly elaborated doctrine, now codified in statute. In other jurisdictions it probably is or has been[26] non-existent, whilst for most countries the position is somewhere in between – a recognised concept, perhaps a statutory basis and a few cases. Paucity of case law may result, as for example in Germany, from a tendency of the courts to construe direct infringement rights rather widely.

There are scholarly writings on the position in individual jurisdictions;[27] erudite practitioner works on specific jurisdictions;[28] at least one regional and comparative monograph;[29] and some comparative sectoral reports.[30]

From these writings and perusal of the World Intellectual Property Organization's Collection of Laws for Electronic Access, one can see further examples of these combinations (see Table 16.1).

Two classes of doctrine may be identified. Earlier-developed doctrines tend to be based on theories of participation in a subsequent act of direct infringe-

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[1988] AC 1013. For U.S. and Australian commentary on copyright issues, see Jane C Ginsburg and Sam Ricketson, 'Inducers and Authorisers: a Comparison of the U.S. Supreme Court's Grokster Decision and the Australian Federal Court's KaZaa Ruling' (2006) 11 Media & Arts Law Review 1.

[26] The concept was doubted in the UK prior to the Patents Act 1977; In *Dunlop v. Moseley* (1904) 21 RPC 274, the sale of wheel rims 'ready for' the wires which would complete the patented product was held not to infringe. See Brian Reid, 'A Practical Guide to Patent Law' (1984) ESC at 113.

[27] Braier, Paul A and Jayaprakash, Azza M, 'Indirect Patent Infringement in the US: Points to Consider for Generic and API Manufacturers' (July 2007) 4(4) Journal of Generic Medicines 287. A highly influential Canadian article was that of F Grenier, 'Contributory and/or Induced Patent Infringement' (1987) 4 CIPR 26, cited in *Warner-Lambert v. Wilkinson Sword Canada* (1988) 19 CPR (3d) 402, 407 (Jerome ACJ) (Federal Court, Trial Division Canada), and in turn by the Canadian Federal Court of Appeal in *Dableh v. Ontario Hydro* (1996) 3 FC 751, 68 CPR (3d) 129, 148–9, leave to appeal refused [1996] SCCA No. 441 (QL).

[28] Eg, Donald C. Chisum, *Chisum on Patents* (New York, Matthew Bender, Looseleaf).

[29] A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993).

[30] Eg, Ron Nicholson and Roger Miselbach, 'Contributory Infringement' [2000] available from http://www.licensingforstandards.co.uk/contrininfr.pdf [last visited 21 February 2008].

Table 16.1 Examples of different bases for contributory patent infringement

Treaty or statutory provisions on contributory infringement	No statute but common or civil law doctrine	No statute or doctrine
Community Patent Convention (Europe, 1975 and revision), Article 30[1]	US prior to 1952[2]	UK prior to Patents Act 1977
German Patent Act, Section 10[3]	Austria[4]	Australia prior to 1990 Act
UK Patents Act of 1977, Sections 60(2) and (3)[5] US s271(b)–(d) Australian Patents Act 1990, Section 117	South Africa[6]	Singapore[7]

Notes:

[1] The text of the Community Patent Convention ('CPC' Luxembourg, 1975) may be consulted at the web site of the European Union, http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=41975A3490&model=guichett. Please note the statement 'no longer in force' at the web site is misleading; the CPC never came into force due to the failure of Ireland and Denmark to ratify it. It was amended by the Community Patent Agreement (Luxembourg, 1989) but this instrument has never taken effect, either.

[2] And the enactment of 35 US sections 2711(b)–(d).

[3] Modeled on Article 26 of the Community Patent Convention. See German Community Patent Act 1979; see Neils Holder and Josef Schmidt, 'Indirect Patent Infringement – Latest Developments in Germany' (2006) 28(9) EIPR 480, N3 (their reference to art 30 CPC is erroneous).

[4] Limited doctrine, based upon intentional contribution to direct infringement: 'Base plate' GRUR Int 324, cited by Ian Muir, Matthias Brandi-Dohrn, and Stephan Gruber, *European Patent Law: Law and Procedure Under the EPC and PCT* (OUP, Oxford, 1999) at para 21.13.

[5] Modeled on Article 26 of the Community Patent Convention; Section 130(7) of the 1977 Act requires Section 60 to be given the same effect as the corresponding provision of the CPC.

[6] David F Sheppard, 'South Africa: Patents – Amendments of Pleadings – Contributory Infringement' (2002) 24(3) EIPR N36 (describing an unreported case in South Africa, *Nel v. Nedcor Bank Ltd.*); Dario F Tanziani, 'South Africa: Patents: Exception in a Patent Infringement Action Against Inclusion of Contributory Infringement in Pleadings – Exception Dismissed' (2004) 26(5) EIPR N67–9.

[7] James Wan, 'The Multi-jurisdictional Nature of Patents' Asia Law & Practice IP Review, September 2004.

ment.[31] The phrase 'contributory infringement' suggests this scenario[32] and there is often a requirement that the supply in question actually leads to infringement.[33] More mature schemes of indirect infringement might be described in terms that it is more efficient to prevent infringement by cutting off the infringer's necessary supplies than to allow infringement and hence damage to take place. It is also more efficient to sue and restrain one supplier than to sue a multiplicity of infringing customers.[34] To be effective, then, this kind of preventive doctrine cannot be dependent on actual infringement downstream. But this model also creates a dilemma – what if the person downstream does not actually infringe, because they are a licensee, have a prior user right,[35] use the invention privately and non-commercially,[36] or enjoy a defence such as a research exemption?[37] In practice, many jurisdictions have a cascade of provisions, depending on the relative likelihood that infringement would occur, and the state of knowledge and intent of the supplier. The outcome will depend upon the importance of the component for the ultimate act of infringement, for example because it is an 'essential means', within the meaning of Article 26 CPC, or because its importance makes it obvious that direct infringement is likely to occur. In the case *Impeller Flow Meter*,[38] the German Federal Supreme Court interpreted 'essential means' broadly, as covering all main features of the claim, or whether the item supplied was specifically adapted for putting the invention into effect or not.

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[31] Chisum on Patents, para 17.02, describes the early US decisions as developing a doctrine of contributory infringement from the 'tort principle of aiding and abetting', citing *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990).

[32] Thus in GRUR Int 1994, 324 (Base plate case), cited by Muir et al at para 21.15, the Austrian Supreme Court held that only an intentional contribution to direct patent infringement would be actionable.

[33] As with the US Patent Act, section 271, eg *Nordberg Mfg Co. v. Jackson Vibrators Inc.*, 153 USPQ 777, (N.D. Ill. 1967). Chisum on Patents, para 17.03 cites US cases where equitable or declaratory relief has been granted.

[34] This rationale is cited by Neils Holder and Josef Schmidt, 'Indirect patent infringement – Latest developments in Germany' (2006) 28(9) EIPR 480.

[35] These would be persons having the right to 'exploit' the invention under Art 26 CPC.

[36] Such a person would be entitled to use the invention without infringing but not to 'exploit' it. See Art 26(3) of the Community Patent Convention.

[37] This class of person is not regarded as having the right to 'exploit' the invention under Art 26 CPC.

[38] Bundesgerichtshof (BGH) (Federal Court of Justice) 4 May 2004, Gewerblicher Rechtsschutz und Uhreberrecht [GRUR] 758, Case No. XZR 48/03 Flugelradzahler, Case XZR 48/03 [2005] IIC 963.

Examples of indirect infringement provisions

Article 26 of the Community Patent Convention reads as follows:

> Prohibition of indirect use of the invention
>
> 1. A Community patent shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply within the territories of the Contracting States a person, other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances, that these means are suitable and intended for putting that invention into effect.
> 2. Paragraph 1 shall not apply to when the means are staple commercial products, except when the third party induces the person supplied to commit acts prohibited by Art 25.[39]
> 3. Persons performing the acts referred to in Art 27(a) to (c)[40] shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1.

Section 101 of Japan's Patent Law No. 121 (as amended 4 June 2004),[41] displays another elegant cascade, from dedicated items to less exclusive supplies, but excluding staple products:

> 101. – The following acts shall be deemed to be an infringement of a patent right or exclusive license:
> (i) in the case of a patent for an invention of product, acts of manufacturing, assigning, etc., or importing or offering for assignment, etc. of, in the course of trade, things to be used exclusively for the manufacture of the product;
> (ii) in the case of a patent for an invention of product, acts of manufacturing, assigning, etc., or importing or offering for assignment, etc. of, in the course of trade, articles to be used for the manufacture of the product (excluding those which are generally distributed in Japan) and indispensable for solving the problems through the invention concerned, knowing that the invention is a patented invention and that the articles are to be used for the working of the invention.

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[39] Ie, direct infringements.

[40] Viz, acts done privately and for non-commercial purposes, acts done for experimental purposes relating to the subject-matter of the invention and extemporaneous pharmacy preparations to prescription. Returning to Art 26 CPC, by implication supply to parties entitled to the other defences of Art 27 (eg, use on Paris Union ships and other means of transport) is protected from infringement, as are supplies to persons with prior user rights.

[41] Translation from http://www.wipo.int/clea/docs_new/pdf/en/jp/jp062en.pdf. In 1977 it appeared that the provisions now appearing as subsections 1 and 3 were little used. Klaus Hoffmann, 'Contributory or Indirect Infringement of Patents', Paper delivered at ordinary general meeting of the Chartered Institute of Patent Attorneys, 20 April 1977. (Report in the archive of Queen Mary Intellectual Property Research Institute, Queen Mary University of London.)

(iii) in the case of a patent for an invention of a process, acts of manufacturing, assigning, etc., or importing or offering for assignment, etc. of, in the course of trade, things to be used exclusively for the working of such invention.
(iv) in the case of a patent for an invention of a process, acts of manufacturing, assigning, etc., or importing or offering for assignment, etc. of, in the course of trade, articles to be used for the use of such process (excluding those which are generally distributed in Japan) and indispensable for solving the problems through the invention concerned, knowing that the invention is a patented invention and that the articles are to be used for the working of the invention.

Australia's Patents Act 1990 has the following provision in section 117[42]

(1) If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.
(2) A reference in subsection (1) to the use of a product by a person is a reference to:
(a) if the product is capable of only one reasonable use, having regard to its nature and design – that use; or
(b) if the product is not a staple commercial product – any use of the product, if the supplier had reason to believe that the person would put it to that use; or
(c) in any case – the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.

'Supply' is further defined[43] as including '(a) supply by way of sale, exchange, lease, hire or hire-purchase and (b) offer to supply (including supply by way of sale, exchange, lease, hire or hire-purchase)'.

35 U.S.C. 271(b) and (c) codify inducement and indirect infringement in US patent law:
(b) Whoever actively induces infringement of a patent shall be liable as an infringer.
(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

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[42] Interpreted in *Bristol-Myers Squibb Co. v. FH Faulding & Co. Ltd.* [2000] FCA 316 as covering the supply of drugs for use in a patented method, including clinical trials.

[43] Schedule 1 of the Patents Act of 1990.

However, another subsection (d) is required to counteract the effect of the patent misuse doctrine on contributory infringement. Despite burgeoning jurisprudence to protect the supplier of staple products, the US courts seem to have felt that contributory infringement was extending the patentee's rights too far. In *Mercoid Corp. v. Mid-Continent Inv Co.*,[44] the Supreme Court applied the doctrine of patent misuse to deny relief to the patentee, Mid-Continent. Mid-Continent had licensed a third party, Minneapolis-Honeywell, to make and sell a patented heating system combining three elements, a stoker, a thermostat and a 'combustion stoker switch'. Royalties were payable on sales of the switch, unpatented in isolation. Mercoid made and sold combustion stoker switches, which had no other use. The patentee sued Mercoid for contributory infringement; Mercoid pleaded patent misuse by way of defence and counter-claimed for relief under anti-trust laws. Assuming other aspects of the infringement case in Mid-Continent's favour, the court applied the doctrine of patent misuse previously developed in relation to unpatented materials to this switch of dedicated design. Thus the doctrine of contributory infringement was seen to be subordinated to anti-trust laws in a manner which cast doubt upon its very existence. Subsection 271(d) reversed the effect of *Mercoid.*

Analysis

In the diagrams that follow for each of the 'unities', those infringements which are normally regarded as direct infringements are central; other activities may be direct infringement, contributory infringement or non-infringing. All, however, affect the patentee's interest to some extent.

We shall assume that the activities concerned are not expressly licensed by the patentee. In some cases a licence must be implied or inferred in order to give business efficacy to a transaction. In jurisdictions like England and Wales, the courts have been particularly ready to imply a licence and may infer authorisation if the patentee does not expressly reserve its rights. This stems from recognition of the broad extent of the patentee's powers over embodiments of the invention. Given the power to control the use of a product, as well as its manufacture and sale, the patentee may sell a patented product *sub modo* – subject to restrictions on use.[45] These could take effect even when the product was seized to satisfy a debt, as in *British Mutoscope and Biograph Co. Ltd. v. Homer*,[46] at least where the distraining party had notice

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[44] 320 US 661, 60 USPQ 21 (1944) rehearing denied, 321 US 802 (1944).

[45] Note that competition law (antitrust) principles or other doctrines relating to contracts in restraint of trade may inhibit this kind of restriction.

[46] [1901] 1 Ch 671.

of the restrictions.[47] Conversely, if a sale is made without communicating restrictions on use, a licence would be inferred to use and resell without restriction. As expressed in *Betts v. Wilmott*,[48] '[w]hen a man has purchased an article he expects to have the control of it, and there must be some clear and explicit agreement to the contrary to justify the vendor in saying that he has not given the purchaser his licence to sell the article, or to use it wherever he pleases as against himself'.

In some cases the implied licence has been held to extend to the export/import of products into another jurisdiction, a situation said to be based on deemed consent and not on a doctrine of international exhaustion.[49] In *Davidoff*,[50] the European Court of Justice expressed concern as to application of deemed consent in cases of parallel imports from outside the European Union and ruled that, as a matter of harmonised European trade mark law:

> Implied consent cannot be inferred:
> . . . from the fact that the trade mark proprietor has transferred the ownership of the products bearing the trade mark without imposing any contractual reservations and that, according to the law governing the contract, the property right transferred includes, in the absence of such reservations, an unlimited right of resale or, at the very least, a right to market the goods subsequently within the EEA [European Economic Area].

Within Europe the concept of regional exhaustion of rights, based on the principles of free movement of goods, is now controlling for goods originating within the EU and EEA.

Unity of time: direct infringement and upstream/downstream activities

Assuming at this stage that all activities take place within a single jurisdiction, where the patent is in force, the scope of infringing activities and their limits will be examined.

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47 In *Roussel-Uclaf SA v. Hockley International Ltd.* [1996] RPC 441, it was held that the limits on a licence would need to be notified to everyone down the chain of commerce.

48 (1871) LR 6 Ch 239 (Lord Hatherley). See, likewise, *Société Anonyme des Manufactures de Glaces v. Tilghman's Patent Sand Blast Co.* (1883) LR 25 Ch D 1 (CA) 9.

49 *National Phonograph Company of Australia, Limited v. Walter T Menck* [1911] AC 336 (Privy Council from Australia). However, in *Canon v. Green Cartridge* [1997] FSR 817 (PC) 822, the court appeared to prefer a doctrine of exhaustion by first sale.

50 Joined Cases C-414, 415, & 416/99 *Zino Davidoff SA v. A&G Imports Ltd.*; *Levi Strauss & Co v. Costco Wholesale UK Ltd.*; *Levi Strauss & Co. v. Tesco Stores Ltd.* (ECJ, 20 November 2001).

Table 16.2 Patent infringement and unity of time

Further upstream activities	Upstream activities	'Core' infringement	Downstream activities	Further downstream activities
Manufacture of components of patented product	Supplying some components for the manufacture of a patented product (or for repair, see column to the right) Supplying all components of patented product Supplying raw materials for manufacture of patented product Supplying product where there is a new use claim Supplying an item which can only be used to infringe Offering to supply the means of infringement Financing the infringer's activity	Making patented product	Selling, offering patented product; Stocking patented product; Using patented product	Repairing patented product
	Offering patented process for use Supplying plant to operate patented process Supplying raw materials for patented process	Using patent process	Selling direct product of patented process	
	Indirect/contributory, direct, or non-infringing	*Direct*	*Direct*	*Direct, if sufficiently extensive*

Making a patented product This category of infringing activity is usually straightforward, subject of course to construction of the claims. 'Making' may occur when a product is repaired so extensively as to amount to re-fabrication.[51] The question of whether making or assembling a complete kit of parts amounts to 'making' is considered below.

Stocking a patented product The verb 'stock' used here suggests a commercial purpose relating to the product itself – stocking for sale, hire, import or export. Such an infringing act does not appear in the US Patent Act – Section 271 proscribes only the unauthorised making, using, offering to sell, or selling of patented inventions. Nor does stocking or possession appear in TRIPs, Article 28(1)(a).

The national patent laws of many European countries follow the Community Patent Convention ('CPC'). This instrument did not receive enough ratifications to come into force but has been highly influential on national laws, as a result of the contemporaneous Resolution on the Adjustment of National Law.[52] Article 25(a) of the CPC states that the patentee's infringement rights include 'making, offering, putting on the market or using a product[53] which is the subject-matter of the patent, or importing or stocking the product for these purposes'.[54]

In the UK even broader phraseology is used in Section 60(1)(a); an unauthorised actor infringes 'where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise'. 'Keeps' has been held not to embrace the activities of a mere carrier, whose economic interest related only to the service of transport,[55] but it would include keeping in the UK for

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[51] As, for example, in *United Wire v. Screen Repair Services (Scotland) Ltd.* [2001] RPC 439 (HL); c.f *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 US 336, 346 (1961). In the Aro cases, the products supplied were replacement hoods for General Motors Cars, some of which were sold with a licence from the patentee and some not. The hoods were described as 'the almost unique case in which the component was hardly suitable for any non-infringing use'. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 US 476, 487–8, 141 USPQ 681 (1964) (Aro II).

[52] See A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993) 13.

[53] Benyamini argues that use of the phrase 'a product' rather than 'the product' gives latitude in claim construction. Ibid 66.

[54] French law, for example, follows this text. See Art L613-3 of the French Intellectual Property code, available online at <http://www.wipo.int/clea/en/index.jsp> accessed 31 January 2008.

[55] *Smith Kline & French Laboratories Ltd. v. RD Harbottle (Mercantile) Ltd.* [1980] RPC 363 (British Airways).

export[56] as well as for disposal within the UK. This overcomes the effect of earlier authority that a defendant in possession of a product would not infringe,[57] unless he could be shown to make use of it. This could be difficult to establish as a matter of evidence. In *McDonald v. Graham*,[58] 'keep' was interpreted to include keeping an item in stock to use for business purposes as and when the occasion arose.

Selling, offering patented product The sale of patented products is where a patentee can expect to profit from her invention. Infringing sales will tend to undermine this opportunity, as the infringer's prices are unburdened by the costs of R&D. As well as losing sales, the patentee may have to reduce her own prices[59] to meet the effect of publicity as to the infringer's prices; this type of loss is particularly difficult to quantify. Most jurisdictions have extended the concept of sale to include an offer to sell. This can be seen from Section 217 of the US Patent Act and is included within the wider terms 'offering, putting on the market' of the CPC and 'disposing of, offering to dispose of' favoured by the UK legislator.[60] This means that infringement is complete before a sale actually occurs. Is it infringement to offer before expiry of a patent to make a sale post-expiry? In *Gerber Garment Technology v. Lectra Systems*,[61] Justice Jacob held that it would not. However, on the facts of that case, the proven offers were deemed infringing, because the parties were indifferent as to when the actual sale should take place. The comment was therefore *obiter dictum*. It was also made in a case where the court was extremely generous to the patentee in terms of damages awarded, and the term 'offer' was given a wide construction, not limited to offers as strictly characterised under contract law. Presumably an offer would infringe even if the ultimate

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56 Or import/export. *Hoffman-La Roche v. Harris Pharmaceuticals* [1977] FSR 200.

57 *British United Shoe Manufacturers v. Collier* (1910) 27 RPC 567 (HL).

58 [1994] RPC 407 (CA).

59 Price erosion may be caused by infringement – *Meters v. Metropolitan Gas* (1911) 28 RPC 157 (CA); *American Braided Wire Co. v. Thomson* (1889) 6 RPC 518 (HL) – but may also be attributed by the court to the activities of non-infringing competitors – *United Horse-Shoe & Nail Co. v. John Stewart & Co.* (1888) LR 13 App Cas 401 (HL). See, also, the US court's robust attitude in *Crystal Semiconductor Corporation v. TriTech Microelectronics International, Inc.* 246 F.3d 1336, 57 USPQ2d 1953 (Fed. Cir. 2001); Roy J Epstein, 'The Market Share Rule with Price Erosion: Patent Infringement Lost Profits Damages after Crystal' 31 AIPLA QJ 1 (2003).

60 Patents Act 1977, section 60(1).

61 [1995] RPC 383 (Patents Court) 411–12; appeal allowed in part at [1997] RPC 443, but this point (*obiter*) was not subject to appeal.

sale be thwarted, although the proper measure of damages might be slight in this cases.

In the UK, 'disposing' appears to include leasing.[62] As a matter of language, disposal would also include destruction; the courts might entertain such an argument if, for example, infringing product were destroyed to defeat the patentee's remedies.

Using patented product This form of infringement is further evidence of the long reach of patent rights. As discussed above, it is this right which potentially gives the patentee continuous control, even where a patented product has been sold on.

Supplying all components of patented product In some jurisdictions, such as Germany, the sale of a complete 'kit of parts' for a patented product was treated as sale of the complete article, even though legislation provided for indirect infringement. A similar approach was taken in England in *Rotocrop International Ltd v. Genbourne Ltd*,[63] where the kit of parts for assembly of a bin was equated for infringement purposes with the patented bin. Benyamini has argued that this approach should be taken generally under the CPC.[64] In the Canadian case of *Faurecia Automotive Seating Canada Ltd v. Lear Corp Canada Ltd*,[65] Judge O'Keefe confirmed that a defendant would not be liable for dealing in components of a patented invention, unless the vendor (alone or in association with another) sold all components, or knowingly induced or procured infringement. The plaintiff's argument that Canadian Law was unsettled on this was rejected, by reference to *Windsurfing International v. Trilantic*.[66]

Supplying some components of patented product As discussed in the Canadian case of *Faurecia Automotive Seating Canada Ltd. v. Lear Corp Canada Ltd.*,[67] noted above, this activity will usually not amount to direct

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62 *Kalman v. PCL Packaging (UK) Ltd.* [1982] FSR 406 (Patents Court); Cornish and Llewelyn also infer that this might be comprised in 'putting on the market' under the CPC paras 6–12.

63 [1982] FSR 241 (Patents Court). In *Lacroix Duarib SA v. Kwikform (UK) Ltd.* [1998] FSR 493 (Patents Court), Justice Laddie declined to depart from this in refusing the defendant's application to strike out the patentee's claims.

64 A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993) 67–77, also commenting on the law in England, Australia, Canada, US, Germany, Belgium, France, Austria and Japan.

65 [2004] 35 CPR (4th) 322 (Federal Court of Canada).

66 (1985) 8 CPR (3d) 241 (Federal Court of Appeal of Canada).

67 [2004] 35 CPR (4th) 322 (Federal Court of Canada).

infringement, unless the missing components are of trivial importance in which case the enquiry collapses into the question whether there has been supply of 'the invention', purposively construed (or an equivalent). If the missing components are of more than trivial importance, taking the enquiry beyond mere construction, then we are in the sphere of contributory or indirect infringement. Here, the issue of whether supply of components ultimately leads to direct infringement is particularly acute. If the components in suit are never assembled into 'the invention', how can it logically be said that there is infringement? Surely to allow patentees such extensive rights is to court abuse of the patent system? Such dilemmas led to the oscillations in US law discussed above[68]. On the other hand, efficiency arguments cited by Holder and others[69] hold good. In European law[70] the logical lacuna is narrowed by requiring that the supply is of a 'means relating to an essential element of the invention' and not a 'staple product'[71], then bridged by resort to notions of intent and knowledge[72]. The wording of provisions such as these may be criticised for complexity, but treading the line between fairness to a patentee and impermissible extension of rights is bound to be difficult. With the right evidence they may be straightforward to apply. For example, *Hazel Grove (Superleague) Ltd v Euro-League Leisure Products Ltd*[73] concerned the refurbishment of patented pool tables. Replacement of the non-trivial 'edge structure' surrounding the flat bed and reassembly of the table by the defendants was regarded as manufacture afresh and therefore infringement. The defendants' supply of 'edge structures' to customers for refurbishing their machines was

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[68] At p 473, citing *Mercoid Corp v Mid-Continent Inv Co* 320 US661, 60 USPQ 21 (1944) and 35 USC 271(d). See, also, *Dawson Chemical Co v Rohm & Haas* 448 US 176; 100 S. Ct 2601 (1980).

[69] Neils Holder, Josef Schmidt, n 34 above. Lionel Bently and Brad Sherman succinctly argue that indirect infringement 'is particularly important where the maker or user is difficult to detect (for example where the manufacture or use occurs in private), or they are not worth suing': *Intellectual Property* (3rd edition, 2009, Oxford, OUP) p 551.

[70] Where the Community Patent Convention is incorporated into national laws, Table 16.1, p 469 above.

[71] Unless there is inducement. This may be established by inference, for example the customising of a sample in *Celem SA v Alcon Electronics PVT Ltd* [2006] EWHC 3042.

[72] Eg UK Patents Act 1977, s 60(2) 'when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect'.

[73] [1995] RPC 529 (Patents County Court). HH Judge Ford had a distinguished career in the European Patent Office (Munich) before returning to England to establish the Patents County Court. In his judgment he cites German jurisprudence, including *Rundfunkübertragungssystem*, 100 BGHZ 249, 87 GRUR 626 (1987); English translation at (1989)19 IIC 811, 813, where it was held that indirect infringement provisions were not to be extended by reference to general notions of complicity.

regarded as indirect infringement, as was supply of staple commercial products (lugs) in the circumstances of the case.

Supplying raw materials for manufacture of patented product There seems little doubt that tangible materials constitute 'means' within the meaning of Article 26 CPC. Benyamini ponders[74] as to whether 'means' can also comprise intangible means, such as know-how, designs, plans or software for the manufacture.

Manufacture of components of patented product/process Japan's contributory infringement provisions[75] extend further upstream from the direct infringement than most others. Section 101 covers the manufacture of means as well as supply or offering to supply. However, it is narrower than the European or American legislation in that staple products are excluded. There seems to be no scope even for inducement where staples are concerned.

Supplying product where there is a new use claim Although the classic European case, *Mobil*,[76] concerns lubricants, many claims to the new use of an old product relate to a second or subsequent medical indication of a pharmaceutical. Assessing infringement involves subjective issues and is therefore difficult;[77] the product itself is not the subject of the patent and it is difficult to prove when it is being used in a particular way, still less supplied for a particular purpose. The Canadian court grasped the nettle in *AB Hassle v. Rhoxalpharma Inc*.[78] A generic manufacturer did not seek marketing approval for the patented new use, but there was evidence the drugs would be so used. The actions and knowledge of practice was sufficient to establish inducement/procurement, intention being irrelevant. In this area Canadian law seems to have applied a less onerous test of inducement than in *Warner-Lambert*.[79] Rather similar facts obtained in the US case of *Warner-Lambert v. Apotex*[80] but the District Court gave summary judgment for the defendant, upheld by the Court of Appeals for the Federal Circuit.

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74 A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993) 198.

75 See text to n 47.

76 Mobil/Friction reducing additive G2/88 [1990] EPOR 73.

77 Lionel Bently and Brad Sherman, *Intellectual Property Law* (OUP, Oxford, 2004) chapter 22, citing Mobil/Friction reducing additive G2/88 [1990] EPOR 73; *Merrell Dow Pharmaceuticals v. HN Norton & Co. Ltd.* [1996] RPC 76 (HL) 82.

78 (2002) 21 CPR (4th) 298, citing *AB Hassle v. Canada* (2001) 16 CPR (4th) 21.

79 See n 27 above.

80 316 F 3d 1348, 65 USPQ2d 1481 (Fed. Cir. 2003).

Offering to supply the means of infringement In jurisdictions where direct infringement is not required,[81] offering the means to infringe may be actionable, as well as actual supply.

Repairing patented product Readers are referred to the distinction made above between making and repair.[82] Insofar as the activity strays beyond permissible repair into infringement, then the next category of activity *Supplying components for repairing patented product* will follow the general rules for contributory infringement.

Using patented process As with a product, use of the process will normally be interpreted as using all the elements of the claim. Substitution of steps by equivalents might still infringe, depending on construction. If all the steps of the process are included for a finite period of time, it does not matter if operation of the process strays periodically outside the claims.[83]

Offering patented process for use/Supplying plant to operate patented process Offering a process for use constitutes direct infringement under the Community Patent Convention Article 25(b) and its daughter laws, despite the component of actual or constructive knowledge. This state of affairs is endorsed by Benyamini[84] in the interests of parity between the infringement provisions for products and processes. It is, however, a less patent-friendly cause of action than infringement of a product claim. 35 USC 271(a) avoids this disparity by referring to 'makes, uses, offers to sell, or sells any patented invention', without distinguishing between product and process inventions.

Supplying raw materials for patented process The Canadian case of *Baker Petrolite Corp v. Canwell Enviro-Industries Ltd.*[85] illustrates this situation. The patent claimed the use of a certain chemical to sweeten natural gas; there was direct infringement by the gas producers and the suppliers of sweetening compound were held liable for inducement.

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81 Eg Germany.

82 See, also, Chapter 17. Horst-Peter Götting and Sven Hetmank.

83 *Hoescht Celanese Corp. v. BP Chemicals Ltd.* [1998] FSR 586. As Bainbridge puts it, 'using the process badly is still using the process for the purposes of infringement'. David Bainbridge, *Intellectual Property* (6th edn, Longman, Harlow, 2007) at 442, n 23, citing *Union Carbide Chemicals v. BP Chemicals Ltd.* [1999] RPC 409.

84 A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993) 136–7.

85 (2001) 13 CPR (4th) 193 (Federal Court, Trial Division of Canada).

The Australian Federal Court in *Collins v. Northern Territory*[86] considered a rather unusual case in which it was alleged that authorities of the Territory had contravened Section 117 of the Patents Act 1990 by granting a statutory licence to enter woodland and remove timber of a particular species, which was identified in a process patent for the production of essential oils. The licence not only permitted but required removal of the trees. The court engaged in an erudite analysis of the principles of contributory infringement and concluded[87] that the licence did indeed constitute 'supply' and that the trees/wood in question were not a 'staple commercial product' in the Territory. The case was remitted to the court below for consideration of further issues.

Selling direct product of patented process This is also a direct form of infringement under CPC Article 25(c). A similar provision appears at Article 64(2) of the European Patent Convention (EPC). In European patent law this provision has led to the demise of product-by-process claims, with the UK's rearguard resistance to abolition being finally quashed by the House of Lords in *Kirin-Amgen Inc. v. Transkaryotic Therapies Inc. (No. 2)*.[88]

Supplying an item which can only be used to infringe The significance of this fact varies from substantive to evidential. Under some laws it may be essential in establishing indirect infringement.

Financing the infringer's activity The Canadian case of *Halford v. Seed Hawk Inc*.[89] involved allegations that the second defendant induced the first defendant to infringe by contributing funds. The court held that the first defendant's non-infringement was determinative, but nor was there inducement, aiding or abetting by the second defendant. An earlier court had discussed this issue in the US: *Tubular Rivet and Stud Co. v. O'Brien*.[90] Judge Lowell made a *reductio ad absurdum*, pointing out that just as a trespasser's cook would not be liable for the tort, nor should an infringer's cook, financier or landlord.

Unity of space: the territorial dimension

These matters overlap to a certain extent with another chapter in this book: Rochelle Dreyfuss's treatment of the enforcement of foreign patents.[91] Comments on this aspect will therefore be brief.

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86 [2007] FCAFC 152.
87 By a majority, French J, dissenting.
88 [2004] UKHL 46; [2005] 1 All ER 667 (HL).
89 (2004) 31 CPR (4th) 434 (Federal Court of Canada).
90 93 F. 200 (CCD Mass 1898), cited in Chisum on Patents, para 17.02.
91 See Chapter 22, Rochelle Dreyfuss.

Table 16.3 Patent infringement and unity of space

Upstream activities	'Core' infringement	Downstream activities
Importing some components of patented product Exporting some components of patented product Importing all components of patented product Exporting all components of patented product	Making patented product in the patent territory	Selling patented product in the patent territory Importing patented product into territory Exporting patented product from patent territory
Offering (where must the offer be made?) patented process for use (where must the use be made?)	Using patent process in the patent territory What if some elements are off-shore?	Importing direct product of patented process into territory Exporting direct product of patented process from the patent territory
Indirect/contributory, direct or non-infringing	*Direct or non-infringing*	*Direct or non-infringing*

Using patent process in the patent territory: What if some elements are off-shore? This question was addressed in the English case of *Menashe Business Mercantile Ltd. v. William Hill Organisation Ltd*.[92] The defendant's customers were supplied with CDs which enabled them to link up with an online interactive gambling network. It was hosted from a server in the Caribbean.[93] In order to succeed in an action for infringement, the claimant had to show that use of the CD involved their customers putting the invention into effect in the UK, that is, operating the patented process. The defendant pleaded that this could not be the case where part of the process was performed out of the jurisdiction. This was tried as a preliminary issue tried upon agreed facts. It was held that since the user was enjoying the benefit of the system in the UK, and it was not important for this use where the server was located, the defendant's contention would be rejected.

Importing patented product into territory In English jurisprudence (at least) the point at which importation takes place and the party liable seem to depend

[92] [2003] 1 WLR 1462, [2003] RPC 31 (CA).
[93] Antigua or Curacao.

upon the moment at which ownership and risk pass under contracts of international trade (*Sabaf v. MFI Furniture Centres*).[94] Thus, if a consignment is shipped Free on Board (FOB) from overseas, the buyer will be deemed the importer rather than the seller. However, in *Radio Controlled Clocks*,[95] a trader in Hong Kong who passed the clocks to a buyer in Hong Kong was also held liable for infringement in Germany.

Importing direct product of patented process into territory The importance of 'direct' and the narrowness of this form of infringement in Europe were demonstrated in *Pioneer Electronics Capital Inc. v. Warner Music Manufacturing*,[96] where the interpolation of further steps between the patented process and the end product ousted infringement.

Offering (to infringe, where must the offer be made?) patented process for use (to infringe, where must the use be made?) It is clear from Article 25 CPC that there is a double jurisdictional requirement. However, in Germany it appears that this double territorial requirement may be circumvented by holding that a near complete operation of a process in Germany can be regarded as direct infringement, if it is passed on for completion of the final stage by a third party which completes the process 'predictably, necessarily and independently of any knowledge of the invention'.[97]

Unity of action: dispersed liability

Many of the activities in Table 16.4 have been considered above, but several of them lead to difficulty where more than one actor is involved. Three areas are of particular interest – different actors using different elements of a patented process, different actors supplying different components of patented product (or different raw materials needed in combination for a patented process), and the repair of a patented product where the repairer is or is not owner of product. This last point is dealt with in another chapter.[98]

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94 [2004] UKHL 45. For similar issues in another jurisdiction, see Case No. 4C 196/2002 [2003] GRUR Int. 561 (Test cassettes case) (Federal Supreme Court (Bundesgericht) of Switzerland), noted at 'Patents: Switzerland: Act on Private International Law, Art.109; Patent Act, Art.66d' (2004) 35 IIC 206.

95 Funkuhr (Mitt 2002, 416).

96 [1997] RPC 757 (CA).

97 Johann Pitz and Gerhard Hermann, 'Territorial Scope of Protection of German Patents' <http://www.buildingipvalue.com> accessed 2 January 2008, characterizing the effect of the case law of the Dusseldorf District Court in BGH GRUR 1977, 250 – Kunststoffhohlprofil; GRUR 1982, 165 – Rigg; LG Dusseldorf, Entscheidungssammlung (Collected Decisions) 1999, 75 – Verglasungklotz; LG Dusseldorf, decision, 7 November 2000, InstGE 1, 26 – Cam-Carpet.

98 See Chapter 17, Horst-Peter Götting and Sven Hetmank.

Table 16.4 Patent infringement and unity of action

Upstream activities	'Core' infringement	Downstream activities	Further downstream activities
Different actors supply different components of patented product Supplying all components of patented product Different actors supplying raw materials for manufacture of patented product	Making patented product	Selling, etc, patented product	Repairing patented product: repairer is or is not owner of product
Offering patented process for use Offering elements of patented process for use Supplying plant to operate patented process Supplying raw materials for patented process	Different actors use elements of patented process	Selling, importing direct product of patented process	May infringe if sufficiently extensive
Indirect/ contributory/direct	Direct/non-infringing	Direct	Non-infringing

Different actors use different elements of patented process Benyamini discusses this problem.[99] He points out that the phrase '*using* the process' may be given a broader meaning than 'carrying out' the process, so might cover the situation where some elements were performed by a third party. The UK case of *Menashe v. William Hill*[100] might be regarded as an example of this type of reasoning. Benyamini also suggests that in the UK and Australia, the concept

[99] A Benyamini, *Patent Infringement in the European Community* (IIC Studies in Industrial Property and Copyright, vol 13, Max Planck Institute, Munich, 1993) 133–4.

[100] [2003] 1 WLR 1462, [2003] RPC 31 (CA), see above at n 92.

of joint infringement by persons sharing a common design[101] could lead to a finding of infringement where different actors operate different parts of a patented process. In the USA, the decision in *BMC Resources Inc. v. Paymentech LP*[102] suggests that the courts may be adopting a stricter approach to this issue than in the past:[103] in order to infringe, either a single party must perform or use each and every step or element of a claimed method or process, or the liable party must control the conduct of the person carrying out the missing steps. The patent claimed a process for processing debit transactions without a PIN number. As there was no evidence that the defendant controlled or directed all of the other steps, judgment was entered for the defendant. Given that there was no direct infringement, a finding of indirect infringement was also ruled out.

Different actors supply different components of patented product or different actors supplying raw materials for manufacture of patented product The *Paymentech* case cited above would suggest that the same outcome should obtain as a matter of US law, in relation to a product claim as to a process/method claim. Again, in UK or Australian law the presence or absence of a common design would probably be determinative.

Conclusion

It is clear that there is considerable variation in the jurisprudence of different countries in drawing the boundaries of infringing activity. This may not always reflect clear differences in approach; so much depends upon the exigencies of procedural law,[104] of the general law on contributory torts and the attitude of the courts to the grant or refusal of judicial remedies.[105] The

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101 Lacking in *CBS v. Amstrad* [1988] 1 AC 1013 (HL). See also *Thompson v. Australian Capital Television Pty Ltd.* (1996) 186 CLR 574 (High Court of Australia).

102 498 F.3d 1373 (Fed. Cir. 2007) (Rader J). The patent claimed a process for processing debit transactions without a PIN.

103 For the expansion and contraction of these doctrines, see Sriranga Veeraraghavan, 'Joint Infringement of Patent Claims: Advice for Patentees' (2006) 23 Santa Clara Computer and High Tech LJ 211. Of course claims may be drafted in such a way that infringement can occur with distributed operation of steps of the process. Veeraraghavan at n 5, citing Mark A Lemley et al, 'Divided Infringement Claims' Stanford Public Law Working Paper No. 100, at 1 (1 December 2004), available at http://ssrn.com/abstract=628241.

104 See Jan Klink, 'Cherry Picking in Cross Border Patent Infringement Actions: A Comparative Overview of German and UK Procedure and Practice' (2004) 26(11) EIPR 493.

105 A subject of harmonisation in the European Union under Directive 2004/48/EC on the enforcement of intellectual property rights. See Peter Meier-Beck,

ease with which infringement may be established depends also upon a court's attitude to claim construction and the role of invalidity in infringement suits.[106] However, there is sufficient variation in infringement rights alone for a patentee to be clear that the extent of her exclusivity may vary significantly from country to country even where the claims are closely aligned. The global harmonisation of patent granting rules, both procedural and substantive, is intrinsically desirable, but it may be futile to harmonise substantive rules on patentability when scope is not constant. Indeed, strict criteria on patentability may offset generous application of the rules on infringement and vice versa.

'Damages for Patent Infringement According to German Law – Basic Principles, Assessment and Enforcement' (2004) 35 IIC 113. For the prior position in France, see Laurence Petit and Christian Le Stanc, 'Sanctions for Patent Infringement in France: Injunctive Relief and Damages' (2002) 24(7) EIPR 353.

[106] This varies widely; for useful background on proposals for unifying procedure in Europe, see Stefan Luginbuehl, 'A Stone's Throw Away from a European Patent Court: The European Patent Litigation Agreement' (2003) 25(6) EIPR 256.

17 The scope of patent protection for spare parts and its extension through other tools of intellectual property

Horst-Peter Götting and Sven Hetmank

1 Introduction

In many cases a patentee is not only interested in controlling primary markets, for example production and distribution of a protected device; his interest also extends to the sector producing spare parts and operating materials that are needed to use the protected invention. This so-called secondary market can be very profitable because it may simply materialize or it can be stimulated with little effort. Therefore, primary products such as vacuum cleaners, ink jet printers or coffee pod machines are often sold at a reduced price to cut the deal on the secondary market. In addition to well-known strategies such as tying, exclusive dealing and creating technical incompatibilities, firms increasingly use intellectual property rights in order to control those secondary markets.

This chapter will give a survey of the scope of patent protection from the perspective of the spare parts market (Section 2). Besides this it may be of interest how patent protection can be supported by other tools of intellectual property and how allocation of secondary markets is dealt with in other branches of intellectual property law (Section 3). This will finally lead to some notes on antitrust law (Section 4) and the question of justification of market foreclosure in spare part markets through intellectual property rights (Section 5).

2 The scope of patent protection for spare parts

It is well known that patent systems all over the world give patentees the right to exclude others from making, using or selling their patented invention. Additionally the patent proprietor is protected in the run-up to a threatened infringement if and when a person supplies or offers to supply components of the patented invention to the infringer (contributory infringement).[1]

But it is just as well known that the purchaser of a patented product has the same rights as any owner of personal property, including the right to use, to

[1] S. 10 of the German Patent Act; s. 60(2) Patents Act 1977; 35 USC s. 271 (c).

repair or to sell. Thus, when sold, patented products 'become the private individual property of the purchasers, and are no longer specifically protected by the patent laws'.[2] According to this so called 'doctrine of exhaustion' the patent proprietor must derive all revenue from the first sale and cannot control the future disposition of the article originally sold. However, the rights of ownership do not include the right to construct an essentially new product based on the template of the original, for the right to make the article remains with the patentee. With regard to patented items that have been put into circulation by the patentee, the distinction between permitted and prohibited activities has been distilled into the terms 'repair' and 'reconstruction' and has been an issue in many court decisions, of which only a few are mentioned below.

Germany

In the *Impeller Flow Meter* decision[3] the German Federal Supreme Court had to decide on a patent infringement concerning an impeller flow meter used to measure water consumption.

The impeller flow meter consists of a casing and a removable measuring capsule. Only the inclined flow impinging area in the casing was new and inventive, whereas the measuring capsules were known. The defendant had supplied those measuring capsules adapted to be arranged in the plaintiff's casing and to be used therein.

The German Federal Supreme Court held that the distinction between a permissible repair and a prohibited remaking depends on whether the measures taken by the purchaser preserve the identity of the purchased patented product or are the equivalent of the creation of a new product according to the invention. The court made this distinction by taking into account the particular nature of the subject matter of the invention and the balancing of the conflicting interests. Accordingly the replacement of expendable parts that usually have to be replaced – possibly several times – during the expected working life of a machine, as a rule, would not constitute a new making of the product. However, the court stated that the situation may be different if this part embodies essential elements of the invention. If the replacement of this particular part implements the technical or commercial benefit of the invention a second time, it could not be said that the patent holder has already drawn the benefits from the invention to which he is entitled as a result of the initial putting into circulation of the device as a whole. The German Federal Supreme Court argued that the advantages of the invention – like the turbulence-free

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2 *Mitchell v. Hawley*, 83 US (16 Wall.) 544, 548 (1872).

3 German Federal Supreme Court (Bundesgerichtshof) – *Impeller Flow Meter (Flügelradzähler)*, 4 May 2004, X ZR 48/03, IIC 2005, 963–71 (English translation).

activation of the measuring cup or the reduction of calcification – are implemented on and in the measuring capsule even if they are caused by the inclined flow impinging area outside the capsule. Therefore the supplying of the capsules would constitute contributory infringement.

This decision was partially understood to the effect that if an invention obviously aims at creating a need for spare parts, the replacement of spare parts inherently realizes the economic advantage of the patent und thus constituted reconstruction.[4]

However, in a recent decision[5] the German Federal Supreme Court clarified that the patentee's commercial interest in stretching the patent protection over the demand for replacement parts is not worth protecting. Otherwise the commercial advantage of distributing a mass product would be allocated to the patentee, although the invention does not have any effect on this product.

The decision concerns a patented pipette system consisting of a mounting portion and an adapted syringe which usually has to be replaced after usage. The defendant supplied those adapted syringes and expressly indicated that his syringes would fit the pipette system of the plaintiff.

The Federal Supreme Court held that the technical advantages of the invention – to make the locking and unlocking of the syringe easier – has no direct effect on the physical characteristics and the functionality of the syringe itself. Therefore the syringe would not embody essential elements of the plaintiff's invention. The weighing of facts and interests by the Federal Supreme Court therefore resulted in non-infringement by supplying the adapted syringes.

Great Britain

Among other decisions the House of Lords had to deal with reconstruction and repair in *United Wire v. Screen Repair Services*.[6] The court held that the reconditioning of sifting screens used to recycle drilling fluid in the offshore oil-drilling industry constituted reconstruction and not repair: 'The product ceased to exist when the meshes were removed and the frame stripped down to the bare metal. What remained at that stage was merely an important component, a skeleton or chassis, from which a new screen could be made.'

USA

The leading US Supreme Court case on this issue is *Aro Manufacturing Co. v. Convertible Top Replacement* from 1961.[7] The plaintiff owned a patent on a

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4 Higher Regional Court (OLG) Düsseldorf, 17 November 2005, 2 U 35/04.

5 German Federal Supreme Court (Bundesgerichtshof), 27 February 2007, X ZR 38/06.

6 *United Wire Ltd. v. Screen Repair Services*, 20 July 2000, 4 All ER 353 (HL).

7 *Aro Mfg. Co. v. Convertible Top Co.*, 365 US 336 (1961).

convertible top mechanism for an automobile. The fabric element usually had to be replaced every three years due to wear and tear. The Supreme Court held that the sale of the replacement fabrics constituted permissible repair because 'mere replacement of individual unpatented parts, one at a time, is no more than the lawful right to the owner to repair his property'. Furthermore the court stated that 'no element, not itself separately patented, that constitutes one of the elements of a combination patent is entitled to patent monopoly, however essential it may be to the patented combination and no matter how costly or difficult the replacement may be'.

Citing the *Aro* case in *Jazz Photo Corp v. International Trade Commission*,[8] the Federal Circuit held that replacing the unpatented film of a used disposable camera by inserting a new film and film container, resetting the film counter, and resealing the broken case is not reconstruction. Taking into consideration the remaining useful capacity of the article and the nature and role of the replaced parts in achieving that useful capacity, the court stated that 'the remanufacturing processes simply reuse the original components, such that there is no issue of replacing parts that were separately patented. If the claimed component is not replaced, but simply is reused, this component is neither repaired nor reconstructed'.

In contrast, in *Sandvik Aktiebolag v. E.J. Co.*[9] the Federal Circuit Court of Appeals held that re-tipping a patented drill by removing the worn tip and brazing a new piece of carbide onto the drill shank constituted patent infringement because the drills were spent before re-tipping and the nature of the re-tipping work was 'more like reconstruction than repair'. The court explained that it was not dispositive that the cutting tip was the novel feature of the invention, but that prohibited reconstruction occurred because a new article was made after the patented article, 'viewed as a whole, has become spent'. Furthermore, the tip was not a part that had to be replaced periodically throughout the useful life of the whole drill and there was no substantial industry or market in replacement tips or re-tipping.[10]

Summary

These few decisions show that in Germany as well as in Great Britain and the USA the line between permissible repair and impermissible reconstruction is difficult to draw. While under US law reconstruction does not hinge upon the

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[8] *Jazz Photo Corporation et al. v. US International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001).

[9] *Sandvik Aktiebolag v. E.J. Co.*, 121 F.3d 669 (Fed. Cir. 1997).

[10] Additional cases are collected and analyzed in Janis. 'A Tale of the Apocryphal Axe: Repair, Reconstruction, and the Implied License in Intellectual Property Law', 58 Md. L. Rev. (1999) 423.

importance of the replaced part but whether the patented product was spent, for the German Federal Supreme Court it is decisive whether this part embodies essential elements of the invention. Besides, these decisions also suggest that in Germany, in the USA as well as in other countries, the patentee is generally not protected against any kind of offering or delivering of spare parts by patent law.

3 Extension of patent protection through other tools of intellectual property

Copyright law

In most of the cases a replacement part will not be protected by copyright because of the absence of originality and creativity. Moreover, copyright protection will not be extended to aesthetic elements that are inextricably interwoven with the utilitarian aspect of the product.

A noteworthy case in UK law is that of *British Leyland Motor Corp. Ltd. v. Armstrong Patents Co. Ltd.*[11] The defendants were component manufacturers who, without the consent or licence of the plaintiffs, copied and sold exhaust systems in competition with the plaintiffs. The defendants, without having seen the design drawings, were able to copy the shape and dimensions of the plaintiffs' spare parts by means of a process known as 'reverse engineering'.

The House of Lords held that this reverse engineering infringed the plaintiffs' copyright in the design drawings for their exhaust system, because the case law had extended artistic copyright to protect the shapes of various types of purely functional objects, even though the object itself might not be capable of being patented and its design might not be capable of being registered.

This decision did not remain undisputed. Under copyright law it is necessary to strictly distinguish between form and content and between copying and free use of information.

In the end, however, the court stated that the plaintiffs' copyright is subject to the right of the car owners 'to repair their cars in the most economical way possible and for that purpose to have access to a free market in spare parts'. Therefore, by analogy with the principle of non-derogation from grant, the plaintiffs were not entitled to use their copyright to maintain a monopoly in the supply of spare parts.[12]

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[11] *British Leyland Motor Corp. Ltd. & al. v. Armstrong Patents Co. Ltd. & al.* [1986] AC 577.

[12] Supra note 11, at 644.

Design law

Differing from US law, industrial designs are the subject of their own legal regime in countries within the European Union. Pursuant to sections 4(2) and 8(1) of the Community Design Regulation,[13] component parts are protected if they remain visible during normal use of the complex product by the end user and in themselves fulfill the requirements as to novelty and individual character.[14]

An important aspect of European design law is the controversial debate on introducing a repair clause whereby the manufacturing and distribution of spare parts for repair purposes by others would be admissible.[15] The commission argued that the sole purpose of design protection is to grant exclusive rights to the appearance of a product, but not a monopoly over the product as such. Protecting designs for which there is no practical alternative would lead in fact to a product monopoly which would come close to an abuse of the design regime and otherwise competition would be eliminated.[16]

Trademark law

The controlling of secondary markets is also a matter of discussion in trademark law.

Firstly, the protection of the shape of goods through trademark law has gained an increasing significance. This is due to both the recognition of three-dimensional marks by the European Trademark Directive and the European community trademark as well as to the recognition of trade dress protection in the USA.[17] Nevertheless, in most of the cases the protection should fail for lack of distinctiveness and non-functionality. In those cases courts often stressed that secondary markets should not be monopolized by trademark law because the rationale for the refusal of registration is to prevent trademark protection from granting its proprietor a monopoly on technical solutions or functional characteristics of a product which a user is likely to seek in the products of competitors.[18]

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13 See also: s. 3(1) No. 1 German Design Act; s. 213(3) British Copyright, Designs and Patents Act 1988.

14 For US design patent see 35 USC s. 171.

15 COM/2004/0582 final: 'Protection as a design shall not exist for a design which constitutes a component part of a complex product used within the meaning of Article 12(1) of this Directive, for the purpose of the repair of that complex product so as to restore its original appearance'.

16 COM/2004/0582 final.

17 *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 US 763 (1992).

18 German Federal Patent Court, 13 October 2004, 28 W (pat) 98/00.

Another question is whether a third party supplier is allowed to use a trademark of a primary market in order to refer to the compatibility of his replacement part with the original product. The European Trademark Directive and the European Trademark Acts as well as the US Lenham Act therefore have a special rule. According to section 23(3) of the German Trademark Act, the proprietor of a trademark or commercial designation shall not be entitled to prohibit third parties from using the trademark or commercial designation where it is necessary to indicate the intended purpose of a product or service, in particular as accessories or spare parts, provided such use is not contrary to accepted principles of morality. In a recent decision[19] the European Court of Justice held that such use of a trademark is necessary when it constitutes the only means of providing the public with comprehensible and complete information in order to preserve the undistorted system of competition in the market for that product. Similar to this, in the USA the use of another's trademark is allowed if (1) the product or service in question is not readily identifiable without use of the trademark, if (2) only so much of the trademark is used as is reasonably necessary to identify the product or service and if (3) the use does nothing that would, in conjunction with the trademark, suggest sponsorship or endorsement by the trademark holder.[20]

A third problem is the refilling or reuse of replacement parts such as ink cartridges for printers or gas cylinders for soda machines by third party suppliers. The German Federal Supreme Court recently held that the refilling does not constitute a trademark infringement if consumers recognize that the content of the cylinders does not emanate from the initial producer of the bottle.[21]

Competition law

Last but not least, a further possible method of gaining protection in secondary markets is by competition law.

Germany Pursuant to section 4(9) of the German Unfair Competition Act, anyone who offers an imitation of products or performances by a competitor acts unfairly, particularly if he exploits or damages the reputation of the imitated goods or services in an inappropriate way. Apart from these criteria there is one central requirement that has to be met in order to qualify for additional protection by unfair competition law: the product has to show a certain

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19 Case C-228/03 *Gillette Company/LA-Laboratories* (ECJ, 17 March 2005).

20 *New Kids on the Block v. News America Publishing, Inc.*, 971 F.2d 302 (1992).

21 German Federal Supreme Court – *SodaStream*, 24 June 2004, I ZR 44/02.

degree of originality. However, the relationship between protection through unfair competition law and protection through specific intellectual property rights in Germany has not been finally settled.

In almost all jurisdictions much emphasis is placed on the principle of freedom of imitation. The arguments that are put forward for the foundation of this principle are straightforward, conclusive and persuasive: unfair competition may not undermine the prerequisites and the underlying policy of intellectual property rights. An additional protection by unfair competition law may not set aside the hurdles that are established by intellectual property rights and it may not extend their duration, which is an essential limitation on the monopoly conferred upon the right holder.

Although the German Supreme Court always emphasizes that the principle of the 'freedom of imitation' applies outside the exclusive intellectual property rights, in practice there has been a tendency for imitation to be regarded as an element of unfairness as such. The change of attitude towards the imitation of products is reflected in the decisions concerning the *LEGO* cases. In two judgments from 1964[22] and 1992[23] the Federal Supreme Court granted LEGO toy bricks an additional protection under unfair competition law. In a recent decision[24] the court reversed this ruling and held that after a period of 45 years since their introduction on the market such an additional protection was not justified any longer, especially because the competitor had informed consumers in an appropriate way, that his toy bricks were not identical to LEGO toy bricks.

The discussion recently reached a preliminary climax in a decision of the German Federal Supreme Court where a jeans manufacturer sought to prevent the sale of imitations based on supplementary protection of achievement under competition law. Although both a registered design right and a three dimensional trademark had been possible, the claimant failed to apply for such protection.

The Federal Supreme Court held that the existing time-limited protection for an unregistered community design 'does not affect the claim, without an a priori time limit, based on supplementary protection of achievement under competition law on the grounds of an avoidable deception as to origin'. Therefore the Court confirmed the supplementary protection of achievement under competition law as independent of intellectual property rights.

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22 German Federal Supreme Court, 6 November 1963, Ib ZR 37/62.
23 German Federal Supreme Court, 7 May 1992, I ZR 163/90.
24 German Federal Supreme Court, 13 December 2005, ZR 30/02.

France In France the law of unfair competition is based on the general clause of article 1382 of the Code Civil that reads as follows: 'Tout fait quelconque de l'homme, qui cause à autrui un dommage, oblige celui par la faute duquel il est arrivé, à le réparer'.

According to the case law that has evolved under article 1382 of the Code Civil the exploitation of the performances of a competitor can be prohibited under the category of the so-called 'concurrence parasitaire'. The conditions for this aspect of unfairness are satisfied if there is either exploitation of reputation or a misappropriation of a valuable innovation or at least of a considerable investment, without a corresponding performance by the imitator. However, according to a recent court decision, in the absence of any exclusive right, marketing products identical to those distributed by a competitor is not wrongful.[25] Thus, a copy of a shape unprotected by intellectual property may be justified in order to make one product compatible with another. For instance, the French Supreme Court dismissed an action for unfair competition because the similarity existing between the references of producers was justified by the interchangeable character of their products and there was neither risk of confusion nor unfair canvassing of clients.[26]

England In contrast, British Common Law follows a different approach under the headline of 'passing off'.

The basic principle of passing off has been characterized in one short general proposition:

> no man may pass off his goods as those of another. More specifically, it may be expressed in terms of the elements which the plaintiff in such an action has to prove in order to succeed. These are three in number. First, he must establish a good will or reputation . . . such that the get-up is recognized by the public as distinctive specifically of the plaintiff's goods or services. Secondly, he must demonstrate a misrepresentation by the defendant to the public . . . leading or likely to lead the public to believe that goods or services offered by him are the goods or services of the plaintiff . . . Thirdly, he must demonstrate that he suffers or . . . that he is likely to suffer, damage by reason of the erroneous belief engendered by the defendant's misrepresentation that the source of the defendant's goods or services is the same as the source of those offered by the plaintiff.[27]

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[25] *See* J. Schmidt Szalewski (2005), 'Recent French Cases on Unfair Competition', in A. Ohly et al. (eds), *Festschrift für Gerhard Schricker zum 70*, Geburtstag, Munich: C.H. Beck, pp. 751–61.

[26] Schmidt Szalewski, supra note 25, at 759.

[27] *Reckitt & Colman Products Ltd. v. Borden Inc.* [1990] RPC 341 at 499.

In implementing these principles it was held that a company enjoyed protection against the imitation of life-size plastic lemons which were used as a container for lemon juice.[28] In another case concerning the imitation of cushions for wheelchairs, the action for passing off failed because the judge said that the burden of proof with regard to the indication of the source of origin by the appearance of the product was so high that the claimant could not overcome this hurdle.[29]

To avoid misunderstanding it has to be noted however, that beyond this, the English law has never taken the step from 'misrepresentation' to 'misappropriation'. It all depends on the question whether the appearance of a product has gained such a degree of reputation that its imitation causes deception.

USA In the United States the so-called 'doctrine of misappropriation' originates in the 1918 Supreme Court case *International News Service v. Associated Press*.[30] The defendant was copying news stories from the plaintiff's bulletin boards on the East Coast and transmitted the fresh news to its own Midwestern and West Coast members who could then print the news at the same time as the competing plaintiffs or, in some instances, earlier.

The Supreme Court found that the plaintiff had a quasi property right in the news and without the revenues derived from this exclusive presentation of the news the plaintiff or other news services would not have sufficient incentive to continue performing their services. Though the decision ceased to have controlling authority in 1938, as a result of *Erie v. Tompkins*,[31] the doctrine has survived, but seems to be of a very limited practical importance.[32]

4 Antitrust law

Finally a survey on foreclosure of secondary markets for spare parts cannot be given without addressing the issue of antitrust law where problems range from tying contracts to the question under which conditions the use of intellectual property rights may constitute an abuse of a dominant position.

Germany and Europe

A first example may again be the foreclosure of the market for refilling gas

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28 Supra note 27; see also W. Cornish and D. Llewelyn, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights*, London: Sweet & Maxwell (5th ed. 2003), p. 597.

29 *Hodgkinson & Corby Ltd. v. Wards Mobility Ltd.* [1995] FSR 169.

30 *International News Service v. Associated Press*, 248 US 215 (1918).

31 *Erie Railroad Co. v. Tompkins*, 304 US 64 (1938).

32 See also *Board of Trade of the City of Chicago v. Dow Jones & Co., Inc.*, 98 Ill. 2d 109 (1983).

cylinders for soda machines. The German Federal Cartel Office held that hindering competing suppliers from refilling gas cartridges by tying contracts and claiming its ownership of the cartridges represents an abusive use of a dominant position and is prohibited. Otherwise the enforcement of the refilling would not be based on competition on the merits.[33]

However the problem is aggravated when intellectual property is involved. In the recent European *Microsoft* case[34] the European Commission held that Microsoft abused its dominant position to conquer the market for work group server operating systems by creating compatibility problems as a leveraging strategy. Microsoft invoked the existence of intellectual property rights such as copyright and patent right – a question which the Commission left open. The Commission, however, referred to the case law, and the *Magill* case in particular, which authorizes compulsory licensing of intellectual property rights in exceptional circumstances.

What those exceptional circumstances could be – particularly in cases of foreclosure of secondary markets – is still in dispute and is a matter raised in the discussion paper of the European Commission on the application of Article 82 of the Treaty to Exclusionary Abuses.[35]

Therein, the Commission states that a supplier may be found to have a dominant position if he restricts the possibilities of other suppliers in the aftermarket. The Commission presumes that it is abusive for the dominant company to reserve the aftermarket for itself by tying or refusal to deal. The refusal to deal may involve not only a refusal to supply information or spare parts needed to provide products or services in the aftermarket but also a refusal to license intellectual property rights.[36] As an example of an abusive refusal, the Commission gives the following conditions which all have to be fulfilled: (1) the behavior can be properly characterized as a refusal to supply; (2) the refusing undertaking is dominant; (3) the input is indispensable; (4) the refusal is likely to have a negative effect on competition; (5) the refusal is not objectively justified and furthermore (6) the refusal to grant a license prevents the development of the market for which the license is an indispensable input, to the detriment of consumers. According to the discussion paper,

> this may only be the case if the undertaking which requests the license does not intend to limit itself essentially to duplicating the goods or services already offered on this market by the owner of the IPR, but intends to produce new goods or

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33 German Federal Cartel Office, 9 February 2006, B 3 39-03.

34 European Commission, 24 March 2004, COMP/C-3/37.792 – *Microsoft*.

35 European Commission, 19 December 2005, Discussion paper on the application of Article 82 of the Treaty to Exclusionary Abuses.

36 European Commission, supra note 23, para. 264.

services not offered by the owner of the right and for which there is a potential consumer demand.[37]

USA

In the USA courts have become rather skeptical about invoking antitrust law in cases concerning a tying arrangement or a refusal to deal, which is reflected in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*.[38] The Supreme Court found that insufficient assistance by a monopolist in the provision of service to rivals is not a recognized antitrust claim: compelling such firms to share the source of their advantage 'may lessen the incentive for the monopolist, the rival, or both to invest in . . . economically beneficial facilities' and 'also requires antitrust courts to act as central planners . . . a role for which they are ill-suited'. Although *Trinko* was not an intellectual property case, it can be assumed that similar logic could apply to intellectual property rights.

In another recent decision, *Illinois Tool Works Inc. v. Independent Ink, Inc.*,[39] the Supreme Court ruled that there is not a presumption of market power when the sale of a patented product is conditional on the sale of a second product in a tying arrangement. Illinois Tool sold a patented ink system on condition that purchasers only *re*fill the system with its unpatented ink and not put another manufacturer's ink into the cartridges. Refusing to establish even a rebuttable presumption of market power, the Court held that 'many tying arrangements, even those involving patents and requirements ties, are fully consistent with a free, competitive market'.

5 Conclusion

Having given this short survey, the concluding question of justification of market foreclosure in replacement part markets through intellectual property rights arises. Or in other words: under which precise circumstances are secondary markets to be allocated to the provider of a primary product and when should secondary markets be opened to third parties to market their products and services?

As it turns out, the problem of drawing the line is a matter of discussion in all branches of intellectual property law with similar constellations and arguments. The problem may arise when it comes to the scope of protection of an intellectual property right as well as in cases of accumulation of different rights or in unfair competition and antitrust matters.

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[37] European Commission, supra note 23, para. 239.

[38] *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 US 398 (2004).

[39] *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 US 28 (2006).

The initial point has to be the freedom of competition. Like every restriction of competition, the allocation of a certain market needs to be justified. The arguments that are usually put forward in cases of intellectual property rights, however, do not always suit the particularities of secondary markets.

Intellectual property is largely based on the idea of property protection, and shall be granted as a reward for intellectual effort. While this should not mean that an owner of an intellectual property right shall be granted the control over all possibilities to exploit the object of intellectual property protection, a further crucial requirement for exclusive rights is not met with regard to spare parts: intellectual property shall stimulate competition by providing incentives for investments and innovation. The granting of an all-embracing intellectual property protection for spare parts, however, will eliminate competition and therefore the incentive for investments and innovation on that market. Though one may stress that there would still be an incentive for even higher leaps of innovation on the primary market, those effects are difficult to predict. A broader exclusive right does not necessarily translate into more innovation. The complete absence of any competition in a market is therefore more an argument in favour of delimiting the scope of intellectual property protection, be it by an extensive interpretation of the term ‘repair’, by establishing legal exceptions or by antitrust law.

18 The exhaustion of patent owners' rights in the European Community

Thomas Hays

Introduction

Until the United Kingdom Patents Act of 1977 – 'until' meaning exiting from the first reasoned judicial notice of the existance of patents in the fifteenth century – patents at common law were choses in action.[1] Choses are things, rights which had to be defended through bringing legal or equitable proceeding rather than by the physical possession of them. Such rights, like the right to work a patent, import protected goods and offer the goods for sale, are exclusory: they are the right to exclude others from doing the acts reserved to the patent owner.

A licence is an expression of a patent owner's giving permission to another to exercise one or more of the exclusory rights, following the general form: 'If you, the licensee, do any of the acts listed herein and pay me, the licensor, for the privilege, I promise not to sue you for infringing my patent'. The existence of a licence is a defence to an allegation of infringement.

Patent rights cover the commercialization of goods made to a patent up to the point the particular rights are waived. For example, a patent owner has the right to exclude products made to the patent from importation into a country where the patent is in force. The exclusory right is exercised by repelling the imports. The patent owner can continue to repell imports, over and over, every time the goods are presented at customs.

An exclusory right can be waived by allowing another to perform one or more of the exclusive acts pursuant to a licence, either expressed or implied. When a right is waived, such as when a patent owner lets otherwise-protected goods come into a country without objection, then he loses the

[1] Section 30(1) of the 1977 Patents Act specifically addresses this historic categorization of intellectual-property rights as being choses in action by redefining a patent owner's interest as being 'personal property (without being a thing in action)'. Similar changes in the property status of trade marks were made under the United Kingdom Trade Marks Act of 1994, § 22, defining registered trade marks as 'personal property', and under the Trademark Regulation, Art. 16. This change in the status of intellectual-property rights is consistent across common-law jurisdictions.

ability to interfere with the further commercialization of the goods. His patent rights as to those goods are said to have been 'exhausted'.[2]

There is a difference between the exhaustion of rights and their unenforceability. With the exhaustion of a right, there is nothing left of the right to enforce; whereas in a case of a right that has become unenforceable, there is something to enforce, at least technically, but some superior legal impediment prevents that enforcement. Such an impediment may be created by the competition laws or some other legally imposed limitation on a right owner's ability to enforce his rights, such as the free movement of goods requirements in the Treaty of Rome.[3]

The difference is analogous to the condition of the fuel tank of an automobile. When the fuel runs out, the tank is empty and the fuel supply is exhausted. Alternatively, the unenforceability of a right is like having plenty of fuel in the tank but with a blocked fuel line so that no fuel reaches the engine. The effects on the engine and driver are the same but the causes differ.

This analogy breaks down in practice because of the intangible nature of patent rights. A driver must accept the tangible nature of petrol: he either has fuel or he does not. No amount of assertion to the contrary is going to make an engine run if there is no fuel in the tank. A patent right on the other hand, regardless of what section 30 of the United Kingdom Patents Act says,[4] exists to the extent a court says it does. In the absence of a firm judgment to the contrary, a patent proprietor can make various arguments as to why he has an enforceable right when, in fact, he does not. The assertion itself, understood by others as coveying the implicit threat of infringement penalties, including in some circumstances in some jurisdictions criminal sanctions,[5] may be

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[2] One will often see this terminology phrased in the reverse, such that right exhaustion is expressed as following the exercise of an intellectual-property right. This puts a positive spin on patent rights, which do not convey any positive entitlements for their owners. Ownership of a patent does not entitle one to do anything, including making the invention. Patent ownership only allows the owner to stop others from doing certain acts without the owner's permission.

[3] Now contained in the Consolidated Versions of the Treaty on European Union and of the Treaty Establishing the European Community (2002), [2002] OJ C325/1, hereafter, 'the EC Treaty'. Article 28 [ex 30] provides: 'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'. Article 29 [ex 34] provides: 'Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States'.

[4] See the discussion in note 1 above.

[5] E.g., Directive 2004/48/EC of the European Parliament and of the Council on 209 April 2004 on the enforcement of intellectual property rights [2004] OJ L195/16; Proposal for a European Parliament and Council Directive on the criminal measures aimed at ensuring the enforcement of intellectual property rights, COM(2005) 276 final; Proposal for a Council Framework Decision to strengthen the criminal law framework to combat intellectual property offences, SEC(2005) 848.

enough to deter others from exploiting the invention. With patents, one can defy legal reality and run on empty.

Because the exhaustion (or not) of a patent right is in the final analysis determined by the courts, the issue of exhaustion takes on the characteristics of the issues involved in the unenforceability of rights. A patent proprietor with exhausted rights can argue the rights are not exhausted, seeking their enforcement against another until a court declares the exhaustion to have occurred, the declared exhaustion being in the mind of the proprietor nothing more than a judicially imposed obstacle preventing him from enforcing his otherwise valid patent monopoly. In practice, the exhaustion of rights and the unenforceability of rights operate in the same way, producing similar commercial effects, and so are treated together here.

Free movement

Another distinct but related issue is that of the free movement of goods within a unitary, common market. In the Common Market,[6] it is a requirement of Articles 28 and 29 of the EC Treaty that goods be unimpeded in their circulation between Member States, subject to a few exceptions contained in Article 30 for, amongst other things, the exploitation of industrial and commercial property,[7] and in Article 295, protecting national systems of property ownership. Intellectual property rights and patents in particular, being forms of industrial property that are for the most part national in character, pose serious impediments to interstate trade. A patent owner in one country could invoke his exclusive rights to repel the importation of goods he sold in another country, thereby creating internal barriers where the goal of market integration requires there to be none.

To address this problem, the European Court of Justice decision in *Deutsche Grammophon*[8] created a quasi-doctrine centred upon what the court

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[6] Taken together with the additional members of the European Free Trade Association, the European Union, the successor to the original Common Market, is part of the largest trading bloc in the world, the European Economic Area.

[7] EC Treaty, note 3 above, Art. 30 [ex 36]:

> The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of . . . the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

[8] *Deutsche Grammophon, GmbH v. Metro- SB- Großmärkte, GmbH & Co. KG*, Case 78/70, [1971] ECR 487, [1971] CMLR 631. Hereafter '*Deutsche Grammophon*'. See also *Musik-Vertrieb Membran, GmbH and K-Tel International v. GEMA*, Cases 55 & 57/80, [1981] ECR 147, [1981] 2 CMLR 44.

classified as the 'specific object' of intellectual-property rights. The exercise of those rights that restrict intra-market trade would be permitted only if the exercise is part of the specific object of the rights themselves,[9] as opposed to an exercise that is the use of intellectual property to achieve some other commercial aim. The court defined the specific object of a patent right as being to allow the patent proprietor 'the exclusive right to utilise their invention with a view to the manufacture and first putting into circulation of industrial products, . . . as well as the right to oppose any infringement'.[10] Thus, a patent affords its owner the opportunity to be the first to exploit the commercial potential of protected products primarily by excluding others from doing so before him. The court was willing to tolerate the disruption to the free movement of goods that results from the exploitation of patent rights only to the extent that the exploitation can be categorized as part of the specific object of the right.[11]

In another case involving Centrafarm,[12] this time based on trade marks, the Court of Justice changed the terminology. It said that the 'specific subject matter' of an intellectual-property right is to guarantee to the owner the right to put his goods into circulation for the first time and to protect the right owner from infringement.[13] This change in wording was procedural rather than substantive. In *Allen & Hanburys v. Generics*,[14] the specific subject matter of a patent was said to involve the three ways a patent owner might use an invention: manufacturing products, putting them into circulation for the first time, and opposing others who might try to usurp these rights.[15] The first two components are extensions of the previously existing definition of the patent

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9 *Deutsche Grammophon*, note 8 above, para. 11.

10 *Centrafarm, BV and Adriaan de Peijper v. Sterling Drug, Inc.*, Case 15/74, [1974] ECR 1147, [1974] 2 CMLR 480, para. 9.

11 *Id*, para. 8; *Centrafarm, BV and Adriaan de Peijper v. Winthrop, BV*, Case 16/74, [1974] ECR 1183, [1974] 2 CMLR 480, para. 7. The ECJ used identical language in both cases:

> In so far as it makes an exception to one of the fundamental principles of the Common Market, Article 36 [now Art. 30] allows derogations to the free movement of goods only to the extent that such derogations are justified for the protection of the rights which constitute the specific object of such property.

12 This time *Centrafarm, BV v. American Home Products Corp.*, Case 3/78, [1978] ECR 1823, [1979] 1 CMLR 326.

13 *Id*, paras 10–13.

14 Case 434/85, [1988] ECR 1245, [1988] 1 CMLR 701.

15 *Id.*, paras 11–13; *Re Compulsory Patent Licenses: E.C. Commission v. United Kingdom*, Case C-30-90, [1992] 2 CMLR 709, para. 21. *See also* the companion case, *E.C. Commission v. Italy*, Case C-235/89, [1989] OJ C-228/10, [1992] 2 CMLR 709.

right, in that the previous definition did not encompass a right or privilege to work a patent or to put goods into circulation for the first time. Rather, the rights of a patent owner were limited to dealing in the exclusive interest represented by the patent: to exclude others from infringing that interest, to license or to assign that interest to others, to grant or mortgage the interest, and the like.[16]

The Community position then, for the sake of preserving the integrity of the internal market, is that a first sale of protected goods anywhere in the market by the right owner or with his consent exhausts the right of the owner to claim that the further commercialization of the goods – by sale or rental – is an infringement, regardless of the legal status of the goods in question at any time in the future under the intellectual-property laws of individual Member States.[17] The Court of Justice has affirmed that the right to a first sale and the right to repel infringements are co-extensive, co-equal, and mutually exclusive when the concepts are applied to the same goods. This solution is attractive in its symmetry and its commercial usefulness, but it is essentially a market-integration solution, rather than one derived from the nature of intellectual property – from its specific subject matter.

Waiver of the right

The definition of the specific subject matter of patents as a negative right would condense the patent monopoly to being the right to exclude others from

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[16] It is interesting that the Patents Act of 1977 makes no mention of any affirmative right conferred by a patent apart from those listed here. Even in the case of the co-ownership of a patent, which the Act addresses at § 36, the rights of one co-owner relative to the other are 'to do in respect of the invention concerned, for his own benefit and without the consent of or the need to account to the other . . . any act which would apart from this subsection . . . amount to an infringement of the patent concerned'. This section gives each co-owner an exemption from liability for infringement relative to the other owners, rather than an affirmative right to work the patented invention.

[17] *Freistaat Bayern (Bavaria) v. Eurim-Pharm, GmbH*, Case C-347/89, [1991] 1 ECR 1747, [1993] 1 CMLR 616, para. 36; *B.A.T. Cigaretten-Fabriken, GmbH v. E. C. Commission*, Case 35/83, [1985] ECR 363, [1985] 2 CMLR 470, para. 35; *Prantl (Criminal Proceedings Against)*, Case 16/83, [1984] ECR 1299, [1985] 2 CMLR 238; *Gesellschaft zur Verwertung von Leistungsschutzrechten, mbH v. E. C. Commission*, Case 7/82, [1983] E.C.R. 483, [1983] 3 CMLR 645, para. 39; *Dansk Supermarked, A/S v. Imerco, A/S*, Case 58/80, [1981] ECR 181, [1981] 3 CMLR 590, para. 12. In agreement: *Hilti, AG v. E. C. Commission*, Case T-30/89, [1991] ECR II-1439, [1992] 4 CMLR 16, para. 81; *The Community v. Arthur Bell and Sons, Ltd*, Decision 78/696/EEC, [1978] OJ L235/15, [1978] 3 CMLR 298, para. 27; *ISA France Sàrl and M. Visser's Industrie & Handelsonderneming- VIHO, BV v. Tipp-EX Vertieb, GmbH & Co. KG*, Decision 87/406/EEC, [1987] OJ L222/1, [1989] 4 CMLR 425.

doing the thing claimed in the patent. In commercial terms, this is expressed as the right to exclude anyone and everyone from working the patent to put goods into circulation for the first time. If goods that would in the first instance be patent protected are encountered in commerce, the only question would be that of whether the goods were counterfeit or not. Because the patent owner or his licensee would be seen as the only first source of legitimate goods, waiver of the exclusionary right could be presumed if the goods are legitimate.[18] This presumption is consistent with the placement of the initial burden of proof in infringement cases, where the onus is on the plaintiff patent owner.[19] If the goods in question are counterfeits, the negative, exclusionary right could then be exercised by the patent owner. If the right is defined as an affirmative right, or as a collection of affirmative rights that must be exhausted before the patent owner loses control over the goods, patent-based barriers to trade could be erected anywhere the goods enter the stream of commerce. Phrased as a negative right, the specific subject matter of patents permits only one entry-way in respect of legitimate, non-counterfeit goods; that is, from the patent owner. Consider the following example

> The owner of a pharmaceutical patent opposes the intra-market circulation of goods lawfully manufactured in a Member State under a compulsory license, claiming patent infringement in a second Member State.[20]

Under the negative definition of the patent right, the analysis would be as shown in Figure 18.1.

Interstate trade is affected by the patent owner's infringement action. The right being exercised, which affects trade, is an intellectual-property right, exempt as to its specific subject matter under Article 30 from the free-movement requirements. The infringement suit was the patent owner's first

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[18] This arrangement would solve the ongoing problems as to the certainty of the application of the exhaustion principle in respect of goods in circulation in the market, as is discussed below.

[19] Symmetry is attractive but not compelling. The ECJ could assign a burden of proof to be applied in parallel-importation cases. *See, e.g.*, *Handels-og Kontorfunktionærernes Forbund i Danmark v. Dansk Arbejdsgiverforening, ex parte Danfoss A/S*, Case 109/88, [1989] ECR 3199, [1991] 1 CMLR 8; *Zino Davidoff, SA v. A&G Imports, Ltd; Levi Strauss & Co. and Levi Strauss (UK) Ltd v. Tesco Stores, Tesco plc, and Costco Wholesale UK Ltd*, Joined Cases C-415–416/99, [2001] ECR I-8691, [2002] 1 CMLR 1, [2002] ETMR 9, para. 54, where the burden was placed on merchants to prove that they have the appropriate consent to resell goods bearing intellectual-property protection in the EEA.

[20] These were the facts in *Pharmon, BV v. Hoechst, AG*, Case 19/84, [1985] ECR 2281, [1985] 3 CMLR 775.

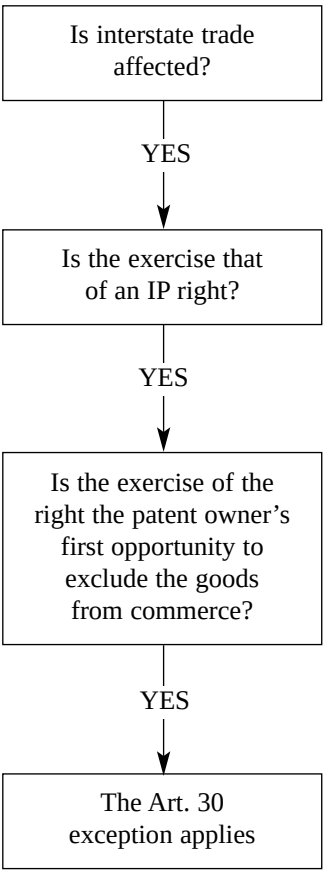

Figure 18.1 Applying the Article 30 exception

opportunity to exclude the goods from the stream of commerce. Thus, the hindrance to interstate trade is justified by the Article 30 exception.[21]

[21] Superficially at odds with this analysis is the Court of Justice's decision in *Musik-Vertrieb v. GEMA*, note 8 above. There the court said that a copyright owner could not use moral rights to prevent the importation into one Member State of goods lawfully marketed in another Member State. This case can be distinguished from the example on the basis of the use of moral rights, but more importantly it can be distinguished on the fact that in *Musik-Vertrieb* the copyright owner had an opportunity to stop the sale of the goods in the first Member State but voluntarily gave licences instead. In the example, the patent owner did not have an opportunity to prevent production in the first Member State.

Application of the Article 30 exception

Under the usual analysis, where the nature of the patent right is undefined, a court would have to ask whether the exercise of a patent right in one Member State to exclude goods manufactured and marketed under a compulsory licence in another Member State is sufficiently close to the core of the specific subject matter of patents generally to allow an exception and whether, under the facts of the particular case, the patent owner was exhibiting some ulterior motive.[22] This analysis also causes a court to consider the place of national compulsory-licensing laws in the conflict. The result is the same,[23] but the analysis that follows without the negative definition is less certain and more prone to unrelated influences. It should make no difference if a patent owner had the most anti-integration, pro-segregation motivation.

Article 30 would allow the exercise of the patent right to exclude the protected product, unless it was a disguised means of market segregation or of arbitrary discrimination. There are two ways to view this limitation. The first is to consider it as applying to the national legislation itself. Rephrased under this interpretation, the Article 30 limitation would read: The exercise of industrial and commercial property rights is exempt from the prohibitions of Articles 28 and 29, unless the national laws upon which the exercise is based are disguised restrictions on trade or are arbitrarily discriminatory.

Several factors argue against this interpretation. First, it contemplates some twist in national intellectual-property laws which makes those laws unusually restrictive or discriminatory. Such laws could be created, for example a national law that requires all patent-protected goods originating outside of the national territory to be registered with a national administrative agency.[24] In the context of the internal market, such measures would be unnecessarily restrictive and arbitrary, but they are not part of the national intellectual-property rights. They are administrative trade regulations. The invoking of the trade law, as opposed to the exercise of the intellectual-property right, would not qualify for an Article 30 exemption for the protection of industrial or commercial property. Litigation involving parallel imports often has caught up

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22 The ulterior motives of interest in this regard are those prohibited under the competition laws based on EC Treaty Arts 81 and 82.

23 *See Merck & Co., Inc. v. Stephar, BV and Petrus Staphanus Exler*, Case 187/80, [1981] ECR 2063, [1981] 3 CMLR 463, paras 10–11, which was reconsidered at length in *Merck & Co., Inc. v. Primecrown, Ltd*, Joined cases C-267 & 268/95, [1996] ECR I-6287, [1997] 1 CMLR 83, paras 36–54, and, though the court distinguished this later case because of the facts involved, the free-movement principles expressed in *Merck v. Stephar* were affirmed.

24 As in the case of *Officer van Justitie v. Adriaan de Peijper*, Case 104/75, [1976] ECR 613, [1976] 2 CMLR 271.

ancillary national intellectual-property rights and has been resolved at the Community level in relation to some offending national trade regulation that had little to do with the exclusive rights themselves.[25]

Similarly, a national legislature could adopt some new, isolationist form of intellectual-property protection, any exercise of which would prejudice intra-market trade. It is reasonable, however, to interpret Article 30 as contemplating those forms of industrial and commercial property[26] in existence at the time the article was drafted and those variations on protection that amount to new applications of an existing form of intellectual property to new subject matter.[27] If a new right created by national legislation were inherently restrictive and discriminatory, it is arguable that the Article 30 derogation would not be available for its application because the new right would not come within the definition of either industrial or commercial property contemplated by the article. This is to say that it would not matter what was the legislature's intention or the right owner's motivation. The free movement provisions of Articles 28 and 29 would apply and no derogation under Article 30 would be available.

Another argument against the interpretation that the prohibitions of the latter portion of Article 30 apply to legislative intentions comes from the structure of the article itself. The article permits derogations from the free-movement provisions where necessary to protect intellectual-property rights. It restricts the availability of the derogation where it would facilitate a disguised means of restricting or discriminating against foreign trade. It is not the nature of national legislation that the latter portion of Article 30 questions but, rather, the intentions of the exerciser.

The alternative view of the article – that it allows derogations from the free-movement-of-goods requirement where necessary to protect patent rights unless the patent owner is exercising his rights to achieve a prohibited purpose

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[25] *See, e.g., Bristol-Myers Squibb v. Paranova, SA*, Joined Cases C-427/93, 429/93 and 436/93, [1996] ECR I-3457, [1997] 1 CMLR 1151; *Eurim-Pharm Arzneimittal, GmbH v. Beirersdorf, AG*, Cases C-71–73/94, [1996] ECR I-3603, [1997] 1 CMLR 1222; *Phytheron Int'l, SA v. Jean Bourbon, SA*, Case C-352/95, [1997] ECR I-1729, [1997] 3 CMLR 199; *Verband Sozialier Wettbewerb, eV v. Clinique Laboratoires SNC and Estée Lauder Cosmetics, GmbH*, Case C-315/92, [1994] 1 ECR 317; *EMI Electrola, GmbH v. Patricia Im- und Export Verwaltungsgesellschaft, mbH and others*, Case 341/87, [1989] ECR 92, [1989] 2 CMLR 413.

[26] Interpreted in *Deutsche Grammophon*, note 8 above, para. 11, as including copyright and, by extension, its variations.

[27] An example of a new application of previously existing intellectual-property protection is that of patent protection applied to computer software. The broad category of patent protection has been in existence in approximately its modern form for over two hundred years. Only the application to software is new.

– is the correct interpretation.[28] Because the subjective question about a patent owner's motivation is asked, the article indicates a broad, ill-defined concept of patent rights, such that an otherwise-permitted exercise of the right, when combined with a wrongful motivation or intention, can result in a prohibited act.

Consider the preceding example with the addition of a motive on the part of the patent owner to maintain higher prices in the market where he works his patent and that being the reason he objects to the importation of the products from the second Member State. The patent proprietor's prohibited purpose of market segregation would eliminate the availability of Article 30 derogation for what, in other circumstances, would be a permitted restriction on the movement of goods within the market. The opposite conclusion would result if patent rights were defined as negative, exclusionary rights. Because there would not be a subjective component in the application of the Article 30 derogation, it would not matter what was the intention behind the exercise of the patent right.[29]

The specific subject matter of patents

The Community has not harmonized national patent rights through legislation. There are many possible reasons for this, and perhaps the most likely is the fact that the Community patent has been waiting in the wings, considered to

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[28] This, implicitly, appears to be the interpretation used by the ECJ. *See Centrafarm v. American Home Products*, note 12 above.

[29] In partial agreement with the position given in the text above, Odudu, *Interpreting Article 81(1): Object as Subjective Intention* [2001] 26 E.L. Rev. 60, 63, where the author points out:

> Subjective intention is thought neither necessary [n]or sufficient to satisfy the object requirement. Thus, Faull and Nikpay write 'the determination of whether an agreement has as its object the restriction of competition is not dependent on the subjective intent of the parties . . . the courts and the Commission cannot find that a particular agreement has as its object a restriction on competition merely because the aim of the parties is to restrict competition' and Bellamy and Child write 'it is unnecessary to investigate the parties subjective intention.'

Odudu's position is that the mental state of an anti-competitive undertaking, what he describes as the actor's subjective intention, is relevant to a determination of whether of not the behavior is in fact anti-competitive. This interpretation would allow for the exception to the operation of Article 81(1) asserted by P. Jakobsen and M. Borberg in *The Concept of Agreement in Article 81 E.C.: On the Manufacturers' Right to Prevent Parallel Trade Within the European Community* [2002] ECLR 127, that inadvertent restrictions on parallel importation should not be actionable.

be a near certainty for quick enactment, for the past thirty years.[30] There would be little need to expend the considerable effort of negotiating the harmonization of national substantive and procedural patent laws if an efficient Community-wide alternative was going to be available and expected to do for patenting what the Trade Mark Regulation[31] did for the marks. Community-wide rights would replace multiple regimes of national rights. Languages, and therefore costs, remain the barrier to the Community patent.[32]

Parallel importation can take credit for generating much of the litigation through which the Court of Justice has partially harmonized national patent laws, particularly in the context of the parallel trade in pharmaceuticals.[33] For example, in *Merck v. Stephar*[34] the court held that the substance of a patent right is to give its owner the right to put products made with the patent into circulation for the first time.[35] This includes situations where a patent owner or his licensee sells goods in a Member State with weak or no patent protection for the particular products or processes involved.[36] In *Allen & Hanburys v. Generics*,[37] the court defined the specific subject matter of patents as including

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[30] While waiting to come into force, the Community Patent Convention (Luxembourg) of 1975 metamorphosed into a proposal to create a Community patent. *See* 'Proposal of a Council Regulation on the Community Patent', COM(2000) 412 final Brussels (1 August 2000).

[31] Council Regulation (EC 40/94) of 20 December 1993, on the Community trade mark [1994] OJ L11/1, 14 January 1994.

[32] The cost of providing translations of patent specifications in the official national languages of all the EC Member States doubles the cost of the patent-application process. *See* http://www.epo.org/patents/Grant-procedure/Filing-an-application/costs-and-fees.html (last visited 31 August 2007).

[33] *Boehringer Ingelheim, KG v. Swingard, Ltd*, Case C-143/00, [2002] 2 CMLR 26 (ECJ), [2002] ETMR 78, [2002] 3 WLR 1697; *Merck Sharp & Dohme, GmbH v. Paranova Pharmazuetika Handels, GmbH*, Case C-443/99, [2002] All ER (EC) 581 (ECJ), [2002] ETMR 80, [2002] 3 WLR 1697; *Bayer, AG v. EC Commission*, Case T-41/96, [2000] ECR II-33083, [2001] All ER (EC) 1; *Eurim-Pharm Arzeimittal, GmbH v. Beirersdorf, AG and others*, Cases 71–72/94, [1996] ECR I-3603, [1997] 1 CMLR 1222; *Generics (UK) Ltd. and Harris Pharmaceuticals, Ltd. v. Smith Kline and French Laboratories, Ltd.*, Case C-191/90, [1992] ECR I-5335, [1993] 1 CMLR 89; *Officier van Justitie v. Sandoz, BV*, Case 174/82, [1983] ECR 2445, [1984] 3 CMLR 43; *Hoffmann-La Roche & Co., AG and Hoffmann-La Roche, AG v. Centrafarm Vertriebsgellschaft Pharmazeuticsher Erzeugnisse, mbH*, Case 102/77, [1978] ECR 1139, [1978] 3 CMLR 217.

[34] *Merck v. Stephar*, note 23 above.

[35] *Id.*, paras 9–11.

[36] *Id.*, para. 14; *Merck & Co., Inc. and others v. Primecrown, Ltd and others*, Joined cases C-267 & 268/95, [1996] ECR I-6285, [1997] 1 CMLR 83, paras 36–47.

[37] *Allen & Hanburys, Ltd. v. Generics (UK) Ltd.*, Case 434/85, [1988] ECR 1245, [1988] 1 CMLR 701.

the exclusive rights of the patent owner to use the patent with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or through licensees, and to oppose infringements.[38]

The court has weakened the right to oppose infringement in cases where compulsory licensing would have been available. In compulsory licensing cases, including those cases where the national territory in question is being supplied by parallel importation rather than from someone working the patent directly within that territory, the right to receive fair amounts of royalties from the unauthorized but otherwise legal exploitation of the patent right is substituted for the right to oppose infringements.[39] The court's concern in this regard has been for overcoming the national bias in compulsory-licensing laws favouring the working of a patent in the country granting the compulsory licence. Where the shortage of the patented product or process in the national territory, such as would justify a compulsory licence, can be supplied by parallel trade from another Member State, even one where there is not equivalent patent protection, then the theoretical availability of a compulsory licence is stretched to cover intra-market parallel imports, subject to a fair return for the patent owner. This forced substitution of royalty payments for the right to control the working of a patent has parallels in copyright law in the context of the *Magill* case.[40]

Patents and the competition laws

The courts and the Commission have held many uses of patent rights, particularly in the context of licensing, not to be part of the specific subject matter of patents and, therefore, subject to being limited by the free-movement provisions or the competition laws where they restrict intra-market trade. For example, the granting of non-exclusive licences, while otherwise permitted, may not include an obligation by the patent holder to restrict his right to grant other licences, even where the existing licensees have gone to the trouble and expense of improving on the invention. A contractual limitation on the patent holder not to grant additional licences is not part of the specific subject matter of patents.[41] The appropriate method, according to the Commission, of adjusting the relationship between a patent proprietor and his licensees is through adjustments in royalty levels, rather than through limitations on core rights.

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38 *Id*., paras 11–13.

39 *Id*., paras 11–14, 17, 19, 21–3, 27.

40 *Radio Telefis Eireann v. E.C. Commission*, Case T-69/89, [1991] ECR II-485, [1991] 4 CMLR 586.

41 *Zuid-Nederlandsche Bronbemaling en Grondboringen, BV v. Heidemaaatschappij Beheer, NV*, Case 75/570/EEC, [1975] OJ L249/27, [1975] 2 CMLR D67, para. 18.

The problem is that of territorial restrictions being enforced through patents to the detriment of competition. Licences of exclusive rights to manufacture and sell protected products in specific national territories restrict competition under Article 81[42] and are not a matter relating to the existence of the specific subject matter of the patents involved.[43] The same applies to bans on licensees exporting protected products to any national territory in which the patent proprietor has either licensed or assigned equivalent patent rights to third parties.[44] Other prohibited clauses in patent licensing agreements include:

1. No-challenge clauses,
2. Non-compete clauses,
3. Requirement to continue paying royalties on the invention after expiration of the patent,
4. Grant-back clauses,
5. Requirements to pay royalties on products not covered by the patent being licensed,[45]
6. Tying clauses requiring licensees to use other products sold by the licensor,
7. Clauses requiring licensees not to deal in products sold by competitors,
8. Requirements basing royalty payments on the net selling price of the licensed invention combined with other products,
9. Clauses requiring manufacture only in a certain location,

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[42] EC Treaty, note 3 above, Art. 81(1):

> The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:
> (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
> (b) limit or control production, markets, technical development, or investment;
> (c) share markets or sources of supply;
> (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
> (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the subject of such contracts.

[43] *Association des Ouvriers en Instruments de Precision (AOIP) v. Beyrard*, Decision 76/29/EEC, [1976] OJ L6/13, [1976] 1 CMLR D14, para. 20.

[44] *Id.*, para. 22.

[45] *Id.*, paras 24–31.

10. Clauses requiring that a notice indicating the protected status be affixed to products other than the invention,
11. Obligations requiring licensees to acknowledge certain words as trade marks of the licensor,
12. Obligations not to sell to other dealers.[46]

Patent licenses must be restricted in scope to the invention being licensed and to the term of the patent that protects it; they must not restrict the licensee's ability to trade with other suppliers or customers or to sell outside of the national territory where he is located. This is because it is not part of the specific subject matter of patent rights to enable a licensor to prohibit his licensees from exporting to other countries or to protect one licensee from competition from other licensees, particularly after the expiration of the patent.[47] Any exclusivity that may be granted for the patent under a licence agreement must be limited to the existence and validity of the patent, and Article 81 prohibits attempts at extensions of licensing restrictions beyond the patent's expiry date.[48] Licensees must retain their freedom of action in all respects, except for those actions that directly involved the working of the licensed invention and putting products made from it onto the market for the first time. This freedom of retained action includes the right to challenge the validity of the patent itself.[49]

The exhaustion of patent rights

Trade marks were the first national rights subject to judicially-imposed Community-wide exhaustion.[50] However, many goods are capable of benefiting from more than one form of intellectual-property protection. Where trade marks could not be used to repel parallel imports after a first sale, other intellectual-property rights in those same goods could be used, unless the exhaustion doctrine was extended to other exclusive rights as well as marks. This has been done, either through judicial interpretations of the needs of the free-movement requirements of Articles 28–30, or through Community legislation

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[46] *IMA, AG and others v. Windsurfing International, Inc. and others*, Decision 83/400/EEC, [1983] OJ L229/1, [1984] 1 CMLR 1, paras 73–166.

[47] *Velcro, SA v. Aplix, SA*, Case 85/410/EEC, [1985] OJ L233/22, [1989] 4 CMLR 157, para. 50.

[48] *Id*., para. 64.

[49] *Windsurfing International, Inc. v. EC Commission*, Case 193/83, [1986] ECR 611, [1986] 3 CMLR 489, para. 93; *Re the Agreements of the Davidson Rubber Comp.*, Decision 65/426/EEC, [1965] JO 2581/65, [1965] CMLR 242.

[50] Rights in semiconductors, under Council Directive 87/54/EEC, were the first rights subject to legislatively imposed first-sale exhaustion.

or both. In varying degrees, all intellectual-property rights are exhausted by a consensual sale in the EEA of the underlying products. The occurrence of this right exhaustion frees goods from the control of the intellectual-property owners and makes the goods available for parallel trade.

Patent rights, like rights in other forms of intellectual property, are exhausted when goods formerly subject to those rights are sold in the market with the consent of the patent owner. Any patent-based control over those goods ceases. A patent owner and his licensees may have preferences for where and under what conditions invention-based goods are sold, but once a sale has taken place, the patent owner's ability to enforce those preferences ends. The goods may be transported throughout the market and resold without the approval of the patent owner. Exceptions to this general exhaustion rule exist where goods, protected by patent rights in one Member State, are manufactured by a third party in another Member State where either patent protection is not available or is subject to a compulsory licence. In such circumstances, a patent proprietor can invoke his patent rights where they exist to oppose the parallel trade in the otherwise legitimate goods originally put onto the market without his consent.[51] However, because of the market-partitioning effect of this use of national rights to block the movement of legitimate goods, the patent owner would have to be particularly careful to avoid competition violations where his commercial position is dominant in the relevant product markets.[52]

These considerations apply to mechanical, electrical and chemical patents, including pharmaceuticals. They do not necessarily apply to biological patents, particularly in self-replicating materials. These are discussed below and that discussion is applicable to patents in new varieties of animals.[53]

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[51] *Thetford Corp. and another v. Fiamma, SpA and others*, Case 35/87, [1988] ECR 3785, [1988] 3 CMLR 549, paras 24–5.

[52] See *Hilti, AG v. EC Commission*, Case T-30/99, [1991] ECR II-1439, [1992] 4 CMLR 16, para. 99.

[53] An early example of a new animal variety is provided by the *Onco-mouse* case, [1991] EPOR 525. There, a mouse's genetics were modified to make the mouse susceptible to particular types of cancer for cancer research purposes. The exhaustion of rights would have to be limited, in approximately the same sense that exhaustion in respect of the rental rights in videotapes is limited, because two sales of modified, patent-protected mice, assuming they could breed, would be enough to defeat the patent owner's ability to realize a fair reward from the commercialization of the invention. *See also* Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, [1998] OJ L213/13, 30 July 1998. Hereafter 'the Biotechnology Directive'. Implemented in UK law by Patents Regulations 2000, SI 2000/2037.

Biotechnology patents

The Biotechnology Directive[54] provides in Article 8 that the patent protection for new plants and animals, including microbes and sub-cellular components, covers the biological material created through the propagation or multiplication of the invention. Article 10 of the directive contains a limited exhaustion-of-rights scheme. Patent rights 'shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent'. This is limited by the requirement that the secondary propagation be incidental to the use of the invention as sold, and the second generation of biological material resulting from the incidental propagation cannot be reused for propagating a third generation.

Article 11 contains derogations of protection in respect of biotechnology patents in favour of farmers similar to that in Council Regulation 2100/94 Article 14. The sale of patent-protected animal and plant material to a farmer implies a right for the farmer to propagate the material in the course of his own farming operation. He may sell the results of that propagation, but not for commercial reproduction activity. This means, for example, that a farmer could use a patented animal invention to make more of the protected animal, and sell the results of that reproduction, but the farmer could not offer the patented material directly to the public for commercial stud purposes. These exceptions create a limited supply of legitimate goods for parallel trade from otherwise unauthorized sources.

National rights and parallel imports

As a result of their market-partitioning potential, all types of national intellectual-property rights have been subjected, to a greater or lesser degree, to the judicial defining of their specific subject matters, such that the permissible exercises of the rights can be distinguished from the impermissible, free-movement-restricting exercises. These specific subject matters are all approximately the same: the right to put goods protected by the right onto the market for the first time and to prevent infringements. In the case of copyrights and patents in the context of EC Treaty Article 82,[55] the specific subject matter has been modified to allow for the substitution of the right to receive royalty payments, where overcoming a restraint on the development of a downstream industry requires, in the opinion of the Commission, a compulsory licence of the right from a commercially dominant intellectual-property owner.[56] The

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54 Note 53 above.

55 EC Treaty, note 3 above, Art. 82, prohibiting the abuse of a dominant position.

56 As in *Magill*, note 40 above.

definition of the specific subject matter of patent rights is critical to the application of that right to parallel trade, because, unless any opposition to parallel imports can be grounded in the specific subject matter of the exclusive rights involved, attempts at blocking parallel importation will be classified as prohibited, anti-competitive conduct.

Conclusion

A different approach to right exhaustion, drawn from the nature of patents, is possible. The right of a patent owner to a first sale of his protected goods in the market – if any sale of the goods by anyone is indeed legal – is subordinate to the right to oppose infringements. Intellectual-property rights give their owners the right to exclude others from doing the thing described by the right, such as working a patent or selling goods under a particular mark, but do not confer upon the intellectual-property owner any truly affirmative rights.[57] A patent owner can exclude from the market all examples of a protected product by not exploiting the patent and by exercising his right to prevent all others from doing so. Even where there would be repercussions under some national laws for a patent owner from the non-exploitation of his patent,[58] the Court of Justice has recognized that the owner's exclusionary right still exists within the market as a whole.[59]

Apart from compulsory-licensing provisions in respect of patents and non-use provisions in respect of trade marks,[60] there is no duty imposed on the owner of intellectual property to engage in the commercial activity encompassed by the right. A copyright owner could refuse to publish; a trade-mark owner could decide not to affix his mark to certain goods; a patent owner could decide not to work a patent. In essence, the exclusionary right of intellectual property ownership allows the owner to exclude everyone, including himself, from the market.

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[57] Thus, a patent for an illegal product does not confer on the patent proprietor the right to manufacture the product. An invalid patent does not confer the right to infringe another's legitimate patent for the same invention.

[58] The non-use provisions discussed in *Allen & Hanburys v. Generics*, note 14 above; *Generics and Harris Pharmaceuticals v. Smith Kline and French Laboratories*, note 33 above; *Pharmon v. Hoechst* note 20 above; *Re Compulsory Patent Licenses: Commission v. United Kingdom*, note 15 above; *Re Compulsory Patent Licenses: Commission v. Italy*, note 15 above; *Volvo, AB v. Erik Veng (UK) Ltd.*, Case 238/87, [1988] ECR 6211, [1989] 4 CMLR 122.

[59] *Thetford Corp. and another v. Fiamma, SpA and others*, Case 35/87, [1988] ECR 3585, [1988] 3 CMLR 549, paras 24–5. Compare *Allen & Hanburys v. Generics*, note 14 above, paras 14, 17, 19, 21–3, 27, 31.

[60] *Simmenthal v. S. A. Import*, 1 ZR 291/91, 22 April 1994, Federal Court of Justice, Germany, [1994] GRUR 512.

The exclusory right can be waived. When a patent owner exploits his invention or licenses someone else to do it and allows the resultant goods to be put into circulation, he waives his right to exclude those goods from the market. According to the Court of Justice, there is no affirmative right in the goods on the part of a patent owner or his licensee after the goods are in the stream of commerce. A way of viewing this is to recognize that no such right ever existed. All patent ownership confers is the right to exclude the goods from the market in the first instance.[61]

Once a patent owner has consented to the injection of the patent goods into the stream of commerce, the exclusionary right is waived as to those particular goods.[62] The effect is the same as that of the exhaustion doctrine adopted by the Court of Justice, the difference being conceptual. The waiver-of-rights construction is based on the negative nature of intellectual-property rights, while the exhaustion-of-rights doctrine as formulated by the Community courts is derived from the needs of market integration under the free-movement requirements[63] combined with a policy decision to give intellectual-property owners a quasi-independent right to a first sale of the underlying goods.

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[61] This is not necessarily the case under all the national intellectual property laws of the Member States since joining the EU. *See, e.g.*, United Kingdom Copyright, Designs and Patents Act of 1988; French Law on the Intellectual Property Code of 1992 in respect of copyright.

[62] An estoppel-like principle would apply to an attempt by a patent owner to re-assert the exclusionary right as to goods put onto the market with his consent. The owner would be estopped from asserting the rights he had previously forfeited.

[63] This is an aspect of European Union law, not of the exhaustion-of-rights doctrine at the national or international level, which has recently been explained as follows: 'The underlying policy of the first sale doctrine as adopted by the courts was to give effect to the common law rule against restraints on the alienation of tangible property'. United States Copyright Office, *Study Required by Section 104 of the Digital Millennium Copyright Act, Executive Summary* (2001) p. xix. The same was true under British law, prior to the Trademarks Directive, [1989] OJ L40/1. *See Betts v. Wilmott*, (1871) LR 6 Ch. App. 239, LC.

19 Enabling research or unfair competition? *De jure* and *de facto* research use exceptions in major technology countries

*Sean O'Connor**

Introduction

To start with the basics, the unauthorized making, using, or selling of patented inventions is normally an infringement of exclusive patent rights. Further, in many countries, the unauthorized import of products embodying the patented invention, or resulting from the patented process, is also an infringement of exclusive patent rights. Thus, absent an exception, all research which either experiments *on* or *with* patented inventions – including both non-commercial research by universities or non-profits and product-oriented research and development (R&D) by commercial firms – constitutes patent infringement.

However, rigid enforcement of patent rights without any exception for research activities may hinder basic science research as well as socially useful follow-on innovation in any given industry. In some cases, the absence of a research exception may give the pioneer patent holder a *de facto* patent term extension as his competitors will not be able to engage in the pre-market R&D often required to create a saleable product that can be brought to market as soon as the pioneer patent expires. This is most apparent in the case of pharmaceutical regulatory regimes where generic or follow-on drug manufacturers cannot even begin research to satisfy a regulatory agency's approval process until the pioneer patent expires: the pioneer manufacturer then gets a *de facto* patent term extension for the time it takes the generic manufacturer to obtain regulatory approval to market its version of the drug. Even outside of this scenario, pioneer patents often give their holders a substantial head start in the marketplace to develop crucial brand strength and valuable trademarks. With

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recent research demonstrating the correlation of successful branding and consumers' differing sensory perceptions of what is arguably the same product (but one is packaged under the famous brand while the other is not),[1] this head start in the marketplace may be more valuable than ever. To some extent, of course, this is still just part of the reward/incentive carrot of the patent system that is designed to call forth new innovations.

At the same time, the patent system should not be heavily biased towards rewarding pioneer innovators at the expense of follow-on innovators, or even basic science researchers for that matter. While it may be true that the pioneer innovator – the inventor of a bold new class of products or services – should reap a greater reward than the 'mere' follow-on innovator who tweaks and enhances the pioneer innovator's invention, the patent system should not unduly hinder the ability of follow-on innovators to improve upon the pioneer invention. Further, a patent system may benefit the overall economy more if it limits itself to exclusive rights in specific *products* or *services* rather than entire nascent *technologies* or *industries*. This was, in part, the logic behind seminal U.S. patent cases such as *O'Reilly v. Morse*[2] in which the Supreme Court invalidated one of Samuel F.B. Morse's issued patent claims for the telegraph:

> It is impossible to misunderstand the extent of this claim. [Morse] claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance.
>
> If this claim can be maintained, it matters not by what process of machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of electric or galvanic current, without using any part of the process or combination set forth in [Morse's] specification. His invention may be less complicated – less liable to get out of order – less expensive in construction, and in its operation. But yet if it is covered by this patent, the inventor could not use it, nor the public have the benefit of it without permission of this patentee.[3]

Even properly limited pioneer patents on inventions such as the telegraph could hinder important basic science research to the extent that they are construed to prohibit non-commercial research *on* the invention itself for classic scientific purposes such as replication of results and derivation of further scientific principles of laws of nature. Thus, another important early U.S.

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1 *See, e.g.*, Associated Press, 'McDonalds Marketing Tricks Tots' Taste Buds', MSNBC (August 6, 2007), *available at* http://www.msnbc.msn.com/id/20148538/.

2 56 U.S. 62 (1854).

3 *Id.* at 112–13.

patent case, *Whittemore v. Cutter*,[4] famously declared 'that it could never have been the intention of the legislature to punish a man, who constructed [the patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects'.[5] Coupled with the long-standing prohibition on the patentability of scientific principles or laws of nature, as evidenced by landmark English cases such as *Hornblower v. Boulton*[6] and *Neilson v. Harford*,[7] this emerging nineteenth-century common law or judicial research use exception seemed to protect pure scientific inquiry from suits for patent infringement.

Thus, while we rightly might want to grant greater rewards to the pioneer innovator who creates a new class of goods or services, we may not want that reward to constitute such strong, long-term exclusive patent rights that effectively choke off the ability of others to enter this nascent category of goods or services, or to conduct basic science research on it. But, what about commercial or non-commercial researchers who want to research *with* the patented invention? In other words, the invention may help the researcher conduct experiments on other subject matter. In this context, the patented invention may be thought of as a *research tool*. On the one hand, a research tool could be as straightforward as a microscope or other piece of laboratory equipment whose primary use is as a research tool. On the other hand, some inventions may be primarily research subject matter – say a new pharmaceutical compound – but can also play the role of a research tool in others – for example, where the compound is used to help develop other drug candidates.

Finally, if one does want to limit the reach of pioneer patents to restrict further research by third parties, then the question of what practical form the limitation takes arises. This has led to the frequently interchanged use of two terms denoting very different conceptualizations of the limitation. The first is a research use *exception* which would denote that the activity does not infringe a patent claiming the subject matter of the activity in the first place. The second is a research use *exemption* which would denote that the activity *is* an infringement of a patent, but that it is exempted from actionable liability for

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4 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

5 *Id*. at 1121.

6 8 T. R. 95 (K. B. 1799) (finding Watt's patent for a steam engine to claim a manufacture and not a philosophical principle, the latter of which would have been prohibited).

7 Webster's Patent Cases 295 (Exch. 1844) (holding that a patent for interposing a heated receptacle between a blower and a furnace such that the air sent into the furnace would be warm, not cold, was not invalid as simply a scientific principle; whereas a patent for only a scientific principle (with no particular application) would be invalid).

the infringement. Because most contemporary statutory limitations take the form of an exception – for example, 'It shall not be an act of infringement to . . .'[8] – this chapter uses the term *exception* rather than *exemption* to refer to these limitations generally.

Similarly, these limitations are often alternately referred to as *experimental use* or *research use* exceptions. However, where the term *experimental* is relied on by courts, they usually require the activities at issue to be in the nature of true scientific experiments, where hypotheses are tested and the results add to the storehouse of scientific knowledge rather than being primarily directed to an individual's or firm's business interests. By contrast, the term *research* can encompass commercial R&D activities that are directed to business interests. Because some national laws provide exceptions for commercial R&D activities as well as purely philosophical or scientific experiments, this chapter uses the *research use* formulation. Further, there is a different *experimental use exception* in U.S. patent law that allows an inventor to engage in some degree of public use of an invention herself before filing a patent application, so long as the use is solely experimental to adequately reduce the invention to practice.[9] Thus, another rationale for using the term *research use exception* in this chapter is to avoid confusion with this other doctrine in U.S. patent law.

In sum, there are two conceptual distinctions and two practical distinctions that form the structure of this chapter. The two conceptual distinctions are: (i) research *on* versus research *with* patented inventions; and (ii) commercial versus non-commercial research. The two practical distinctions are: (x) exceptions established for general research versus exceptions for regulatory review processes; and (y) *exceptions* which remove the uses from the scope of infringing activities versus *exemptions* which maintain the uses as infringements, but excuse them or provide for no actionable liability on the part of the researcher. However, as the title suggests, this chapter also seeks to demonstrate that there are both *de jure* and *de facto* research use exceptions, with the latter especially important in understanding the current U.S. system. Yet, while to some degree the U.S. system has functional equivalents of the research use exceptions of other jurisdictions, a critical difference is that the exceptions in the U.S. generally only allow government and/or non-commercial use, rather than use by commercially minded competitors. Therefore, research use exceptions are yet another way in which, as a matter of comparative patent law, the U.S. patent system stands to one side on a key policy issue, while most other developed

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[8] 35 U.S.C. § 271(e).

[9] *See, e.g.*, *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877).

nation patent systems cluster on the other. This chapter does not seek to argue which is 'better' as a policy matter, but rather only to highlight the difference and the benefits and shortcomings of each side.

Practical strategic aspects of research use exceptions

Most patent systems allow, or even encourage, others to 'design around' the pioneer patent such that new, perhaps better, goods or services enter the market to compete with the pioneer product or service. These follow-on products may themselves be patentable inventions. Of course, the pioneer innovator may herself produce these follow-on products and therefore attempt to continue to dominate the emerging class by patenting a number of the commercially practical versions of products in the class. Further, in jurisdictions that have no commercialization or local working requirement for patents, a savvy innovator might have his team explore all of the practical embodiments of a broad new class-creating innovation, and then patent them all, before introducing any product into the marketplace. Through this tactic, he might then preclude others from entering the market with new products in the class he creates with his first product, and can then himself decide whether, where, and how to introduce follow-on products to maximize his returns.

The foregoing strategy, while clearly advantageous to the pioneer innovator, may not represent the best outcome for the economy at large. The pioneer is easier able to monopolize what might turn out to be a critical new industry segment. In the worst case scenario, the pioneer's stranglehold on the budding class may in fact choke it off and prevent it from becoming the kind of broad new industry segment that could play a vital role in the economy.

A solution to this is the compulsory license, which essentially allows the government to step in and license others to market products covered by the pioneer's patent. In some countries, this is established by a commercialization requirement that forces the patent holder to market products, or at least license out the patent rights for someone else to market products under it, within some fixed period of time – generally three years – under pain of the government granting another party a license to the patent rights.[10] Even in the U.S., the Bayh-Dole Act,[11] which governs the ownership of patents arising from federal funding, establishes a commercialization requirement for such patents.[12]

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[10] *See, e.g.*, U.K. Patent Act of 1977 § 48-48B; Japanese Patent Act art. 83; Canadian Patent Act, R.S.C. ch. P-4, S. 65; German Patent Law § 24.

[11] Pub. L. No. 96-517, 94 Stat. 3015, 3019–27 (1980) (codified at 35 U.S.C. §§ 200–211).

[12] 35 U.S.C. § 203 (establishing the failure to commercialize a patent covering a federally funded subject invention as a trigger for 'march-in rights' whereby the government funding agency can grant a compulsory license to another party).

Where a pioneer inventor has not attempted to dominate the emerging class of goods or services through patenting of all feasible ways of bringing alternate functionally equivalent inventions to market, it is still not always clear how much freedom competitors have to 'design around' the pioneer patent(s). It sounds good to say that competitors are free to do so, but in a strong exclusive patent rights regime, is this really practical? In many cases, would-be competitors will need to experiment *on* or *with* the patented invention just to design around it. But, absent an exception, any unauthorized research on or with the patented invention will constitute actionable infringement. One answer is simply that competitors will research on or with the patented invention in secret and rely on the relatively small chance of detection, such that they run a small risk of being sued for infringement. However, this strategy, while constituting a clear moral hazard first and foremost, may in practice be more or less available depending upon the particulars of the original patent and factors such as whether the competitor is developing truly competing products or instead complementary products such as interoperable components to work with the pioneer product.[13]

The more finely tuned solution for the problem of balancing pioneer innovator rights (and incentives/rewards) with follow-on innovator rights (and, again, incentives/rewards) is, of course, the research use exception. As discussed above, this broad concept covers particular instances of both statutory and judicial law that seek to permit limited unauthorized use of otherwise exclusive patent rights solely for research *on* or *with* the patented invention for purposes such as: advancing science or technology generally; allowing the government to provide important services to citizens; and permitting potential competitors to freely develop new products (*provided that* the final product brought to market does not itself infringe the pioneer patent, or, if it does, that the follow-on innovator has duly licensed the patent before bringing the infringing product to market). The remaining sections of this chapter will detail the different *de jure* and *de facto* instantiations of the broad concept of a research use exception.

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[13] *See* Dan Laster, *The Secret is Out: Patent Law Preempts Mass Market License Terms Barring Reverse Engineering for Interoperability Purposes*, 58 BAYLOR L. REV. 621 (2007) (discussing the 'detection paradox' which makes the marketing of interoperable goods more of a tip off to a patent holder that the interoperable product manufacturer may have engaged in unauthorized research on or with the patented invention (else how would the manufacturer be assured that the product was indeed interoperable?) than the marketing of substitute goods for which the manufacturer may in fact have engaged in unauthorized research but there is nothing to indicate this simply from the availability of the substitute product in the marketplace).

Standard forms of *de jure* research use exceptions

This section sets out the two major variants of *de jure* research use exceptions, that is, exceptions that arise in statutory or case law and which are formally referred to as research use exceptions (or the alternate formulations based on terms like *experimental* or *exemption* as discussed above). The first, R&D and experimental exceptions, trace their origins back to nineteenth-century case law. The second, regulatory review exceptions (sometimes called '*Bolar* exemptions'), are of more recent vintage.

R&D and experimental exceptions

In general, the patent systems of most major technology-oriented countries provide a statutory research use exception covering even some kinds of commercial R&D activities. The U.S. is the most notable exception to this trend. While the U.S. may have formally introduced the idea of a research use exception in the 1813 case of *Whittemore v. Cutter*, that exception was more narrowly an experimental use exception focused on private and/or truly philosophical or purely scientific experiments to 'construct [the patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects'.[14]

Throughout the course of the nineteenth and twentieth centuries, this 'common law' or judicially created exception in the U.S. was interpreted expansively by universities and non-profit research organizations to become a kind of patent law version of the 'fair use' doctrine in copyright law. However, the Court of Appeals for the Federal Circuit sought to clarify the proper scope of the exception through a trilogy of cases beginning in 1984 with *Roche Products, Inc. v. Bolar Pharmaceuticals*,[15] a case that is more famous for leading to the statutory regulatory review exceptions (sometimes, in fact, called '*Bolar* exemptions') discussed in the next section. This was followed by *Embrex v. Service Engineering*[16] in 2000 and then the trilogy culminated in the controversial 2002 decision in *Madey v. Duke*,[17] which some have argued effectively eliminated the common law research use exception in the United States.

Arguably, though, the Federal Circuit has been quite consistent throughout this trilogy in its interpretation of Justice Story's foundational commentary from *Whittemore v. Cutter*. In *Roche*, the court explained that 'Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have

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14 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).
15 733 F.2d 858 (U.S. Federal Circuit 1984).
16 216 F.3d 1343 (U.S. Federal Circuit 2000).
17 307 F.3d 1351 (U.S. Federal Circuit 2002).

an intent to use a patented invention for profit, . . .' and that his 'seminal statement evolved until, by 1861, the law was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee" '.[18] The logic of the exception was that the patent holder was not harmed by non-commercial use of the patented invention.

At the same time, the surface sensibility of the exception potentially masks two very different conceptualizations of it. The first could be characterized as a *de minimis* type argument – the use is so inconsequential as to warrant being excused from enforcement. This comports well with the *Roche* court's analysis of Bolar's activities: 'It is obvious here that it is a misnomer to call the intended use *de minimis.* It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.'[19] Yet, a true *de minimis* basis for the exception would seem to justify insubstantial other kinds of uses of the patented invention. Why should it matter, then, whether the exception were limited to amusement or philosophical inquiry? As a practical matter, if the basis was a *de minimis* argument, then this would change the common law research use *exception* into an *exemption*. More substantial experimental uses might then be actionable.

The second conceptualization is that purely philosophical or idle amusement uses of a patented invention are categorically excluded from the definition or scope of infringement, and thus properly lie as *exceptions*, not *exemptions*. This version comports better with the apparent importance of the 'philosophical inquiry' and 'idle amusement' limitations – in a true *de minimis* exemption, such qualifiers should be unnecessary.

At any rate, *Roche* was decided on the basis that regardless of whether Bolar's activities could be characterized as true scientific experiments, they were solely undertaken 'with a view to the adaption of the patented invention to the experimentor's business [as] a violation of the rights of the patentee to exclude others from using his patented invention'.[20] Further, the *Roche* court relied on a precedential opinion from its predecessor, the Court of Claims, to also suggest that where the unauthorized use of the invention advances the alleged infringer's legitimate business interests, then the activities fall outside

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18 733 F.2d 858, 862 (U.S. Federal Circuit 1984) (quoting *Peppenhausen v. Falke*, 19 Fed.Cas. 1048, 1049 (C.C.S.D.N.Y.1861) (No. 11,279)).

19 733 F.2d 858, 863 (U.S. Federal Circuit 1984).

20 *Id.*

of the common law research use exception.[21] Arguably, this theme set the stage for the court's later concern that large-scale unauthorized use of patented inventions by non-profit organizations such as universities, while nominally scientific or philosophical in nature, nonetheless represented significant lost market share for the patent holder and advanced essentially business-type interests of these institutions. In *Embrex*, the Federal Circuit affirmed the lower court's decision to look through 'the guise of scientific inquiry' based on Service Engineering's directed research by a university professor that nonetheless was done 'expressly for commercial purposes'.[22] The court also seemed to more clearly distinguish a *de minimis* exemption from the common law experimental exception deriving from Justice Story.[23]

Despite these clear judicial pronouncements, many universities and non-profit research organizations continued to interpret the exception to cover virtually all of their research activities. They would have done well to note the Federal Circuit's language in *Roche*: Bolar's activities were 'no dilettante affair such as Justice Story envisioned'.[24] Any fair reading of the enormous and expensive undertaking that constitutes modern university and non-profit-based scientific research should have found such activities equally unlikely to be characterized as a 'dilettante affair'. Accordingly, the big story with the Federal Circuit's 2002 decision in *Madey v. Duke* should have been why so many universities and non-profits seemed to be blind-sided by it.

In fact, the basis of the *Madey* case was not well suited to be the test case for such an important area of IP and research activities. Without restating all of the facts here, suffice it to say that the dispute was in many ways the soured fruit of a relationship gone bad between a researcher and his university.[25] For purposes of this chapter, the essential elements of the story are that Madey owned some patents relating to a free electron laser technology that covered a number of core research activities within his lab at Duke University (Duke). After he left Duke in the wake of the dispute over control and use of his lab, he brought a patent infringement suit against Duke to prohibit it from using his lab for the covered activities. Duke raised a number of interesting defenses, including the common law research use exception. While the main focus by commentators was on the Federal Circuit's ruling with regard to the common

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21 *Id.* (quoting *Pitcairn v. United States*, 547 F.2d 1106, *cert. denied*, 434 U.S. 1051 (1978)).

22 216 F.3d 1343, 1349 (U.S. Federal Circuit 2000).

23 *Id.* ('This court has construed both the experimental use and *de minimis* exceptions very narrowly.')

24 733 F.2d 858, 863 (U.S. Federal Circuit 1984).

25 For more details on the nature of this relationship, see *Madey v. Duke*, 307 F.3d 1351 (U.S. Federal Circuit 2002).

law exception defense, Duke effectively catalogued a number of other possible defenses that are available to most universities and non-profit research organizations in the U.S. Because these defenses are not directly intended to be research use exceptions, I have taken to calling them '*de facto* research use exceptions'.[26]

Focusing narrowly on the Federal Circuit's analysis of Duke's use of the common law research use exception, we see that the court was simply making explicit a modern conceptualization of universities as substantial economic players who have business objectives similar to other economic actors. Thus, the court states that:

> [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.[27]

The court also picks up another developing theme about the debated commercialization of universities: 'Duke's patent and licensing policy may support its primary function as an educational institution. . . . Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream.'[28] This latter point may be seen as the direct, logical outcome of the purpose and substance of the Bayh-Dole Act. Once universities were given the right to elect to take title to patentable inventions arising from federally funded research, they began to have commercial interest in the research leading to the inventions. Indeed, this was the point of Bayh-Dole: to give universities exactly that kind of economic incentive so that federally funded inventions would not languish in university or government labs, but rather be actively patented and licensed out to the private sector for commercialization such that the public might get access to the practical applications of the research. Of course, Bayh-Dole, and the universities' responses to it, have not been without their critics, but that debate is well outside the scope of this chapter.

Accordingly, the court remanded the case back to the district court on the research use exception ground with the following direction:

> . . . [T]he district court attached too great a weight to the non-profit, educational status of Duke . . . . On remand, the district court will have to significantly narrow

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26 *See* p. 599 *infra*.
27 *Madey v. Duke*, 307 F.3d 1351, 1362 (U.S. Federal Circuit 2002).
28 *Id*. at note 7 (internal citations omitted).

> and limit its conception of the experimental use defense. The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.[29]

Because the Supreme Court declined to review the Federal Circuit's opinion in *Madey* – and in *Roche* and *Embrex* for that matter as well – the Federal Circuit's interpretation of the common law research use exception continues to stand as the law of the land in the U.S.

In sum, the U.S. rule regarding a general R&D or experimental research use exception is that the activity must indeed be limited to the kind of 'dilettante affair' that the *Roche* court paraphrases from Justice Story's famous commentary. It may not involve even the slightest taint of commercial or commercially oriented activity, nor advance the individual's or organization's 'legitimate business activities' – including non-profit or non-commercial endeavors – in any substantial way. The only activities which may qualify are those done 'solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry',[30] where 'philosophical inquiry' apparently excludes large or organized philosophical inquiry such as that conducted at research universities – in other words, a limited and likely historically wrong conceptualization of 'philosophical inquiry'.[31]

While the scope of the U.S. research use exception is thus extremely narrow and almost irrelevant for purposes of protecting any meaningful research activities, the general R&D or experimental research use exceptions in most other developed, technology-oriented countries are much broader. To wit, they generally cover some commercial or commercially oriented activities. Further, they appear to distinguish research *on* and research *with* the patented invention. Note that in the *Madey* case it appears that Duke was raising the common law

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[29] *Id*. at 1362–3 (footnote omitted).

[30] *Id*. at 1362.

[31] Note that it is not just happenstance that all university colleges and departments – save the professional and religious schools – grant the 'doctor of philosophy' degree (Ph.D.) as their highest degree. Historically, all of the arts and sciences were established as components of philosophy and philosophical inquiry (e.g., natural philosophy) within European and then American universities and colleges. Thus, as a technical matter, all faculty and graduate students operating within these departments are engaged in 'philosophical inquiry'. I am reluctant to argue this as a more substantial flaw in the Federal Circuit's opinion because I wager that many faculty and students in these departments do not consider themselves to be doing philosophy. This, of course, is as much a misunderstanding on their part as on that of the Federal Circuit judges. However, it suggests a commonality and evolution in the use of the term 'philosophical inquiry' by contemporary university researchers and the judiciary such that their collective use should be given some deference.

research use exception for research *with* the patented free electron lasers, not research *on* them. It is unclear whether the Federal Circuit would allow the exception to cover narrow, non-commercial university research *on* some patented invention, although it is hard to see how that research would not also fall within the court's definition of 'legitimate business interests' of the university. The remainder of this section will briefly review the general R&D and experimental research use exceptions of representative major technology nations: the U.K., Germany, Japan, and Korea.

The U.K. Patent Act states, 'An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if (a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject-matter of the invention; . . .'.[32] Similarly, the German Patent Law specifies that 'The effects of a patent shall not extend to (1) acts done privately and for non-commercial purposes; (2) acts done for experimental purposes relating to the subject matter of the patented invention; . . .'.[33] The strong similarity of these provisions is no accident: both nations adopted them pursuant to Article 31 of the [European] Community Patent Convention of 1976.[34] As a significantly different formulation, the Japanese Patent Act provides that 'A patent right shall not be effective against the working of the patented invention for experimental or research purposes'.[35] Similarly, the Korean Patent Law provides, 'The effect of a patent right does not extend to . . . (i) working a patented invention for research or experimental purposes; . . .'.[36]

While the statutory language appears to be roughly similar in all of these examples, there are notable differences between the German and British statutes, on the one hand, and the Japanese and Korean statutes on the other. Only the German and British statutes seem to clearly convey a sense that otherwise unauthorized commercial R&D activities must be limited to research *on* the patented subject matter ('acts done for experimental purposes relating to the subject matter of the patented invention'). The Japanese and Korean statutes appear to also allow commercial R&D *with* the patented

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[32] U.K. Patent Act, 1977, ch. 37, § 60(5). This section of the U.K. Patent Act also contains a regulatory review – or 'Bolar exemption' – which will be discussed at pp. 538–9.

[33] German Patent Law § 11(2). This section of the German Patent Law likewise also contains a regulatory review – or 'Bolar exemption' – which will be discussed at p. 539.

[34] Convention for the European Patent for the Common Market (Community Patent Convention) art. 31(A)–(B) 76/76/EEC (1975), *superseded* by Agreement Relating to Community Patents art. 27(a)–(b) 89/695/EEC (1989).

[35] Japanese Patent Act art. 69(1).

[36] Korean Patent Act § 96(1).

subject matter. Accordingly, the German and British statutes then provide a separate subsection that appears to allow unauthorized private, non-commercial research both *on* and *with* the patented subject matter. The Japanese and Korean statutes do not have this separate section, but arguably they would not need it as their more expansive commercial R&D exceptions likely also permit unauthorized private, non-commercial research *on* and *with* the patented subject matter.

As a further gloss on the themes above, private, non-commercial research exceptions may be easier to justify than commercial R&D exceptions, as a policy matter, because it seems to take little away from the pioneer patent holder to allow others to perform solely non-commercial research on her patented invention. This is especially true when the research is strictly limited to non-commercial or purely scientific research conducted in research organizations that do not directly engage in any commercialization, such as universities. However, it might matter quite a bit whether the research is performed in universities or other organizations that routinely seek to develop and patent new inventions, in which case the organization may still seem to be in competition with the R&D activities of the patent holder, and to have an economic interest in the downstream commercialization that its patent licenses enable. Further, one might consider whether the unauthorized use by a non-profit entity that is not directly in competition with the patent holder's business may still reap a marketplace advantage for that organization by way of a wholly different set of goods or services – say scientific or technological education – from that which the patent holder markets.

On the other hand, private, non-commercial research use *with* the patented subject matter – particularly in its use as a research tool – could very much adversely affect the patent holder's economic interests.[37] At its most glaring, this harm would arise when the patent covers subject matter that will primarily be used as a research tool sold or licensed to universities and other non-profit research organizations. The question is whether the particular research tool – including biotechnology inventions such as genetically engineered DNA fragments or cellular mechanisms such as RNA interference (RNAi) – is more like a microscope, in which case university and non-profit labs should pay for it, or a fundamental building block that should be free and available to all basic science researchers. This policy debate might be affected by considerations of whether the university and non-profit researchers can create or replicate the research tool by themselves in their own labs with their own existing equipment, or whether they need to obtain physical or biological materials from the patent holder, or use specialized lab equipment. The foregoing is no mere

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[37] *See supra* note 18.

academic debate: arguably the future of much of the biotechnology industry rests on its outcome in that many biotechnology companies produce research tools as some or all of their primary product lines. Furthermore, for companies that produce services, rather than goods, a broad non-profit or non-commercial exception for research *with* their patented services may destroy a sizeable portion of their marketplace.[38]

Finally, the debate could be affected by the interpretation of the limiting term 'private' in the British and German statutes. In other words, does the limited exception for research *with* the patented subject matter in these countries that is done 'privately' and for non-commercial purposes mean that publication of scientific research results arising from research with the patented subject matter destroys the exception for the researchers? What about the status of the organization – for example, a public university whose activities must largely be open to the public – or the nature of the research and whether it is conducted 'publicly' or openly or with only restricted access? These concerns may seem to unduly narrow the scope of the non-commercial research use exception in the British and German statutes, yet just this kind of interpretive narrowing occurred in *Madey v. Duke* in the U.S. Accordingly, the British and German private, non-commercial exceptions that seem to authorize some free use of patented research tools might not extend to large-scale basic science research at universities and non-profit labs.

There is, however, case law in Britain and Germany on the scope of their respective general R&D research use exception statutory provisions. In Britain, the 1985 case of *Monsanto Co. v. Stauffer Chemical Co.*[39] discussed the difference between the § 60(5)(a) and § 60(5)(b) research use exceptions as in part relying on:

> [t]he distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) [which] indicates that experimental purposes in sub-head (b) may yet have a commercial end in view . . . . [it is similar to] the sort of experimental activity which was considered by the Supreme Court of Canada in Micro-Chemicals Ltd. v. Smith Kline and French Inter-American Ltd. (1971) 25 D.L.R. 79 . . . a limited experiment to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent, as

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[38] For a more detailed discussion of the interaction of physical property and intellectual property rights in research activities, as well as the underestimated extent of a particular form of service – the 'lease-license' model whereby owners of physical property and intellectual property package both together to avoid patent exhaustion and reverse engineering and/or loss of trade secrets – see Sean M. O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics & Therapeutics*, 21 BERKELEY TECH. L.J. 1017 (2006).

[39] [1985] RPC 515.

> being covered by the words 'for experimental purposes relating to the subject-matter of the invention'.[40]

Further,

> Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions, e.g. of soil or weather, will work in different conditions can fairly, in my judgment, be regarded as experiments. But trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a [regulatory] body . . . , that the product works as its maker claims are not, in my judgment, to be regarded as acts done 'for experimental purposes'.[41]

Accordingly, whereas § 60(5)(a) permits unauthorized individuals or organizations to engage in research *on* or *with* the patented invention, so long as the research is private and non-commercial, § 60(5)(b) only permits unauthorized individuals or organizations to engage in research *on* the patented invention that truly take the form of experiments and not clinical trials or demonstrations to third parties. Thus, as discussed in the next section, a separate statutory section – § 60(5)(c) – needed to be passed to introduce a regulatory review or Bolar exemption into U.K. patent law.

In Germany, statutory provisions substantially the same as those of the U.K. were nonetheless interpreted differently for a similar regulatory review use fact pattern. In *Klinische Versuche I (Clinical Trials I)*,[42] the German Federal Court of Justice stated:

> According to its wording, § 11 No. 2 of the Patents Act is . . . concerned not with particular types of act but exclusively with the purpose of the acts in question. The purposes meant are defined by the Act by using the concept of the experiment. An experiment in the sense relevant here is any (planned) procedure for obtaining information, irrespective of the purpose which the information gained is eventually intended to serve. To limit this intrinsically broad concept of the experiment, the provision requires as further factual characteristic determining the scope of exemption that the experiments must relate to the subject-matter of the patented invention. This indicates a finality between the act for a particular experimental purpose and the subject-matter of the invention. The subject-matter of the invention must be the object of the experimental act for the purpose of gaining information.
> . . . [T]he wording of the Act when examined naturally rather indicates that § 11 No. 2 of the Patents Act in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-

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40 *Id.* at 538
41 *Id.* at 542.
42 [1997] RPC 623.

> matter of the invention, including its use. There are then included, for example, utilization acts for experimental purposes undertaken with the subject-matter of the invention in order to discover the effects of a substance or possible new uses hitherto unknown. Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests . . . .[43]

Accordingly, unauthorized uses of the patented invention for purposes such as research *on* it to develop information for regulatory review and approval have been interpreted to be within the scope of the German version of the Community Patent Convention language, even as it is nearly identical to that of the U.K. Patent Act. The following year's *Klinische Versuche II (Clinical Trials II)*[44] affirmed and clarified this interpretation of § 11 No. 2:

> Therefore the wording of section 11 No. 2 of the Patent Act, the basis of the law, as well as the meaning and purpose of section 11 No. 2 of the Patent Act speaks for the fact that clinical research in which the digestibility and effectivity of a pharmaceutical contained in a protected active agent are tested on human beings is exempted even in the event that these tests were undertaken with the purpose of obtaining data necessary for the obtainment of legal pharmaceutical authorisation. This does not in any way mean that research activities of any and every sort are exempted. Should the research have no relation whatsoever to technological theory or should the experiments be undertaken in such proportions as to no longer allow for justification on research grounds, then the activities are not considered to be permissible research activities within the meaning of section 11 No. 2 of the Patent Act. The same would be considered to be case if experiments are carried out with the purpose of persistently disturbing or hindering the inventor's distribution of his product. In such cases the research does not serve the purpose of technological progress, rather it serves as a means for the accomplishment of competitive purposes.[45]

Thus, it may be that clinical trials performed exclusively to gather regulatory information are not covered by the § 11 No. 2 statutory exception. However, even a modicum of legitimate research as to the action of the regulated subject matter, or for new uses, etc. will likely be enough to bring all of the research within the exception.

By contrast, the Japanese and Korean general R&D and experimental research use exceptions are drafted broadly enough so that it is hard to see how they prohibit research *on*, *with*, or to generate data for regulatory review and

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43 *Id*. at 638.
44 [1998] RPC 423.
45 *Id*. at 436.

approval.[46] However, up until 1997, Japanese courts held that unauthorized use of patented inventions to generate data for regulatory approval did not advance science or technology and thus was not covered by § 69(1).[47] In that year, the Tokyo District Court dismissed a patent infringement case brought by Ono Pharmaceuticals against seven generic drug manufacturers who were producing generic versions of Ono's patented drug based not on the research use exception in § 69(1), but rather on the patent term provisions of § 67(1). The logic behind this was quite similar to that behind the balancing act of the Hatch-Waxman Act in the U.S.:[48] if generic manufacturers are prohibited from using patented compounds even solely for generating data for regulatory approval, then the pioneer drug manufacturer will receive a *de facto* patent term extension as no generic company will be able to market a product immediately upon termination of the pioneer patent term. Following this first break with precedent, the Tokyo District Court then began ruling that development of generics, and clinical trials to determine bioequivalency for regulatory approval, in fact constituted advancements of science and technology that were properly within the actual § 69(1) research use exception. The Tokyo High Court affirmed this interpretation of § 69(1) in *Otsuka Pharmaceutical Co., Ltd. v. Towa Yakuhin K.K.*[49]

In 1999, the Japanese Supreme Court finally weighed in and ruled that use of a patented drug for regulatory approval came within the research use exception of § 69(1) in *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*[50] However, it did not clearly resolve whether this was because such use represented an advancement in science and technology, or rather that the advancement requirement was no longer part of § 69(1). Regardless, the scope of § 69(1) appears to be quite broad and permits commercial as well as non-commercial research up until the point where an unauthorized user would begin selling an infringing product in the marketplace.[51]

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[46] At the same time, in the case of biotechnology research tools any research *with* the tool that thus misappropriates the tool's commercial value in the research enterprise will not be covered under the § 69(1) exception. *See, e.g.*, Center for Advanced Studies and Research on Intellectual Property (CASRIP), Patent Policies, Research Ethics and IP Education 65 (symposium held at Tokyo Medical & Dental College, Tokyo Japan, in February 2005) (statement of Honorable Ryuichi Shitara, Presiding Judge, Tokyo District Court).

[47] *See* Jennifer A. Johnson, *Comment: The Experimental Use Exception in Japan: A Model for U.S. Patent Law?*, 12 PAC. RIM L. & POL'Y. J. 499, 512–13 (2003).

[48] *See infra* p. 536.

[49] *See supra* note 47 at 515.

[50] *Id.* at 516.

[51] The exception is likely limited to research *on*, however, in the case of biotechnology research tools. *See supra* note 46.

Regulatory review exceptions

While much of the foregoing section discussed the status of regulatory review use of patented inventions, particularly in the pharmaceutical industry, the focus was still on the general purpose R&D and experimental research use exceptions in our four countries of interest. Further, this preliminary discussion of regulatory review uses was appropriate because it often has generated the most controversy for these R&D and experimental research use exceptions. In this section, we turn to a different set of specifically regulatory review exceptions, or so-called Bolar exemptions.

The U.S. appears to have been the first major nation to adopt a statutory provision specifically directed to a regulatory review exception. Congress was already debating various bills aimed at resolving the conflict between pioneer and generic drug manufacturers when the Federal Circuit decided *Roche*. Noting this Congressional debate, and inviting Congress to pass legislation specifically directed at the regulatory review exception issue, the Federal Circuit declined to judicially create such an exception. Shortly thereafter, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (better known as the 'Hatch-Waxman Act').[52] Among many other provisions, the Act added § 271(e)(1) to the U.S. Patent Act's definition of infringement:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product . . . which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[53]

While some commentators have suggested that this statutory provision was intended to narrowly remove from the definition of infringement only the use of patented compounds (i.e., drugs) in clinical trials by generic drug manufacturers to show bioequivalence for purposes of the new abbreviated regulatory approval mechanism for generics, the Supreme Court gave a much more expansive interpretation to the clause in its 2005 decision in *Merck KGaA v. Integra Lifesciences I, Ltd*.[54] Thus, instead of limiting the reach of § 271(e)(1) to research *on* patented compounds in the context of clinical trials, the Supreme Court interpreted the exception to cover 'all uses of patented inven-

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52 98 Stat. 1585 (1984).
53 35 U.S.C. § 271(e)(1).
54 125 S. Ct. 2372 (2005).

tions that are reasonably related to the development and submission of *any* information under the [Food, Drug and Cosmetics Act]'. Further, '[t]his necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process'.[55] The Court could not have literally meant what it said in the first statement above, because then the unauthorized use of all patented lab equipment, software, etc. would seem to come within the § 271 (e)(1) exception. At the same time, the Court claimed that it made no ruling as to the status of biotechnology research tools in a footnote to its opinion.[56]

Outside of these two particular uncertainties in the opinion, the Court focused on constructing the § 271(e)(1) research exception in both chronological and subject matter breadth dimensions. Thus, the Court found that the exception explicitly includes uses of patented inventions to perform the early stage research required to file an IND, as well as the later stage research involved in clinical trials leading to submission of an NDA. At the same time, the Court rejected the Federal Circuit's construction that seemed to restrict the exception to only research that produces safety data in the preclinical phase. Instead, the Court asserted that because research leading to data on the pharmacological, toxicological, pharmokinetic, and biological qualities of a drug can be required by the FDA to be included in the IND, then the research and collection of any data related to these qualities can properly fall under the exception. Further, the Court explained that, in certain circumstances, the § 271(e)(1) exception can cover '(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA'.[57]

Essentially, the Court took the 'reasonably related' phrase in § 271(e)(1) at face value and stated that:

> Properly construed, §271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA . . . .[58]

Based on this, the Court held that 'the use of patented compounds in preclinical studies is protected under §271(e)(1) as long as there is a reasonable basis

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55 *Id*.
56 *Id.* at 2382 note 7.
57 *Id*. at 2382.
58 *Id*. at 2383.

for believing that the experiments will produce "the types of information that are relevant to an IND or NDA" '.[59] Ultimately, then, this means that the regulatory review exception in the U.S. is quite broad.

While the statutory provisions now used for regulatory review exceptions in Japan and Korea – the R&D and experimental research use exception statutes in § 69(1) and § 96(1) respectively – predate the § 271(e)(1) exception introduced into the U.S. Patent Act via the Hatch-Waxman Act of 1984, the Japanese provision was only found to contain a regulatory review exception in 1997.[60] It is unclear when Korea began interpreting its provision to encompass a regulatory review exception. Germany began allowing its R&D and experimental use exception in § 11 No. 2 as partially a regulatory review in 1997. However, the U.K., with essentially the same R&D and experimental exception as Germany, never interpreted it to cover regulatory review uses.

However, in 2004 the European Union passed Directive 2004/27/EC to amend Directive 2001/83/EC which established guidelines and national legislation for the regulation of medicinal products. For purposes of this chapter, the most salient part of Directive 2004/27/EC is that it amended Article 10(6) of the earlier Directive to read: 'Conducting the necessary studies and trials with a view to [satisfying the abbreviated regulatory approval process for generic medicines] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products'.[61]

Since then, member states have been implementing this new requirement into their national patent laws. In the U.K. this has added § 60(5)(i):

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if . . . it consists of –
>
> (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of [the regulatory approval processes of various EU Directives], or
>
> (ii) any other act which is required for the purpose of the application of those paragraphs [of the Directives].[62]

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[59] *Id.* at 2383–4. Note that the Court shifts over the course of its opinion from referencing 'patented inventions' generally to the far more limited 'patented compounds' as the touchstone for what is being covered by the exception. This adds to the uncertainty created by the ruling.

[60] *See supra* note 35.

[61] European Directive 2004/27/EC art. 1 No. 8 (2004) *available at* http://eur-lex.europa.eu/RECH_naturel.do.

[62] U.K. Patent Act § 60(5)(i).

This statutory provision closely tracks the language in the Directive itself, and thus may be interpreted by analysis of the legislative history and commentary of the Directive.

In Germany, the Patent Law was amended to add § 11 No. 2b:

> The rights conferred by a patent shall not extend to . . . studies and trials and the consequential practical requirements necessary for obtaining an authorization to market a drug in the European Union or for obtaining an authorization to market a drug in the Member States of the European Union or in other countries.[63]

The German statute varies more stylistically from the Directive language (even accounting for translation), but seems to provide the same substantive exception.

While these national patent law amendments now clearly codify regulatory review exceptions, their form and substance raise some questions. First, to the extent that the existing R&D and experimental research use exception statutes had been interpreted by courts to cover regulatory review uses (e.g., in Germany), then is the new statute superfluous? If not, then what exactly does it cover that was not covered within the pre-existing provisions? Or, does it mandate revised interpretations of the scope of those pre-existing provisions? Second, these provisions seem no more clear in their scope as to research *on* and research *with* than the U.S. § 271(e)(1). Thus, significant court interpretation may be required to determine how broad the scope of the exception is and how far back in the development process it will reach.[64] While there appears to be legislative history and commentary at both the EU and national levels to suggest that the exception should be limited to research or clinical trials *on* the patented subject matter, in at least one case a member state has implemented legislation that clearly seems to except research *with* the patented subject matter as well.[65] Thus, as national courts work through their interpretations of the various statutes implementing the Directive, will substantially different results be reached? If so, will this largely undermine the stated purpose of the Directive to further harmonize the regulatory review and marketing of medicinal products in member states? In some ways, the only uniformity that can be

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[63] German Patent Law § 11 No. 2b *translated in* Henrik Holzapfel and Joshua D. Sarnoff, 'A Cross-Atlantic Dialog on Experimental Use and Research Tools' (working paper) *available at* http://ssrn.com/abstract=1005269.

[64] *See* Holzapfel and Sarnoff, *supra* note 63.

[65] The Italian version appears to authorize use of patents in research and clinical trials for regulatory review processes 'regardless of the subject of the invention'. Esther Pfaff, '*Bolar*' *Exemptions – A Threat to the Research Tool Industry in the U.S. and the EU?*, 3 INT'L REV. INTELL. PROP. AND COMP. L. (IIC) 258, 270 (2007) (citing Italian Patent Act art. 68(1)(a)).

counted on to apply across the member states is that: (i) research and clinical trials *on* the subject matter of the pioneer patent will be covered; and (ii) that the nature of the exception is truly that of an exception – and not an exemption – because the statutes are being implemented as part of the 'limitation on the patent right' section of national legislation that removes certain activities from the scope or definition of infringement in the first place.

In sum, the state of *de jure* research use exceptions across the globe evinces quite a bit of variation. Even among the five major technology-oriented nations which this chapter has concentrated on, there is a range of such exceptions established by statute, as interpreted by case law, and established solely by case law. At one end of this range, Japan and Korea appear to have the broadest overall research use exceptions. The only activities clearly not covered by the Japanese and Korean statutes, as interpreted by the courts, are those that are intended to be directly injurious to the legitimate commercial interests or ability to operate of the patent holder. The Japanese and Korean exceptions do not meaningfully turn on whether the activity is commercial or non-commercial, or research *on* versus research *with* the patented invention. They may turn on whether the activity can be properly characterized as either promoting the stated purposes of the patent laws in those countries overall or as advancing science or technology. The corollary is that exceptions might be argued when their absence may allow patent holders to exercise rights or control of a field of endeavor that hinder some goals of the patent system. Germany and the U.K. seem to occupy a middle space on the spectrum in that they have R&D and experimental research use exceptions that cover even commercially oriented research so long as some legitimate scientific or experimental purposes can be established. Further, the recent addition of specific regulatory review exceptions – or Bolar exemptions – into their respective patent laws remedies the disadvantage they used to operate under vis-à-vis the U.S., Japan, and Korea. However, the distinction between research *on* and research *with* still seems to have interpretive power when courts are deciding whether specific activities should fall under the exceptions.

The U.S. then occupies the most restrictive end of this research use exception spectrum. While the U.S. regulatory review exception under § 271(e)(1) may be broader than those of the other countries under consideration – particularly after the U.S. Supreme Court ruling in *Integra v. Merck* – the category of regulatory review exceptions currently only covers activities in the medicinal products space. It is thus quite limited as to impact on the overall economy of any of the countries, even when restricting consideration to the technology-oriented parts of the economy that interact with the patent system. The statutory R&D and experimental research use exceptions of the four other countries are markedly broader than the very narrow common law research

use exception as interpreted by the Federal Circuit. Coupled with the vastly wider impact of a research use exception not limited to a specific field such as medicinal products, the broader research use exceptions of Japan, Korea, Germany, and the U.K. dwarf the practical scope of the U.S. common law research exception. Finally, even granting a broader scope of the U.S. regulatory review exception may be short lived as courts in Germany and the U.K. have yet to meaningfully interpret the new regulatory review exception statutes in those countries. The courts in one or both countries may interpret the statutes as broadly as the U.S. Supreme Court interpreted the U.S. statute. Likewise, courts in Japan and Korea may yet interpret the scope of those countries' unitary research use exception statutes to be broader than currently established in the case law.

De facto research use exceptions in the United States

While analysis of research use exceptions in the U.S. and elsewhere usually ends with consideration of the R&D and experimental exceptions and regulatory review exceptions, the U.S. and other countries have some *de facto* research use exceptions that are especially important to basic science and government or non-commercial research – exactly the areas that are sometimes claimed to be the most adversely affected by inadequate research use exceptions. Due to the nature of these exceptions, the extensive federal funding of research, and the important role of state public universities in the U.S., all of which directly influence the extent of the exceptions' impact, this section will focus primarily on *de facto* research use exceptions in the U.S.

Section 1498: government use clause

Some countries, such as the U.K., have a 'Crown Right' doctrine by which the government is free to practice patented inventions owned by its subjects.[66] To some extent, the Crown can authorize non-governmental parties in writing to practice the patent on behalf of the Crown.[67] Compensation for loss of profit must be paid to the patent owner only to the extent that the owner could have supplied the patented subject matter to the Crown, and only for that amount which the owner could reasonably have provided, in sufficient quantity for Crown use.[68]

The U.S. Supreme Court formally rejected any sense that the federal government might hold a power similar to the Crown Right in the 1888 case

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66 *See* Patents Act, 1977 (as amended) §§ 55–9.
67 Patents Act, 1977 (as amended) § 55.
68 Patents Act, 1977 (as amended) § 57A.

of *U.S. v. Palmer*.[69] However, the absence of an analogue to the Crown Right led to considerable confusion as to the ability of the federal government to practice patented inventions, even when they were invented by government employees. Theories ranging from tort to 'takings' of property, to quasi-contract were invoked until a federal statute authorizing government use of privately held patented inventions was passed in 1910.[70] The statute formally immunized the federal government from suit for unauthorized use of patented inventions by establishing as the only remedy to such use an action in the Court of Claims for reasonable compensation. Congress promoted the bill as also protecting the rights of inventors and patent owners, who had very uncertain prospects in suing the government on any theory for unauthorized government use.[71]

The new statute was silent as to contractors working on behalf of the federal government and so they continued to be sued by patent owners. The matter came to a head during World War I when there was concern that defense contractors might stop working for the government on projects where the government was using its rights under the Act of 1910 to practice a patent without authorization. Accordingly, the Act was amended in 1918 specifically to bring government contractors under the immunity of the Act of 1910.[72] The amended Act of 1910 was originally codified in Title 35 of the U.S. Code, which continues to be the repository for U.S. patent law.[73]

During World War II, further issues arose as to the scope of the Act. In particular, there were debates as to whether subcontractors to prime contractors of the federal government were also covered by the exemption from liability for infringing activities provided by the Act, and, in any case, whether formal authorization from the federal government for activities on its behalf was required. These issues were formally resolved in a further amendment to the Act in 1942 which expanded the definition of parties who could be covered by the exemption, but required those parties to show that they had the specific authorization and consent of the federal government for these activities.[74] In this case, 'authorization' means evidence that the federal government specifi-

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69 128 U.S. 262, 270 (1888) ('It was at one time somewhat doubted whether the government might not be entitled to the use and benefit of every patented invention, by analogy to the English law, which reserves this right to the crown. But that notion no longer exists. It was ignored in the Case of Burns.').

70 Act of June 25, 1910, c. 423, 36 Stat. 851.

71 *See, e.g.*, H.R. Rep. No. 1288, at 1, 3 (1910).

72 Act of July 1. 1918, c. 114, 40 Stat. 705.

73 Originally codified as 35 U.S.C. § 68.

74 Royalty Adjustment Act, 56 Stat. 1013 (1942) *originally codified at* 35 U.S.C. §§ 89–96.

cally authorized the contractor[75] to engage in activities which the government knew might infringe specific patents.[76] 'Consent' means that the government has waived its normal sovereign immunity to suits by private parties and accepted liability on behalf of itself and the authorized contractor (or other party) to appear in an appropriate Court of Claims proceeding brought by the aggrieved patent holder, which might result in the government being ordered to pay reasonable compensation to the patent owner for the unauthorized use.[77] In addition, authorization and consent by the government to contractors could supersede any private, pre-existing licenses or other agreements that the contractor might have with the patent owner.

After World War II, the various codified parts of the Act of 1910, as amended, were transferred from Title 35 to Title 28, and ultimately to its current codification at 28 U.S.C. § 1498 ('§ 1498').[78] The statute is essentially an *exemption* in that it redirects the normal channel of patent infringement actions from federal district courts to the Court of Claims. The actions are still considered to be infringements, but the patent owners remedies are limited to

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[75] Use of this term includes subcontractors and other parties as defined in the Royalty Adjustment Act amendment to the Act of 1910. *See id*.

[76] *See, e.g., Larson v. U.S.*, 26 Cl.Ct. 365, 369–70 (1992).

[77] *See Id.*

[78] The statute reads in relevant part:

> a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture [including, in some cases, costs of bringing the action in the Court of Claims] . . . .
>
> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. . . .
>
> A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

those provided by the statute and in only one venue.[79] Most critically, the patent owner may not seek injunctive relief against either the government or its contractors. However, whereas the patent owner may only sue the government in the Court of Claims, it may sue contractors in federal district court. The contractors then must raise § 1498 as an affirmative defense.[80] Such an affirmative defense can be the grounds for dismissal on a proper motion, but this is distinct from dismissal for lack of subject matter jurisdiction, which is not authorized by the statute.

While the origins and applications of § 1498 so far seem oriented primarily towards manufacture of military hardware, the statute has been invoked as a kind of research use exception (in this case, *exemption*) by federally funded university and non-profit researchers. In particular, Duke raised it as one of its alternate defenses to Madey's patent infringement action. Duke claimed that its infringing use was within the scope of a research grant from the Office of Naval Research, and thus covered under § 1498 as activities performed on behalf of the U.S. While the trial court partially dismissed the case on these grounds, the Federal Circuit reversed this decision on appeal because the trial court: (i) treated the § 1498 issue as jurisdictional; and (ii) did not engage in proper fact finding to discover what portion of Duke's uses could be considered as performed under the ONR grant and whether there was evidence of authorization and consent of ONR for the infringement.[81] Madey argued that a government research grant could not be a contract for purposes of § 1498. However, the Federal Circuit disagreed with any categorical exclusion of research grants as contracts. In particular, it acknowledged that research grants can take the form of formal contracts and that these could be covered by § 1498.[82]

On remand, the district court has found that many of Duke's activities with Madey's patents are indeed being performed on behalf, and with the authorization and consent, of the federal government.[83] However, since not all of

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[79] Of particular note, § 1498 does not provide for increased damages for willful infringement – which the activities almost certainly will be where the government has given authorization and consent to a contractor for the activities.

[80] *See Madey v. Duke University*, 307 F.3d 1351, 1359 (U.S. Federal Circuit 2002) (citing *Sperry Gyroscope Co. v. Arma Engineering Co.*, 271 U.S. 232 (1926); *Crater Corp. v. Lucent Technologies*, 255 F.3d 1361 (U.S. Federal Circuit 2001); *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544 (U.S. Federal Circuit 1990)).

[81] *Madey v. Duke*, 307 F.3d 1351, 1358–9 (2002).

[82] *Id.* at 1359. Note that the Bayh-Dole Act, which governs the disposition of patents arising from federally funded research, refers to funding recipients as 'contractors' and mandates the form and substance of funding agreements as formal contracts. *See* 35 U.S.C. § 200 *et seq.*

[83] *Madey v. Duke University*, 413 F.Supp.2d 601, 616–21 (M.D.N.C. 2006).

Duke's activities have been explicitly brought within § 1498 by the evidence presented so far – consisting of federal funding agreements and documentation of the actual activities of the lab through notebooks and logs – the court has ordered a trial on the merits.

Accordingly, it now seems clear that federally funded researchers can avail themselves of § 1498 as a *de facto* research use *exemption*, provided that the appropriate documentation is obtained from the government and lab notebooks or logs. First, the research should be conducted under a formal funding contract that identifies the researcher or organization as performing the research as a contractor on behalf of the government. Second, the grant contract must contain appropriate 'authorization and consent' language. This can take the form of a broad authorization for the contractor to infringe any U.S. patents needed to perform the research,[84] or a narrow authorization for certain enumerated patents.[85] Third, the researcher or organization will need to keep scrupulous lab logs or notebooks to account for all of the uses of any apparatus or procedures that may infringe third party patents.[86] Finally, lest this *de facto* exemption seem too narrow to warrant inclusion in this chapter, note that the vast majority of university-based science research in the U.S. is performed under federal grant funding.[87]

Bayh-Dole government license defense

Under § 202(c)(4) of the codified version of the Bayh-Dole Act, federal research funding recipients must grant the U.S. government a non-exclusive

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[84] *E.g.*, ' "[t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier" '. *Madey v. Duke University*, 413 F.Supp.2d 601, 608 (M.D.N.C. 2006) (quoting 48 C.F.R. § 52.227-1).

[85] 'In contrast, 48 C.F.R. § 27.201-2(a) and 48 C.F.R. § 52.227-1 provide in other instances for inclusion of a narrower or "limited" authorization and consent clause, based on the use of language which grants the Government's authorization and consent, but only where (i) the patented invention is embodied in the structure or composition of an article accepted by the Government, or (ii) the patented invention is used in tools or methods which necessarily results from compliance with specifications in the contract or specific written instructions from the contracting officer.' *Id.* While courts will consider implied authorization and consent by the federal government, a dispute arising in this context will likely require expensive and time-consuming litigation.

[86] While not *all* funding for § 1498 authorized activities need come from the federal government, all activities must be in furtherance of the federal research grant.

[87] For example, the University of Washington received more than $1 billion in research funding in the 2006–07 fiscal year, 80% of which came from federal government sources. *See* University of Washington Office of News and Information, 'University of Washington achieves $1 billion research milestone' (August 1, 2007) *available at* http://uwnews.washington.edu/ni/article.asp?articleID=35716.

license to any patents arising from the research for use by or on behalf of the government ('Government License').[88] This license is *completely different* from its more famous statutory neighbor: the 'march-in rights', under § 203, that a funding agency can exercise only if the funding recipient has failed to commercialize the patent or otherwise triggered one of the specific bases for petition.[89] March-in rights might be thought of as similar to commercialization or working requirements in other countries.[90] By contrast, the Government License requires no triggering event to become effective, and indeed may become operative as a matter of law as well as by contract through the funding agreement. Every federal funding agreement executed after Bayh-Dole took effect must include a provision giving the government a non-transferable non-exclusive license. Thus, the government already has a non-exclusive license to any patent that might issue on an invention arising from federally funded research.[91]

The Government License was also invoked by Duke University as one of its defenses in *Madey v. Duke*.[92] Duke asserted that because much of its alleged infringing activity was work done under contract to the U.S. government, which had a Government License to Madey's patents from an earlier funding agreement, Duke now stood in as the agent of the government with rights to practice the patents as licensee. While the trial court initially seemed to favor this as an alternate ground to the common law research use exception,[93] the Federal Circuit made it clear on appeal that any invocation of a Government License must be supported by specific evidence that: (i) the patents in suit arose from federal funding and issued either after Bayh-Dole was implemented or the pre-Bayh-Dole funding agreement contained a clause reserving rights to the government; and (ii) the current research was performed

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88 'With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.' 35 U.S.C. § 202(c)(4). This license may also arise as a matter of law under this statutory provision, in addition to being included in the funding agreement. *See Madey v. Duke*, 413 F.Supp.2d 601, 611 (2006).

89 35 U.S.C. § 203.

90 *See supra* p. 523.

91 Note that even though Bayh-Dole was passed in 1980, much research leading to currently patented inventions was funded before Bayh-Dole's passage. Even though many federal funding agreements before Bayh-Dole contained the non-exclusive license grant back to the government, not all did. *See* Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 681–7 (2005).

92 307 F.3d 1351 (U.S. Federal Circuit 2002).

93 *See supra* pp. 527–9.

on behalf of the federal government and with specific authorization to practice the Government License on the federal government's behalf.[94]

On remand, the trial court determined that because the Bayh-Dole Act creates no private right of action it cannot create a private defense either.[95] Further, the trial court determined that any invocation of the Government License must be either in suits where the federal government is also a party or as part of a § 1498 defense. The court's rationale for the latter is that something more than the mere existence of a Government License to certain patents and a new funding agreement to a private party for research that might infringe those patents must exist. To wit, the new funding agreement must contain essentially the same kind of authorization and consent language as would extend the cover of § 1498 to the contract researcher. Accordingly, the trial court ultimately rejected Duke's invocation of the Government License defense, although it did allow that the existence of a Government License could play a role in any proceeding in the Court of Claims if Duke were successful in its § 1498 defense. In other words, the federal government could then assert that it owes no compensation to Madey because of the Government License.

There are some problems with the trial court's analysis, which is why this chapter does not treat the court's decision as the final word on use of the Government License defense. First, nothing in the Federal Circuit's comments on the Government License defense indicates that it categorically rejects that defense when used by a private party. To the contrary, the Federal Circuit merely raised evidentiary problems with Duke's reliance on the defense, while noting that Duke might well be able to develop the record further at trial to support such a defense.[96]

Second, a requirement that government funding agencies incorporate § 1498 authorization and consent language into funding agreements that cover activities for which a Government License exists is inappropriate. There is a tremendous difference between the government authorizing patent *infringing* activity for which it also then consents to be liable for reasonable compensation, on the one hand, and merely authorizing a private contractor to practice a Government License on its behalf, on the other. While it is understandable

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94 307 F.3d 1351, 1363–4.

95 *Madey v. Duke University*, 413 F.Supp.2d 601, 612–13 (2006) (citing the following cases for holding no right to a private action under Bayh-Dole, but *not* for the proposition that no private defenses might exist: *Platzer v. Sloan-Kettering Inst. for Cancer Research*, 787 F.Supp. 360, 364–5 (S.D.N.Y. 1992); *Gen-Probe, Inc. v. Center for Neurologic Study*, 853 F.Supp. 1215, 1217–18 (S.D.Cal. 1993); *Fenn v. Yale Univ.*, 393 F.Supp.2d 133, 141–2 (D.Conn. 2004)).

96 307 F.3d 1351, 1363–4.

that courts might require specific language from government agencies authorizing contractors to practice a Government License, this language could (and probably should) be different from that giving authorization and consent for infringing activities under § 1498. Requiring similar language which could have the effect of imposing compensatory liability on the government for infringing acts may well chill the government's use of its Government License, gravely cutting against the sound policy reasons for the license in the first place.[97]

Third, what is the point of the statutory language allowing the government to have the license practiced on its behalf, if contractors cannot use the license as a defense?[98] But why should government contractors have to either pay a license fee (if a license is even available from the patent owner) or scramble to find another *de jure* or *de facto* research use exception when the government holds a Government License for the research? Again, this vitiates a key part of the benefits that the government and public are supposed to be receiving in exchange for allowing private contractors to retain title to patents arising from federal funding.

State sovereign immunity under the U.S. Constitution

The last *de facto* research use exception to be considered in this chapter is of somewhat more limited scope, because it only applies to state agencies. Under

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[97] To wit, to enable the government to use that which it had already paid for, and to manifest one of the government and public's benefits to be received in exchange for public funding of private research.

[98] The trial court's ruling puts government contractors who are explicitly supposed to be practicing a Government License on behalf of a funding agent in an impossible bind. They cannot raise the Government License defense unless the government is also a party to the litigation, but no federal court other than the Court of Claims has jurisdiction over the government as a defendant in a patent infringement related case. So when would the government ever be a defendant in a patent infringement suit in a federal district court? Therefore, even if a federal agency added specific language to a funding agreement authorizing the research contractor to act on the government's behalf under a Government License, what good would this do the contractor? The contractor would be barred from raising the Government License defense unless the government also gave authorization and consent for the research contractor to infringe privately held patents. Even assuming that the trial court envisions some kind of limited § 1498 authorization and consent language narrowly addressing the patents to which a Government License exists – so that the contractor can properly raise a § 1498 defense and then the government can invoke its Government License to avoid paying reasonable compensation in a Court of Claims proceeding – such contortions require the inextricable tethering of two very different statutory provisions which, by their own language and legislative history, have never been linked before. Federal agencies and their contractors could decide to use such an approach as a 'belt and suspenders' contractual measure; they should not be *required* to do so.

the Eleventh Amendment to the U.S. Constitution, the federal courts may not be used to sue a state by citizens of either another state within the U.S. or foreign states.[99] Further, while the Eleventh Amendment is silent about whether citizens may sue their *own* state in federal court, the Supreme Court has ruled that they may not.[100] At the same time, patent infringement suits may only be brought in federal courts.[101] Ergo, patent owners cannot directly sue states for patent infringement. Because many state universities are state agencies, patent owners cannot sue them as this would be tantamount to suing the state. The limitation of this *de facto* exception – actually an *exemption* – to state researchers does not make it inconsequential though, as many of the largest and most influential research universities in the U.S. are state agencies.[102]

The history of the doctrine as applied to allegedly infringing activities by state researchers has had an uneven history however. Case law alternated between upholding state sovereign immunity against patent suits and abrogating it, until it appeared that the former had finally won out by the 1980s. In response to that, Congress passed both the Copyright Remedy Clarification Act (CRCA)[103] and the Patent and Plant Variety Protection Remedy Clarification Act (PRCA)[104] in the early 1990s that explicitly abrogated the doctrine for copyright and patent infringement. But, in 1999 the Supreme Court invalidated the PRCA as unconstitutional in the landmark case of *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.[105]

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[99] U.S. Constitution, 11th Amend. (1795) ('The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.').

[100] *See Florida Prepaid Secondary Education Expense Board v. College Savings Bank*, 527 U.S. 627, 634–5 (1999) (explaining that Article III of the U.S. Constitution was never meant to supersede the sovereign immunity that the states had before entering the Union).

[101] 28 U.S.C. § 1338(a) ('The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights, and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.').

[102] E.g., the entire University of California system, including branches at Berkeley, Los Angeles, San Francisco, etc., and the University of Washington system.

[103] Pub. L. No. 101-553 (November 15, 1990).

[104] Pub. L. No. 102-560 (October 28, 1992).

[105] 527 U.S. 627 (1999). The Court ruled that Congress had no direct power to pass the PRCA and abrogate state sovereign immunity, but rather could only have done so as a remedial measure to enforce the 14th Amendment's requirement of procedural due process for any state that deprives any person of life, liberty, or property. *Id.* at

Despite the general doctrine of state sovereign immunity, there are some extra complications that provide cautionary notes to any state research agency that wishes to rely on it as a *de facto* research use exception. The first, is that states can be deemed to have waived their sovereign immunity where they: (i) bring a case in federal court (immunity waived only for the subject matter of the particular case narrowly defined and compulsory counterclaims);[106] (ii) successfully remove a case from state to federal court;[107] or (iii) voluntarily participates in an administrative proceeding with a federal agency.[108]

The second complication is based on the doctrine first articulated in *Ex Parte Young*[109] wherein an action for injunctive relief against a state official as an individual – and not as a representative of the state – might lie even where the state itself enjoys the protections of state sovereign immunity. In that case, railway stockholders filed suit against the Minnesota State Attorney General complaining that a state statute establishing railway rates was unconstitutional. The district court enjoined the enforcement of the statute and when the Attorney General violated the injunction by attempting to enforce the statute anyway, the court found him in contempt. The Attorney General

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634–47. Section 5 of the 14th Amendment gives the Congress the power to pass laws to enforce other sections of the 14th Amendment, while § 1 provides that states shall not 'deprive any person of life, liberty, or property, without due process of law'. U.S. Constitution, 14th Amend. The patent owner argued that Congress passed the PRCA to remedy the problem of state infringement of patents, which constituted a deprivation of the patent owner's property. However, the Supreme Court found that this argument gave too little emphasis to the due process focus of the 14th Amendment: it does not authorize Congress to pass laws restricting states from taking *any* actions that might deprive someone of life, liberty, or property, but only those actions which are done *without due process of law*. The Court further found that there was not enough evidence in the legislative history of the PRCA nor the trial record to show that: (a) state patent infringement was widespread enough to pose a problem that Congress needed to redress; and (b) there were no adequate remedies available under state laws. Additionally, the Court asserted that, even though unintentional or negligent infringement of a patent is still actionable *as a matter of patent law*, unintentional or negligent actions on the part of a state do not violate the Procedural Due Process Clause of the 14th Amendment. Accordingly, absent any showing that states were willfully infringing patents, there would be no due process violation on the part of states that Congress could remedy through a new law.

106 *See Clark v. Barnard*, 108 U.S. 436 (1883); *Tegic Communications Corp. v. Board of Regents of the University of Texas System*, 458 F.3d 1335 (Federal Circuit 2006); *Regents of the University of New Mexico v. Knight*, 321 F.3d 1111 (Federal Circuit 2003).

107 *See Lapides v. Board of Regents of the University System of Georgia*, 535 U.S. 613 (2002).

108 *See Vas-Cath, Inc. v. Curators of the University of Missouri et al.*, 473 F.3d 1376 (Federal Circuit 2007).

109 209 U.S. 123 (1908).

appealed on the basis of state sovereign immunity. Ultimately, the Supreme Court held that state officials did not enjoy the protection of sovereign immunity when they attempt to enforce unconstitutional laws.

In further development of the *Ex Parte Young* doctrine, the Supreme Court has stated that private parties can sue state officials in their individual capacity for prospective injunctive relief when the officials are violating federal law.[110] Similar to *Young*, this requires identification of the specific officials and a finding of a threat of ongoing violations of law (else what would the injunction achieve). In particular, there must be 'some connection with the enforcement of the act, or else the suit is merely making [the official] a party as a representative of the state, and thereby attempting to make the state a party'.[111]

Accordingly, in the recent case of *Pennington Seed, Inc. v. University of Arkansas et al.*,[112] Pennington sought an injunction against various officials of the University of Arkansas but both the district court and then the Federal Circuit found that the named officials had insufficient connection to the alleged infringing activities. Specifically, Pennington named individuals then serving as the Chairman of the Board of Regents for the University of Arkansas System, the President of the University of Arkansas System, and the Chancellor of the University of Arkansas at Fayetteville as individual defendants. The Federal Circuit affirmed the district court's ruling that simply because some of these officials oversaw university IP policy, that fact did not create a sufficient nexus to the actually infringing activities. Additionally, because the suit was brought in Missouri, yet the university and officials were located in Arkansas, the court dismissed the individual defendants for lack of personal jurisdiction. Thus, even though Pennington did name one university professor as a defendant – and presumably one who truly was engaged in the allegedly infringing activities – its claims against that individual were dismissed as well, but only on the jurisdictional grounds.

Thus, while some commentators have suggested that the *Ex Parte Young* doctrine renders the state sovereign immunity doctrine unhelpful to state researchers, the picture is not so clear. Before *Pennington* there seems to have been a sense that courts would allow suits for injunctive relief against high level state university officials who could then be enjoined to order a stop to all manner of infringing activities on campus. This was probably always an incorrect reading of *Young* and its progeny; it is certainly wrong in light of

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110 *See, e.g., Frew v. Hawkins*, 540 U.S. 431 (2004).
111 *Ex Parte Young*, 209 U.S. 123, 157 (1908).
112 457 F.3d 1334 (Federal Circuit 2006).

Pennington.[113] Further, it is not clear that the *Ex Parte Young* doctrine is very helpful to *patent owners*. Because they can only sue to get an injunction on prospective infringing activities – and not for monetary damages either for retrospective or prospective infringements, nor presumably costs or attorneys fees – a lawsuit under the *Ex Parte Young* doctrine is a very expensive way to stop a researcher from experimenting either *on* or *with* your patented invention. Further, based on prior cases the odds are very long against the patent owner prevailing. I am unaware of any successful injunctions obtained by a patent owner against university researchers. Thus, while there seems to be a fairly clear path to obtaining such an injunction, one wonders in a legal realist way whether courts are just opposed to enjoining state public researchers from doing their work and will find ways to avoid issuing the injunction.

As a final practical point, the limitation of the *Ex Parte Young* doctrine to actual researchers directly engaged in infringing activities means that the injunction ceases to have much impact if/when researchers move on, either to new research or to a new institution. Of course, the research may well continue at the state university, but now the patent owner will have to seek a new injunction against the new researchers. For large labs with long-term principal investigators or directors who actually engage in the infringing activities, the injunction may have some value to the patent owner. But one wonders whether the actual infringing acts could nearly always be pushed on to a temporary student or post-doctoral-type researchers, such that the principal investigator (PI) or director is merely overseeing the activities. After *Pennington* a court might come out either way as to whether the PI or director has a sufficient nexus to the activities to be enjoined to stop the infringing activities. Of course, none of this has even raised the public relations challenges for patent owners – especially large well-known corporations – who can be easily demonized as trying to stifle public servants from doing their job on behalf of the public, for example, to try to find cures for cancer and other serious social problems.

To be sure, the foregoing *de facto* research use exceptions are a bit of a mixed bag. Further, they must be applied in a rather piecemeal way and each contains a certain degree of uncertainty. Finally, none of them directly covers commercially oriented R&D. In fact, all of them rely on characterizing the infringing activities as by or on behalf of federal or state governments. Thus, the

[113] Of course, the Supreme Court may still take a case on *certiorari* that could overrule *Pennington*. Until then *Pennington* governs for purpose of patent-based lawsuits (because of the Federal Circuit's exclusive jurisdiction with regard to appeals of patent cases).

commercial R&D exceptions found in other countries simply do not exist in the U.S. (except for the *de jure* regulatory review exception of § 271(e)(1)).

At the same time, collectively the *de facto* research use exceptions could go a long way to ameliorating the concerns raised by non-profit and government researchers in the wake of *Madey v. Duke*. With relatively small changes in law or practices, the exceptions could be made much more powerful as well. Federal funding agencies could employ the Government License to greater effect,[114] and could even give § 1498 authorization and consent to researchers to enable them to do their work with less worry about lawsuits. States could implement § 1498 type provisions in their law so as to provide an adequate remedy for unauthorized state use of patented inventions. This would likely stave off, or render unconstitutional, any future attempts by Congress to abrogate state sovereign immunity because the states would have provided due process for any deprivations of property.[115] Done properly, these measures could largely refill the perceived vacuum of research exceptions after *Madey*. Admittedly, state universities might have somewhat of an edge in this model over private universities (for whom state sovereign immunity plays no role). Coupled with the fact that there does not seem to have been a deluge of lawsuits against public or private university researchers after *Madey* anyway, the *de facto* research use exceptions may well be adequate for non-profit, non-commercial research.

The special case of biomedical research tools

One particular aspect of the debate over the proper scope of research use exceptions – whether general or regulatory review – focuses on research *with* biotechnology-based biomedical research tools. The nature of these tools as molecules or cellular processes can challenge our intuitions about what should properly be construed as laboratory tools or equipment – and hence not covered by research *with* type exceptions – and what instead should be viewed as basic research methods or raw products that should be freely available for practice by all researchers. Of course, if the biotechnology research tool at issue is really a basic research method that is already known or obvious, or a product of nature, then any patent covering it is likely invalid. Thus, it may be that the debate over the extent to which research *with* type exceptions should cover patented biotechnology research tools should really be reconstituted as a debate over whether those tools should have been patented in the first place.

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[114] A 2003 Report by the U.S. General Accounting Office suggested that the Government License has been underutilized. GAO, Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions (July 2003).

[115] *See supra* note 103.

Because if the patents covering them are valid, then they must represent novel, non-obvious, useful, and enabled inventions over the prior art, within acceptable patent eligible subject matter. Accordingly, it is hard to see why they should be treated any differently from patented microscopes and other more conventional lab equipment that researchers normally do not question their obligation to purchase and/or license from their proprietors.[116]

Nonetheless, there has been substantial debate over the question of whether particularly university or non-profit researchers who are engaged in nominally non-commercial research should be covered in their use of such biotechnology research tools by a research use exception.[117] Commentators have proposed solutions based on mechanisms such as reach through royalties that would only begin if/when a successful new product emerged from the work done with the research tool,[118] or that focus more attention on the research *on* and research *with* distinctions.[119] Because of the extensive coverage of this issue elsewhere, this chapter does not further delve into the debate.

Conclusion

This chapter has considered the range of research use exceptions in use around the world in major technology-oriented countries. While most of the countries considered have fairly robust R&D and regulatory review research use exceptions, the U.S. has no commercial R&D exception, an extremely limited *de jure* common law exception for 'dilettante' experiments, and yet arguably the broadest regulatory review exception. At the same time, researchers employed by the federal or state governments, or funded by the federal government, can in many cases enjoy the protection of certain *de facto* research use exceptions. While some of these have analogues elsewhere – for example, the § 1498 government use clause and the Crown Right in the U.K. – these *de facto* exceptions may have more potential in the U.S. because of the extraordinary amount of research still conducted by or on behalf of the government. Further, it is not actually clear whether stronger or weaker research use exceptions are better for spurring innovation. Thus, the concluding paragraphs merely summarize the policy dimensions for policymakers considering their full range of options.

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116 *See, e.g., Integra Lifesciences I, Ltd.v. Merck KGaA, slip op. cited* (Federal Circuit, July 27, 2007) (Rader, J., dissenting).

117 *See, generally*, Pfaff, *supra* note 65; Holzapfel and Sarnoff, *supra* note 63).

118 *See, generally* Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001).

119 *See, generally* Katherine Strandberg, *What Does the Public Get? Experimental Use and the Patent Bargain*, WIS. L. REV. 81 (2004).

The first major dimension concerns commercial R&D exceptions versus government or public non-profit research exceptions. While it may seem easier to justify an exception for the latter, an exception for the former may do more to spur actual commercial innovation. At the same time, as other countries adopt Bayh-Dole-type laws, they will join the U.S. in having non-profit and educational institutions owning and licensing out potentially valuable patents – essentially becoming commercial players. Further muddying the waters, if the exception is limited to research *on* the patented invention, then allowing commercial parties to experiment in such a way can facilitate the goal of many patent systems to spur innovation by encouraging others to design around the patent.

Following from this, the second major dimension is the implications of allowing research *with* instead of just research *on* the patented invention. This is particularly important in the area of regulatory review exceptions. Policymakers should distinguish between research 'on' a patented drug – that is, study of the drug for purposes of creating fully bioequivalent generic versions – and research 'with' a patented drug – that is, using the drug to perform other sorts of research. Research 'on' the drug hews closest to the policy justifications for regulatory review exemptions

Finally, attention must be paid to whether exceptions can be combined. Because different kinds of research use exceptions have different scopes of coverage, follow-on researchers may seek to combine them to gain broader or 'longer' coverage. For example, in the U.S. one could theoretically combine the Government License under § 202(c)(4) with the regulatory review exception under § 271(e)(1) to gain essentially continuous coverage from public basic research through private commercialization R&D.

In conclusion, policymakers should be aware of the full range of research use exceptions – from exceptions for competitive commercial R&D to very narrowly tailored *de facto* research use exceptions for government research – and employ models that match broad research, public domain, and competition policies in their country. For example, U.S. policy seems to strongly disfavor compulsory licenses and government-granted head starts to a patent owner's commercial competitors, thus exceptions in the U.S. are largely limited to government use and regulatory review. However, policymakers may decide that the sorts of knowledge spillovers that might occur where strong, broad competitive commercial exemptions allow robust experimentation on and with a competitor's patented materials lead to a stronger innovation-based economy overall. While so many regions of the world apparently want to emulate Silicon Valley, simply adopting U.S.-style innovation laws, including research use exceptions, may not be the right path. As a threshold matter, the re-creation of U.S. state and federal innovation in another region will likely not by itself bring into being the next Silicon Valley. More importantly, innovation law and

research use exceptions can resonate deeply with a regional culture's views on the proper place of the arts, sciences, technology, and law in ordering a society and its broad welfare. Accordingly, policymakers need to consider deeply the goals and aspirations of all the stakeholders before changing innovation law and policy.

20 Compulsory licensing under TRIPS and the Supreme Court of the United States' Decision in *eBay v. MercExchange*

*Christopher A. Cotropia**

1 Introduction

The compulsory licensing of patents is a contentious issue in international patent law. Various countries support the practice as necessary to ensure access to socially beneficial technologies. Other countries disfavor compulsory licensing because of the harm it inflicts on the incentive to invent and creation of the very technology at issue. The dispute over whether and when a government may issue a compulsory license has focused, in part, on the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS').[1] Questions have arisen since TRIPS' adoption as to the circumstances under which TRIPS makes compulsory licensing available to Member States.

Recently, the dispute as to when unauthorized use of a patented invention should be allowed has also arisen under United States patent law in a unique context. Traditionally in the United States a patentee was awarded a permanent injunction preventing unauthorized use by an adjudged infringer as a matter of course. In 2006, the issuance of permanent injunctions in essentially all patent cases was revisited by the Supreme Court of the United States in *eBay Inc. v. MercExchange L.L.C.*[2] The Supreme Court decided the statute that gave courts the power to issue an injunction, 35 U.S.C. § 283, required the usage of a four-factor equitable test to decide whether an injunction should be awarded. As a result of this opinion, injunctions have been denied by United States district courts in at least seven cases, allowing the infringer to continue practicing the patented technology without the patentee's consent. While

* I would like to thank Dawn-Marie Bey, Graeme Dimwoodie, Tim Holbrook, and Joe Santamauro for their helpful comments.

1 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

2 126 S. Ct. 1837 (2006).

injunctions have issued in at least triple the number since *eBay*, the *eBay* decision and the multiple denials of injunctions represent a significant change in United States patent law.

The reason the *eBay* decision and its application are mentioned in the same context as TRIPS and compulsory licensing is that one of the arguments before the Supreme Court, advanced by the United States and others, is that a move away from automatic permanent injunctions potentially puts the United States in noncompliance with TRIPS. The Supreme Court did not address this question; however, with the denial of injunctions and resulting unauthorized use due to *eBay*, the question is ripe for answering.

This chapter does just that, first placing the *eBay* decision in the context of compulsory licensing and next, evaluating the decision under TRIPS. In particular, the chapter evaluates the effect of an injunction denial pursuant to *eBay* both under the exceptions in TRIPS Articles 30 and 31 and the remedial provision – Article 44. While this discussion is important on a micro-level, the discussion also has macro ramifications, potentially prompting a shift in the overall discourse concerning compulsory licensing and TRIPS. Furthermore, *eBay* may identify an optimal method for Member States to address social objectives by giving their judiciaries the flexibility to allow unauthorized uses on a case-by-case basis. This approach may protect the public interest while doing minimal violence to the patentee's rights and ability to recoup research and development costs.

2 Compulsory licensing of patents under TRIPS

While the phrase 'compulsory license' never appears in the patent part of the TRIPS agreement,[3] TRIPS does address the concept. TRIPS handles compulsory licenses as an exception to the agreement's minimum requirement that all Member States afford a patentee a right of exclusivity during the complete patent term. TRIPS describes a set of circumstances that establish a floor at which any Member State is allowed to issue compulsory licenses. The compulsory licenses that are allowed fall into two categories – where there is an overriding public interest or where the patent rights are being used in an anticompetitive manner. This framework regarding compulsory licensing under TRIPS is described in more detail below. However, before the specifics of TRIPS are explored, a brief primer on compulsory licenses is given for background.

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[3] TRIPS does, however, mention compulsory licensing by name when discussing trademarks. *See* TRIPS, art. 21 ('Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.').

2.1 Primer on compulsory licensing

The grant of a patent traditionally gives its owner a limited period of exclusivity where the patentee can prevent others from practicing the patented invention. This limited period of exclusivity affords the patentee control over the invention's price and, in turn, gives the patentee a mechanism by which she can recoup her research and development costs.[4] Exclusivity maintains the incentive to invent because would-be inventors know there is a vehicle – the patent – by which invention costs can be regained. This right to exclusivity is enforced in most countries by the judicial system, with the unauthorized manufacture, use, sale, offer to sale, or import of a patented technology deemed to be infringement.[5] The usual remedy for patent infringement is monetary damages to compensate for past harm and the issuance of an injunction to prevent any future harm.[6]

Compulsory licensees take away the patentee's exclusive control over the patented technology. The patentee can, and quite often does, authorize others to practice the patented technology, which is usually done for a negotiated fee. Compulsory licenses, in contrast, are basically 'involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state'.[7] Compulsory licenses are an abrogation of a patentee's right, where the government allows itself or a third party to practice the patented invention without the patentee's consent. The method of implementation and the scope of compulsory licenses vary, but most focus on the patent right to exclusivity and vitiate it under specific circumstances. Such compulsory license laws can be targeted. For example, the Thailand government announced in 2006 that it intended to issue a compulsory license for a patent covering an AIDS treatment drug.[8] In contrast, compulsory licenses laws can be more general. Brazil's local working requirement law is an example of this broader approach. Article 69 of Brazil's 1996 Industrial Property Law allows the

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[4] *See* Christopher A. Cotropia, '*After-Arising*' *Technologies and Tailoring Patent Scope*, 61 N.Y.U. ANN. SURV. AM. L. 151, 168–71 (2005); Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129–30 (2004).

[5] *See, e.g.*, 35 U.S.C. § 271.

[6] *See, e.g.*, 35 U.S.C. §§ 283, 284.

[7] Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349 (1993) (*quoting* Paul K. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes* (Economic Council of Canada 1981)).

[8] Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public Use of Patent for Pharmaceutical Products (Nov. 29, 2006) *available at* www.wcl.american.edu/pijip/documents/ThailandCL Announcement.doc.

government to issue a compulsory license if the patentee does not manufacture the patented technology locally within three years of the patent's issuance.[9]

The concept of compulsory licensing runs counter to basic patent theory.[10] The possibility of compulsory licensing and the involuntary breaking of exclusivity can erode the incentive to invent. A would-be inventor can no longer depend on patent exclusivity as a means of recouping costs because of the uncertainty of such exclusivity. As the likelihood that the patent system will bust patents via compulsory licenses increases, the incentive to create patentable inventions decreases. Compulsory licensing also harms a patentee's ability to recover invention costs by controlling distribution and pricing of the patented technology across different markets. Given that compulsory licensing may deter the creation of the very technology the patent system intends to foster, there must be a significant countervailing interest to justify such licensing. There needs to be some overriding 'political or social objective' that requires a compulsory license for the objective to be met.[11]

2.2 Compulsory licensing allowed under TRIPS

Pursuant to Article 28, TRIPS requires that a Member State provide a patentee with the right to exclude the practice of the patented invention.[12] Article 27 provides that this right to exclude shall be 'enjoy[ed] without discrimination'.[13] Patent rights must also stay in force for the full term of exclusivity.[14] TRIPS, through these requirements, establishes patent exclusivity as a minimum level of protection that all Member States must observe. Compulsory licenses abrogate this exclusivity by forcing the patentee to allow the government or a third party to practice the patented invention.

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9 *See* Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 380–83 (2002).

10 *See* Colleen Chien, *Cheap Drugs at What Price to Innovation: Does Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 872–3 (2003).

11 Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT'L L. & POL'Y 769, 812 (1997).

12 TRIPS, *supra* note 1, art. 28.1 (noting that a 'patent shall confer on its owner . . . exclusive rights').

13 TRIPS, *supra* note 1, art. 27.1 ('[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.').

14 TRIPS, *supra* note 1, art. 33 ('The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.').

TRIPS provides limited exceptions to this right of exclusivity under which compulsory licenses are allowed.[15] Article 8 of TRIPS sets forth principles that define the situations under which exceptions are acceptable. First, a Member State may protect 'public health and nutrition' and other 'public interests in sectors of vital importance to [a state's] socio-economic and technological development'.[16] A Member State may also minimize 'abuse[s] of intellectual property rights' that 'unreasonably restrain trade or adversely affect the international transfer of technology'.[17] These are, however, only general principles. Article 8 does not explicitly identify a mechanism by which Member States can allow unauthorized use of the patented technology.

Articles 30 and 31 do provide such a mechanism. Article 30 is a substantive exception, detailing three criteria for any exception to exclusivity. Article 31, in contrast, is primarily procedural in nature, detailing a list of requirements for a limitation to exclusivity. Taken together, the Articles appear to define the universe of allowed unauthorized use under TRIPS.[18] Both articles are introduced below.

2.2.1 Article 30 – a substantive-based exception Article 30 allows Member States to 'provide limited exceptions to the exclusive rights conferred' under TRIPS. There are three substantive requirements in Article 30 that must be met for there to be an allowed exception to patent exclusivity. An exception (1) must be a limited one; (2) cannot 'unreasonably conflict with a normal exploitation of the patent'; and (3) cannot 'unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties'.[19] The plain language of Article 30 would allow a

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[15] *See* J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, 29 INT'L L. 345, 351–8 (1995) (identifying arts 30 and 31 as limitations to a patentee's exclusive rights).

[16] TRIPS, *supra* note 1, art. 8.1 ('Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.'); *see also* Reichman, *supra* note 15, at 355–6.

[17] TRIPS, *supra* note 1, art. 8.2 ('Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'); *see also* Reichman, *supra* note 15, at 355–6.

[18] As will be discussed *infra*, Article 44.2, allowing Member States to deny injunctions in certain circumstances, may create another, *de facto*, exception.

[19] Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. OF INT'L ECON. L. 431, 437 (2004).

Member State to issue a compulsory license – which limits a patent's exclusivity – if these substantive requirements are met. However, many have argued that Article 30 is intended to allow only very specific exceptions to exclusivity such as private noncommercial use, prior user rights, and experimental use.[20] Regardless of one's view on Article 30, it clearly allows unauthorized use and the accompanying circumvention of patent rights when the three criteria are met.

The first substantive requirement under Article 30 is that any exception must be a 'limited exception'. This requirement 'connotes a narrow exception – one which makes only a small diminution of the rights in question'.[21] For the second requirement, 'exploitation' 'refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent'.[22] The modifying term 'normal' means that the exploitation that cannot be unreasonably conflicted includes both 'what is common within a relevant community' and those activities that would fall under 'a normative standard of entitlement'.[23] '[N]ormal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity.'[24] The third, and final substantive requirement under Article 30, compares the legitimate interests of the patent owner and third parties. The 'legitimate interest[s]' that can be considered include those that reflect 'widely recognized policy norm[s]'.[25]

Notably, these three requirements speak to when, substantively, a break in exclusivity is allowed under TRIPS. Article 30 does not articulate any procedural requirements that must be met when determining whether Article 30's requirements are fulfilled. Article 31, in contrast, is much longer on procedure and includes very few substantive requirements.

2.2.2 Article 31 – a procedural-based exception Article 31 provides another ground for a Member State to disturb a patentee's exclusivity and

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20 *See* Carlos Correa, PATENT RIGHTS, IN INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE, THE TRIPS AGREEMENT, 207–08 (Carlos Correa & A. Yusef eds., 1998).

21 *See* Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Report of WTO Dispute Settlement Panel, 2000) ('*Canada – Pharmaceutical Products*') at ¶ 7.30; *see also* Dinmwoodie & Dreyfuss, *supra* note 19, at 438.

22 *Canada – Pharmaceutical Products*, *supra* note 18, at ¶ 7.54.

23 *Id.* at ¶ 7.54.

24 *Id.* at ¶ 7.55.

25 *Id.* at ¶ 7.77.

issue a compulsory license. The exception provided for under Article 31 is in addition to, and is not supposed to overlap with, the exceptions provided for by Article 30.[26]

Article 31, like Article 30, speaks to when others can use a patented technology without the authorization of the patentee. If the list of procedural requirements is met, then the government is allowed to issue a compulsory license that allows a government or third party to engage in unauthorized use of a patented technology.[27] The procedural requirements run the gamut. For example, unauthorized use must be considered on a case-by-case basis.[28] The unauthorized use must also be limited in 'scope and duration', non-exclusive, and subject to review.[29] In addition, the unauthorized user must have made prior efforts to license the patented technology before unauthorized use is allowed under TRIPS.[30] And the use must be limited to the domestic practice of the patented technology.[31]

Article 31 relaxes the procedural requirements when there are certain substantive reasons for allowing the unauthorized use. For example, if the unauthorized use is meant to remedy a public interest that rises to the level of a 'a national emergency or other circumstance of extreme urgency', prior efforts to license are not required.[32] If the unauthorized use is being used to remedy anticompetitive use of the patent, neither prior efforts to license or limiting the compulsory license to domestic use is required.[33]

Article 31's lack of substantive criteria was addressed in 2001 in a Declaration on TRIPS and Public Health issued by World Trade Organization ('WTO') Members at the Doha Ministerial Conference (the 'Doha Declaration').[34] The Declaration was spurred by Member States' efforts to use

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[26] TRIPS, *supra* note 1, art. 31 n.7 (' "Other use" refers to use other than that allowed under Article 30.').

[27] TRIPS, *supra* note 1, art. 31 ('Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions . . . .)'.

[28] TRIPS, *supra* note 1, art. 31(a).

[29] TRIPS, *supra* note 1, art. 31(c), (d), and (i). These provisions are further qualified when particular circumstances are present. *See, e.g.*, art. 31(c) (noting that the limit scope and duration requirement is further limited 'in the case of semi-conductor technology' to either 'public non-commercial use or to remedy a practice determined after judicial or administrative process to be anticompetitive').

[30] TRIPS, *supra* note 1, art. 31(b). This provision also has various exceptions.

[31] TRIPS, *supra* note 1, art. 31(f).

[32] TRIPS, *supra* note 1, art. 31(b).

[33] TRIPS, *supra* note 1, art. 31(k).

[34] *See* Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT'L REV.

compulsory licensing for certain pharmaceuticals patents to remedy the AIDS epidemic.[35] For example, South Africa passed the Medicines and Related Substances Control Act of 1997, which allowed the South African health minister to either ignore patent rights and import generic drugs or grant compulsory license patents in light of a national health emergency.[36] Some Member States, such as the United States, argued that such compulsory licensing is not allowed under TRIPS. The Doha Declaration attempts to resolve this disagreement by further clarifying Article 31. The Declaration indicates that TRIPS allows a Member State to take steps to combat urgent health crises by 'promot[ing] access to medicines for all'.[37] The Doha Declaration continues, stating that '[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted' and that '[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme emergency . . .'.[38] Since the Declaration's drafting, Member States adopted a proposal to amend Article 31 to include parts of the Doha Declaration.[39]

3 United States Supreme Court's Decision in *eBay*

The United States Supreme Court issued its decision in *eBay Inc. v. MercExchange, L.L.C.* in 2006. The decision addressed the circumstances

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1299, 1339 (2002) ('The WTO met in Doha to provide guidance to Members because TRIPs failed to clearly define the circumstances that would justify a Member's authorization of an exception, such as a compulsory license.'). Such an action was needed, particularly with respect to Article 31. *See, e.g.*, Thomas F. Cotter, *Market Fundamentalism and the TRIPs Agreement*, 22 CARDOZO ARTS & ENT. L.J. 307, 316 (2004) ('TRIPs does not, in so many words, address what might appear to be the most obvious question surrounding the issue of compulsory licensing, namely the grounds which nations may invoke as reasons for requiring owners to license their patents.').

35 *See* Cotter, *supra* note 34, at 317–18.

36 World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 [hereinafter Doha Declaration], available at http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/Min01/DEC2.doc.

37 Doha Declaration ¶ 4.

38 Doha Declaration ¶ 5(b), (c).

39 *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Proposal for a Decision on an Amendment to the TRIPS Agreement*, IP/C/41 (Dec. 6, 2005), available at http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc.

under which a permanent injunction can issue to remedy the infringement of a valid patent. The decision itself, and its recent application by district courts in the United States, are explored below. Of particular interest is under what set of facts injunctions will not issue pursuant to *eBay* and what remedy courts will award in the injunction's place.

3.1 Remedies in United States patent law

In the United States, as in most countries, the judicial remedy for the infringement of a valid patent is comprised of two components. First, the patentee is awarded monetary damages for past harms – the infringement prior to judgment.[40] This past damages award can take the form of lost profits – the profits the patentee would have enjoyed but for the infringement[41] – or, at the very least, a reasonable royalty – the royalty rate a willing patentee and infringer would have negotiated just before the beginning of infringement.[42] Second, the patentee enjoys a permanent injunction starting at the time of judgment that prohibits the infringer from continuing to engage in the infringing activity.[43] This second remedial component goes to the heart of the grant of exclusivity that accompanies a valid patent in the United States.[44]

The United States Patent Act gives courts the authority to grant injunctions in patent cases. Specifically, 35 U.S.C. § 283 provides that:

> The several courts having jurisdiction of cases under [the Patent Act] may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Prior to the Supreme Court's decision in *eBay*, the United States Court of Appeals for the Federal Circuit, the appellate court with exclusive jurisdiction over patent appeals in the United States,[45] consistently held that a permanent injunction should issue pursuant to § 283 as a matter of course if a valid patent is found infringed.[46] The Federal Circuit noted that '[b]ecause the "right to

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[40] *See* 35 U.S.C. § 284 ('Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less that a reasonable royalty for the use made of the invention by the infringer . . . .').

[41] *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978) (reciting the factors for determining entitled to lost profit damages).

[42] *See Georgia-Pacific Corp. v. U.S. Plywood Co.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (listing the factors for determining the reasonable royalty).

[43] *See* 35 U.S.C. § 283.

[44] *See* Christopher A. Cotropia, Note, *Post-Expiration Patent Injunctions*, 7 TEX. INTELL. PROP. L.J. 105, 106 (1998) ('The injunction and its ability to exclude is the most important remedy from the patentee's point of view.').

[45] *See* 28 U.S.C. § 1295(a).

[46] *See, e.g., Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246–7 (Fed. Cir. 1989).

exclude recognized in a patent is but the essence of the concept of property," the general rule is that a permanent injunction will issue once infringement and validity have been adjudged'.[47] The court recognized only 'rare instances' in which an injunction should not issue, such as when the patentee's failure to practice frustrates an important public health need for the invention.[48]

3.2 The eBay Inc. v. MercExchange, L.L.C. *Decision*

The *eBay* case involved eBay, Inc., which owns and operates an Internet website that allows buyers and sellers to search for goods and to purchase them by participating in live auctions or by buying them at a fixed price. The technology at issue in the case was the fixed-price purchasing feature of eBay's website.[49] MercExchange, L.L.C. alleged that eBay infringed three of MercExchange's patents. After a jury trial, eBay was found liable for willfully and directly infringing one of MercExchange's patents and MercExchange was awarded $ 10.5 million.[50]

The district court did not grant MercExchange a permanent injunction.[51] The court found the MercExchange would not suffer the required irreparable harm to justify an injunction because of MercExchange's 'willingness to license its patents, its lack of commercial activity in practicing the patents, and its comments to the media as to its intent with respect to enforcement of its patent rights'.[52] The Federal Circuit, on appeal, reversed the district court's denial and instituted a permanent injunction. The court specifically noted that:

> The fact that MercExchange may have expressed willingness to license its patents should not, however, deprive it of the right to an injunction to which it would otherwise be entitled. Injunctions are not reserved for patentees who intend to practice their patents, as opposed to those who choose to license. The statutory right to

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47 *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1338–9 (Fed. Cir. 2005).

48 *Id.* at 1338; *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547–8 (Fed. Cir. 1995) (en banc); *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found.*, 146 F.2d 941, 944–5 (9th Cir. 1945) (finding that public interest warranted refusal of injunction on irradiation of oleomargarine); *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (denying a permanent injunction against city operation of sewage disposal plant because of public health danger).

49 There were two other defendants whose technology was at issue in the case. Half.com, a wholly owned subsidiary of eBay, owns and operates an Internet website that allows users to search for goods posted on other Internet websites and to purchase those goods. And ReturnBuy, which owned and operated an Internet website that was hosted by the eBay website.

50 *MercExchange, L.L.C. v. eBay, Inc.*, 275 F. Supp. 2d 695, 710 (E.D. Va. 2003).

51 *Id.* at 711–15.

52 *Id.* at 712.

> exclude is equally available to both groups, and the right to an adequate remedy to enforce that right should be equally available to both as well.[53]

The permanent injunction issue was then appealed to the Supreme Court. The Supreme Court took the appeal to determine 'the appropriateness of [the] general rule' that permanent injunctions should issue when patent infringement is found.[54]

In a unanimous opinion, the Supreme Court rejected the Federal Circuit's general rule and held that courts must apply the well-established, general four-factor test for determining whether a permanent injunction should issue.[55] 'We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.'[56]

For an injunction to issue, '[a] plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'[57] The Court concluded that '[n]othing in the Patent Act indicates that Congress intended such a departure. To the contrary, the Patent Act expressly provides that injunctions "may" issue "in accordance with the principles of equity" '.[58] Section 283 mandates the use of this equitable, four-part test.

The Court also explicitly rejected categorical rules that went against injunctions. The Court dismissed the district court's analysis because, while it 'recited the traditional four-factor test', the district court 'appeared to adopt certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases'.[59] The Court rejected the conclusion that all patentees who are both willing to license and are not commercially practicing their patents should not be awarded injunctions. The Court identified 'university researchers' and 'self-made inventors' as those who, while falling into the district court's categories, 'may be able to satisfy the traditional four-factor test'.[60]

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53 *eBay*, 401 F.3d at 1339.
54 *eBay Inc. v. MercExchange*, L.L.C., 126 S. Ct. 1837, 1839 (2006).
55 *Id.*
56 *Id.* at 1841.
57 *Id.* at 1839.
58 *Id.* (quoting 35 U.S.C. § 283).
59 *Id.* at 1840.
60 *Id.*

There were two concurrences. The first concurrence was authored by Chief Justice Roberts and joined by Justice Scalia and Justice Ginsburg. In the concurrence, the Chief Justice noted that '[f]rom at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases'.[61] While the Chief Justice acknowledged that this historical practice does not create a general rule, he also explained that the discretion to issue injunctions is not unbounded.[62] The brief concurrence concluded by noting that '[w]hen it comes to discerning and applying those standards, in this area as others, "a page of history is worth a volume of logic" '.[63]

The second concurrence was authored by Justice Kennedy and joined by Justices Stevens, Souter, and Breyer.[64] Justice Kennedy indicated that district courts should take note of 'the nature of the patent being enforced and the economic function of the patent holder', which in present cases is 'quite unlike earlier cases'.[65] He identified the existence of industries where firms use patents to mainly obtain licensing fees and injunctions in these instances 'can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent'.[66] In addition, '[w]hen the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest'.[67] Finally, with respect to business method patents, their 'potential vagueness and suspect validity . . . may affect the calculus under the four-factor test'.[68]

3.3 Doctrinal implications of eBay *on United States patent law*

The Supreme Court's decision in *eBay* is short and to the point. The Court holds simply that 'the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards'.[69] Section 283 does not mandate a permanent injunction in all patent cases – injunctions need to be determined on a case-by-case basis.

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61 *eBay*, 126 S. Ct. at 1841 (Roberts, C.J., concurring).
62 *Id.* at 1841–2.
63 *Id.* at 1842 (quoting *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921) (opinion for the Court by Holmes, J.)).
64 *Id.*. (Kennedy, J., concurring).
65 *Id.*
66 *Id.*
67 *Id.*
68 *Id.*
69 *eBay*, 126 S. Ct. at 1841.

3.3.1 Failure to commercialize as the basis for the denial of an injunction under eBay However, the doctrinal implications of the opinion's holding are still unclear. Specifically, the opinion leaves open how, exactly, particular facts should influence the four-factor analysis. The Court's opinion lists three facts that should not, by themselves, control the injunction question. A patentee's willingness to license the patent does not automatically result in a denial of an injunction.[70] In addition, a patentee's lack of commercial practice of the patented technology does not automatically deny an injunction.[71] On the other side, a finding of patent infringement does not automatically result in a grant of an injunction.[72]

The concurrences try to provide more guidance as to how certain facts should affect the discretionary analysis. The concurrence authored by Chief Justice Roberts suggests that the existence of patent infringement 'often implicates the first two factors of the traditional four-factor test' – irreparable injury and inadequate remedy at law.[73] And the implication is that these two factors should favor an injunction in most cases. As a result, Chief Justice Roberts's concurrence suggests that, while the four-factor test should be used in all cases, injunctions will still usually issue.

The concurrence by Justice Kennedy focuses on those facts that support a denial of a permanent injunction. The use of the patent to 'primarily . . . obtain licensing fees' supports the denial of an injunction.[74] If the patent is to a small component in a multi-component device and the threat of an injunction is 'employed simply for undue leverage in negotiations', two of the equitable factors should indicate no injunction – that there is an adequate remedy at law and concerns for the public interest.[75] Finally, if the patent is a business method patent, the patent's 'vagueness and suspect validity' can effect the discretionary decision and result in a denial of an injunction.[76] Justice Kennedy's concurrence has a very different take on the Court's holding than Chief Justice Roberts. Justice Kennedy sees the *eBay* decision significantly changing the landscape of the patent system and resulting in more denials of permanent injunctions.

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70 *Id.* at 1840.

71 *Id. See also Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 422–30 (1908) (rejecting that a court of equity has no jurisdiction to issue an injunction when the patentee has unreasonably declined to use the patent).

72 *Id.*

73 *eBay*, 126 S. Ct. at 1841 (Roberts, C.J., concurring).

74 *Id.* at 1842 (Kennedy, C.J., concurring).

75 *Id.*

76 *Id.*

Thus, the main opinion does not give that much direction on how certain facts should influence the equitable, four-factor test. The concurrences, in contrast, provide a little more direction. The problem is that they are concurrences and are not supposed to control future decisions. In addition, they push in opposite directions – Chief Justice Roberts supporting the same level of permanent injunctions and Justice Kennedy supporting less. The concurrences also expose a potential problem with the *eBay* decision. The Court is specific – there cannot be any categorical rules. It must be a true, case-by-case equitable analysis. But the concurrences show the temptation to create rules – identify specific factual circumstances where injunctions should or should not be granted. The concurrence also demonstrates the likelihood that courts, like the Supreme Court Justices did, will disagree on these rules.

Lower court cases applying the *eBay* decision shed some light on the actual impact of the Supreme Court's decision. Most courts after *eBay* are still issuing permanent injunctions, with a permanent injunction currently being issued at the rate of three cases for every case that denies an injunction. And for these few denials, the single factor that courts look to most often to support a denial of a permanent injunction under *eBay* is the patentee's failure to commercially practice the patented invention.[77]

The district court's decision in *Paice LLC v. Toyota Motor Corp.* provides a good example of how the patentee's failure to commercialize the invention results in a denial of a permanent injunction under *eBay*.[78] The patented technology at issue covered a component of a hybrid automobile's transmission. The patent was found valid and Toyota's hybrid transmission was found to infringe. The district court, however, denied the patentee a permanent injunction against Toyota. The court applied the four-factor equitable test identified in *eBay*. The court concluded, under the first factor, that the patentee would not suffer any irreparable harm if Toyota was allowed to continue to use the infringing component. The court also concluded, under the second factor, that monetary damages were enough to compensate the patentee for Toyota's continued patent infringement. The main fact relied upon to reach these conclusions was the patentee's failure to practice the invention.

For the first factor under *eBay*, the patentee's failure to produce and sell the patented component or compete with Toyota meant that any future harm from Toyota's infringement was easily remedied by a damage award.[79] The paten-

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[77] *See, e.g., Visto Corp. v. Seven Networks, Inc.*, No. 2:03-CV-333-TJW, 2006 WL 3741891, at *4 (E.D. Tex. Dec. 19, 2006); *Paice LLC v. Toyota Motor Corp*., No. 2:04-CV-211-DF, 2006 WL 2385139, at *5 (E.D. Tex. Aug. 16, 2006); *z4 Techs., Inc. v. Microsoft Corp*., 434 F. Supp. 2d 437, 440–41 (E.D. Tex. 2006).

[78] *See Paice*, 2006 WL 2385139 at *5.

[79] *Id.*

tee would not lose any market share or brand name recognition. Instead, the patentee would simply lose licensing revenue that 'can be remedied via monetary damages in accordance with the reasonable royalty set by the jury'.[80] This analysis also supported the court's next conclusion that, under the second factor under *eBay*, there was an adequate remedy at law.[81]

Other district courts have followed a similar analysis after *eBay*, focusing on the patentee's failure to practice the patented invention to justify a denial of a permanent injunction.[82] The courts all go through the four-factor analysis in an attempt to stay true to the holding in *eBay*. But the practical effect is that this single fact – lack of commercialization – dictates the result in most cases. This demonstrates a heavy reliance on Justice Kennedy's concurrence and potentially ignores the specific instruction in the majority opinion that such facts should not, by themselves, control the discretionary inquiry.

There have been, however, cases in which a non-producing patentee has been granted a permanent injunction under *eBay*. In *Commonwealth Scientific & Industrial Research Organistion v. Buffalo Technology Inc.*, the district court granted a permanent injunction to the non-producing research institution and technological licensing arm of the Australian Government.[83] The patentee did not commercialize its patent on wireless local-area networks, but did assert that Buffalo Technology, and others, infringed the patent.

The district court found, under the first factor under *eBay*, that the patentee would suffer irreparable harm because if no injunction issue, the 'brand recognition or good will' of the patentee could be damaged.[84] In addition, there was not an adequate remedy at law because any royalty rate for continuing infringement would 'not necessarily include other non-monetary license terms that are as important as monetary terms'.[85] 'Monetary damages are not adequate to compensate [the patentee] for its damages, which are not merely financial.'[86]

The decision in *Buffalo Technology* rebuts the notion that all non-producing patentees will be denied injunctions after *eBay*. But it also highlights that courts are still unclear how certain facts play out under the *eBay* factors. The

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80 *Id.*

81 *Id.*

82 *See, e.g., z4 Techs.*, 434 F. Supp. 2d at 440–41.

83 No. 6:06-CV-324, slip op. at 1 (E.D. Tex. June 15, 2007).

84 *Id.* at 6–9 (noting that the patentee competes for research dollars and licensing fees and allowing another company to use their technology without a license would hurt the patentee's ability to obtain these).

85 *Id.* at 9–10.

86 *Id.* at 10 (using this fact as the basis to conclude there is no adequate remedy at law).

uncertainty, and potentially contradictory decision-making after *eBay*, should settle down, particularly after the Federal Circuit weighs in on how certain facts should influence the *eBay* factors. However, until the Federal Circuit speaks to this issue, it is still an open question as to how factors such as the patentee's failure to commercialize will affect the grant or denial of a permanent injunction. The one thing that does appear certain is that injunctions will continue to be awarded in most patent cases.

3.3.2 Remedy granted when an injunction is denied pursuant to eBay Another open question after *eBay* is what remedy should substitute for a denied permanent injunction. The district court in *Paice*, as well as other district courts, have continued to apply the reasonable royalty awarded for past infringement to the unauthorized use going forward.[87] That is, the infringer must pay only a reasonable royalty for each future use of the patented invention. District courts could, however, increase the payment rate going forward in an attempt to deter future infringement. Such an upward adjustment of the royalty rate for future infringement could be justified because any future activity is arguably a willful violation of the patent right. Under United States patent law willful infringement justifies up to trebling the damages amount.[88]

Therefore, there are two open doctrinal questions regarding the *eBay*'s application in patent cases – whether injunctions will always be denied for non-producing patentees and whether patentees will just be awarded reasonable royalties for future unauthorized use. How each of these questions is answered will affect how the *eBay* decision and its usage by United States courts are treated under TRIPS.

4 Analyzing *eBay* and its application under TRIPS

TRIPS requires exclusivity during the lifetime of the patent. Exceptions to this exclusivity must fall within one of two exceptions – set forth in Articles 30 and 31. The result of the *eBay* decision is that district courts, in some cases, will deny a permanent injunction. In turn, the courts erode the grant of exclusivity, allowing unauthorized use of the patented technology by a third party – the adjudged infringer. This prompts the question – does the denial of a permanent injunction pursuant to the *eBay* decision violate the TRIPS agreement?[89]

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87 *See Paice*, 2006 WL 2385139, at *5; *z4 Techs*, 434 F. Supp. 2d at 441.

88 35 U.S.C. § 284 ('[T]he court may increase the damages up to three times the amount found or assessed.'); *Knorr-Bremse Systeme Fuer Nutzafahrzeuge GmBH v. Dana Corp*., 383 F.3d 1337, 1342 (Fed. Cir. 2004) (en banc).

89 The question should, perhaps, be broadened to include the inquiry as to whether 35 U.S.C. § 283 is in compliance with TRIPS, given that the Supreme Court in *eBay* based its decision in part on the language of § 283. *See eBay*, 126 S. Ct. at 1839.

This question has been asked before. The denial of permanent injunctions and its impact on the United States' obligation under TRIPS was an issue briefed before the Supreme Court in *eBay*. Some argued, including the United States government, that making a denial of a permanent injunction more likely could put the United States in noncompliance. The Court, however, did not expressly answer the question. And situations have arisen where *eBay* has lead to the denial of a permanent injunction. The *eBay* holding has resulted in the denial of an injunction in at least seven patent cases.[90] Under these circumstances, the question as to *eBay*'s compliance with TRIPS needs to be answered.

This chapter attempts to answer the question in the following manner. First, the result of a denial of an injunction pursuant to *eBay* is further described by comparing such denials to the concept of a compulsory license. This further description of *eBay* is critical, given that compulsory licensing usually focuses on curtailing patent rights, while the *eBay* decision focuses on patent remedies. The *eBay* decision's application is then analyzed under the various TRIPS' articles governing exceptions to patent exclusivity.

4.1 An injunction denial pursuant to eBay *creates a* de facto *compulsory license*

A compulsory license is the involuntary licensing of the patented technology to either the government or third party to accomplish a socially beneficial goal. Article 8 of TRIPS articulates two common objectives for compulsory licenses – protecting a public interest or stopping anticompetitive behavior. Compulsory licensing can protect a public interest by either increasing production or access to the patented technology.[91] Or a compulsory license can cure abusive use of the patent right by allowing the legitimate use of the patented technology by another and, in turn, punishing the patentee. Compulsory licenses traditionally reach these goals by creating an exception to patentee's right to exclusivity. The government takes away the patentee's right of exclusivity for a particular period of time or for a particular use to achieve these social goals.

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[90] *See Sundance, Inc. v. DeMonte Fabricating Ltd*., 2007 WL 37742, at *2 (E.D. Mich. Jan. 4, 2007); *IMX, Inc. v. Lendingtree*, LLC, No. 03-1067-SLR, 2007 WL 62697, at *17 (D. Del. Jan. 10, 2007); *Visto Corp. v. Seven Networks, Inc.*, No. 2:03-CV-333-TJW, 2006 WL 3741891, at *4 (E.D. Tex. Dec. 19, 2006); *Voda v. Cordis Corp.*, No. CIV-03-1512-L, 2006 WL 2570614, at *5 (W.D. Ok. Sept. 5, 2006); *Paice*, 2006 WL 2385139, at *5 (E.D. Tex. Aug. 16, 2006); *z4 Techs*, 434 F. Supp. 2d at 440-41 (E.D. Tex. 2006). On remand, the district court in *eBay* denied MercExchange a permanent injunction. *See MercExchange, L.L.C. v. eBay, Inc.*, No. 2:01-CV-736 (E.D. Va. July 27, 2007).

[91] *See* Gianna Julian-Arnold, *supra* note 7, at 349–55.

In contrast, the *eBay* decision focuses on patent remedies, not patent rights. The Supreme Court case simply interprets 35 U.S.C. § 283 and instructs courts on how to determine whether to issue a permanent injunction as part of the remedy for patent infringement. The phrase 'compulsory license' does not appear in the opinion. Nor have the district court opinions after *eBay* really focused on the issue of compulsory licensing.[92]

Additionally, the four-factor test under *eBay* is not necessarily trying to accomplish one of the common goals of compulsory licenses. Keeping with its remedy-focused nature, the factors look more toward properly compensating, but not overcompensating, the patentee for the found infringement. The third and fourth factors under *eBay* do focus on the impact of exclusivity on third parties – the infringer and the public. But these later factors are considered in conjunction with the first two, which both look exclusively at whether an injunction is truly needed to make the patentee whole. Again, the main question in an *eBay* inquiry setting is remedying patent infringement, not whether to limit the patentee's rights.

A denial of a permanent injunction pursuant to *eBay*, however, forces the patentee to allow a third party to continue practicing the invention, regardless of the patentee's consent. This unauthorized use can be viewed as government sanctioned given that it is a statute, 35 U.S.C. § 283, that gives courts the discretion to deny an injunction. The Supreme Court recognized, and relied upon, this government-mandated discretion in coming to its decision.[93] Therefore, while *eBay* speaks to patent remedies, the *de facto* effect of an injunction denial is, by definition, a government-allowed compulsory license. Unauthorized use by a third party – the infringer – is mandated by the government in certain cases because of the discretionary language in 35 U.S.C. § 283.

But still, the traditional policy objectives of compulsory licenses may not be met under *eBay*. Courts may require a high royalty rate in lieu of an injunction in those cases where an injunction is denied pursuant to *eBay*. Courts may consider the infringer's continued use of the patented invention as an intentional disregard for the patentee's rights. Under U.S. patent law, willful infringement is the proper remedy in these circumstances, resulting in up to treble damages.[94]

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92 District courts have used the phrase, equating the denial of a permanent injunction to a compulsory license. *See, e.g.*, *Commonwealth Sci. & Indus. Research Organisation v. Buffalo Technology Inc.* No. 6:06-CV-324, 2007 U.S. Dist. LEXIS 43832 (E.D. Tex. June 15, 2007). But none of the cases has engaged in a thorough analysis as to whether such denials truly fall within the traditional understanding of a compulsory license.

93 *See eBay*, 126 S. Ct. at 1839.

94 *See supra* note 88.

A court may also award a higher rate to deter future, unauthorized use of the patented technology by the infringer. Courts, such as the one in *Paice*, determined under the first two equitable factors set forth in *eBay* that a permanent injunction overcompensated the patentee and was not needed to make the patentee whole. A court may still believe, however, that any future, unauthorized infringement should be stopped. A high royalty rate for future unauthorized use would fulfill these goals – not overcompensating the patentee like an injunction would, but compensating the patentee enough to deter future infringement. Such an application of *eBay* would run antithetical to the traditional concept of a compulsory license, where the royalty rate is set at a level to encourage, not deter, use of the patented technology by a third party. And such a result would not be surprising given that the first two equitable factors set forth in *eBay* – whether there is irreparable harm and an inadequate remedy at law – focus on proper compensation for the patentee, not on the public's interests or deterring a patentee's abusive behavior.

However, United States courts are just as likely to award only reasonable royalties going forward as a substitute for a permanent injunction. This has been the result in multiple district court cases applying *eBay*. In addition to the decision in *Paice*, the district court in the *Finisar Corp. v. DirecTV Group, Inc.* applied the reasonable royalty rate awarded by the jury for past damages to future uses of the patented technology by the infringer.[95] This type of judgment falls more in line with a traditional compulsory license because such a rate is more likely to allow the infringer to economically practice the patented invention without the patentee's authorization. A reasonable royalty for the future practice of the invention combined with the view that the discretion afforded under 35 U.S.C. § 283 is government approval of the unauthorized use brings *eBay* in line with the definition of a compulsory license.

Therefore, while the *eBay* decision is remedy oriented, its *de facto* effect is to limit a patentee's rights. The infringers in cases such as *Paice* and *Finisar* are allowed by the courts, via the discretion afforded by the government under 35 U.S.C. § 283, to continue to practice the patented invention against the patentee's wishes. If courts set the rates going forward at a high level to deter future infringement, the patentee's rights may be protected for all practical purposes. The judicial result is still, however, the allowance of unauthorized use, regardless of whether the infringer is able to take advantage of this use. All of this makes the effect of the *eBay* decision, in those cases where injunctions are denied, to be very compulsory license-like.

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95 No. 1:05-CV-00264 (E.D. Tex. July 6, 2006).

4.2 eBay *is compliant with TRIPS*

The *eBay* decision creates the real possibility that permanent injunctions may not issue against adjudged infringers. Such a result has already occurred in United States district court cases. And it runs counter to the situation before *eBay*, where injunction denials were essentially non-existent. While *eBay* is focused on patent remedies, its practical effect, as discussed above, is to permit unauthorized use by a third party at a defined royalty rate. As the United States government argued before the Supreme Court in *eBay*, a change in permanent injunction law could leave the United States noncompliant with TRIPS.

The question then becomes whether the *eBay* approach to denying exclusivity falls within any of the exceptions set forth in TRIPS. The following looks at the relevant TRIPS articles and concludes that *eBay*, while not meeting the criteria in Article 31, meets the substantive requirements articulated in Article 30 and falls in line with the principles set forth in Article 8. Furthermore, the *eBay* decision, since it is remedy focused, may also be allowed pursuant to Article 44, which deals directly with the injunction remedy.

4.2.1 Article 31 The four-factor equitable test described in *eBay* does not fall into the limited exception to exclusivity set forth in Article 31. This is the case because the test in *eBay* is focused on the substantive circumstances when an injunction should or should not issue and does not address procedure. As a result, the test in *eBay* does not include all of the necessary procedural requirements in Article 31. For example, Article 31(b) is not met because none of the equitable factors in *eBay* requires the infringer to have 'made efforts to obtain authorization from the' patentee before a permanent injunction can be denied.[96] In addition, nothing in the *eBay* decision requires a court to limit the unauthorized use to supplying the United States market, as required by Article 31(f). The equitable factors in *eBay* also fail to ensure that many of the other provisions of Article 31 are met. Put simply, an application of the *eBay* decision that results in a denial of a permanent injunction and unauthorized use does not necessarily meet the Article 31 requirements.

4.2.2 Article 30 There is, however, the general, more substantive-based exception to patent exclusivity set forth in Article 30. For *eBay* to meet the requirements of Article 30, the denial of injunctions pursuant to *eBay* must

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[96] TRIPS, *supra* note 1, art. 31(b). Prior licensing offers have been considered under the first two *eBay* factors. *See, e.g.*, *IMX*, 2007 WL 62697 at *17. But such prior offers are not required by the four factors nor are they considered in every case.

occur in cases where the allowed unauthorized use (1) is a limited exception; (2) does not 'unreasonably conflict with a normal exploitation of the patent' and (3) does not 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'.[97] The four-factor equitable test set forth in *eBay* falls in line with these requirements. All four factors work together to make sure that the three requirements of Article 30 are taken into account when determining whether an injunction should issue.

The first requirement under Article 30 is that any exception must be a 'limited exception'. For *eBay* to make only a limited exception, the denial of an injunction pursuant to the decision must result in 'only a small diminution of the rights in question'.[98] Here, the four-factor equitable inquiry creates such a limited exception. The *eBay* decision can result in unauthorized use. But, at most, this unauthorized use is with regards to a specific infringer, for a specific patent claim or claims, and for a particular infringing product or process. The case-by-case nature of the equitable inquiry under *eBay* prevents a blanket reduction in a patentee's rights. The *eBay* decision's limited nature even holds true when considering general categories of patentees. For example, comparing the decisions in *Paice* and *Commonwealth Sci. & Indus. Research Organisation* demonstrate that the *eBay* decision will not result in all non-producing patentees being denied a permanent injunction. Moreover, the exception created by *eBay* can potentially be even more limited if a court awards a high royalty rate in lieu of an injunction. This further minimizes the impact of an injunction denial on the patentee's rights because the high royalty rate going forward can have the same protective effect as an injunction.

The second requirement under Article 30 is that the limited exception cannot 'unreasonably conflict with a normal exploitation of the patent'.[99] Here, a denial of a permanent injunction under *eBay* has the potential to disturb the 'normal exploitation of the patent' as the concept has broadly been defined by the WTO.[100] A denial of an injunction allows an unauthorized use, one that a patentee could have licensed. Such licensing is an activity that qualifies as normal exploitation of the patent.[101]

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97 *See supra* note 18.

98 *See id.*

99 *See supra* note 19.

100 *Id.*

101 Patentees that purchase and assert patents to only extract licensing fees – so-called 'patent trolls' – may not be engaged in 'normal exploitation'. *See* Brenda Sandburg, *Trolling for Dollars*, Recorder (S.F. Cal.), July 30, 2001, at 1 (defining a patent troll as 'somebody who tries to make a lot of money off a patent that they are not practicing and have no intention of practicing and in most cases never practiced').

However, because of the first and second factor in *eBay*, there will be no 'unreasonabl[e] conflict' with such commercial exploitation. These two factors consider whether a monetary remedy will not irreparably harm the patentee and, in turn, properly compensate her for any continued infringement of her patent rights. For example, the district court in *Paice*, when looking at these two factors, considered whether an injunction was needed to aid in the patentee's licensing efforts or protect the patentee's market share in the patented technology. The court in *Commonwealth Sci. & Indus. Research Organisation* considered similar facts and also looked at potential harm to the patentee's goodwill and brand. These are all related to the impact of a denial on a patentee's ability to commercially exploit the patent. If the denial of an injunction will not commercially harm the patentee – mainly because monetary damages will serve as a true substitute – then the first two factors in *eBay* support a denial of an injunction. This is the very instance in which an injunction denial will not unreasonably conflict with the patentee's exploitation of the patented technology. The first two *eBay* factors have the same focus as Article 30's second requirement.

The third requirement under Article 30 compares the legitimate interests of the patent owner with that of third parties. The 'legitimate interest[s]' that can be considered include those that reflect 'widely recognized policy norm[s]'.[102] All of the four factors in *eBay* take policy norms into account and balance those of the patentee with those of the infringer and public at large. The first and second factors under *eBay* consider the legitimate interests of the patentee under patent policy. By showing concern for adequately compensating and preventing irreparable injury to the patentee, the first two *eBay* factors are concerned with protecting the patentee's rights and maintaining the incentive to invent. If the patentee cannot get an adequate remedy, then the trust in patent law's ability to assist an inventor in recouping her research and development costs is eroded. So, under the first two factors, courts make sure the patentee is properly compensated for any patent rights violations. In *Paice* and in *Commonwealth Sci. & Indus. Research Organisation*, the courts expressed concern for the patentee's research and development and licensing programs. While the cases came to different conclusions, the goal in each case was to ensure the patentee's rights were adequately protected to allow her to pursue

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But, the WTO's current definition of 'normal exploitation' observes that '[t]he specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices'. *Canada – Pharmaceutical Products*, *supra* note 18, ¶ 7.55. Patent trolls may be part of the 'evolution' of patent exploitation and thus considered the new 'normal' under TRIPS.

102 *See supra* note 23.

relevant commercial interests. Keeping in line with patent policy, the first two factors in *eBay* also make sure the opposite does not occur – that the patentee is not overcompensated and, in turn, over-incentivized. For example, if the patent covers a small part of a larger technological product, such as in *Paice*, an injunction can be used to hold up the whole product and, in turn, give the patentee leverage to extract value from other parts of the infringing product not covered by her patent. Put another way, the first two factors weed out those illegitimate interests of the patentee – interests to compensation beyond the value of the patented technology.

The third factor under *eBay* balances the impact of an injunction on both the patentee and the infringer – further ensuring that the third requirement of Article 30 is met. And the fourth factor under *eBay* looks at the public interest in the grant or denial of an injunction. For example, the impact on public health is considered under the fourth factor and qualifies as a policy norm to be considered in an Article 30 analysis. Through the fourth factor, *eBay* considers another third party interest – those of the public at large.

If one views *eBay* as solely focused on patent remedies and Article 30 solely focused on patent rights, the above analysis does not hold true. Article 30 creates narrow exceptions for such limited abrogation of patent rights such as *de minimis* use or an experimental use exception.[103] The denial of an injunction in a specific case is not an exception to a right, *per se*, but rather an acknowledgement that an existing right has been violated and a determination of an appropriate remedy for that violation. Issues regarding injunctions are not meant to be evaluated under Article 30 of TRIPS. But, as has already been discussed, an *eBay*-based denial of an injunction creates a *de facto* exception to the patent rights at issue. Furthermore, the plain language of Article 30 is focused on government action, and *eBay* is based on a statute – 35 U.S.C. § 283.

4.2.3 Article 44 Article 44 of the TRIPS agreement is different than Articles 30 and 31 in that it focuses on remedies, as opposed to rights. Specifically, Article 44 speaks to injunctions in intellectual property cases. Article 44.1 requires all Member States to give their judiciaries the 'authority to order a party to desist from an infringement'. Article 44.2 provides for alternatives to injunctions, allowing Member States to award declaratory judgments or 'adequate compensation' pursuant to the 'Member's law'.

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103 'Article 30 is commonly viewed as permitting exceptions for such things as private noncommercial uses (which many countries, though not our own, exempt from the scope of patent liability); prior user rights (which are more important in a first-to-file system than in our rather peculiar first-to-invent system); and some experimental uses.' *See* Cotter, *supra* note 34, at 314–15.

The discretionary approach in *eBay* may be more properly sanctioned under Article 44.2 of TRIPS. The Supreme Court in *eBay* applies the standard, equitable test for the remedy of an injunction under United States law. And in lieu of an injunction, a patentee receives monetary compensation. The *eBay* decision also does not take away a court's ability to grant a permanent injunction. In fact, after *eBay*, permanent injunctions are still being granted in most cases where infringement is found. All of this makes the *eBay* decision appear to fall in line with the Article 44. Furthermore, the *eBay* decision may better fall under Article 44 given that both *eBay* and Article 44 are remedy-oriented, as opposed to the right-oriented nature of Articles 30 and 31.[104]

Article 44.2, however, qualifies the allowance for Member States to award alternatives to injunctions in patent cases. Article 44.2 begins by requiring that the 'provisions of Part II addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with' before limiting remedies to the 'payment of remuneration'.[105] Part II of the TRIPS agreement includes the provisions governing such government allowance of unauthorized use – Articles 30 and 31. Article 44.2 thus requires that in patent cases either the substantive requirements of Article 30 or the procedural requirement of Article 31 be met first before a government action can substitute damages for an injunction.[106] This reads directly on the *eBay* situation, where the four-factor test born from a government statute – 35 U.S.C. § 283 – may dictate such a substitution. Article 44, as it is currently worded, may therefore add little to the discussion of the *eBay* decision and the United States' compliance with TRIPS.

But this interpretation potentially renders the second sentence of Article 44.2 meaningless. The second sentence of Article 44.2 defines a universe of 'other cases' where, if an injunction is 'inconsistent with a Member's laws, declaratory judgments and adequate compensation shall be available'. The requirements of Article 30 and 31 are irrelevant. *eBay* is one of these 'other cases', where the United States' remedies laws preclude an injunction under certain circumstances and compensation is awarded instead. While technically a government-born action, a denial of a permanent injunction is not the typical government-allowed use. One usually thinks of an adjudged infringer acting on behalf of a government agency or contractor. The *eBay* decision, in

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104 *See* Dinwoodie & Dreyfuss, *supra* note 19, at 444–5 (discussing the remedial flexibility that Article 44 provides).

105 *Id.*

106 *See* Mitchell N. Berman, R. Anthony Reese, & Ernest A. Young, *State Accountability for Violations of Intellectual Property Rights: How To 'Fix' Florida Prepaid (And How Not To)*, 79 TEX. L. REV. 1037, 1182–3 (2001) (noting the special obligations under Article 44.2 for governments with regards to patents).

contrast, can be considered a remedies decision only tangentially linked to government action. By falling into the second sentence, the requirements of Article 30 or 31 need not be met for an injunction to be denied pursuant to *eBay*. To place the *eBay* decision in the first sentence expands what is considered government authorization under the Article so much as to leave no 'other cases' to fall within the second sentence. Every non-enforcement of exclusivity would have some basis in government authority. Put simply, the second sentence in Article 44.2 appears to exactly contemplate an *eBay*-like situation.

4.2.4 Article 8 To complete the analysis, it is helpful to see if the *eBay* test falls within the general TRIPS' principles articulated in Article 8. Through the fourth factor in *eBay*, the equitable analysis directly considers the public interest identified in Article 8.1. Issues of public health that would fall under the principles in Article 8.1 are the very same concerns that would push against an injunction under the fourth factor of the *eBay* analysis. The first two factors under *eBay*, which aim at providing adequate, but not over, compensation for patent rights, fall in line with the directive against abuse of patent rights in Article 8.2. Use of the threat of an injunction to hold up and obtain more than the patent is worth is the very circumstances district courts are using *eBay* to avoid. The first two *eBay* factors give courts the tools to target such abuses. The third factor under *eBay* also effectuates Article 8.2's goal of stopping 'practices which unreasonably restrain trade or adversely affect the international transfer of technology'. If such a circumstance is present, it would be considered a hardship on the infringer that weighs against the grant of an injunction under *eBay*.

For these reasons, the application of the *eBay* decision most likely does not violate TRIPS. While not meeting the requirements of Article 31, the four factors considered under *eBay* map directly onto the three factors for limiting exclusivity under Article 30. In addition, by focusing on the remedial nature of *eBay*, Article 44 provides another avenue under which *eBay* is in compliance with TRIPS. Finally, the four *eBay* factors are based on principles similar to those in Article 8 of TRIPS that support limiting intellectual property exclusivity.

5 Conclusion

In the end, it is not so much *whether* the application of *eBay* to deny an injunction complies with TRIPS, as *how* exactly the decision complies with TRIPS.

If *eBay* is seen as complying because it falls within the Article 30 exception, the *eBay* discussion shifts the compulsory license compliance debate back to Article 30 and potentially expands the Article's scope. Not that Article 30 has ever been considered when evaluating compulsory licenses, but the Doha Declaration and related talks pushed the focus on Article 31. The

response so far to the Doha Declaration has looked at further interpreting Article 31 to allow certain compulsory licensing. *eBay* could open this discussion back up to include Article 30. This is an occurrence that would be welcomed by many commentators who believe the issues discussed in the Doha Declaration are better handled by Article 30.[107] Furthermore, if *eBay* were seen as complying with TRIPS because of Article 30, the breadth of Article 30 would be greatly increased. No longer would Article 30 be seen as simply allowing a predefined group of exceptions to patent rights. Instead, Article 30 would be viewed as a completely robust exception under which any Member State action that limits patent rights could be justified if the three-part substantive criteria are met.

In contrast, if *eBay* is seen as being allowed by Article 44, the decision may shift Member States' focus from limiting patent rights to limiting patent remedies when they want to meet certain social goals. The *eBay* decision demonstrates how tweaking remedies, as opposed to patent rights, may have the same net effect when trying to create an exception to patent exclusivity in order to reach a particular social goal. There may also be less friction under TRIPS with this approach because the Member State's law controls the parameters for an injunction denial under Article 44.2. The fear is that this approach swallows up the patentee's exclusive rights. And a broadened view of Article 44 makes the safeguards against unauthorized use set forth in Articles 30 and 31 worthless with regards to patent remedies. This fear is most likely overblown, especially since Article 44 requires adequate compensation in the injunction's place. The patentee is made whole, her rights being observed. And any unauthorized use is limited to a specific infringer willing to expend the resources to engage in litigations and risk that, in the end, they may be enjoined. An *eBay* approach allowed under Article 44 may be the best of both worlds – allowing a case-by-case determination on unauthorized use under an equitable test that protects the patentee by ensuring adequate compensation for her rights.

A final concluding thought. The *eBay* decision may impact the credibility of the United States' strong stance against compulsory licensing by other Member States. The *eBay* decision, regardless of how it is described and applied, weakens the patentee's right to exclusivity in the United States. In order to stay in compliance itself, the United States will have to, at the very least, allow others to adopt similar equitable inquiries into the issuance of patent injunctions. The United States' objections to other government

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[107] *See generally* Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101 (2003) (setting forth an Article 30 solution to the problem set forth in paragraph 6 of the Doha Declaration).

allowances of unauthorized use are more likely to look hypocritical and hold less force before the WTO after *eBay*.[108] At the very least, the *eBay* decision forces the United States back into the discussion surrounding the allowance of some unauthorized use of patent technology.

[108] *See, e.g.*, Harold C. Wegner, *Injunctive Relief: A* Charming Betsy *Boomerang*, 4 NW. J. TECH. & INTELL. PROP. 156 (2006) (arguing that the decision in *eBay* will make it difficult for the United States pharmaceutical industry to oppose local-working requirements laws that provide for compulsory licensing, like those in Brazil).

21 Adequate compensation for patent infringement damages: a comparative study of damage measurements in Japan and the United States

Toshiko Takenaka

1 Introduction

To recover from its deep recession, the Japanese government set a national goal to become 'a nation based on intellectual property' and began an overhaul of its intellectual property system.[1] Japan's Ministry of Economy and International Trade (METI) and its agency, the Japan Patent Office (JPO) were convinced that the revival of the US economy resulted from new business opportunities arising from technological innovations, which were promoted by the increased incentives brought about by the Reagan and Bush presidential administrations' adoption of a 'pro-patent policy'.[2] To follow the US example, all aspects of the Japanese IP system were reviewed in light of that of their US counterparts. A huge difference in patent infringement damage awards by US and Japanese courts revealed by the review led to a revision of Japanese patent law, which involved codifying US case law in order to reduce the patentee's burden of proof to establish causation.[3]

Cases decided during the discussion and enactment of the revision indicated a significant impact of the revision on Japanese patent infringement damages.[4] These cases awarded much bigger damages than those that had

[1] Toshiko Takenaka and Ichiro Nakayama, 'Will Intellectual Property Policy Save Japan from Recession? Japan's Basic Intellectual Property Law and its Implementation through the Strategic Program', (2004) 35 IIC (No. 8) 877.

[2] For a general discussion of US Pro-Patent Policy, see Yoshitake Kihara, 'US Pro-Patent Policy: A Review of the Last 20 Years', (2000) CASRIP Newsletter, 2000 Winter, Vol. 7, Issue 1 available at: <http://www.law.washington.edu/Casrip/Newsletter/Vol7/newsv7i1Kihara.pdf> accessed March 3, 2008.

[3] Tokkyo Ho [Patent Law], Law No. 51 of 1998, art. 102, para. 1.

[4] Toshiko Takenaka, 'Big Change in Measurement for Japanese Patent Infringement Damages? Tokyo District Court Awards $23.5 Million in Lost Profits Damages, CASRIP Newsletter', Autumn 1998, Vol 5, Issue 3, available at <http://www.law.washington.edu/Casrip/Newsletter/Vol5/newsv5i3jp1.htm> accessed March 3, 2008.

been awarded by Japanese courts before the revision. Some of these early cases indicated a risk of overcompensation for infringement of Japanese patents because courts refused to find factors for reducing the amount of lost profits resulting from the presumption.[5]

This chapter will evaluate the impact of Japan's 1998 patent law revision on infringement damages. To understand this impact, it will review theories and policies in general tort laws and patent laws in the US and Japan and try to identify the source of the difference between patent infringement damages awarded by US and Japanese courts. It will examine the patent law provisions for calculating damages in the form of lost profits and reasonable royalties, which were amended in the 1998 revision, and discuss the impact of revision based on statistics of damages from the comparative law perspective.

2 The theoretical frameworks

Statistics cited by the Japan Patent Office revealed a huge difference: the average damages awarded by US courts are two hundred times more than those of Japanese courts.[6] This huge difference could not be justified even if one were to take account of the differences in the legal system and the size of markets. A comparison of US and Japanese cases which involve similar facts and claims confirmed the huge difference resulting from Japanese courts' preference for awarding damages equal to a reasonable royalty which is equal to or less than the industry average if the patentee made and sold the patented invention exclusively.[7]

One may wonder if this huge difference has resulted from the fundamental difference in legal structure under US and Japanese tort laws. However, the theoretical frameworks used by the two jurisdictions to determine the scope of damages are not very different. In determining the scope of damages, both US and Japanese courts use a 'but for' test to establish the cause in fact and then use a 'foreseeability' test to further limit the scope to the legal cause or adequate cause (soutou inga kankei).[8] The concept of 'foreseeability' or 'legal/adequate cause' is commonly used to define the boundary between those causes which are closely connected with the result and others which are only remotely connected with the result, and has the effect of limiting responsibility

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[5] Toshiko Takenaka, 'Patent Infringement Damages in Japan and the United States: Will Increased Patent Infringement Damage Awards Revive the Japanese Economy?'(2000) 2 Wash. U. J.L. and Pol'y 309.

[6] Industrial Property Right Committee, Invitation of Comments on the Proposal for Revising Patent Law and Other Industrial Property Laws (1997) 25.

[7] Takenaka, *supra* note 5.

[8] For Japanese tort law, *see* Toru Shinozuka et al., *Tort* (New Case Law Annotation Series, Sanseido, Tokyo, 1993) 97.

for the consequences of one's act.[9] The only difference is that US courts' analysis includes two distinct steps for each course because a jury decides the cause in fact and a judge decides the legal cause. In contrast, Japanese judges decide both legal and factual causes and the steps to analyze the two types of causes are not distinct.[10] This difference aside, the process used to analyze the scope of damages is similar.

Measurements used by the two jurisdictions are also similar. To overcome the difficulty of calculating infringement damages, both US and Japanese patent law provide options to calculate damages resulting from infringement.[11] The two options for measuring patent infringement damages, lost profits and reasonable royalties are common to the Japanese and US patent statutes. A third option of defendant's profits was also once available under US patent law but has been eliminated.[12]

3 Tort and patent policies

3.1 General tort policy

In contrast to the similarity of the theoretical framework, there is a huge difference in tort and patent policies under US and Japanese laws. The legal cause or adequate cause which defines the boundary of liability is set upon the basis of some social idea of justice or policy in their minds.[13] Accordingly, the huge difference in damages in the US and Japanese jurisdictions is likely the result of different senses of justice and policy in the two societies that cause judges to apply the same framework in a radically different manner.

The most significant difference between the US and Japanese legal systems is the role of individuals in enforcing the law. The Japanese legal system more clearly separates the functions of criminal sanctions and civil remedies.[14]

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9 Toru Ikuyo, *Tort Law* (Yuhikaku, Tokyo, 1993) 122 et seq. and 134.

10 Yoshio Hirai, *Theory of Damage Compensation Law* (12th edn, 1997, Kobundo, Tokyo, 1997) 429 et seq.

11 Patent Law, art. 102; 35 USC 284.

12 Donald Chisum, *Chisum on Patents*, Section 20.02[3] (Lexis Nexis-Matthew Bender, New York, 1978, supp. 2007). Congress eliminated this option in 1946 because the option was considered to be redundant with lost profits and difficult to establish by patentees. Act of August 1, 1946, Ch. 726, Section 1, 60 Stat. 778. For a discussion of the legislative history of 35 USC 284, see Vincent Tassinari, 'Patent Compensation under 35 USC.', (1997) 5 J. Intell. Prop. L. 59.

13 W. Page Keeton, Dan Dobbs et al. (eds), *Prosser and Keeton on the Law of Torts* (West Group, St. Paul, Minnesota, Hornbook Series, 5th edn, 1984) §41 at 264.

14 Hideo Tanaka and Akio Takeuchi, 'The Role of Private Individuals in Enforcing Law' (1972) 88 (No. 5/6) 521, (1971) 89 Hougaku Kyoukai Zasshi (No. 3) 243, (No. 8) 879, (No. 9) 1033.

Under the Japanese legal system, the government exclusively controls punishment and deterrence of tortious acts.[15] The individual's role in maintaining public order is limited.[16]

This clearly affects the function of damages under the general tort theory. Under Japanese tort law, tort damages function purely to restore the tort victim to the condition he would have been in but for the tort.[17] The Japanese civil legal system does not provide for increasing damages depending on the character of the tortious act, such as willful tort. Because deterrence is not a function of tort damages, Japanese courts do not distinguish tort damages from breach of contract damages.

Further, Japanese courts have adopted the principles originally developed for defining contract damages, and applied them directly to measure loss resulting from a tort.[18] As a result, contract principles control the measurement of loss resulting from both a tort and a breach of contract.

In contrast, the separation between the functions of tort damages and criminal sanctions under the Common Law Tradition, which the US legal system follows, is not as clear as that of the Japanese system.[19] The US legal system combines criminal sanctions and civil remedies to deter people from engaging in tortious acts. Under the US system, individuals are encouraged to actively participate in enforcing the law by bringing a case to court.[20] Thus, civil remedies of damages are used not only to compensate but also to deter tortious acts.

Under US law, damages are classified as either compensatory damages or punitive damages.[21] Although the function of compensatory damages is to compensate tort victims, the common law tradition distinguishes contract damages from tort damages[22] and the US courts traditionally apply different principles to measure tort and contract damages.[23] With respect to the burden

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15 *Id.*

16 *Id.*

17 Ichiro Katou, *Tort* (Yuhikaku, Tokyo, 1974).

18 Judgment of the Great Court of Cassation, May 22, 1926, 5 Minshuu 386.

19 Tanaka and Takeuchi, *supra* note 14.

20 Tanaka and Takeuchi, *supra* note 14.

21 For a general discussion of tort damages, see Dan Dobbs, *Dobbs on Laws of Remedies: Damages, Equity, Restitution* (West Publishing Co., St. Paul, 1992).

22 R. W. Byrom, 'Do Damages Depend on the Same Principles Throughout the Law of Tort and Contract?' (1968) 6 U. Queensland L.J. 118.

23 *Felder v. Reeth*, 34 F. 2d 744 (9th Cir. 1929). However, US legal commentators suggest that tort law swallows up contract law through courts' application of tort law principles to measure both tort and contract damages. Grant Gilmore, *The Death of Contract* (Ohio State University Press, Columbus, 1974); Jeffrey O'Connell, 'The Interlocking Death and Rebirth of Contract and Tort', 75 Mich. L. Rev. 659 (1977). This development in US tort and contract law contrasts highly with Japanese courts' practice of applying contract principles to both tort and contract damages.

of proof, to prevent a wrongdoer from benefiting from the difficulty of proving causation between the tortious act and damages, US courts require less certainty in the proof of damages for a tort than in the proof of damages for a breach of contract.[24]

Further, reflecting the policy of encouraging individuals to enforce the law, US tort law provides punitive damages that may be awarded beyond the amount assessed to compensate actual damages. Punitive damages function to punish and deter torts and also to financially assist tort victims by covering attorney fees and other costs of bringing a case to court.[25] This aspect contrasts sharply with breach of contract damages, where breaches are not distinguished by 'willfulness' and no punitive damages are awarded.[26]

3.2 Patent law policy

Another source of difference comes from patent policy. Prior to the 1998 revision, patent law provisions for measuring patent infringement damages also reflected the policies of Japanese general tort law. Article 102 of the pre-1998 law provided two options for calculating patent infringement damages: (1) defendant's profits;[27] and (2) a reasonable royalty.[28] Patentees could also claim damages in the form of lost profits under the general tort provision of the Civil Code,[29] but the patent statute did not expressly provide that option until the 1998 revision introduced a presumption of causation for lost profits.[30]

The language of the pre-1998 Article 102 indicated that the legislature was more concerned about protecting innocent infringers than about protecting patentees. This emphasis was expressed by paragraph 3 of that provision, which gave Japanese courts the discretion to limit damages to an amount equal to a reasonable royalty, even if actual damages were higher, unless the infringer willfully or with gross negligence engaged in infringement.[31] Thus, Japanese patent law did not guarantee a full compensation of damages because courts are allowed to reduce the amount assessed to compensate the patentee's

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24 Restatement (Second) of Contracts, Section 351, cmt. a (1979).

25 Dobbs, *supra* note 21, at 311.

26 Restatement (Second) of Contracts, Introductory Note (1979). Pre-1998 Patent Law, art. 102, Para. 1.

27 Pre-1998 Patent Law, art. 102, para. 1.

28 Pre-1998 Patent Law, art. 102, para. 2.

29 Civil Code, Article 709.

30 Pre-1998 Patent Law, art. 102. For the relationship between Pre-1998 Patent Law, art. 102 and Civil Code 709, see Nobuhiro Nakayama, *Patent Law Annotated* (2nd edn, Seirin Shoin, Tokyo, 1989) 861.

31 Pre-1998 Patent Law, art. 102, para. 3. This provision remains as paragraph. 4 in the 1998 revised Patent Law.

loss.[32] One can interpret this provision, at least under the pre-1998 Article 102, as evidence that reasonable royalty has been the primary basis for calculating patent-infringement damages and that damages in the form of infringer's profits or lost profits have been exceptional and additional. Records on the legislative history of the pre-1998 Article 102 also support this interpretation.[33]

In contrast, the goal of US patent infringement damages is adequate and full compensation for damages resulting from infringement.[34] The patent statute expressly stated this goal.[35] The current statute provides two options for calculating infringement damages: (1) lost profits and (2) reasonable royalties.[36] The language of Section 284 indicates that US legislators are more concerned about insufficient compensation for patentees than about harsh results for innocent infringers. No provision exists to enable courts to reduce damages resulting from innocent infringement. Instead, the section expressly prevents courts from awarding damages of less than a reasonable royalty.[37] Accordingly, the language of the section is interpreted by courts as being expansive rather than limiting.[38]

Unlike Japanese patent law[39] and US copyright and trademark laws,[40] no provision allows courts to reduce the amount assessed to compensate damages even if damages are awarded in the form of lost profits beyond a reasonable royalty. The section only allows courts to increase compensatory damages up to three times for victims of willful infringement.[41] Further, under Section 285, in exceptional cases courts may also grant attorney's fees, which sometimes results in an amount greater than for a damages award.[42] As a result, unlike Japanese patentees, US patentees often make money out of suing infringers.

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32 *Id.*

33 Yoshiyuki Tamura, *Intellectual Property and Compensation of Damages* (Kobundo, Tokyo, 1993) 56.

34 *General Motors Corp. v. Devex Corp.*, 461 US 648, 654; 76 L.Ed. 2d 211, 103 S. Ct. 2058 (1983).

35 35 USC §284, para. 1.

36 *Id.*

37 35 USC. §284, para. 1.

38 *Rite-Hite Corp. v. Kelley Co. Inc.* 56 F.3d 1538, 1544, 35 USPQ2d 1065 (1995).

39 Pre-1998 Patent Law, art. 102, para. 3.

40 17 USC §504(c)(2); 15 USC §1117(a).

41 35 USC §284, para. 2.

42 35 USC §285.

4 Case law: pre-1998 Japanese practice and US practice

4.1 Lost profits

In interpreting the language of the pre-1998 section 102 to reflect the underlying policies, Japanese courts have awarded damages in the form of a reasonable royalty in more than 50% of all cases, and have awarded damages in the form of lost profits in less than 10% of all cases.[43] The first reason for the small chance of obtaining an award of lost profits was that courts do not even bother to examine the claim of damages in the form of lost profits if patentees do not exploit their inventions by themselves.[44] Since a significant proportion of patents have never been exploited,[45] the patentees of these patents were automatically disqualified from making claims for lost profits in Japanese courts.

US courts also interpret Section 284 to reflect the underlying policies. First, US courts, particularly the United States Court of Appeals for the Federal Circuit (Federal Circuit), indicates its preference for awarding actual damages in the form of lost profits to accommodate the goal of full compensation expressed in the language of Section 284.[46] Thus, courts regard actual damages such as lost profits as the primary option for compensation, and award a reasonable royalty only if the patentee is unable to prove actual damages.[47]

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[43] Institute of Intellectual Property, *Study of Appropriate Civil Remedies for Compensating Intellectual Property Damages* [hereinafter, IIP Damages Report] 33 (Institute of Intellectual Property, Tokyo, 1996). For a report in English on Japanese patent infringement damages, *see* Toru Toyama, 'Study with Respect to Proper Civil Remedies for Infringements of Intellectual Property' 1996 IIP Bulletin (Institute of Intellectual Property, Tokyo, 1996) 62.

[44] Kasuo Masui and Yoshiyuki Tamura, *Guidebook of Patent Court Decisions* (2nd edn, Yuhikaku, Tokyo, 1997) 277.

[45] For Japanese patents, see Commission on Intellectual Property Rights in the Twenty-First Century, Toward the Era of Intellectual Property Creation: Challenges for Breakthrough (Japan Patent Office, Tokyo, 1997) 25 <http://www.jpo.go.jp/shiryou_e/toushin_e/kenkyukai_e/21cene.htm> accessed March 3, 2008. For US patents, see Joseph Rossman and Barkev S. Sanders, 'The Patent Utilization Study', in L. James Harris (ed.), *Nurturing New Ideas: Legal Rights and Economic Roles* 106 (BNA Books, Arlington, Virginia, 1969).

[46] For a general discussion of Federal Circuit case law on patent infringement damages, see Paul Janicke, 'Contemporary Issues in Patent Damages (A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit', 42 Am. U. L. Rev. 691 (1993); Laura Pincus, 'The Computation of Damages in Patent Infringement Actions', 5 Harv. J. Law and Tech. 95 (1991).

[47] *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1164, 17 USPQ2d 1922 (Fed. Cir. 1991).

Courts also interpret legislative intent as giving only the bottom line but no ceiling.[48] In other words, courts are not limited in expanding the scope of damages to fully compensate patentee's loss in the form of lost profits, but are only limited on when they can award damages in the form of a reasonable royalty. US courts make every effort to award damages in the form of lost profits, and are reluctant to accept a defendant's argument denying causation, which would lead to an award of reasonable royalty.

Accordingly, it is not difficult to persuade US courts to grant an award of lost profits. Unlike Japanese courts' pre-1998 revision practice, US courts do not automatically reject claims of damages in the form of lost profits when a patentee does not exploit his invention.[49] Instead, the Federal Circuit emphasizes the danger of insufficient compensation and a retroactive compulsory license that may result from the practice of requiring patentees' exploitation of the patented invention because such practice would encourage infringement.[50] In its *en banc* decision, the Federal Circuit emphasized that 'whether a patentee sells its patented invention is not crucial in determining lost profits damages', although it acknowledged that normally there can be no lost profits when the patentee does not exploit his invention at all.[51] This is because denying the patentees their recovery of lost profits where they chose to market a competing but non-patented product would undermine the constitutional goal of giving incentives for innovation.[52]

The Federal Circuit expressly rejected the Japanese court's practice of checking whether the patentee's product embodies the infringing claim because the practice makes the litigation more cumbersome and complex.[53] As a result, US patentees are given a fair chance to prove lost profits even if they themselves have not made or sold any products embodying the infringed patent.

The second reason for difficulty in establishing a claim of lost profits in Japanese courts was the high burden of proof. Even if a patentee exploits her invention and passes the first test, she must establish causation between the infringer's infringement and damages. Under the Japanese Code of Civil Procedure, a plaintiff wishing to establish damages has the burden of producing evidence which removes all possible doubts with respect to the presence or absence of the fact.[54] This standard is considered by Japanese civil procedure

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48 *Rite-Hite*, 56 F.3d at 1544.
49 *Id.* at 1546.
50 *King*, 65 F.3d at 951.
51 *Rite-Hite*, 56 F.3d at 1548.
52 *King*, 65 F.3d at 950.
53 *Id* at 952.
54 A. Mikazuki, T. Nakano and M. Takeshita, *New Edition: Civil Procedure Seminar* (Yuhikaku, Tokyo, 1983) 288.

scholars to be much higher than the preponderance rule but a little bit lower than a clear and convincing rule.[55] Even after the finding of liability on infringers, Japanese courts treat parties equally and impose this high burden of proof on patentees. Thus, Japanese patentees often fail to establish causation between lost profits and the act of infringement.

Japanese patentees were further hindered from recovering lost profits by the lack of an effective measure under the old civil procedure to collect evidence on damages.[56] Although Article 105 of the pre-1999 revision enabled patentees to request that infringers produce documents necessary for the calculation of damages,[57] courts often allowed infringers to refuse to produce the requested document when the document included proprietary information.[58] Japanese courts accepted this excuse because Japanese civil procedure law provided no proceeding to protect proprietary information at trial. Documents necessary for calculating lost profits often include proprietary information, such as net profits and costs of materials. Therefore, infringers often avoided the duty imposed by the pre-1999 version of Article 105 by requesting protection of proprietary information. As a result, patentees often failed to introduce sufficient evidence to support the number of infringer's sales it claimed. As a result, courts recognized only the number of sales to which the infringer admitted.[59]

In contrast, US courts do not impose such a high burden of proof on patentees. Reflecting the general tort policy of requiring less certainty for proving tort damages, US courts only require patentees to show causation with a reasonable probability.[60] Unlike Japanese courts, US courts clearly show their preference for patentees once an infringer's liability is decided. The Federal Circuit has repeatedly emphasized that patentees need not negate every possi-

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55 In Japanese courts, parties must convince judges about the absence or presence of fact to an 80% certainty. Ryuji Funakoshi, *Order of Law and Burden of Proof* (Kogakusha, Tokyo, 1996) 12; Hiromi Murakami, Burden of Proof in Civil Procedure (Hanrei Taimuzu, Tokyo, 1980) 6.

56 For a general discussion of the revised Civil Procedure Law, *see* Ryu Takabayashi, 'Practices of Patent Litigation in Japanese Courts', 5-2 CASRIP Newsletter 13 (Center for Advanced Study and Research in Intellectual Property, University of Washington School of Law, Seattle, Spring/Summer 1998), available online at http://www.law.washington.edu/Casrip/Newsletter/Vol5/newsv5i2jp2.html> accessed March 3, 2008.

57 Pre-1999 Japanese Patent Law, art. 105.

58 Civil Procedure Law, art. 220, Item 4. Japan Patent Office, *Report by Planning Subcommittee of Industrial Property Committee: In Furtherance of Pro-Patent Policies* (Japan Patent Office, Tokyo, 1998) 35.

59 IIP Damages Report, *supra* note 43, at 37.

60 *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 21, 23 USPQ 235 (Fed. Cir. 1984).

bility that customers of infringing products might not have bought another product or might not have bought a comparable product at all.[61] The court also noted that any doubts regarding the calculation of damage amounts must be resolved against the infringer.[62]

Additionally, the discovery process under US civil procedure enables patentees to collect the documents necessary to calculate lost profits.[63] Due to extensive sanctions, US patentees can readily obtain the information necessary to calculate lost profits. US civil procedure provides a proceeding for protecting proprietary information at trial.[64] Thus, US patentees seldom fail to establish their own net profits.

The third reason for the difficulty in claiming lost profits in Japanese courts was the lack of case law on positive tests or factors to show causation between the act of infringement and lost profits. Japanese patentees often argued that their lost profits were the amount of net profits of their own products multiplied by the number of infringing products sold by infringers. Japanese courts found that showing such an amount was alone insufficient to show causation, and did not grant any part of lost profits recovery.[65] They developed significant case law on multiple factors to negate causation.[66] Japanese courts' positive test to affirm causation is limited to exceptional cases where only two competitors exist in a unique market[67] or where the infringing product is exactly the same as the patentee's product.[68] As a result, Japanese patentees are completely prevented from recovery of lost profits except for exceptional

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61 *King Instruments Corp. v. Otari Corp*., 767 F.2d 853, 226 USPQ 402 (Fed. Cir. 1985), appeal after remand, 814 F.2d 1560, 2. USPQ2d 1210 (Fed. Cir. 1987).

62 *Kaufman Co., Inc. v. Lautech, Inc.*, 926 F.2d 1136, 17 USPQ2d 1828 (Fed. Cir. 1991).

63 For a general discussion of discovery procedure, see Kimberly Moore et al., *Patent Litigation and Strategy* (1st edn, West Publishing Co., Columbus, 1999) 97; Roger S. Haydock and David F. Herr, *Discovery Practice* (Little Brown Co., Boston, 1988, Supp. 1989).

64 *Id*, Section 1.9.

65 Judgment of Tokyo District Court, December 25, 1963, Hanrei Taimuzu No. 156, 218 (1964).

66 Masui and Tamura, *supra* note 44, at 278. Such factors include: (1) the patented part did not attract customers to purchase the whole product; (2) the infringing product was not exactly the same as the patentee's product; (3) infringing products were less expensive than the patentee's product; and (4) a substitute of the patented product was available in the market.

67 Judgment of Tokyo District Court, September 21, 1963, Hanrei Taimuzu No. 154, 138 (1964).

68 Judgment of Tokyo District Court, September 14, 1963, Hanrei Taimuzu No. 152, 163 (1964). For a review of cases granting a recovery of lost profits, see IIP Damages Report, *supra* note 43, at 33–5.

cases where courts recognized a full or substantial part of the amount claimed by the patentee (all or nothing rule).[69]

This all or nothing rule significantly discouraged Japanese patentees from claiming lost profits. Therefore, if Japanese patentees exploited their patented inventions, they preferred to claim a recovery of the defendant's profits.[70] The patent statute provides a presumption that the infringer's profits are presumed to be equal to the patentee's lost profits.[71] This practice saved Japanese courts from spending time examining complicated factual issues in order to find causation. At the same time, this practice imposed on Japanese patentees the burden of showing the infringer's net profits, instead of their own profits, as would be the case if lost profits were claimed. Because of the difficulty in obtaining evidence to show the opposing party's net profits, patentees often failed to establish such profits.[72]

Moreover, patentees were not allowed to recover infringer's profits with respect to the entire product when the patent covers only part of the entire product, and are required to show the contribution rate or apportionment, *kiyo-ritsu*, of the patented part versus the non-patented part.[73] Patentees had to show apportionment between the patented part and the non-patented part and were entitled only to recovery of the patented part of the defendant's profits.[74] If a patentee was unable to establish the contribution rate, the court could deny the entire claim for the defendant's lost profits.[75]

Even if patentees were entitled to defendants' profits for the entire product, such profits were often less than the patentee's own lost profits because infringers are often the second comer in the market and do not enjoy the benefit of monopoly price.[76] Because of these difficulties, full recovery of the claimed defendant's profits was awarded in only 16.4% of cases seeking recovery of defendant's profits.[77] On average, Japanese courts have granted only 53% of the amount claimed by patentees as infringer's profits.[78]

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69 *Supra* note 43, IIP Damages at 34.

70 IIP Damages Report, *supra* note 43, at 29. Patentees included lost profits as their main claims on damages in only 15.8% of all cases.

71 Japanese Patent Law (pre-1998), art. 102, para. 1.

72 Judgment of Tokyo District Court, March 14, 1988, Hanrei Tokkyo Jitsuyou Shin-an 400-114 (1988).

73 Masui and Tamura, *supra* note 44, at 294.

74 *Id.*

75 Judgment of Osaka District Court, June 19, 1968, Hanrei Taimuzu No. 223, 200 (1968).

76 A good example is *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc*., 575 F.2d 1152, 197 USPQ 726 (6th Cir. 1978). The infringer cut the patentee's price by 30% to compete with the patentee's product.

77 IIP Damages Report, *supra* note 43, at 36.

78 *Id.*

In contrast, the Federal Circuit developed case law with more positive tests for causation than negative tests. US courts seldom completely reject a claim of lost profits. A significant difference between the patentee's product and the infringing product which would completely eliminate a claim of lost profits in Japanese courts does not completely eliminate a claim of lost profits in US courts but only reflects the number of sales the patentee could have sold but for infringement.[79] Evidence that the infringer's product is much less expensive than the patentee's product is also not sufficient to negate causation.[80]

US courts find causation where only the patentee and infringer are competitors in the market, which is an exceptional circumstance in which even Japanese courts would find causation, and courts find causation without further evidence.[81] Other circumstances which courts find sufficient to show causation include when the patent owner lost the sales to the infringer under a bidding system;[82] when the entry and departure of the infringer's product in the market forces a change in price of the patentee's products;[83] and when the infringer was either a former customer or supplier to the customer.[84]

Even in cases where such exceptional circumstances do not exist, US courts have developed a positive test to infer causation. The test includes four factors to infer causation and is called the *Panduit* test, after the first case to adopt the test.[85] These four factors are (1) a presence of demand for patented products in the market; (2) an absence of acceptable non-infringing alternatives; (3) the

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79 *King*, 65 F.3d at 953.

80 *Dobson v. Dornan*, 118 US 10, 6 S. Ct. 946, 30 L.Ed 63 (1886); *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 12 USPQ2d, 1375, (E.D. Tex. 1989), *aff'd* 926 F.2d 1161, 17 USPQ2d 1922 (Fed. Cir. 1991). However, if demand for the patented product is elastic, courts may negate causation. See, *BIC Leisure Prods. v. Windsurfing Int'l Inc.*, 1 F.3d 1214, 27 USPQ2d 1671 (Fed. Cir. 1993).

81 *Yale Lock Co. v. Sargent*, 117 US 536, 6 S. Ct. 934, 29 L.Ed. 954 (1886); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 219 USPQ 670 (Fed. Cir. 1983); *Marsh-McBirney, Inc. v. Montedoro-Whitney Corp.*, 882 F.2d 498, 11 USPQ2d 1974 (Fed. Cir. 1989).

82 *Wallace and Tiernan Co. v. Syracuse*, 45 F.2d 693, (2nd Cir. 1930) ; *Manville Sales Corp. v. Paramount Systems Inc.*, 14 USPQ 2d 1219 (E.D. Pa. 1989), *further opinion* 14 USPQ2d 1299 (E.D. Pa. 1989), *aff'd*, 917 F.2d 544, 16 USPQ2d 1587 (Fed. Cir. 1990).

83 *Pressed Prism Glass Co. v. Continuous Glass Prism Co.*, 181 F. 151 (CCWD Pa. 1910); *Hall v. Stern*, 20 F. 788, (CCDNY 1884).

84 *Central Soya Co. v. Geo. A. Hormel and Co.*, 723 F.2d 1573, 220 USPQ 490, 74 ALR Fed. 863 (1983).

85 *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 197 USPQ 726 (6th Cir. 1978).

patentee's own capacity to have met that demand; and (4) the amount of profits the patentee would have made.[86]

A patentee can demonstrate the demand for the patented products by showing that the infringers sold infringing products.[87] Showing the capability is not difficult because courts require only potential capability, which can be demonstrated by the possibility of subcontracting the increased portion of manufacture and of hiring new sales persons to sell that portion.[88] This was in stark contrast to Japanese courts' pre-1998 practice of requiring patentees to show the capability to manufacture and sell additional products with a high degree of certainty.[89]

Of the first three factors, showing the second factor, the absence of alternatives, is most difficult. However, in fact, even this showing is easy because the Federal Circuit has developed a strict test for showing acceptable alternatives in order to shift the burden of proof from the patentee to the infringer. This test requires a finding that the alleged alternative has all of the features and functions of the patented products, which often leads to an absence of acceptable alternatives, the alternatives being less effective and inadequate.[90] Because a non-infringing product by definition lacks at least some features or functions of the patented product, a patentee can easily point out the difference between the non-infringing alternative alleged by the infringer and the patented products, and argue that the alternative is inadequate to constitute an acceptable alternative.[91] Even if an infringer successfully shows an acceptable alternative so that the patentee fails on the second factor, courts may exercise their own discretion and award lost profits on the basis of market share.[92]

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[86] For a general discussion of these factors, see *supra* note 12, Chisum, Patents, §20.03[1][b][v].

[87] *Gyromat Corp. v. Champion Spark Plug Company*, 735 F.2d 549, USPQ 4 (Fed. Cir. 1984).

[88] *Id.*

[89] Judgment of Osaka District Court, March 25, 1991, Tokkyo to Kigyou No. 270, 54 (1991).

[90] *Radio Steel and Mfg. Co. v. MTD Products, Inc.*, 788 F.2d 1554, 229 USPQ 431 (Fed. Cir. 1986). The Federal Circuit may apply a less strict test, see *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 12 USPQ2d, 1375 (E.D. Tex. 1989), *aff'd*, 926 F.2d 1161, 17 USPQ2d 1922 (Fed. Cir. 1991). For a general discussion of the definition of non-infringing alternatives, see *supra* note 12, Chisum, Patents (1978) § 20.03[1][b][v] [E] (Supp. 1999).

[91] Judge Nies criticized the definition requiring strict identity and clarified that acceptable alternatives do not represent an embodiment of the patented invention. *SmithKline Diagnostics, Inc*., 926 F.2d at 1166.

[92] *State Industries, Inc. v. Mor-Flo Industries, Inc*, 883 F.2d 1573, 12 USPQ2d 1026 (Fed. Cir. 1989), *cert. denied*, 493 US 1022 (1990). For a general discussion of the market share approach, see Note, *State Industries, Inc. v. Mor-Flo and the Market*

Once the first three factors are demonstrated, patentees show the fourth factor of profits by simply estimating the expected profits that the patentee would have made from the infringing sales.[93] This amount is calculated simply by multiplying the patentee's net profits per unit of product by the number of units sold by infringers.[94] Unlike Japanese practice, which requires patentees to show the defendant's profits, US practice is patentee-friendly because the patentee can readily show its own profits.

Finally, the entire-market-value rule relieves patentees of the significant burden of establishing apportionment between the patented part and the non-patented part when a patent covers only a part of the product.[95] The difficulty relating to apportionment was well understood by the US patent community from past experience of dealing with the measurement of the defendant's profits.[96] Before US courts widely adopted the entire-market-value rule, US courts had responded to apportionment problems in the same way as Japanese courts, rejecting any recovery of lost profits because of the patentee's failure to provide a basis for apportionment.[97] Patentees now establish that the value of the entire product depends on the patented part, instead of contending with the perplexities of apportionment, and they can recover lost profits for the entire product.[98]

4.2 Reasonable royalty

Prior to the 1998 revision, Japanese courts granted damages in the form of a reasonable royalty in more than half of all cases.[99] Japanese patent law defined damages in the form of a reasonable royalty as the amount that a patentee *ordinarily* receives as compensation for allowing exploitation of the patented invention.[100] Because some damages were awarded if the patentee claimed damages in the form of reasonable royalty, one can see that the reasonable royalty functioned as a minimum compensation for infringement, though the statute does not expressly provide so. However, unlike US case law, the reasonable royalty did not function as a minimum compensation to guarantee

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Share Approach to Patent Damages: What is Happening to the Panduit Test? 1991 Wisc. L. Rev. 1369 (1991).

93 *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (1988).

94 Pincus, *supra* note 46, at 113.

95 *Supra* note 12, Chisum, Patents, § 20.03[1] [c].

96 *Supra* note 12, Chisum, Patents, § 20.02[3] (Supp. 1999).

97 *Westinghouse v. New York Air Brake Co.*, 140 F. 545, 550–51 (2nd Cir. 1905), *cert. denied*, 201 US 648 (1906); *Roemer v. Simon*, 31 F.41 (CCSDNY 1887).

98 The leading case for the entire-market-value rule is *Goulds Manufacturing Co. v. Cowing*, 105 US 253 (1881).

99 IIP Damages Report, *supra* note 43, at 39.

100 Japanese Patent Law (pre-1998), art. 102, para. 3.

at least reasonable royalty for infringing products for which the patentee failed to show causation for lost profits.

Damages awarded by Japanese courts were very low.[101] One reason for the low royalty award was the difficulty of establishing the number of infringing products sold by the defendant. The same problem of collecting evidence explained earlier with respect to lost profits also applies to the proof of defendant's sales.[102] Because of lack of proof, courts often allow recovery of royalty only with respect to the number of sales that infringers admit.[103]

Another reason was that Japanese courts attempt to limit royalty rates to a minimum. First, if there was a prior actual license for acts comparable to those engaged in by the infringer without authority, courts did not award a reasonable royalty of more than the royalty rate which was agreed upon in that legally negotiated license.[104] In other words, the royalty rate for the prior license functioned as the maximum recovery.

Although many courts adopted the prior royalty rates as a reasonable royalty,[105] a significant number of courts reduced the awarded rate to the lower of two published royalty rates if either was lower than the prior royalty, namely:[106] (1) the rate published by the Japanese Patent Office for licensing government owned patents;[107] and (2) the industry-standard royalty rate published by a quasi-governmental research institution.[108]

In contrast, reasonable royalties awarded by US courts are much more than the reasonable royalties awarded by Japanese courts. The patent statute expressly guarantees that the reasonable royalty is a minimum compensation.[109] US courts interpret the statute to mean that patentees are guaranteed to recover a reasonable royalty with respect to infringing products for which they could not establish causation for lost profits.[110]

For US courts, an existing royalty rate agreed upon between the patentee and its licensees is important evidence for deciding a reasonable royalty

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101 In a minority of cases (31.1%) the requested amount was fully awarded. The amount of royalty actually awarded on average is much less (63%) than the amount requested by patentees. *Supra* note 43, IIP Damages Report, at 43.

102 Part 1, 3(1)b.

103 IIP Damages Report, *supra* note 43, at 40.

104 *Id.* at 41. Courts consistently rejected patentees' arguments for adopting a rate higher than the legally negotiated prior royalty rate.

105 *Id.* at 41. Courts adopted prior royalty rates in 29 out of 90 cases (32.2%).

106 *Id.* at 40.

107 Reprinted in Hatsumei Kyoukai Kenkyuusho, *Royalty Rates*, 159 (4th edn., Hatsumai Kyokai, Tokyo, 1993).

108 *Id.*

109 35 USC §284.

110 *Rite-Hite Corp.*, 56 F.3d at 1554.

rate.[111] US courts should not award less than an 'established' royalty.[112] An established royalty does not function as a maximum compensation because US courts can award a reasonable royalty which tends to be higher than an established royalty when the established royalty was depressed because the patent had not yet gained public recognition or acceptance or because of widespread infringing activity.[113] They may deny the presence of an 'established' royalty as being artificially low and adopt a royalty higher than that for prior licenses.[114]

When no established rate exists, US courts, like Japanese courts, give considerable weight to the royalty rate of a prior license even if the rate is not qualified as being 'established'.[115] However, US courts' practice is in striking contrast to that of Japanese courts because US courts give less weight to the industry standard royalty for a license of comparable technology.[116] Instead, they rely heavily on particular license policies and arrangements selected by the patentee for the infringing patent and related technology fields. In particular, if the patentee has chosen not to license the patent in order to benefit from exclusivity, courts increase the 'reasonable royalty' because otherwise it would result in a compulsory license to the infringer.[117] US case law frequently adopts as a definition of reasonable royalty that which would have resulted from a hypothetical negotiation between a willing patent owner and a willing potential user.[118] However, the royalties granted by US courts are much more than reasonable, which often leaves no profits for infringers, and can even force them into bankruptcy.[119]

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111 For a general discussion of the established royalty, *see supra* note 12, Chisum, Patents, §20.03[2].

112 *See supra* note 12, Chisum, Patents, § 20.03[2][d]. A prior royalty rate is qualified as the established royalty if the royalty is (1) paid or secured before the infringement; (2) paid by a sufficient number of licensees to indicate general acquiescence in its reasonableness; (3) uniform in the region where issued; (4) not paid under threat of suit or in settlement of litigation; and (5) in consideration of comparable rights or activity under the patent. *Rude v. Wescott,* 130 US 152, 9 S. Ct. 463, 32 L.Ed. 888 (1899); *Faulkner v. Gibbs*, 199 F.2d 635, 95 USPQ 400 (9th Cir. 1952).

113 *See supra* note 12, Chisum, Patents, §20.03[2][c].

114 *Nickson Industries, Inc. v. Rol Manufacturing Co. Ltd*., 847 F.2d 795, 6 USPQ2d 1878 (Fed. Cir. 1988).

115 *See supra* note 12, Chisum, Patents, §20.03[3][b][i].

116 *Bio-Rad Laboratory Inc. v. Nicolet Instrument Corp*., 739 F.2d 604, 222 USPQ 654 (Fed. Cir. 1984).

117 *King*, 65 F.3d at 950.

118 *Supra* note 12, Chisum, Patents, §20.03[3][a].

119 *Radio Steel*, 788 F.2d 1554; *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 38 USPQ2d 1288 (Fed. Cir. 1996).

This is in stark contrast to Japanese courts' pre-1998 practice of adopting the JPO's published rate or the industry standard rate for patent damages in cases where the patentee never licensed the patent. As a result, the average for damages in the form of reasonable royalty awarded by US courts, 11%,[120] was significantly higher than the average rate of 4.2% awarded by Japanese courts. Moreover, US rates were spread over a wide range from less than 1% to more than 20%.[121]

The absence of prior license led to vast differences in US and Japanese damages. If the patentee has not licensed any comparable technology and has no information for calculating a royalty rate, courts tended to rely on the JPO's published rate. Accordingly, cases adopting JPO's royalty rates occupied a significant portion of all cases awarding damages in the form of a reasonable royalty.[122] Because the JPO's royalty rates are kept to a minimum in order to encourage transfer of technology from government to industry, the average rate of reasonable royalty awarded by Japanese courts was very low (4.2%),[123] even lower than the average rate under the industry standard of reasonable royalty (4.6%).[124]

In contrast, US courts give less weight to the industry standard[125] and more weight to the patent owner's licensing policy.[126] Absence of a prior license allows US courts to increase a royalty rate because this may be viewed by US courts as evidence that the patentee adopted a policy not to license to others and instead to use the right exclusively. Award of a reasonable royalty determined by the market would result in a compulsory license on patentees who have never wanted to license. Thus, to avoid such a result, courts tend to award more than the rate that would have been reached by a willing licensee and licensor.[127]

5 Japan's infringement damages after 1998 revision

5.1 1998 revision and change of policy

The Japanese government showed a serious concern over lack of incentive for

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120 IIP Damages Report, *supra* note 43 at 67.

121 *Supra* note 12, Chisum, Patents, §20.03[3][d] (1978, Supp. 1999).

122 IIP Damages Report, *supra* note 43, at 41. 21.1% of all cases awarding a reasonable royalty adopted JPO's published rates.

123 *Id.* at 41.

124 Hatsumei Kyokai Kenkyuusho, *supra* note 107, at 22–3.

125 *Supra* note 12, Chisum, Patents, §20.03[3][b][ii].

126 *Supra* note 12, Chisum, Patents, §20.03[3][b][iii].

127 *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc*., 575 F.2d 1152, 197 USPQ 726 (6th Cir. Mich. 1978); *Georgia-Pacific Corp. v. United States Plywood Corp.*,*1, 318 F. Supp. 1116, 166 USPQ 235 (SDNY 1970).

R&D due to undercompensation resulting from Japanese courts' practice under the pre-1998 patent law. It asked JPO's Industrial Property Right Committee to review the practice and invited comments on whether any aspects of the patent statute needed to be revised. The JPO's Committee extensively reviewed US case law on calculation of damages in the form of lost profits and reasonable royalties and proposed a revision amending Article 102. The proposed revision included (1) introduction of a presumption of causation by codifying the factors under the *Panduit* test; (2) a definition of a reasonable royalty which is higher than a legally negotiated prior royalty; (3) a removal of courts' discretion for reducing the amount exceeding a reasonable royalty; and (4) introduction of punitive damages.[128]

Responding to the Committee's proposal, the JPO introduced a bill to revise patent law and other industrial property laws, which became effective on January 1, 1999.[129] The most important aspect of the revision is the introduction of a presumption to facilitate patentees in establishing causation for a claim of damages in the form of lost profits. The new Article 102, paragraph 1 provides that the patentee is entitled to an amount of the profits per unit of goods that would have been sold but for the infringement multiplied by the number of said assigned goods, as long as the amount does not exceed the patentee's ability to exploit the patented invention. For the first time, the option of lost profits was expressly provided in the patent statute. The new provision for lost profits was inserted in paragraph 1, and the existing provisions for defendant's profits and reasonable royalties were moved to paragraphs 2 and 3 respectively. Under the Japanese rules of statutory construction, a general rule is normally followed by exceptions to the general rule.[130] Accordingly, the insertion of the new provision in the first paragraph may be interpreted as announcing a change of policy in the measurement of damages from infringement of Japanese patents.

The JPO's revision also included a change in the provision for calculating damages in the form of a reasonable royalty.[131] The new provision removed the term 'ordinarily' from the definition of the amount received as damages in the form of a royalty.[132] Elimination of this term was designed to allow Japanese courts to take into account the circumstances of a particular case and

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128 *Supra* note 6, Invitation of Comments.

129 A Law to Revise Patent Law and Other Intellectual Property Laws, Tokkyo Ho, Law No. 51 of 1998.

130 Nobutoshi Tajima, Metrologies for interpreting Statute 109 (Gyosei, Tokyo, 1980).

131 Japanese Patent Law, art. 102, para. 3 (Revision, Law No. 51 of 1998).

132 Cf. Pre-1998 Japanese Patent Law, art. 102, para. 2.

grant a royalty higher than that available under the published industry standard rates or JPO license rates for government-owned patents.[133]

Unfortunately, the 1998 revision did not remove or amend the provision for giving Japanese courts discretion to reduce the amount exceeding a reasonable royalty.[134] Retaining the provision casts doubt on whether guaranteeing adequate compensation and emphasis on patentee's interests are the priority for the goal of awarding damages under the Japanese patent system after the 1998 revision. The revision did not implement the Committee's proposal to introduce punitive damages, which is in conflict with public policy under the Supreme Court precedent.[135]

5.2 Case law: lost profits

The legislative history of the 1998 revision is evidence that the new Article 102, paragragh 1 codified the third and fourth factors of the *Panduit* test in presuming causation between the patentee's lost sales and defendant's infringement. Although the US *Panduit* test's presumption is based on a basic economic theory, the JPO's Committee did not examine the underlying economic theory when they proposed to adopt a presumption of causation. The Committee did not engage in in-depth analysis of the impact of the new provision on pre-1998 practice and simply imported US case law doctrine. As a result, the revision introduced a lot of ambiguity in interpreting the newly introduced provision with respect to important issues which prevented Japanese courts from awarding lost profits under pre-1998 patent law.

The first ambiguity of the new paragraph exists with respect to its nature. It is unclear from the language of the statute whether the defined amount is merely based on a presumption to shift the burden of proof from the patentee to the infringer or constructive, which prevents infringers from rebutting the amount by introducing evidence for lack of causation. The legislative history suggests that the defined amount is based on a presumption and thus the infringer can introduce evidence to rebut the presumption. Accordingly the presumption is followed by the sentence that gives courts power to deduct the presumed amount: where circumstances indicate that the said patentee or exclusive licensee would have been unable to sell all or some of the said assigned products.[136] The second sentence of the new paragraph can be read as allowing courts to completely eliminate a claim of lost profits. However, reflecting the revision's emphasis on patentees' interests, courts should try

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133 Yasukazu Irino, 'A Law for Revising Part of Patent Law and Other Industrial Property Laws', 1140 JURISTO 71 (1998).

134 Japanese Patent Law, art. 102, para. 4 (Revision, Law No. 51 of 1998).

135 Judgment of Supreme Court of Japan, July 11, 1997, 51 Minshu No. 6, 2573.

136 Japanese Patent Law, art. 102, para. 1.

their best to determine the number of products the patentee could have sold, rather than rejecting a claim of lost profits completely by taking advantage of the fact-finding power introduced by the 1999 revision.[137]

For those courts which view the new paragraph as introducing a presumption, circumstances can be established by showing the negative factors which were shown to have eliminated causation under the pre-1998 practice. Such circumstances include the presence of substitutes, the infringer's own sales efforts and distribution mechanism, the infringer's own reputation, the difference in structure and function between the infringer's product and the patentee's product.[138] Some of those courts found that the patentee could not have sold a substantial portion of products sold by the infringer and significantly deducted the presumed amount with respect to the unsold products.

Other courts viewed the amount in the new paragraph as constructive. In their view, the new paragraph is based on a legal fiction in which only two competitors, the patentee and infringer, exist because the exclusive right of a patent creates a special market for the patented product.[139] This view ignores the reality of the market and departs from the economic theory underlying the US *Panduit* test. Thus, these courts do not allow infringers to show the presence of substitutes as a circumstance for deducting the presumed amount.

Another ambiguity is whether the patentee has to exploit the patented invention to establish a claim of lost profits. The new paragraph does not expressly require exploitation for the patentee to take account of the presumption. However, those courts which view the amount of the new paragraph as constructive require 'the products the patentee could have assigned but for infringement' to be limited to embodiments of the patented invention.[140] The product claimed for lost profits must be an embodiment of the patented invention because of the legal fiction of a special two-competitor market for the patented product.

However, the majority of courts do not require the patentee to exploit the patented invention. They interpret 'the could-have-sold product' to include a product which is not an embodiment of the patented invention.[141] Like US case law, these courts allow the recovery of lost profits because the sales of the product competing with the infringing products are affected by the infringement and could have been sold but for the infringement. This view is supported by the legislative history and widely supported by legal commenta-

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137 Japanese Patent Law, art. 105-3 (Revision, Law No. 41 of 1999).
138 Judgment of IP High Court, September 25, 2006; Judgment of April 19, 2007.
139 Judgment of Tokyo District Court, March 19, 2002.
140 Judgment of Tokyo District Court, March 19, 2002.
141 Judgment of Tokyo High Court, June 15, 1999.

tors.[142] The could-have-sold products do not include non-competing products because the patentee's sales of such products would not have been affected by infringement.[143]

Although the new paragraph does not mention apportionment between patented and non-patented portions, some courts have applied a contribution rate to the presumed amount.[144] Other courts have not applied a contribution rate although the patent does not cover the entire product.[145] Instead, they have examined the significance of the patented portion with respect to consumer demand. They found a circumstance that the patentee could not have sold products and deducted the presumed amount if the patented portion has little influence on consumers' incentive to purchase infringing products. This view is more in line with the language of the new paragraph. Unlike pre-1998 practice, courts find lost profits even if the patentee's product is not identical to the infringer's product. The difference in structure and function, including both the patented and the non-patented portion, should be evaluated if the difference would have resulted in there being a number of products that the patentee could have sold but for infringement.[146] Some commentators encourage applying the entire market rule where the patented portion creates demand for the entire product.[147] Reflecting this view, one court applied a 95% contribution rate when the patented portion significantly influenced consumers' decision to purchase the infringer's product.[148]

Regarding the patentee's capability which limits the recovery of the presumed amount, actual capability during the period of infringement is not necessary. Courts find it sufficient for the requirement if the patentee had potential capability during the infringing period.[149] This interpretation is supported by the legislative history and legal scholars.[150]

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142 Kouichiro Semoto, 'Patent Infringement and Establishing Amount of Damages', Minjijouho No. 149 (1999) 2; Ryu Takabayashi, *Standard Patent Law in Japanese*, 248 (2nd edn, Yuhikaku, Tokyo, 2005).

143 Judgment of Tokyo District Court, October 9, 2003.

144 Judgment of Tokyo High Court, June 15, 1999; Judgment of Tokyo District Court, March 19, 2002; Judgment of Tokyo District Court, December 26, 2003.

145 Judgment of IP High Court, September 25, 2006.

146 Tatsuki Shibuya, *Lectures in Intellectual Property Laws I* (2nd edn, Yuhikaku, Tokyo, 2006) 297.

147 Ryoichi Mimura, 'Damages (1) – Patent Law Art. 102 Para. 1' in Toshiaki Makino and Toshiaki Iimura (eds), *Procedural Laws of Intellectual Property* 303 (Shin Jitsumu Taikei Series, Seirin Shoin, Tokyo, 2001); Yoshiaki Tamura, 'Revision of Patent Law and Other Intellectual Property Laws Regarding Infringement Damages', 49 Patent Management (No. 3), (2004) 329.

148 Judgment of Tokyo District, March 26, 2003.

149 Judgment of Tokyo District, July 17, 2001; Judgment of Tokyo District Court, March 19, 2002.

150 Shibuya, *supra* note 146, at 301; Mimura, *supra* note 147, at 293.

5.3 Case law: reasonable royalty

Reflecting the legislative intent to remove the term 'ordinarily' from Article 102, paragraph 3,[151] courts began to determine a reasonable royalty in adopting case-by case analysis by taking account of a variety of factors, which are similar to factors that US courts take into account when calculating a reasonable royalty.[152] Such factors include a legally negotiated and agreed upon royalty, an average royalty in the industry of the invention, the significance of the patented invention, the act of infringement, profits made by the infringer from the infringement, the relationship between the patentee and infringer in the relevant market and the patentee's market strategies. They no longer solely rely on an industry average royalty.[153] As a result, Japanese courts are more willing to set a reasonable royalty higher than a prior royalty or the industry average royalty by taking account of factors unique to each case.

So far, courts have given little weight to the relationship between the patentee and infringer or the patentee's business strategies. However, these factors are important in setting a reasonable royalty. As US case law indicates, if the patentee and infringer compete head to head in the relevant market and the patentee adopts a strategy to exclusively make and sell patented products, rather than giving a license, it is very unlikely to give a license at an industry average royalty.

Even if the patentee has given a license, a reasonable royalty should be different from a royalty agreed by legally negotiated licensor and licensee. In a real license negotiation, licensees often must take account of the risk of commercialization and thus an agreed-upon royalty can be discounted to reflect such a risk. Infringers avoided the risk if the patentee and licensee commercialized the patented invention and established a market for an embodiment of the invention before infringement.

5.4 Case law: guarantee of minimum compensation

Although the legislative history made it clear that the goal of the 1998 revision was to guarantee patentees adequate compensation for damages resulting from infringement, no term to indicate the goal was introduced. Further, the provision for giving courts discretion to reduce the amount exceeding a reasonable royalty was affected by the revision.[154] Retaining this discretion blurred the legislative intent because courts can still reduce the amount which is assessed as actual damages resulting from infringement.

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151 Because new para. 1 was introduced, Pre-1998 art. 102, para. 2 has become para. 3.

152 Judgment of Osaka District Court, October 29, 2002.

153 Judgment of Nagoya District Court, February 10, 2003.

154 Japanese Patent Law, art. 102, para. 4 (Revision, Law No. 51 of 1998). Pre-1998 Revision art. 102, para. 3 has become para. 4.

Legal scholars read this provision as clarifying the function of a reasonable royalty as a minimum compensation.[155] Because they view a claim of reasonable royalty as based on unjust enrichment, the patentee is entitled to a reasonable royalty regardless of whether he is negligent or innocent.[156] Infringers are unjustly enriched by circumventing a payment of royalties that they owe to the patentee for the amount equal to a reasonable royalty. Some courts have adopted this view and allowed the patentee to recover a reasonable royalty with respect to infringing products where the patentee's claim of lost profits was denied.[157]

However, other courts deny a claim of reasonable royalties with respect to infringing products where claim of lost profits was denied.[158] These courts view both lost profits and reasonable royalty provisions as defining the boundary of liability for recoverable damages in different calculation methods.[159] Accordingly once the patentee has failed to establish causation under the lost profits theory, he or she cannot do so under the reasonable royalty theory. This view is inconsistent with the language of Article 102, paragraph 4, which language presumes separate boundaries of damage liability under the reasonable royalty and lost profits theories. This view also conflicts with the emphasis on the patentee's right for compensation in the legislative history for revising Article 102.

6 Impact of 1998 revision

In theory, the introduction of the *Panduit* presumption in Article 102 moved Japanese patent infringement damages substantially in line with US damages. The revision significantly reduced the patentee's burden of establishing causation, which led to a significant increase in the number of cases claiming lost profits.[160] Courts replaced the pre-1998 'all or nothing rule' with a new rule in which at least some portion of a lost profits claim is awarded. According to 2004 statistics, the four largest damage awards were based on lost profits under the new paragraph 1, and the patent community was led to believe that the 1998 revision significantly increased the amount of damages available in

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155 Takabayashi, s*upra* note 142, at 254.

156 Shibuya, s*upra* note 146, at 283.

157 Judgment of Tokyo District Court, June 15, 1999.

158 Judgment of IP High Court, September 25, 2006; Judgment of Osaka District Court, April 19, 2007.

159 Yutaka Koike, 'Direction of Practice in Interpreting Patent Law Art. 102', Ryu Takabayashi, Toshiko Takenaka and Tatsuki Shibuya (eds), *2007 IP Annual Report* (Shoji Homu, Tokyo, 2007) 281.

160 Japan Intellectual Property Assocation, 'Study of Patent Infringement Damages', 54 Intellectual Property Management (No. 5) 1287 (2004).

Japanese courts.[161] In particular, because early decisions did not allow deduction of the presumed amount by taking a view that the amount under the new paragraph is constructive based on a legal fiction of a two-competitor market and did not allow any deduction, they suggested a risk that the revision had introduced a scheme to overcompensate damages.[162]

In practice, the impact of the 1998 revision was much smaller than expected. More recent statistics indicate a decrease in the average amount of damages awarded in Japanese courts.[163] The proportion of the amount awarded in contrast to the amount claimed by patentees has declined in more recent cases.[164] The average damage award has doubled from that given by statistics before the revision but is still one-hundredth of the average damage award in US courts in 1992 statistics cited by the JPO in justification of the 1998 revision.

Obviously, importing US case law doctrine has not pushed up Japanese damage awards to the level of damage awards available in US courts. A possible source of this marginal impact is the unclear impact of the revision on patent policy. Although Japanese judges were affected by the patent policy's emphasis on the patentee's right of compensation during and immediately after the 1998 revision, they gradually returned to the pre-1998 practice because such a policy was unclear from the language of Article 102.

Another factor is that the needs of Japanese industry were poorly served by the goal of the 1998 revision. Pre-revision statistics did not clearly show any necessity for increasing damages.[165] Post-revision statistics indicate that overall Japanese industry views current damages as just as adequate as pre-1998 damages.[166] The impact of the revision on Japanese judges' sense of social justice did not last because a significant increase in damages was not necessary to maintain the appropriate balance in intellectual property for Japanese society. Thus, judges converted pre-1998 negative factors for eliminating causation into deductable factors to establishing circumstances where patentees could not have sold but for infringement.

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161 *Id.*

162 Takenaka, *supra* note 5, at 362.

163 Institute of Intellectual Property, 'Report on Current Situations in Industrial Property Rights Disputes' (Institute of Intellectual Property, Tokyo, 2006) 90-93; Koji Miyahara, 'Study of Damage Calculation under Patent Law Art. 1' <http://www.grips-ip.jp/ip/paper/MJI04057miyahara.pdf> last visited March 4, 2008.

164 *Id.* at 91. 70% of the claimed amount was awarded in 2000 but only 20% was awarded in 2003.

165 *Supra* note 43, IIP Damages Report at 24.

166 *Supra* note 163, Report on Current Situations at 175, 179.

The third cause of this marginal impact is the limited use of the new presumption which requires a disclosure of per-unit net profit.[167] Many patentees prefer to keep such profit secret and have thus refrained from taking advantage of the new presumption. Because the revision did not make clear the function of reasonable royalty as minimum compensation, any claim of compensation may be denied with respect to the number of infringing products where a claim of lost profits is denied under paragraph 1. A patentee may prefer to claim reasonable royalties and secure compensation for all infringing products sold by the infringer.

It is important to note that the number of cases in which Japanese courts award infringement damages is very low, about 15 cases per year. Thus, the pool of cases used in the statistics for this chapter may not be sufficiently large to show the impact of the revision. This small number has resulted from the difficulty patentees face in establishing infringement in Japanese courts.[168] Patentee's lower chance of winning in Japanese courts compared with other major jurisdictions should be of more serious concern for Japanese industry than limited damage awards in the context of a national strategy to build an intellectual property-based nation.

7 Conclusion

Japan's experience reveals the challenge of changing a well-established legal system by importing a foreign system. In particular, restructuring patent infringement damages presents a big challenge because common law and civil law traditions strongly influence the theory and policy of civil remedies. European countries are in the process of harmonizing their patent enforcement procedure and civil remedies for infringement through the European Union Directive on Enforcement of Intellectual Property (EU IPR) Enforcement Directive[169] and the European Patent Enforcement Agreement. They should expect a similar challenge in overcoming the differences in civil remedies available in common law countries such as the UK and civil law countries such as Germany.

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167 *Supra* note 163, Report on Current Situations at 173. Patentees requested lost profits under art. 102, para. 1 in only 10% of all cases in which damages were awarded.

168 Michael Elmer, 'International Patent Enforcement Strategy – Choice of Jurisdiction' in Toshiko Takenaka and Kazunori Yamagami (eds), *Legal Consultation of International Intellectual Property Disputes Resolution* (Seirin Shoin, Tokyo, 2006) 191.

169 Directive 2004/48/EC of the European Parliament and of the Council of 24 April 2004 on the enforcement of intellectual property rights (http://www.urheberrecht.org/topic/enforce/eu/1_19520040602en00160025.pdf).

Although the huge gap between damage awards available in Japanese and US courts remains, one may argue that the 1998 revision was successful. The goal of the revision was not harmonization but the provision of adequate compensation for patent infringement damages. The revision attained this goal because the relatively marginal increase in damages may reflect that there was little need to change the balance between the competing interests of patentees and the public in Japanese industry. In any event, the Japanese economy has recently shown a strong recovery from its recession. Accordingly, the Japanese government's mission has been successfully completed, although there is no evidence that the recovery was promoted by METI-JPO's adoption of the pro-patent policy and national strategies.

22 Resolving patent disputes in a global economy

*Rochelle C. Dreyfuss**

1 Introduction

As with other businesses, the patent industries have discovered the global marketplace. In the last dozen years, patent applications filed in countries other than the inventor's place of residence have increased annually by 7.4% worldwide,[1] and over the last two decades, licensing revenues in the OECD states have grown ten-fold.[2] To a large extent, these developments stem from a dynamic familiar to other sectors of the economy: as countries grow wealthier and more sophisticated, as tastes and preferences converge, as transportation costs decline, foreign goods become more familiar, attainable, desirable and available. For the technology community, there are other factors that are also at play. The inclusion of the TRIPS Agreement within the World Trade Organization (WTO) framework means that patents are now readily available in many nations and across a broad array of creative endeavors.[3] Intellectual production is becoming increasingly collaborative, involving inventors of different nationalities, working in a multiplicity of locations.[4] Technology

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1 World Intellectual Property Organization (2006), 'WIPO Patent Report: Statistics on Worldwide Patent Activities 4', *available at* http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2006.html#P137_14557.

2 Organization for Economic Cooperation Development, Directorate for Science, Technology and Industry, 'Valuation and Exploitation of Intellectual Property' 18–19 (June 30, 2006), DSTI/DOC 2006/5, *available at* www.oecd.org/dataoecd/43/39/37202362.pdf.

3 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

4 Dreyfuss, Rochelle Cooper (2000), 'Collaborative Research: Conflicts on Authorship, Ownership, and Accountability', *Vanderbilt Law Review*, **53,** 1162.

itself is changing. Digital products, such as software, can be transmitted around the globe instantaneously.[5] There are also new developments, such as radio navigation systems, where patent claims are 'divided' in the sense that they describe conduct that can span jurisdictions.[6]

Although the *practice* of patented technologies is now international, patent law and patent *rights* remain territorial. Accordingly, firms operating in, or worried about competition from, foreign jurisdictions need multiple patents to protect their interests. As the numbers suggest, acquisition of foreign patents is becoming easier. One hundred and fifty countries are currently members of the WTO. While examination and registration are required in each country where protection is sought, various international arrangements facilitate that process. The Patent Cooperation Treaty (PCT)[7] offers preliminary examination functions to its 137 signatories. Regional agreements go even further. For example, the European Patent Convention (EPC), which as of 2008 will have 33 members including all of the members of the EU, centralizes examination (and also deepens the degree of harmonization).[8]

Much harder are the issues that arise in connection with dispute resolution. When markets were mainly local, it was clear that disputes would be resolved, and judgments would be enforced, in local courts, under local law. However, the advent of global exploitation makes this approach cumbersome, unpredictable, costly and – in some cases – unfair. Consider, for example, a computer programmer (let us call him Developer, or D), working from his residence in the nation of Xandia, who reverse-engineers software that a producer, P, has patented in several nations. D creates an independent product that simulates all of the original's functionality and sells access to it from his Internet site, which is hosted on a server in Patria. From there, it can be utilized globally and 'mirrored' (duplicated) by sites elsewhere. If P wants to enforce his patent to enjoin utilization and receive compensation for past infringements, where should P sue?

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[5] *Microsoft Corp. v. AT & T Corp.*, 127 S.Ct. 1746 (2007) (software supplied abroad from the United States*); Eolas Technologies Inc. v. Microsoft Corp.*, 399 F.3d 1325 (2005) (same).

[6] *Decca Ltd. v. United States*, 544 F.2d 1070 (Ct. Cl. 1976) (system operated inside and outside the United States). Wasserman, Melissa Feeney (2007), 'Divided Infringement: Expanding the Extraterritorial Scope of Patent Law', *New York University Law Review*, **82**, 281.

[7] Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

[8] The Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199. Thomas, John R. (1996), 'Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement', *Law & Policy International Business*, **27**, 277, 294 (listing other regional agreements).

In a purely territorial system, P may find it necessary to sue in every country of registration where utilization (or mirroring) takes place. The following scenarios illustrate the difficulties P could encounter:

(1) States have differing views on personal jurisdiction. Some may limit the assertion of adjudicatory authority to damages caused by Internet activity specifically directed at, or used by, locals. If usage is widely dispersed, it may be too expensive for P to pursue all alleged infringements. Further, while a court in Xandia, D's residence, may assert plenary power and find for P on all infringing activity, a court in Patria could decide the assertion of power was exorbitant and refuse to recognize the judgment by shutting down the server. In the final analysis, P may receive incomplete relief.[9]

(2) The relevant states may disagree on whether reverse engineering and using the fruits of that process are infringing activities. If so, multiple suits could lead to a patchwork of different outcomes; at the end of the day, it may be impossible to prevent D from locating in a country where his activity is not considered infringing and unclear what measures P can require D to take to bar access from places where the product or its use is considered infringing.[10]

(3) Because the software can be utilized in places remote from the server on which it resides, the 'divided' aspect of the case may raise special problems. There may be important differences in how national patent laws are interpreted and how specific claims in each nation's patent are construed. If some countries' laws fail to consider utilizations occurring through a Xandian server as infringing activity and Xandian patent law does not cover practice of the invention abroad, some uses will escape liability.[11]

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[9] *Pavlovich v. Superior Court*, 58 P.3d 2 (Cal. 2002) (insufficient evidence of contact with the forum to exercise authority over out-of-state website operator in a trade-secret case); *Young v. New Haven Advocate*, 315 F.3d 256, 264 (4th Cir. 2002) (refusing to exercise jurisdiction in Virginia over a Connecticut defendant who allegedly posted defamatory material because there was no 'manifest intent' to target a Virginia audience). *Cf. Dow Jones & Co. Inc. v. Gutnick* (2002) 210 C.L.R. 575 (Austl.) (limiting jurisdiction over Internet libel action to reputational harm in Victoria, Australia); *Yahoo! Inc. v. La Ligue Contre Le Racisme et L'Antisemitisme*, 433 F.3d 1199, 1209 (9th Cir. 2006) (en banc) (objecting to French decision impinging on U.S. Internet site).

[10] *Cf. Twentieth Century Fox Film Corp. v. iCraveTV*, 53 U.S.P.Q.2d 1831 (W.D.Pa. 2000) (right to rebroadcast sports games over the Internet potentially handled differently in Canada and the United States).

[11] *Cf. NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005) (patent practiced by Americans, using a server in Canada). The term 'divided claims'

At first blush, D might welcome an outcome that allows him to forum shop (by locating his server where he can escape infringement), or that lets him avoid paying compensation for all infringements. On further contemplation, however, he may find that territorial enforcement creates even more problems for technology consumers like him than it does for technology producers like P. In Scenario (2), D may not know when he is developing his product what law will apply to his efforts. As a result, it will be hard for him (and his investors) to quantify business risks. There are other potential scenarios that may also prove problematic:

(4) The states where D's activity is localized may disagree on how to calculate damages. Patrian law could regard supplying programming services abroad (or even offering to sell them abroad) as infringing its laws and calculate damages based on worldwide use (or even worldwide availability); Xandia might similarly decide that D's activities give rise to global liability. Furthermore, every country where utilization occurs could award damages based on local uses. Unless each judgment is recognized by all relevant courts, D could wind up paying for the same activity multiple times.[12]

(5) P may use the territoriality of patent law strategically. The territorial principle means that one state's decision that a patent is not infringed (or is invalid) will not foreclose litigation in other countries. P will thus have multiple bites of the apple. Successive suits could wear D down to the point where he must abandon lawful activities because he can no longer afford to mount a defense.[13]

The territorial approach also compromises the public interest. Multiple lawsuits strain judicial resources. The high cost associated with global

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comes from Lemley, Mark A., David O'Brien, Ryan M. Kent, Ashok Ramani and Robert Van Nest (2005), 'Divided Infringement Claims', *American Intellectual Property Law Association Quarterly Journal*, **33**, 255.

[12] *Cf. Society of Composers, Authors & Music Publishers of Canada v. Canadian Ass'n of Internet Providers*, [2004] 2 S.C.R. 427, ¶ 78 (Can.) (noting that the decision to find jurisdiction over an Internet service provider 'raises the spectre of imposition of copyright duties on a single telecommunication in both the State of transmission and the State of reception'). The problem presented in this scenario is a general problem and can also arise as an alternative outcome in divided infringement cases as exemplified by Scenario (3).

[13] *Cf. Computer Associates Intern., Inc. v. Altai, Inc*., 126 F.3d 365 (2d Cir. 1997) (successive suits in the United States and France over theft of trade secrets). There is anecdotal evidence that patent holders also choose *where* to sue strategically, starting with a big market, where a win may be enough to shut D down worldwide. If that suit is a loser, P then sues in the next biggest market, and so forth.

enforcement could undermine the value of patent protection and chill innovation. At the same time, the risk of being haled before multiple courts may pose a barrier to entry, especially for cash-poor start-ups. Further, the potential for multiple recoveries could alter the distribution of patent rewards among technologies, skew incentives to invent and encourage 'trolls', who buy patents for the sole purpose of profiting from litigation. In cases where the risk of successive suits forces D to abandon lawful research and development activity, the public domain is needlessly impoverished.

This chapter begins by considering various attempts litigants have made to use traditional legal practices to alleviate the problems posed by the territoriality of patent law – extraterritorial application of local law, consolidation of foreign and domestic claims and private agreements. To date, courts and legislatures have responded to these practices unsympathetically. Nonetheless, the current atomized approach to dispute resolution is unlikely to remain stable. It is in tension not only with the way that businesses operate, but also with the WTO's commitment to a globalized marketplace in which intellectual goods move freely. The chapter ends by describing the alternative mechanisms available to national authorities – deep harmonization and an agreement on a procedural framework for coordinating multinational litigation and judgment recognition.

2 Litigant-mediated approaches: exploitation of traditional practices

2.1 Extraterritorial application of local law

It is not as though the creative community has failed to recognize that territorial enforcement is at odds with global exploitation.[14] The situation in the United States is a good example. Controversies such as those illustrated by Scenarios (1) to (3), where there is a risk that compensation will not cover all uses of protected works and that infringing activity will not be effectively enjoined, have inspired the holders of U.S. patents to rely on U.S. law and to argue either that infringement should be construed to cover foreign acts or that the remedy for local infringement should take foreign usages into account.

NTP, Inc. v. Research in Motion, Ltd.,[15] is an example of the former approach. In this divided infringement case (Scenario (3)), Blackberry devices

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[14] International Association for the Protection of Intellectual Property, Resolution, Question Q174 – Jurisdiction and Applicable Law in the Case of Cross-border Infringement of Intellectual Property Rights (Oct. 25–8, 2003), *available at* http://www.aippi.org/reports/resolutions/Q174_E.pdf; Clermont, Kevin M. (2004), 'A Global Law of Jurisdiction and Judgments: Views from The United States and Japan', *Cornell International Law Journal*, **37**, 1, 20.

[15] 418 F.3d 1282 (Fed. Cir. 2005).

were used within the United States, but the communications were facilitated by a relay located in Canada. NTP sued, arguing that it had a U.S. patent claiming aspects of the Blackberry system and its method of operation and that these claims were infringed when the devices were utilized. The Federal Circuit found that method claims could not be infringed if some of the elements of the claims were practiced abroad. However, it also held that despite the location of the relay in Canada, the locus of Blackberry use was centered in the United States and thus the claimed system was 'used' within the meaning of § 271(a) of the federal Patent Act.[16]

The Federal Circuit has also flirted with the latter approach. In *Eolas Technologies Inc. v. Microsoft Corp.*[17] and *AT&T Corp. v. Microsoft Corp.*,[18] software was sent from the United States to another country without authorization and was downloaded there onto computers, which were then sold in the international market. Essentially following the 'root copy' or 'predicate act' approach pioneered in federal copyright cases such as *Update Art, Inc. v. Modiin Publ'g, Ltd.*,[19] the Federal Circuit held that the U.S.-based act of sending a single copy of software abroad constituted 'supply' of a 'component' from the United States within the meaning of § 271(f) of the Patent Act.[20] It further held that damages should be calculated on the basis of the total number of downloads made abroad.[21]

It is not, however, clear whether this approach will provide a general solution to the multiterritorial infringement problem. The Supreme Court reversed the *AT&T* decision, albeit in an opinion of unclear scope.[22] Thus, a strong argument can be made that the decision is quite narrow. The Court focused heavily on what was meant by 'supply' of a 'component'. Noting that § 271(f) was enacted in response to a specific case, *Deepsouth Packing Co. v. Laitram*

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16 35 U.S.C. § 271(a) ('[W]hoever without authority . . . uses . . . any patented invention, within the United States, . . . infringes the patent').

17 399 F.3d 1325 (Fed. Cir. 2005).

18 414 F.3d 1366 (Fed. Cir. 2005).

19 843 F.2d 67 (2d Cir. 1988). *Sheldon v. Metro-Goldwyn Pictures, Corp.*, 106 F.2d 45 (2d Cir. 1939), *aff'd*, 309 U.S. 390 (1940).

20 35 U.S.C. § 271(f)('Whoever without authority supplies . . . from the United States . . . components . . . in such manner as to actively induce the combination of such components outside of the United States . . . shall be liable as an infringer').

21 *Stac Elecs. v. Microsoft Corp.*, Civil No. 93-0413-ER (Bx) (C.D. Cal. Feb. 23, 1994); Judge Orders Microsoft Recall, S.F. Examiner, June 11, 1994, at D2 (as discussed in Thomas, John R. (1996), 'Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement', *Law & Policy International Business*, **27**, 277, 279, the court ordered an extraterritorial injunction based on a finding that a single national patent was infringed; the case settled without review).

22 127 S.Ct. 1746 (2007).

Corp.,[23] it reasoned that the meaning of the provision should be confined to fact patterns similar to the one presented there. In *Deepsouth*, every component supplied from the United States was physically manufactured in the United States. Accordingly, the Court held that physically embodying the software invention abroad (through downloading) was not covered by the statute.

Since the results in *NTP* and *Modiin* were not predicated on an interpretation of § 271(f), they are not explicitly affected by the *AT&T* decision. Furthermore, the Court expressly suggested that Congress could always amend the Patent Act to extend its reach.[24] Still, there are elements of *AT&T* that suggest the decision is broader than it looks. The Court emphasized that U.S. patents are not infringed by foreign activity unless Congress makes its extraterritorial intentions clear[25] – a specific instantiation of the general canon of construction 'which teaches that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States'.[26] As the Court explained in *F. Hoffmann-La Roche Ltd. v. Empagran*, a case narrowing the extraterritorial reach of an antitrust law, a modest approach to construction reflects principles of customary international law and 'helps the potentially conflicting laws of different nations work together in harmony'.[27] Because neither *NTP* nor *Modiin* was based on statutes that were explicitly extraterritorial, *AT&T* may have effectively overruled them.

More important, were Congress to consider amending these laws to make its intent explicit, it is sure to discover that the extraterritorial approach is not without its problems. Both *AT&T* and *Empagran* hint strongly at deeper limitations. One of these problems is illustrated by Scenario (4): application of the law of one country to control activity in another country does not exclude the second country from applying its own law to the same conduct. Were Canada to decide that use of its relay infringed a Canadian patent, or were the countries where Microsoft downloaded software to find infringement under their own laws, the defendants in these cases could be subject to double liability, depending on whether satisfaction of the U.S. judgment was recognized as a set-off. Thus, although Congress might be drawn to overrule *AT&T* legislatively in order to help U.S. plaintiffs like AT&T, it must also evaluate the

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23 406 U.S. 518 (1972). In that case, the parts of a patented machine were made in the United States and assembled into kits. The kits were sold abroad with assembly instructions. Although foreign buyers were able to easily recreate the patented invention, the Court held that U.S. law was not infringed by the activity.

24 127 S.Ct. at 1760.

25 127 S.Ct. at 1750.

26 *Blackmer v. United States*, 284 U.S. 421, 437 (1932).

27 542 U.S. 155, 164–5 (2004).

harm it could do to U.S. defendants like Microsoft. If the *Empagran* Court is right that 'legislators take account of the legitimate sovereign interests of other nations when they write American laws'.[28] then Congress will presumably consider whether the expression of these sovereign interests would put defendants at risk of incurring multiple damage awards.

More problematic is the question of prescriptive authority. In a sense, all of these cases are based on *Steele v. Bulova Watch Co.*,[29] the first modern Supreme Court case on the extraterritorial application of intellectual property law. In that case, Steele, an American, made and sold watches in Mexico under the name 'Bulova', a trademark that the U.S. Bulova Watch Company had registered in the United States. When Bulova found that some U.S. consumers were confused by the Mexican watches, it sued Steele in Texas and in Mexico, claiming trademark infringement. Initially, the Mexican case was unfruitful for Bulova because Steele held the Mexican registration of 'Bulova' for watches. However, Bulova's U.S. suit fared much better: the Supreme Court held that Congress had prescriptive authority over international commerce and that the federal Lanham (Trademark) Act[30] was intended to protect U.S. trademark holders against foreign activity that spilled over into U.S. territory.[31] Accordingly, the case was remanded with instructions to provide Bulova with a remedy.

While *Bulova* is similar to the *Microsoft* cases and *Modiin* in its willingness to help U.S. right holders protect their markets, it differs markedly from these cases in the substantiality of the contacts between the United States and the dispute. In *Bulova*, the Court was careful to note the many connections between Steele's activities and the United States – purchase of component parts in the United States, filtration of watches across the border and (perhaps most important) reputational injuries inflicted in U.S. markets. A similar nexus can be discerned in *NTP*. According to the Federal Circuit:

> RIM's customers located within the United States controlled the transmission of the originated information and also benefited from such an exchange of information. Thus, the location of the Relay in Canada did not, as a matter of law, preclude infringement of the asserted system claims in this case.[32]

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28 542 U.S. at 164.

29 344 U.S. 280 (1952). Austin, Graeme W. (2006), 'The Story of *Steele v. Bulova*: Trademarks on the Line', in Jane C. Ginsburg and Rochelle Cooper Dreyfuss (eds), *Intellectual Property Stories*, New York: Foundation Press, p. 395.

30 15 U.S.C. §§ 1051–1141n.

31 344 U.S. at 286.

32 *NTP*, 418 F.3d. at 1317.

But the same nexus cannot be found in the *Microsoft* cases. As in *Bulova*, the parties were both American. However, the infringers were satisfying *foreign* demand for the U.S. patent holder's product, not *domestic* demand. There was nothing about the activities abroad that bled into the business climate within the United States. Lower courts in trademark cases have struggled with the application of *Bulova* in circumstances where the U.S. effects have been equally insubstantial,[33] as have copyright courts following *Modiin*.[34] Congress may be equally concerned.

Even more difficult is the issue of comity. In *AT&T*, the Supreme Court explained its parsimonious interpretation of the Patent Act as follows:

> Foreign conduct is [generally] the domain of foreign law,' and in the area here involved, in particular, foreign law 'may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions.[35]

The problem of offending another sovereign was not at issue in *Bulova* because by the time the Supreme Court considered the case, Mexico had concluded that Steele's bad faith required nullification of his trademark registration. When there is no such finding – when a defendant holds a valid trademark in the other country's market – trademark courts tend to tread quite gingerly.[36] In cases where there is a conflict in copyright interests, courts behave similarly.[37]

But as the *AT&T* Court suggested, the potential for a clash of sovereign values is clearly most severe in patent cases. The well-known marks that are mostly likely to be the object of extraterritorial application of trademark law enjoy heightened protection by reason of international law.[38] Under international copyright law, copyrights arise automatically.[39] Accordingly, a work

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[33] *McBee v. Delica Co.*, 417 F.3d 107, 117–21 (1st Cir. 2005); *Nintendo of Am. v. Aeropower Co.*, 34 F.3d 246, 251 (4th Cir. 1994); *Wells Fargo & Co. v. Wells Fargo Express Co.*, 556 F.2d 406, 428–9 (9th Cir. 1977).

[34] *Los Angeles News Service v. Reuters Television Int'l. (USA) Ltd.*, 340 F.3d 926 (9th Cir. 2003).

[35] *AT&T*, 127 S.Ct. at 1758 (quoting Brief for United States as Amicus Curiae at 28).

[36] *Vanity Fair Mills, Inc. v. T. Eaton Co.*, 234 F.2d 633, 647 (2d Cir. 1965).

[37] *Los Angeles News Service*, 340 F.3d at 931–2. Scenario (2), transposed to a copyright case, illustrates a conflict that could arise in the copyright context.

[38] TRIPS Agreement, art. 2, incorporating Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, revised in Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305, art. 6bis.

[39] Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, revised in Paris, July 24, 1971, 25 U.S.T. 1341, 828 U.N.T.S. 221 [hereinafter Berne Convention], art. 5(2).

that is protected in one country will almost always be protected in all Berne (and WTO) countries.[40] By contrast, international patent law is not well harmonized. Indeed, there are disagreements on the patentability of whole classes of advances. TRIPS is confined to technologies 'capable of industrial application'. Further, the Agreement permits WTO members to exclude animals, therapeutic and surgical methods, and inventions raising moral or *ordre public* considerations.[41] Software is a case in point: in some states, it is not regarded as creating the 'technical effect' required for patent protection;[42] some states may even have affirmatively decided that for software, open-source development is a more effective driver of innovation than patent rights. Extraterritorial application of U.S. patent law to software distributions outside the United States (as in the *Microsoft* cases), or to uses that partly occur in Canada (as in *NTP*), would (as Scenarios (2)–(4) suggest) interfere with these decisions. And, of course, extraterritorial application of U.S. patent laws in the health and safety arenas would raise even stronger comity (and human rights) concerns.[43]

Given these considerations, Congress may refrain from altering the *AT&T* resolution: it may decide that it lacks the authority to broadly expand the reach of U.S. law, or that such expansion would be unwise. If Congress fails to act, then the extraterritorial approach will be of limited value. It may be available in divided infringement cases (although even here, a strong argument could be made that the better course is to require patentees to draft their claims so that they read on activity that takes place entirely within a single territory).

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[40] The TRIPS Agreement largely incorporates the Berne Convention, TRIPS Agreement art. 9(1). There are a few exceptions to the universality of copyright protection because Berne sets only a floor on such matters as the duration of protection.

[41] TRIPS Agreement, art. 27.

[42] Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199, arts. 52–3; Panagiotidou, E. (2003), 'The Patentability of Computer Programs, According to the Commission's New Proposal for a Directive and to EPO Boards of Appeal Decisions', *Computer & Telecommunication Law Review*, **9**, 126. Other differences include the protectability of higher life forms, which are excluded in Canada, *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45 (Can. 2002) and 'second use' pharmaceutical inventions, which are not protectable in India, Choudhary, D.N. (2006), 'Evolution of Patent laws "Developing Countries' Perspective" ', p. 134.

[43] Arguably, cases involving litigants from a single country always create sufficient contact with that country to support its prescriptive authority. However, intellectual property rights impact heavily on the local availability of intellectual products. Accordingly, the interests of the nation where utilization is occurring can be as strong as that of the nation where the litigants are resident. Since the United States is a large producer of intellectual products, foreign sovereigns may have an especially strong concern about extraterritorial application of its law.

However, in the typical case of systematic infringement of multiple national rights, the extraterritorial approach may be unavailing in the United States. As demonstrated below,[44] other countries appear to have an even stronger commitment to territoriality, making it equally unlikely litigants could pursue this approach elsewhere.

2.2 Consolidation of worldwide claims

As Jay Thomas described in a prescient article written over a decade ago, another popular strategy that litigants have used to cope with the disjuncture between the territoriality of protection and the international scope of exploitation is to consolidate multinational claims in a single court.[45] To go back to the introductory hypothetical, P could sue D in Xandia and assert claims arising under the laws of each of the places where D's software is hosted or accessed.

For the plaintiff, this approach represents considerable cost savings. It eliminates the problems in Scenario (1) because the defendant could be sued at his residence in Xandia, which presumably has plenary personal jurisdiction over him. Since that court could issue a comprehensive judgment, the problem illustrated in Scenario (2) disappears. The divided claim issue in Scenario (3) is so new, national patent systems have yet to fully deal with it. Consolidation would not solve the problem, but a court seized with authority over the entire dispute is in a better position to find a just resolution than are courts that consider the claims piecemeal.[46]

Consolidation is equally helpful to the defendant. The prospect of excessive liability in Scenario (4) is reduced once all national claims are presented together because it is unlikely that the court hearing the consolidated case would make multiple awards based on the same activity. The problem in Scenario (5) could also be eliminated: if the plaintiff fails to assert all its national claims, the defendant could counterclaim for nonliability on any causes of action that were omitted. By putting all potential claims into issue, the defendant could achieve global peace in a single adjudication.

This strategy is also well attuned to the public interest. It conserves judicial resources: while the court handling the consolidated suit will face a formida-

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[44] See text at notes 89–92.

[45] Thomas, John R. (1996), 'Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement', *Law & Policy International Business*, **27**, 277.

[46] *Cf.* Dinwoodie, Graeme B. (2000) , 'A New Copyright Order: Why National Courts Should Create Global Norms', *University of Pennsylvania Law Review*, **149**, 469 (suggesting that adjudication has an important role to play in answering open questions of international intellectual property law).

ble undertaking, other courts will save time and money. Multiple judges will be spared the need to learn the intricacies of the technology in issue and will never confront the problem of reconciling conflicting judgments. Consolidation also does the least damage to sovereign interests. Admittedly, one nation's laws will sometimes be applied by the courts of a different state. However, that practice is common in other contexts – indeed, much ink has spilled on choice of law questions in such fields as torts and contracts.[47] Careful attention to conflicts rules permits each sovereign to regulate activity localized in its territory or strongly connected to its national interests. Surely, a nation's sovereign interests are less offended by the application of its own law by another nation's court than by the application of foreign law to conduct within its borders. Indeed, were an efficient method of dealing with transnational infringement established, legislatures might have less of an appetite for pushing the limits of their prescriptive authority. Even the overall burden of litigation may diminish, for as actors become familiar with the outcomes of consolidated cases, they will learn to determine accurately what law regulates their conduct.

Given the many advantages of consolidated litigation, it is no wonder that this strategy has been pursued repeatedly in the United States and elsewhere.[48] Federal courts in the United States would appear to be particularly good candidates to hear such cases because they enjoy fairly broad subject matter authority. If the defendant is an American but the plaintiff is not (or if the litigants are domiciled in different U.S. states), then all the claims between them fall into federal court 'diversity' jurisdiction.[49] U.S. courts have discretionary authority to dismiss cases on forum non conveniens grounds,[50] but disputes that include claims under U.S. law do not tend to be dismissed.

Federal courts also possess 'federal question' jurisdiction over all cases arising under U.S. patent law, irrespective of the domicile of the parties.[51] Once a court is seized with a federal patent claim, it has discretionary power to entertain supplemental jurisdiction over all claims that are so related that they 'form part of the same case or controversy' within the meaning of the

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47 Eechoud, Mireille M.M. van (2003), *Choice of Law in Copyright and Related Rights: Alternatives to the Lex Protectionis*, New York: Kluwer Law International, pp. 15–46 (tracing the development of conflicts rules).

48 In addition to the cases presented here on U.S. and EU adjudication, Nagasawa, Yukio (Jan. 2007), 'Settlement Conferences at Japanese Courts', *Association Internationale Pour la Protection de la Propriété Industrielle Journal*, **3** (describing the Wakai judicial settlement procedure, which creates a mechanism to judicially mediate settlement of multiterritorial patent claims).

49 28 U.S.C. § 1332.

50 *Cf. Piper Aircraft Co. v. Reyno*, 454 U.S. 235 (1981).

51 28 U.S.C. § 1338.

Constitution.[52] Allegations concerning rights under a plaintiff's parallel (or 'counterpart') patents (patents claiming the same discovery, particularly when they arise out of the same PCT application) would appear to fall within this concept. The provision on supplemental jurisdiction also supports counterclaims and could be read to include any claims by the defendant involving either party's foreign patents, so long as they relate to the same controversy.[53]

District courts have, in fact, proved receptive to this approach.[54] The Federal Circuit does not, however, share their enthusiasm. First in *Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux*[55] and then a dozen years later in *Voda v. Cordis Corp.*,[56] it refused to permit the exercise of supplemental jurisdiction over foreign patent claims. In *Mars*, the plaintiff asserted rights under a U.S. patent and a Japanese patent, both of which were related to the same technology. Although the court acknowledged that 'certain of the devices accused of infringing the Japanese patent may be similar to the . . . device [sold in the United States]',[57] it found substantial differences: in the U.S. part of the case, all of the alleged infringements were of method claims; the Japanese case involved an apparatus claim. The U.S. case involved a single device; the Japanese case involved nine devices. Different infringing acts were alleged in the two parts of the case and only in the U.S. part were there claims of inducing infringement. To the court, these differences meant the claims were not a part of the same constitutional case.

In *Voda*, the plaintiff initially asserted claims under three U.S. patents and then moved to amend the complaint to add supplemental claims for infringement of British, Canadian, French, and German patents, all of which issued from a single PCT application – and in the case of the European patents, from common examination under the EPC.[58] The district court granted the motion and the defendant appealed. The Federal Circuit reversed. Although the court acknowledged that 'there appear to be more commonalities [among the patent

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52 28 U.S.C. § 1367(a). The court's discretionary authority is delineated in § 1367 (c). U.S. Const. Art. III, § 2 extends the judicial power to 'Cases' and 'Controversies'.

53 *Ideal Instruments, Inc. v. Rivard Instruments, Inc*., 434 F. Supp. 2d 598, 631–2 (N.D. Iowa 2006) (drawing distinctions among various fact patterns).

54 *Ortman v. Stanray Corp*., 371 F.2d 154 (7th Cir. 1967) and *Distillers Co. v. Standard Oil Co*., 150 U.S.P.Q. 42 (N.D. Ohio 1964). *Cf. Boosey & Hawkes Music Publishers, Ltd. v. Walt Disney Co*., 145 F.3d 481 (2d Cir. 1998) (ordering district court to entertain a consolidated case involving 18 national copyrights).

55 24 F.3d 1368 (Fed. Cir. 1994).

56 476 F.3d 887 (Fed. Cir. 2007).

57 24 F.3d at 1375.

58 Curiously, diversity jurisdiction was not alleged even though the parties were from different U.S. states.

claims] than in *Mars*',[59] it nonetheless intimated that the foreign and domestic cases were not sufficiently related. It suggested that the 'case or controversy' determination depended on whether (1) the claims stemmed from a 'common nucleus of operative fact' and (2) whether the plaintiff would 'ordinarily expect' the claims to be tried in a single judicial proceeding. Given that the 'norm is that patent claims are adjudicated by the courts within the jurisdiction where such patents are created', the court reasoned that the second prong of this test was not satisfied.[60]

The court did not, however, rest its reversal on that ground. Instead, it held that the decision to hear the case was an abuse of the trial court's discretion. It argued that courts are bound by the Paris Convention and TRIPS Agreements and held that by reason of Article 4bis of the Paris Convention (on the independence of national patents), Article 2(3) of the Paris Convention (reserving matters of judicial procedure to member states), and Article 41 of the TRIPS Agreement (requiring each member to enforce the rights delineated in TRIPS), courts of one state are not allowed to adjudicate the patent rights of another.

Next, the Federal Circuit considered comity. Noting that none of the foreign governments expressed a willingness to have a U.S. court exercise jurisdiction over its patent claims, the court reasoned that in the absence of an affirmative showing that the assertion of supplemental jurisdiction would be convenient, entertaining the case would imply that the courts of other countries would not do an adequate job protecting the plaintiff's rights. Relying on cases from the 19th century and comparing patents to rights in land, it found that patent claims fall within the local action doctrine, meaning they can only be decided by courts of the territory in which the offending conduct took place. Citing *Empagran*, it held that the complexity of patent cases made it likely that deciding a foreign patent case would interfere with the sovereign authority of other nations.

Finally, the court considered issues of economy, convenience and fairness. It reasoned that district courts grappling with foreign claims would consume judicial resources, that juries would be confused, and that the parties would be strapped with high costs – all without any assurance that the resulting judgment would be recognized and enforced. Arguing that the 'act of state' doctrine barred U.S. courts from inquiring into the validity of a foreign patent, the court concluded that it would be unfair to issue infringement judgments in cases involving patents that were alleged, but could not be proved, to be invalid.

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59 476 F.3d at 895.
60 476 F.3d at 897.

Somewhat surprisingly, the situation is little different in the European Union. There, the impetus to consolidate has proved especially strong because the EU's commitment to the free movement of goods means that transnational patent cases are relatively common.[61] The Dutch courts famously stepped into the gap between the territoriality of the law and the pan-European nature of business interests and courts in Germany soon followed suit.[62]

These national courts made two important procedural moves. First, they removed the impediment to consolidation created by Article 22(4) of the Brussels Regulation (or, more accurately, by the predecessor provision in effect at the time the case was filed[63]). This provision, which reserves jurisdiction over validity determinations to the country of patent registration, was interpreted as applying only when invalidation is the *sole* object of the suit. The courts took a variety of approaches to cases where the validity issue arose in other litigation ('incidentally'). Generally, they asserted jurisdiction, issued interim orders (including cross-border injunctions) and stayed the ultimate resolution until the proper court dealt with the validity issue; or they decided the entire case, but limited the effect of the determination on validity to the immediate parties.

Second, the courts exploited Article 6(1) of the Brussels Regulation (or more accurately, its predecessor[64]), which permits a European domiciliary who is one of a number of defendants to be sued 'in the courts for the place where any one of them is domiciled'. According to cases interpreting the provision (and the explicit wording of the current Regulation), the claims must be so closely connected that hearing them together avoids the risk of irreconcilable judgments resulting from separate proceedings. Arguing that contradictory decisions on parallel patents met this requirement, courts permitted joinder of all the parties engaged in a concerted enterprise of infringement.[65]

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61 Treaty Establishing the European Community, Feb. 7, 1992, [1992] 1 C.M.L.R. 573, (Incorporating changes made by the Treaty on European Union, Feb. 7, 1992, O.J. C 224/1 (1992), [1992] 1 C.M.L.R. 719, 31 I.L.M. 247, arts. 9–11.

62 For a description of these cases, Thomas, John R. (1996), 'Litigation Beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement', *Law & Policy International Business*, **27**, 277, 279–80.

63 Council Regulation (EC) No. 44/2001 of Dec. 22, 2000 on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, 2001 O.J. (L 12) 1 [hereinafter Regulation No. 44/2201]. The predecessor provision was art. 16(4) of the Brussels Convention.

64 This provision was art. 6 of the Brussels Convention.

65 Expandable Grafts P'ship/Boston Scientific, Gerechtshof [Hof] [Court of Appeal], Den Haag, Apr. 23, 1998 (Neth.), reported in (1998) *European Intellectual Property Review*, 20(8), N132.

However, just as in the United States, this approach has been limited by a higher court – in these cases, the European Court of Justice (ECJ). In *Gesellschaft für Antriebstechnik mbH & Co KG v. Lamellen und Kupplungsbau Beteiligungs KG* ('*GAT v. Luk*'),[66] the decision concerned the interpretation of the predecessor to Article 22(4), the exclusive jurisdiction provision. The case, which was litigated in Germany, involved two German companies and French patent rights. Although the German court felt it could adjudicate the dispute by treating the issue of the patents' validity as incidental to the issues of infringement, the ECJ refused to permit the case to go forward. It held that the goal of exclusive jurisdiction is to assure that validity determinations are made by the tribunal with the specialized knowledge necessary to adjudicate them accurately. The court noted that validity issues often arise in proceedings raising other questions and held that principles of exclusive authority and predictability would be undermined if a party could determine jurisdiction by the way it pleaded its case. Furthermore, if courts were permitted to consider foreign patent issues, the risk of conflicting decisions would multiply. The court also rejected the idea of limiting the judgment to its effect inter se, saying that such a procedure would lead to distortions and undermine equality and uniformity values.

In a second case, *Roche Nederland BV v. Primus*,[67] the ECJ dealt with the predecessor of Article 6(1), the joinder provision. There, two Americans brought an action in the Netherlands against Dutch, U.S, Belgian, German, French, UK, Swiss, Austrian and Swedish companies, alleging that each infringed European patents arising from an EPC application. Although the companies were all part of a single group and one of the companies was domiciled in the Netherlands, the ECJ rejected use of the joinder provision. It held that even though the patents were parallel, potentially differing outcomes were not 'irreconcilable' because the defendants were different and infringement is governed by each relevant country's law. Like the Federal Circuit, the ECJ also doubted that consolidation would be efficient. It thought that greater reliance on the joinder provision would make it hard for parties to predict where they would be sued, encourage plaintiff forum shopping, lead to additional costs and create new sources of delay. And given *GAT v. Luk*, cases involving the validity of foreign patents could not be fully consolidated in any event.

There is much to criticize in all these opinions. The Federal Circuit's position is especially difficult to understand. As the court itself has noted in other cases, the Paris Convention is not self-executing.[68] Further, the TRIPS

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66 Case C-4/03, [2006] F.S.R. 45.
67 Case C-593/03, [2007] F.S.R. 5.
68 *In re Rath*, 402 F.3d 1207, 1209 (Fed. Cir. 2005).

Agreement clearly contemplates national implementation.[69] Even if the international provisions on which the court relied had the direct effect *Voda* posits, it is difficult to construe them as barring courts from entertaining foreign cases – quite the contrary. The provision on the independence of national patents is best read in connection with Article 4 of the Paris Convention, which gives patent applicants the option of linking the priority dates of all their applications to the date of the earliest filing. By explicitly providing for independence, Article 4bis prevents the invalidation of the earliest patent from invalidating all the patents that relied on its filing date.[70] If the provision has deeper meaning, it implicates the core commitment to territoriality – to the notion that each state independently controls what happens within its borders. Surely, an approach that consolidates foreign patent claims, but permits each nation's laws to govern how these claims are decided, protects that principle – and comity interests generally – better than the rule the Federal Circuit promulgated in the *Microsoft* cases, where it would have allowed U.S. law to determine whether foreign conduct constituted infringement. The other international provisions on which the *Voda* court relied safeguard procedural opportunities to enforce patent rights. Arguably, that objective is best furthered if *more* courts are available to resolve disputes.

The *Mars* and *Voda* courts' construction of the supplemental jurisdiction provision is similarly flawed. Other courts interpret 'case or controversy' far more capaciously and extend supplemental jurisdiction to all claims that arise out of a transaction, occurrence, or series of transactions or occurrences on which the original claim is based.[71] Their goal is to avoid piecemeal litigation and to open fora where the parties can comprehensively resolve their disputes (which is, of course, also the goal of the parties in these consolidated suits). Other courts measure expectations not by deeming the parties cognizant of the principles of judicial jurisdiction, but rather pragmatically, by considering which issues those who are embroiled in a dispute would want resolved in a

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69 TRIPS Agreement, art. 1.

70 The Madrid Agreement Concerning the International Registration of Marks, Apr. 14, 1891, revised July 14, 1967, 828 U.N.T.S. 389, furnishes a counterexample: under art. 6(3), trademark registrations made pursuant to that arrangement are dependent for validity on the validity of the first-filed application.

71 *Jones v. Ford Motor Credit Co*., 358 F.3d 205 (2d Cir. 2004) (holding that courts have supplemental authority over counterclaims that are merely permissive; the case involved a claim of racial discrimination under the Equal Credit Opportunity Act and the counterclaim was for unpaid car loans); *Saglioccolo v. Eagle Ins. Co*., 112 F.3d 226, 233 (6th Cir. 1997*); Robert E. Blake Inc. v. Excel Envtl*, 104 F.3d 1158, 1162 (9th Cir. 1997).

unitary fashion.[72] Supplemental jurisdiction codifies a procedural innovation, intended to deal with modern litigation problems. That purpose is undermined if the provision is interpreted by looking at expectations derived from past practices, old-fashioned fears of prejudice and outdated categories (like local versus transitory rights of action). Ironically, these decisions do not even fix the economy, convenience, and fairness problems with which the Federal Circuit was concerned: in many international cases, only one party will be resident in the trial court's jurisdiction and a U.S. patent will be in contention. As a result, diversity jurisdiction would, in any event, presumably support the assertion of foreign patent claims.[73]

The ECJ decisions similarly evince outmoded ideas about the procedural difficulties parties now encounter. When disputes affect relations in several countries simultaneously, accurately predicting where pieces of the dispute will be resolved is less important than finding a place where the resolution will be efficient, and where the risks of under- or over-compensation are minimized. As a group of intellectual property scholars have pointed out, the ECJ appears to have relied on the English draft of the exclusive jurisdiction provision. That draft specifies 'proceedings concerned with' the validity of patent rights. However, drafts in other languages support the 'incidental' distinction that the national courts were making.[74]

The *Roche* court's decision on irreconcilability is also surprising. It is certainly true that parallel patents can be interpreted quite differently.[75] The issue – to paraphrase a famous question about software – is whether that is a *feature* or a *bug* (is it what the system intends to do, or a glitch in the way it operates?). The European patents at issue in *Roche* stemmed from a single

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[72] Friedenthal, Jack H., Mary Kay Kane and Arthur R. Miller (4th ed. 2005), *Civil Procedure* §§ 2.12–2.13.

[73] *Baker-Bauman v. Walker, No. 3:06cv017*, 2007 U.S. Dist. LEXIS 23080 (S.D. Ohio May 29, 2007). .

[74] European Max-Planck Group for Conflict of Laws in Intellectual Property (CLIP) (Dec. 2006), Exclusive Jurisdiction and Cross Border IP (Patent) Infringement Suggestions for Amendment of the Brussels I Regulation, *available at* http://www.ivir.nl/publications/eechoud/CLIP_Brussels_%20I.pdf. In the other official languages of the EC, the provision refers to 'proceedings which have as their object' determinations of validity.

[75] Notorious cases include the Fosamax litigation, *Merck v. Teva* cases in the U.S. and U.K, *Istituto Gentili SpA, Merck & Co. Inc. v. Teva Pharm. Indus. Ltd*., [2003] F.S.R. 29 498 (Patents Court 2003), *aff'd* [2004] F.S.R. 16 330, [2003] EWCA Civ 1545 (Court of Appeals 2003); *Merck & Co., Inc. v. Teva Pharms. USA, Inc*., 288 F. Supp. 2d 601 (D. Del. 2003), *rev'd*, 395 F.3d 1364 (Fed. Cir. 2005); and the *Epilady shaver-head litigation, Improver Corp. v. Remington Prods. Inc*., 21 IIC 572 (1990), 24 IIC 838 (1993), [1993], GRUR Int. 242 (F.R.G.*); Improver Corp. v. Remington Consumer Prods. Ltd*., [1990] F.S.R. 181 (Eng. Ch., 1989).

EPC filing, and in such a case, disparate results are almost certainly a bug. The Convention is intended to harmonize the rules on patentability; that goal is undermined if validity depends on the jurisdiction in which it is litigated. In addition (and apparently ignored by the ECJ), members of the Convention have also entered into a protocol on claim interpretation.[76] Accordingly, infringement determinations should also be uniform. Indeed, if the ultimate goal of patent law is to promote social welfare (rather than merely to enrich patentees), then inconsistent decision making involving parallel patents is a bug from the international perspective as well: differing rules can impede trade and slow the flow of technological information.

The ECJ's concern for the distortionary impact of inter partes adjudication also appears overblown. Strategic use of serial litigation (Scenario (5)) is at least as worrisome to the sound administration of justice. In the name of avoiding distortion, the decision makes Scenarios (2), (3), and (4) more likely – but these hardly present pretty pictures either. Significantly, the United States (which has always had a unitary patent system) did not give court determinations of validity erga omnes effect until 1971.[77] Until that time, the parties presumably found ways to cope with any distortions caused by inter se adjudication. Indeed, experience since 1971 reveals that ergo omnes decision making also has disadvantages. It encourages would-be challengers to sit back and take a free ride on a rival's decision to incur the expense of challenging validity.[78]

Still, there is an undeniable core to what these courts say. Consolidated actions involving complex legal questions and technologically complicated products would be difficult to entertain and costly to pursue, particularly in the absence of an international agreement among states or, at least, an established procedural framework on how to proceed. Choosing the right law is critical to a just adjudication, but because of the longstanding territorial tradition, choice of law rules for intellectual property are largely undeveloped. Enforcing foreign judgments raises difficult issues in international litigation generally and would be especially problematic in consolidated cases, where there is no prior agreement on the basis for acquiring personal jurisdiction over all the parties.

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[76] Protocol on Interpretation of Article 69 of the Convention, Oct. 5, 1973, 13 I.L.M. 348. Sherman, Brad (1991), 'Patent Claim Interpretation: The Impact of the Protocol on Interpretation', *The Modern Law Review*, **54**(4), 499.

[77] *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) (abolishing mutuality of estoppel in patent cases).

[78] Hemphill, Scott (2006), 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem', *New York University Law Review*, **81**, 1553, 1605 (noting the need to create a bounty to induce challenge of pharmaceutical patents).

Inaccuracy is, as the ECJ suggested, an especially difficult issue. When one jurisdiction applies the law of another, the usual appellate procedure is inadequate to protect the parties' interests. The parties' appeal would be to an appellate court in the jurisdiction where the case was heard, but that court lacks expertise to determine whether the trial court applied foreign law correctly. A court in the state whose law was applied may have an opportunity to scrutinize the judgment at the enforcement stage, but permitting that court to consider the accuracy of the determination creates a new source of delay and violates long-standing legal norms against relitigating the merits of decided cases.[79]

Finally, there is the question of validity determinations. A strong argument could be made that these determinations are not especial affronts to sovereign interests because patent examination and registration are ministerial activities and not 'acts of state'. But there is no guarantee that every nation (and every enforcement court) would agree with that position. Besides, cancellation or nullification of registration is clearly beyond the control of a foreign tribunal.

To put this another way, there is a chicken-and-egg problem: unless courts start entertaining consolidated cases, the rules of the road (jurisdiction rules, conflicts rules, enforcement and recognition of judgments rules) will not be worked out. But without such rules, higher tribunals are rightly reluctant to require the courts they supervise to take on these difficult cases.

2.3 Private agreements

As the Scenarios illustrate, the problems with serial territorial dispute resolution affect both patent holders and information users. Accordingly, there will be cases where the opposing parties have one goal in common: they would all like the controversy decided expeditiously. In such cases, they could take matters into their own hands and agree on an efficient dispute resolution mechanism.

Arbitration is one alternative. It is commonplace for domain name disputes, which raise many of the problems illustrated by the Scenarios. In fact, in many registers, arbitration is a contractual obligation undertaken upon domain name registration.[80] Relatively cheap and quick, this model has been suggested for resolving other multinational intellectual property cases.[81]

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[79] *Fauntleroy v. Lum*, 210 U.S. 230 (1908) (a judgment cannot be impeached on the ground that it was based on a mistake of law); Regulation No. 44/2201, art. 36.

[80] Internet Corporation for Assigned Names and Numbers, Uniform Domain Name Dispute Resolution Policy (1999), available at http://www.icann.org/udrp/udrp-policy-24oct99.htm.

[81] Helfer, Laurence R. and Graeme B. Dinwoodie (2001), 'Designing Non-National Systems: The Case of the Uniform Domain Name Dispute Resolution Policy', *William & Mary Law Review*, **43,** 141, 237–50.

After some controversy, arbitration of patent disputes is now well accepted internationally, including for cases that raise patent claims under a multiplicity of national laws,[82] and there are well-known arbitral organizations available for resolving them. [83]

Arbitration does, however, suffer several severe shortcomings from a public interest perspective. One reason courts may be reluctant to permit extraterritorial application of local law and consolidated adjudication is that they appreciate the collateral effects that these decisions can have on promoting innovation and assuring public access; they know that decisions on intellectual production affect cultural development and political discourse – and in the case of patent law, health, safety and scientific progress. If decisions by foreign courts endanger these interests, then a fortiori, decisions by arbitrators do so as well. After all, arbitrators are chosen by the parties and the parties will often be established commercial enterprises with shared interests that are inimical to those of new entrants, researchers or the public at large. When the number of firms in a particular technological field is low, arbitration could be a screen for allocating markets and engaging in other anticompetitive conduct.

Furthermore, as the discussion above highlighted, there is inadequate legal guidance on many of the issues, such as choice of law, that arise in international disputes. Arbitrators may resolve controversies, but they do not make law: their decisions can be secret and they have no stare decisis effect. Thus, arbitration cannot contribute to developing the jurisprudence that the international marketplace requires. Particularly in the early years of coping with global dispute resolution, it would be a pity to rely too heavily on this approach.[84]

Another way that parties to a dispute might construct their own resolution mechanism is by agreeing to a particular forum and body of law. This approach is widespread in other types of litigation and, at least as far as choosing a court is concerned, will likely become even more prevalent when the Hague Conference on Private International Law's Convention on Choice of

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[82] Smith, M.A., M. Couste, T. Hield, R. Jarvis, M. Kochupillai, B. Leon, J.C. Rasser, M. Sakamoto, A. Shaughnessy and J. Branch (2006), 'Arbitration of Patent Infringement and Validity Issues Worldwide', *Harvard Journal Law and Technology*, **19**, 299, 326–27 (noting that U.S. law specifically permits arbitration of patent disputes, 35 U.S.C. §§ 294(a) & § 135(d), but that the power of the parties to choose the law applied is unclear).

[83] The American Arbitration Association, Resolution of Patent Disputes Supplementary Rules (2006), *available at* http://www.adr.org/sp.asp?id=27417.

[84] Janicke, Paul M. (2002), ''Maybe We Shouldn't Arbitrate': Some Aspects of the Risk/Benefit Calculus of Agreeing to Binding Arbitration of Patent Disputes', *Houston Law Review*, **39**, 693, 726. This article also outlines the risks arbitration poses to the parties.

Court Agreements is fully implemented.[85] If this general approach were viable for patent disputes, choice of law and court provisions could be incorporated into licensing agreements; for infringement actions (as for other tort actions), the parties could agree to court and law after the dispute arose.

But here again, there appear to be crucial constraints. As to choice of court agreements, the Hague Convention covers only business-to-business agreements. Although that limitation is not significant for multinational patent cases, which are mainly among businesses, a more severe problem is that the Hague Convention specifically excludes most patent disputes. It does not cover determinations of 'the validity of intellectual property rights other than copyright and related rights'[86] and 'infringement of intellectual property rights other than copyright and related rights, except where infringement proceedings are brought for breach of a contract between the parties relating to such rights, or could have been brought for breach of that contract'.[87] Arguably some of the patent matters that are ostensibly excluded could be classified as 'incidental' to broader disputes – indeed, the Hague Convention's provision on preliminary questions contemplates that patent issues might arise in some of the disputes that fall within its coverage.[88] However, if the ECJ's decisions in *Primus* and *Luk* are any indication, the 'incidental' argument is unlikely to go very far.

At least in Europe, there is also considerable hostility to allowing the parties in patent disputes to choose the law applicable to their cases. As *Primus* and *Luk* demonstrate, the ECJ is not willing to let parties take an inter se approach to validity. Furthermore, the new Regulation on the law applicable to non-contractual obligations ('Rome II'),[89] which generally adopts a rule of party autonomy concerning applicable law,[90] does not apply that principle

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85 Hague Conference on Private International Law, Hague Convention on Choice of Court Agreements, June 30, 2005, 44 I.L.M. 1294 [hereinafter Choice of Court Agreements], available at http://www.hcch.net/index_en.php?act=conventions.text&cid=98.

86 Choice of Court Agreements, art. 2(2)(n).

87 Choice of Court Agreements, art. 2(2)(o).

88 Choice of Court Agreements, art. 10(3).

89 Regulation (EC) No. 864/2007 of the European Parliament and of the Council of 11 July 2007 on the Law Applicable to Non-Contractual Obligations (Rome II), available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_199/l_19920070731en00400049.pdf.

90 Art. 14(1) ('The parties may agree to submit non-contractual obligations to the law of their choice: (a) by an agreement entered into after the event giving rise to the damage occurred; or (b) where all the parties are pursuing a commercial activity, also by an agreement freely negotiated before the event giving rise to the damage occurred.').

to intellectual property torts,[91] preferring (as the preamble states) that 'the universally acknowledged principle of the lex loci protectionis should be preserved'.[92] Clearly, Europe is committed to the notion that intellectual property rights are territorial and to the power of each member state to control the production and utilization of knowledge goods within its borders.[93]

It is conceivable that U.S. courts would be more accommodating to private agreements. *Voda* and *Mars* both involved situations where one of the parties objected to consolidation. Thus, the decisions do not determine whether an agreement between the parties would be honored. In other contexts, courts have been willing to give effect to party autonomy in intellectual property cases, even when the result impinges on the public interest.[94] Significantly, the *Voda* court grounded its decision on abuse of discretion rather than on the scope of supplemental jurisdiction: had it decided on supplemental jurisdiction grounds, the parties' agreement could have no effect because defects in a federal court's subject matter jurisdiction cannot be waived. Furthermore, the court has authority to consider the issue on its own.[95]

Nonetheless, it seems unlikely that, without more, private agreements will be honored by courts in the United States. The tenor of the *Voda* decision, including its extensive discussion of what constitutes a constitutional case, makes it unlikely that the court grounded its decision on the exercise of judicial discretion in order to preserve the parties' ability to agree to federal court adjudication.[96] More important, many of the considerations underlying the *Voda* case (enforceability, comity, resource management) are present even when the parties agree on both court and law. The decisions in the Federal Circuit cases on consolidation were so well aligned with those of the ECJ, it

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91 Art. 8(3) ('The law applicable under this Article [determining the law applicable to intellectual property infringement] may not be derogated from by an agreement pursuant to Article 14.').

92 Recital 26 (italics omitted).

93 Interestingly, the Convention on the law applicable to contractual obligations ('Rome I'), June 19, 1980, 1980 O.J. (L 266), available at http://www.rome-convention.org/instruments/i_conv_orig_en.htm, does not evince this concern and instead applies a general rule of party autonomy, art. 3 (except to consumer transactions, art. 5). This Convention predates the recent spate of international intellectual property cases; it remains to be seen whether its revision will retain this view. So far, it has, Proposal for a Regulation of the European Parliament and the Council on the law applicable to contractual obligations (Rome I) COM (2005) 650 final (Dec. 15, 2005).

94 *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447 (7th Cir. 1996)(permitting price discrimination in copyright licenses).

95 Fed. R. Civ. P. 12(h)(3).

96 More likely, the court decided as it did because it had recently been reversed on another case involving an interpretation of 'case or controversy', *MedImmune, Inc. v. Genentech, Inc*., 127 S.Ct. 764 (2007).

is unlikely that the concerns animating Europe would be ignored in the United States.

3 State-mediated approaches

As the previous section demonstrated, it appears there is little that disputants can do on their own to solve the difficulties imposed by the global nature of the technology marketplace. Any attempt to choose one jurisdiction's laws to apply to foreign conduct runs into the commitment to territoriality. The parties cannot rely on judicial acceptance of novel litigation practices because courts suffer a collective action problem: individually, they cannot be sure that the expense poured into consolidated adjudication will pay off because they lack the power to order foreign tribunals and administrative agencies to recognize or enforce their judgments. These obstacles suggest two points. First, the only way to solve the multiterritoriality problem in a definitive way is at the international level – by an agreement among nations. Second, national authorities have two options, substance or procedure. They can agree to adopt the same patent law or they can agree on a procedural mechanism for resolving global disputes.

3.1 Deep harmonization

Significantly, the World Intellectual Property Organization (WIPO) has long had complete ('deep') harmonization of patent law under consideration.[97] While the initial phase of its proposed Substantive Patent Law Treaty (SPLT) is directed at patentability issues, such as novelty, nonobviousness and disclosure, the ultimate goal is also to harmonize the law relevant to issues of infringement (and perhaps, ultimately, licensing).

Harmonization would solve many of the problems in international dispute resolution. It would not matter whether one court applied its own jurisdiction's law extraterritorially, or consolidated multiple cases or applied the law designated by the parties – the same result would be reached and that result would coincide with the relevant sovereigns' legislative determinations. The divided claim problem in Scenario (3) would disappear because the harmonized law would likely take care of conduct that spans jurisdictions. The risks in Scenario (4) would be diminished because countries that agree to harmonize

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[97] WIPO Standing Committee on the Law of Patents, (SCP), Draft Substantive Patent Law Treaty (SPLT), 10th Sess., May 10–14, 2004, WIPO doc. SCP/10/2 (Sept. 30, 2003); WIPO Standing Committee on the Law of Patents, (SCP), Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT), 10th Sess., May 10–14, 2004, WIPO doc. SCP/10/8 (Mar. 17, 2004); WIPO Standing Committee on the Law of Patents, (SCP), Report, 10th Sess., May 10–14, 2004, WIPO doc. SCP/10/11 (June 1, 2005).

their law would presumably also agree on how to localize particular infringing acts. Decisions on invalidity would not raise 'act of state' concerns because any patent invalid under the law of the court's state would be invalid everywhere.

Harmonization would have other advantages as well: it would be easier for international actors to conform their behavior to the law – D, for example, would not have to worry about the analysis of his activity under foreign law because his own law would tell him whether his conduct was lawful globally. There would also be benefits outside the infringement context. At present, worldwide licensing is complicated by differences in ownership rules.[98] These and other disparities (for example, in rules on recording transfers, on securitizing assets) currently make it hard to draft global licenses. Worldwide patent offices would also benefit. They could check each other's decisions or share their workload.[99]

But despite these many advantages, a truly global patent system is unlikely to be instituted in the foreseeable future. Disputes within WIPO are notorious; indeed, they are considered the main reason for the shift in international intellectual property lawmaking to the WTO.[100] The reasons for disagreement are readily apparent. The law that is appropriate to developed countries will often be distinctly suboptimal for other nations. Strong patents force developing countries to pay supracompetitive prices, but because these countries are not yet producers of knowledge products, they do not reap the benefits that come from using strong patents to encourage innovation. Indeed, unless the price of advances needed for education are kept low, these countries may not be able to afford the education their citizens need to become intellectually productive. At the same time, however, developed countries see attempts to eliminate patents as undermining incentives to innovate. Similarly, they regard actions that reduce the prices patentees can demand as confiscations of 'property rights'. In addition, many observers believe it is pointless to adopt a harmonized patent law without an accompanying governance and judicial infra-

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98 This is especially true for inventions by employees, Meier, Jürgen, Thure Schubert and Hans-Rainer Jaenichen (2005), 'Employees' Invention Remuneration – Money (F)or Nothing?', *Biotechnology Law Report*, **24**, 168.

99 Takenaka, Toshiko (2003), 'The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a "First-To-Invent" Exception for Domestic Applicants', *Texas Intellectual Property Law Journal*, **11**, 259.

100 Dreyfuss, Rochelle (2d ed. 2007),' Intellectual Property Law and the World Trading System', in Andreas Lowenfeld, *International Economic Law*, New York: Oxford University Press, Ch. 12; Helfer, Laurence R. (2004), 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking', *Yale Journal International Law*, **29**, 1.

structure capable of interpreting and amending it. Without such capacity, the law cannot be easily changed to deal with new technological fields. Furthermore, doctrine might drift to the point where new disparities among nations emerge.[101]

At first blush, it may appear that a more geographically modest attempt to harmonize patent law would be workable. Thus, one reason the ECJ may have been reluctant to support consolidated adjudication in *Primus* and *Luk* is that it did not want to diminish the impetus to adopt a Community Patent.[102] Because of the free movement of goods, the need for a unitary patent right, good throughout the EU, is clear. It should, in theory, be straightforward to establish. EU member states are, roughly speaking, at equivalent levels of technological sophistication. Because poorer nations are subsidized, they are equally able to bear the higher costs associated with exclusive rights. And they share similar philosophies on the policy issues at stake – indeed, they are already working together successfully in the EPC. Finally, the ECJ's power over national courts would likely be sufficient to keep the law uniform.[103] Nonetheless, the Community Patent has run into considerable political trouble;[104] that it has yet to come into being strongly suggests that the harmonization route is not likely to be the way that the multinational dispute resolution problem is ultimately solved.

3.2 Coordinated adjudication

Even if the substantive approach is unworkable, procedural reform may offer a remedy to the international dispute resolution problem. As Section 2 demonstrated, litigants have long understood that consolidated litigation can make global adjudication more efficient without impinging on any sovereign's power to strike the balance between access and proprietary interests that is appropriate for its territory. At the same time, however, party-initiated attempts to pursue this route floundered on the rules of the road (personal jurisdiction, judicial competence, choice of law and enforcement of judgments). These problems

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[101] Reichman, Jerome H. and Dreyfuss, Rochelle C. (2008), 'Harmonization Without Consensus: Critical Reflections On Drafting A Substantive Patent Law Treaty', *Duke Law* Journal, **57,** 85.

[102] For information on the negotiations of the Community Patent, see The European Union Single Market, http://ec.europa.eu/internal_market/indprop/patent/index_en.htm.

[103] As noted below, there is also a proposal on the table to establish European patent courts.

[104] Commission of the European Communities, Communication from the Commission to the European Parliament and the Council, Enhancing the Patent System in Europe, COM (2007) 165 final (3 April 2007), available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0165en01.pdf.

could be overcome by international agreement. If nations found mutually accepted terms on which foreign judgments were enforceable, the Federal Circuit's and ECJ's concerns about wasting resources on complicated cases would diminish. Similarly, once nations agreed to foreign adjudication, there would be no need to worry that entertaining foreign claims would give offense or that foreign invalidations of patent rights would violate the act of state doctrine.

For many years, members of the EPC have been working on a highly stylized approach along these lines. The proposed European Patent Litigation Agreement (EPLA)[105] would create a new court system, including both trial and appellate courts, to hear disputes involving EPC-issued patents. The instrument would set out rules of procedure and case management as well as substantive patent law on issues not already covered by the EPC. National courts would enjoy concurrent power to order provisional and protective measures, but ultimately, cases would be adjudicated and remedies – including revocation of invalid patents – would be awarded by the new European Patent Court.[106] An Administrative Committee would oversee the Agreement, and revisions would be handled by a conference of the contracting states. Disputes among contracting states would be resolved by the International Court of Justice.

The EPLA is envisioned as a treaty among the states that belong to the EPC. Since the EPC is not a creature of the European Union, adopting the EPLA would bypass the apparent stalemate concerning the Community Patent. And because it involves states that are fairly homogeneous, the EPLA would likewise avoid the disagreements plaguing the SPLT negotiations in WIPO. Nonetheless, there are many disadvantages to this proposal. It largely relies on harmonized law and therefore can solve the problem of global dispute resolution only for nations willing to adopt the legal regime proposed. Moreover, it requires nations to cede judicial power, which has apparently led the European Parliament and various European nations to oppose it.[107] Finally, the EPLA requires the establishment of an entirely new set of courts. Experience with specialized courts in the United States has revealed many

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105 Working Party on Litigation (Feb. 16, 2004), Draft Agreement on the Establishment of a European Patent Litigation System, www.european-patent-office.org/epo/epla/pdf/agreement_draft.pdf.

106 In actions where the patent holder is not a party, validity determinations would only be effective inter se.

107 Linklaters (2007), 'The European Patent Litigation Agreement: The End of the Line, or a Bump in the Road?', *World Intellectual Property Report*, 21(3), *available at* http://subscript.bna.com/SAMPLES/wipr.nsf/444869f9ff2a52aa85256d6d0075f734/ bab635867d8787978525728f006cf9f3?OpenDocument.

potential deficiencies, including capture by repeat players; tunnel vision; departure from mainstream trends; inability to correct mistakes; and over-dependence on the specialized law to further social policy.[108] There is little reason to think the courts established by the EPLA would avoid these pitfalls. Nor is it clear that setting up a special judicial system would save resources. The parties would be forced to split up their cases for adjudication, while member states would need to support a whole new set of tribunals.

A less resource-intensive approach to reform is to use existing courts and existing law. In the 1990s, the Hague Conference took a stab in that direction. In its proposed Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters, contracting states were to agree on specific bases of personal jurisdiction that would support judgment recognition.[109] The proposal was never adopted, largely because many countries (mainly in the EU) objected to the jurisdictional choices afforded to plaintiffs. Like the ECJ in *Primus* and *Luk*, these nations favored a system where the situs of suit would be highly predictable. In any event, the Convention would have made little difference for patent litigation. Like the Brussels Regulation, validity issues were placed within the exclusive jurisdiction of the country of registration.[110] As important, because the proposal never grappled with jurisdiction over the Internet, it failed to provide jurisdictional solutions in situations such as the one in Scenario (2).[111]

The Hague Conference responded to the Convention's failure with the Choice of Court Agreement discussed above. As noted, it also largely ignores the problems in patent litigation. However, several organizations, including the Max Planck Institute in Germany,[112] an informal working group in Japan

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[108] Dreyfuss, Rochelle Cooper (2004), 'The Federal Circuit: A Continuing Experiment in Specialization', *Case Western Reserve Law Review*, **54**, 769; Dreyfuss, Rochelle Cooper (1989), 'The Federal Circuit: A Case Study in Specialized Courts', *New York University Law Review*, **64**, 1.

[109] Hague Conference on Private International Law (Aug., 2000), Preliminary Draft Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters adopted by the Special Commission and Report by Peter Nygh and Fausto Pocar, Prelim. Doc. No. 11 [hereinafter 2000 Draft Hague Convention], *available at* http://www.hcch.net/upload/wop/jdgmpd11.pdf. The Convention would have also required members to refuse to enforce judgments predicated on any of a series of specified prohibited bases of jurisdiction.

[110] 2000 Draft Hague Convention, art. 12(4).

[111] Dreyfuss, Rochelle Cooper (2001), 'An Alert to the Intellectual Property Bar: The Hague Judgments Convention', *University of Illinois Law Review*, **2001**, 421.

[112] European Max Planck Group for Conflict of Laws in Intellectual Property (2007), Comments on the European Commission's Proposal for a Regulation on the Law Applicable to Contractual Obligations ('Rome I') of 15 December 2005 and the

and the American Law Institute (ALI),[113] have taken cues from the Hague model and are now drafting instruments responsive to the needs of the intellectual property community. Of these the ALI initiative, which was crafted with the help of advisers from the Americas, Europe, Asia, Africa, and Australia, is the farthest along. Its Intellectual Property: Principles Governing Jurisdiction, Choice of Law, and Judgments in Transnational Disputes was approved by the membership of the ALI in March, 2007 and will be published by the end of 2008.[114] As its name implies, this project takes the form of principles rather than a convention or rules of law; it is intended to guide courts and parties to efficient and fair decisions on the underdeveloped procedural issues that have stymied courts thus far.

Thus, the project makes no attempt to change national law on personal jurisdiction or competence. Rather, it identifies jurisdictional bases that are appropriate predicates for consolidating multinational claims and cases.[115] On the theory that the litigants will be engaged in complex and expensive proceedings, these generally require a closer connection between the parties and the forum than may be contemplated by domestic law. However, because the overall goal is to achieve global peace, some of the Principles expand jurisdictional scope. For example, the provision on infringement, which allows a plaintiff to sue in any country where the defendant has substantially acted to initiate or further an alleged infringement, permits the assertion of all claims arising from the defendant's activities, regardless of where the injuries occur.[116] Parties engaged in a concerted action can also be sued in any coun-

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European Parliament Committee on Legal Affairs' Draft Report on the Proposal of 22 August 2006, *International Review of Intellectual Property and Competition Law*, **38**, 471 and the papers posted at http://www.conflictoflaws.net/2007/property/clip-papers-on-intellectual-property-in-brussels-i-and-rome-i-regulations/.

113 Dreyfuss, Rochelle (2005), 'The ALI Principles on Transnational Intellectual Property Disputes: Why Invite Conflicts?', *Brooklyn Journal of International Law*, **30**, 819; Dreyfuss, Rochelle and Jane Ginsburg (2003), 'Principles Governing Jurisdiction, Choice of Law and Judgments in Transnational Disputes', 2 Comp. L. Rev. Int'l., **2**, 33; Dreyfuss, Rochelle C. and Jane C. Ginsburg (2002), 'Draft Convention on Jurisdiction and Recognition of Judgments in Intellectual Property Matters', *Chicago-Kent Law Review*, **77**, 1065.

114 The American Law Institute, Current Projects – Intellectual Property: Principles Governing Jurisdiction, Choice of Law, and Judgments in Transnational Disputes [hereinafter ALI Project], *available at* http://www.ali.org/index.cfm?fuseaction=projects.proj_ip&projectid=1.

115 ALI Project, §§ 201–7. The principles also specify insufficient grounds for the assertion of jurisdiction, § 207.

116 ALI Project, § 204(1). An even looser connection is permissible in cases where the alleged infringer.

try in which one of them is resident.[117] The project similarly relies on domestic rules of judicial competence regarding power over the subject matter of the suit. At the same time, however, it admonishes courts to refrain from using discretionary authority to dismiss claims on the sole ground that they sound in foreign law.[118] In this way, the Principles provide litigants with a large choice of fora, thereby increasing the chances that they will find a tribunal where a global dispute can be comprehensively resolved.

Of course, expanding the bases of jurisdiction creates the predictability problem that bothered the ECJ. On this, the project takes the view that the predictability concern arises, at least in part, from a fear that the forum will apply its own law to the dispute, unsettle the parties' expectations (the Scenario (2) problem), and disregard the commitment to territoriality. To remedy that problem, the project supplies Principles on choice of law.[119] On the whole, these adopt the territorial approach: the court hearing the case is required to apply the law of the state of registration on the 'existence, validity, duration, attributes, and infringement' of patent rights.[120] However, the Principles further efficiency goals by departing from territoriality in a few respects. The parties are permitted to choose the law applicable to remedies.[121] For works arising out of a preexisting relationship, the law on initial title and transfer of rights is determined by the law governing the relationship rather than the laws of the states of registration.[122] When infringement is ubiquitous but the court can identify a country (or small set of countries) with close connections to the dispute, it can apply the law of that country (or those countries) to the controversy as a whole.[123] In addition, the Principles incorporate a public-policy (or 'ordre public') exception, which permits courts to refuse to apply foreign laws that conflict with fundamental norms.[124]

Most important for these purposes, the Principles provide a framework for coordinating litigation and ensuring the enforcement of judgments. The court in which the first claim in a larger dispute is lodged has coordination authority to

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117 ALI Project, § 206. This provision is modeled on art. 6 of the Brussels Convention (and Regulation), albeit without the ECJ's gloss. In the United States, the constitutionality of such a provision would be based on concepts of 'necessity'. *Mullane v. Central Hanover Bank & Trust Co*., 339 U.S. 306 (1950).

118 ALI Project, §§ 211, 212(2).

119 ALI Project, §§ 301–24.

120 ALI Project, § 301.

121 ALI Project, § 302.

122 ALI Project, §§ 311 and 315.

123 ALI Project, § 321. Parties are permitted to rebut the presumption in favor of the most closely connected law.

124 ALI Project, § 322. Courts may also take mandatory rules into consideration, ALI Project, § 323.

deal with any later-filed cases that arise from 'the same transaction, occurrence, or series of transactions or occurrences'.[125] On motion by a party, the 'coordination court' must decide whether it should consolidate the global dispute (as was attempted in *Voda* and *Primus*), or facilitate cooperation among the courts where pieces of the global dispute are pending. If consolidation is the chosen route, the coordination court next determines which court, among the fora where actions are lodged, should hear the entire dispute.[126] Once the case is adjudicated by that court, review is within its appellate hierarchy. However, the appeals court could presumably use procedures such as stays and certification to obtain advice from tribunals in the states whose law was applied.[127] During the pendency of the consolidated case, courts where related actions are pending must suspend their proceedings and, if the coordination and consolidation courts proceed in a timely manner, dismiss these cases after the judgment in the consolidated case is rendered.[128]

The Principles require enforcement and recognition of the full scope of the judgment (in the case of consolidation) or judgments (in the case of cooperation).[129] There are, however, several exceptions. One deals with the validity problem, where the Principles give foreign determinations of invalidity effect only among the parties.[130] If validity is in issue and the litigants seek an ergo omnes determination, their option is to file actions in each state of registration and then move in the coordination court for a structured cooperative arrangement among these tribunals. By such actions as stipulating the documents and practices that constitute the prior art, agreeing to take the inventor's testimony a single time, focusing their disputes on the same embodiments of the accused device, and agreeing to be bound by a single court's factual determinations, the parties can save resources without incurring the expertise, comity and judicial competence problems that concerned the ECJ and the Federal Circuit.

Courts are also to deny enforcement and recognition to judgments that violate public policy or that are based on violations of due process.[131] In addition, the Principles on jurisdiction, choice of law and coordination are enforced by allowing courts to refuse to recognize judgments when jurisdiction was exercised on a basis inconsistent with the Principles' jurisdiction

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125 ALI Project, § 221.
126 ALI Project, § 222.
127 *Redgrave v. Boston Symphony Orchestra, Inc.*, 855 F.2d 888 (1st Cir. 1988), where a federal appellate court reviewed a district court decision after it had certified a state law question to the Massachusetts Supreme Judicial Court.
128 ALI Project, § 223.
129 ALI Project, §§ 401–3.
130 ALI Project, §§ 213(3), 413(2).
131 ALI Project, § 403(1).

norms, when the law applied was inconsistent with the Principles' choice of law provisions, or when the rendering court failed to defer to the decisions of the coordination court.[132] Finally, to account for residual concerns regarding each sovereign's power over innovation policy within its territory, enforcement courts have authority to tailor the remedies to special conditions, such as health and safety concerns, that obtain within its territory.[133]

To be sure, the ALI Principles are no more likely to be approved by higher courts than were the streamlining efforts of the parties: true procedural reform requires an international agreement. However, the Principles can help national authorities envision a solution to the problems of global dispute resolution that stops short of deep harmonization. Indeed, once the Japanese and German initiatives reach fruition, the three projects should furnish interested countries with a firm basis for negotiating a comprehensive convention. In addition, courts may find immediate use for specific parts of the project, such as the rules on jurisdiction over Internet activity or the choice of law provisions, where legal development has been slow. They may also be able to utilize the procedures for cooperation, which are based on mechanisms used successfully in other areas of the law.[134] Even partial utilization of the Principles could make international dispute resolution more efficient. And if the only effect of these projects is to initiate a debate, that too will serve an important purpose.

4 Conclusion

Technological and social developments have changed the ways in which knowledge goods are distributed and utilized. Because patented inventions are usually embodied in physical products, patent holders have been able to cope with territorial enforcement regimes for far longer than have holders of copyrights and trademarks. But as the introductory hypothetical demonstrated, the Internet – along with business method and software patents – has brought the limitations of local enforcement to the fore. Indeed, it is becoming increasingly clear that a commitment to territorial adjudication is not sustainable when protected products enjoy global distribution.

The patent bar's own attempts to solve this problem have run afoul of tradition-bound courts. This leaves the international community with three options: it can fully harmonize patent law, cede dispute resolution to extrajudicial institutions (such as arbitrators), or work to develop a comprehensive dispute resolution mechanism. In the near future, harmonization is highly improbable.

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132 ALI Project, § 403(2).

133 ALI Project, §§ 411–13.

134 Westbrook, Jay Lawrence (2003), 'International Judicial Negotiation', Texas International Law Journal, 38, 567.

Strong arguments can also be made that it is unwise. Arbitration also has negative implications, both in terms of the development of law and on public welfare. Although coordinated adjudication of the type envisioned by the ALI Principles will also pose complex problems, the free movement of goods will increasingly propel the free movement of disputes and judgments.

PART 5

CORE ISSUES IN THE FUTURE?

23 Challenges to the *sui generis* regime of pharmaceutical patents

John R. Thomas

1 Introduction

Nowhere is the social impact of intellectual property more keenly felt than in the discipline of pharmaceutical patents. When we confront both glaring inequities in the global health care system, and the list of loathsome diseases for which no treatment is available at any price, the patent system appropriately stands at the center of the discussion. For the pharmaceutical industry may be the sole market segment where traditional accounts of the patent system hold true. Pharmaceutical patents almost invariably support a single supplier for the innovative drug company for the full length of their term. And for many drugs, the very day relevant patents expire is the moment generic competition begins.[1] This commonplace reality provides strong testimony to the significance of patents to the drug industry.

Yet nowhere in the world, it seems, are pharmaceuticals subject to a garden variety patent law. Jurisdictions have modified the everyday patent law regime in different ways when it comes to drugs. Many countries include detailed statutes allowing compulsory licenses that, although generally worded, are effectively specific to pharmaceuticals.[2] Other patent statutes enumerate provisions establishing precise standards of inventive step that will govern the granting of pharmaceutical patents.[3] Still others supplement patent rights with new forms of intellectual property, data protection and marketing exclusivities, that effectively time the commencement of patent litigation.[4] In the United States, this level of specificity has perhaps gone the furthest of any

[1] Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM. L. REV. 477, 479 (2003).

[2] *See* Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceutical in Developing Countries*, 45 BRANDEIS L.J. 623 (2007).

[3] *See* Janice M. Mueller, *Taking TRIPS to India–Novartis, Patent Law, and Access to Medicines*, 365 NEW ENG. J. MED. at 541 n. 6 (Feb. 8, 2007).

[4] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359–64 (2007).

patent-granting state. The current version of its Hatch-Waxman Act[5] features, among other provisions, the grant of quasi-patents to non-innovators,[6] a government-sponsored patent clearinghouse,[7] and a pharmaceutical patent enforcement regime that is both unique and elaborate.[8]

This heavily modified version of patent law certainly supports the account that the patent law may operate in a manner that is technology specific.[9] There is an irony in this reality. Of all the forms of intellectual property, pharmaceutical patents were the ones that drove the formation of the TRIPS Agreement. Yet that agreement's commandment that the patent system treat all manner of inventions equally continues to be observed in the breach within this very field.[10] As the United States increasingly employs Free Trade Agreements to leverage the provisions of the Hatch-Waxman Act into other jurisdictions,[11] the trend towards a *sui generis* pharmaceutical patent law on a global basis is likely to continue.

This chapter reflects upon the fact that in the entire gamut of global intellectual property law, no other subject matter has been subject to more legislative manipulation than pharmaceutical patents. Yet it remains an open question whether these industry-specific modifications have proven worthy of the considerable effort they have entailed. Focusing upon the U.S. experience, Section 2 of this chapter provides an overview of the provisions of the Hatch-Waxman Act, the groundbreaking legislation that endeavors to set the balance point between pharmaceutical innovation and access to medicines. In Section 3, this chapter identifies some of the controversial practices that statute has inspired, and how they threaten to compromise the aims that the legislators

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5 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 84-417, 98 Stat. 1585 (1984).

6 21 U.S.C. § 355(j)(B)(iv) (2006) (generic marketing exclusivity).

7 The clearinghouse consists of a registry of patents, known as the 'Orange Book', that the FDA maintains. CTR. FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMIN., U.S. DEPT. OF HEALTH AND HUMAN SERVS., ELECTRONIC ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EVALUATIONS, *available at* http://www.fda.gov/cder/ob/.

8 35 U.S.C. § 271(e) (2006).

9 Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002).

10 *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, vol. 31, 22 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]; *see also* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/SD114/R (Mar. 17, 2000).

11 *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH, POL'Y L. & ETHICS 193 (2005).

sought to achieve. Section 4 of the chapter then offers some observations based upon a quarter-century of experience with a specialized pharmaceutical patent law. Section 5 concludes.

2 Overview of the Hatch-Waxman Act

Pharmaceutical patent law stands as one of the most complex disciplines in the entirety of legal practice. Even among specialists in patents, food and drug law, and competition law, few practitioners are familiar with its tortured statutory provisions and often unsettling terminology.[12] Surprisingly, the origin of this morass of legislation, regulation, and case law was an early opinion of the Court of Appeals for the Federal Circuit that decided a routine legal issue. The seminal decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* might today stand as the Federal Circuit's most important ruling, in terms of both its domestic impact and its consequences for patent regimes overseas.[13] The congressional response to *Roche v. Bolar* was the Drug Price Competition and Patent Term Restoration Act of 1984,[14] popularly known as the Hatch-Waxman Act.[15] Not only did the Hatch-Waxman Act effectively establish a robust generic drug industry in the United States, it deeply impacted pharmaceutical research and development by innovative pharmaceutical firms. This chapter next reviews both the *Roche v. Bolar* decision and its consequences in the United States.

2.1 Roche v. Bolar

The 1984 Federal Circuit decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[16] placed the balance of rights and responsibilities between innovative and generic pharmaceutical companies squarely on the legislative agenda. In that case, Roche Products, Inc. owned a patent claiming flurazepam hcl, the active ingredient of the prescription sleeping pill

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[12] What other intellectual property discipline could feature the term 'shared exclusivity'? *See* Food and Drug Admin., U.S. Dep't. of Health and Human Servs., *Department of Justice Appeals Court Decision Regarding FDA's 'Shared Exclusivity' Determination for Generic Paroxetine Hydrochloride Tablets*, FDA TALK PAPER, Feb. 5, 2004, *available at* http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01279.html.

[13] *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).

[14] Pub. L. No. 84-417, 98 Stat. 1585 (1984).

[15] The Act was named for its primary sponsors, Senator Orrin Hatch and Representative Henry Waxman. *See, e.g.*, Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373 (2000).

[16] *Roche Products*, 733 F.2d at 858 (Fed. Cir. 1984).

DALMANE®.[17] Bolar Pharmaceutical Co., a manufacturer of generic drugs, became interested in marketing a generic equivalent of DALMANE®. Bolar recognized that securing marketing approval of a drug was a time-consuming process and wished to sell a generic version immediately after the Roche patent expired. Bolar therefore obtained a supply of flurazepam hcl from a foreign manufacturer during the patent's term and began to experiment with the compound.[18]

Roche ultimately learned of Bolar's activities and filed a patent infringement suit. The litigation proceeded to the Federal Circuit, which concluded that Bolar had infringed Roche's patent. Writing for the court of appeals, Judge Nichols initially observed that the 1952 Patent Act states that whoever 'uses . . . any patented invention, within the United States during the term of the patent therefore, infringes the patent'.[19] This language on its face prohibits all unauthorized uses of the patented invention, the Federal Circuit reasoned.[20]

The Federal Circuit next considered two contentions offered by Bolar. First, Bolar urged that the experimental use defense exempted its efforts to comply with federal food and drug law.[21] After reviewing the precedents, Judge Nichols disagreed, concluding:

> Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes.[22]

Bolar finally urged the Federal Circuit to resolve a perceived conflict between the food and drug laws and the patent code. Bolar observed that substantial regulatory delays were associated with the receipt of FDA marketing approval. According to Bolar, if a generic manufacturer could not

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17 *See* Novel 1 and/or 4-substituted alkyl 5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones, U.S. Patent No. 3,299,053 (filed Feb. 11, 1964).

18 *Roche Products*, 733 F.2d at 860.

19 35 U.S.C. § 271(a) (2006).

20 *Roche Products*, 733 F.2d at 862–3.

21 *Id*. at 863.

22 *Id.*

commence seeking FDA approval until the appropriate patents had expired, then the patentee could preserve its market exclusivity beyond the statutory patent term. Bolar characterized this situation as a *de facto* patent term extension inconsistent with the Patent Act.[23] The Federal Circuit also rejected this argument. According to Judge Nichols, the judiciary was not the proper forum to engage in policy argumentation that led to results inconsistent with the text of the patent statute. The court observed that bills addressing these issues had been placed before Congress and suggested that any aggrieved parties seek redress there.[24]

The ruling in *Roche v. Bolar*, in combination with the requirement of marketing approval for new drugs under the food and drug laws, was broadly perceived as leading to two distortions of the statutory patent term. First, the patent term clock would run whether or not the FDA had approved the claimed pharmaceutical for marketing. As a result, the period of time that the proprietor of a patent claiming a regulated drug actually could enjoy market exclusivity could be quite significantly reduced. Second, under *Roche v. Bolar*, competitors that commenced activities necessary for regulatory approval before a patent had expired could be enjoined as patent infringers. This possibility was seen as a *de facto* period of market exclusivity that the patent proprietor enjoyed beyond the actual term of the patent.[25] The Federal Circuit's forecast that a legislative solution was required to ameliorate the impact of these distortions proved prophetic, as soon after the *Roche v. Bolar* opinion issued Congress took action.

2.2 The Hatch-Waxman Act

Although innovative and generic drug firms had been engaged in congressionally sponsored negotiations prior to *Roche v. Bolar*, the Federal Circuit's holding hastened the pace of discussion.[26] The outcome of these negotiations was the Drug Price Competition and Patent Term Restoration Act of 1984.[27] That law has come to be known as the Waxman-Hatch Act or, more commonly, the Hatch-Waxman Act.[28]

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[23] *Id.* at 863–4.

[24] *Id.* at 864–6.

[25] *See* Erik K. Steffe & Timothy J. Shea, Jr., *Drug Discovery Tools and the Clinical Research Exemption from Patent Infringement*, 22 BIOTECHNOLOGY L. REP. 369, 370 (Aug. 2003).

[26] *See* Alfred J. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have they Outlived their Usefulness?*, 39 IDEA 389 (1999).

[27] Pub. L. No. 84-417, 98 Stat. 1585 (1984).

[28] *Compare* Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47 (2003) *with* Kevin J. McGough, *Preserving the Compromise: The Plain Meaning of Waxman-Hatch Exclusivity*, 45 FOOD DRUG COSM. L.J. 487 (1990).

The Hatch-Waxman Act includes elaborate provisions governing the mechanisms through which a potential generic manufacturer may obtain marketing approval on a drug that has been patented by another. Although the Hatch-Waxman Act is a complex statute, it provides a straightforward tradeoff: In exchange for permitting manufacturers of generic drugs to gain FDA marketing approval by relying on safety and efficacy data from the innovative firm's New Drug Application (NDA), the innovative firms received a period of data exclusivity and patent term extension.[29] A review of the legislation's more significant provisions follows.

2.2.1 The statutory experimental use exception The Hatch-Waxman Act modified the patent code by creating a statutory exemption from certain claims of patent infringement. As codified in 35 U.S.C. § 271(e)(1), this provision mandates that: 'It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products'. This provision effectively overturned the opinion of the Court of Appeals for the Federal Circuit in *Roche v. Bolar*.[30] As a result, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

2.2.2 Abbreviated new drug applications Prior to the introduction of the Hatch-Waxman Act, the food and drug law contained no separate provisions addressing generic versions of drugs that had previously been approved.[31] The result was that a would-be generic drug manufacturer had to file its own NDA in order to market its drug.[32] Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug. Because these sorts of studies were not available for all drugs, however,

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29 *See, e.g.*, Jill B. Deal, *Striking the Right Balance Between Innovation and Drug Price Competition: Putting the Hatch-Waxman Act into Perspective*, 54 FOOD & DRUG L.J. 185 (1999).

30 *See* Janice M. Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 22 (2001).

31 *See* Engelberg, *supra* note 26, at 389, 396.

32 *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 34 CATH. U. L. REV. 433, 439 (1986).

not all generic firms could file these so-called paper NDAs.[33] Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval.[34] The result was that some generic manufacturers were forced to prove independently that the drugs were safe and effective, even though their products were chemically identical to those of previously approved drugs.

It was widely believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process prior to the Hatch-Waxman Act.[35] Although patents on important drugs of the era had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[36] The Hatch-Waxman Act therefore created a new type of application for market approval of a pharmaceutical, termed an 'Abbreviated New Drug Application'. An ANDA allows a generic drug manufacturer to rely upon the safety and efficacy data of the original manufacturer, so long as its active ingredient is the bioequivalent of the approved drug. The availability of an ANDA allows a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. ANDAs also allow a generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.[37]

2.2.3 Certifications for Orange Book-listed patents All approved drug products, both innovative and generic, are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*.[38] This so-called 'Orange

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[33] *See* Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interest or Survival of the Fittest?*, 57 FOOD & DRUG L.J. 247, 249 (2002).

[34] *Id.*

[35] *See, e.g.*, Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY. & L. 275, 276 (1996) ('The Act streamlined the approval process by eliminating the need for [generic drug] sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.').

[36] *See* Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?*, 64 U. PITT. L. REV. 201, 202 (2002) ('Hatch-Waxman has also increased the generic drug share of prescription drug volume by almost 130% since its enactment in 1984. Indeed, nearly 100% of the top selling drugs with expired patents have generic versions available today versus only 35% in 1983.').

[37] *See, e.g.*, Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18 (Aug. 13, 2003).

[38] CTR. FOR DRUG EVALUATION AND RESEARCH, FOOD & DRUG ADMIN., U.S. DEPT. OF HEALTH AND HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (CCH 23d ed. 2003).

Book' uses an elaborate coded lettering system to identify those approved drugs the FDA considers therapeutically equivalent. In the Hatch-Waxman Act era, however, the Orange Book also plays a role in the resolution of patent disputes. That statute requires each holder of an approved NDA to list pertinent patents it believes would be infringed if a generic drug were marketed before the expiration of these patents.[39] Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market. Four possibilities exist:

(1) that the brand-name firm has not filed any patent information with respect to that drug;
(2) that the patent has already expired;
(3) the date on which the patent will expire; or
(4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.[40]

These certifications are respectively termed paragraph I, II, III, and IV certifications.[41] An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[42] A generic firm that files an ANDA including a paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[43] A paragraph IV certification leads to more dramatic possibilities, as described next.

2.2.4 Patent enforcement proceedings Charges of patent infringement traditionally are based upon activities in the marketplace, not the filing of papers with a government agency. Yet under the Hatch-Waxman Act, the filing of an ANDA with a paragraph IV certification is deemed a 'somewhat artificial' act of patent infringement.[44] The Hatch-Waxman Act requires the ANDA applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification.[45] The patent owner may then commence patent

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39 21 U.S.C. § 355(c)(2) (2006).
40 21 U.S.C. § 355(j)(2)(A)(vii) (2006).
41 *See* Douglas A. Robinson, *Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?*, 81 WASH. U. L.Q. 829, 835 n. 59 (2003).
42 21 U.S.C. § 355(j)(5)(B)(i) (2006).
43 21 U.S.C. § 355(j)(5)(B)(ii) (2006).
44 *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 1047 (1990).
45 21 U.S.C. § 355(j)(2)(B)(i) (2006).

infringement litigation against the ANDA applicant in federal district court. This charge of infringement is technical in nature. At this stage the generic manufacturer has done nothing more than request FDA approval to market a drug. If the patentee's charge of infringement is successful, however, it may prevent the marketing of that generic equivalent until the date the patent expires.[46]

If the patent owner brings a patent infringement charge within forty-five days of receiving notice from the ANDA applicant, then the Hatch-Waxman Act provides the patentee with a significant benefit. Under these circumstances the FDA must suspend approval of the ANDA until one of the following times:

(1) the date of the court's decision that the listed drug's patent is either invalid or not infringed;
(2) the date the listed drug's patent expires, if the court finds the listed drug's patent infringed; or
(3) subject to modification by the court, the date that is thirty months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.[47]

Congress intended that this latter, thirty-month period would give the parties sufficient time to resolve their patent dispute before the ANDA applicant introduced its generic product to the market. This period of time, commonly called the 'thirty-month stay', is effectively the equivalent of a preliminary injunction that is awarded against the generic drug company for the stipulated period of time. The thirty-month stay is awarded automatically by statute, however, provided that the innovative drug company has timely followed the appropriate procedures. In particular, the innovative drug company need not make any of the usual showings required for a preliminary injunction.[48]

2.2.5 Patent term extension The Hatch-Waxman Act also provides for the extension of patent term. Ordinarily, the patent term is set to twenty years from the date the patent application is filed.[49] The Hatch-Waxman Act provides that for pharmaceutical patents, the patent term may be extended for a portion of

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46 35 U.S.C. § 271(e)(4) (2006).
47 21 U.S.C. § 355(j)(5)(B)(iii) (2006).
48 *See* H. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 387 ('The statute thus gives the pioneer drug manufacturer an automatic preliminary injunction for two-and-a-half years to pursue an infringement action.').
49 35 U.S.C. § 154 (2006).

the time lost during clinical testing.[50] In particular, the patent holder is entitled to have restored to the patent term one-half of the time between the Investigational New Drug (IND) application and the submission of an NDA, plus the entire period spent by the FDA approving the NDA. The statute sets some caps on the length of the term restoration. The entire patent term restored may not exceed five years.[51] Further, the remaining term of the restored patent following FDA approval of the NDA may not exceed fourteen years.[52]

2.2.6 Innovator marketing exclusivities The Hatch-Waxman Act includes provisions that create marketing exclusivity for certain FDA-approved drugs. The FDA administers these provisions by issuing approval to market a pharmaceutical to only a single entity. A grant of marketing exclusivity does not depend on the existence of patent protection. Indeed, it is possible that two completely different entities may own PTO-granted patent rights, on one hand, and FDA-issued marketing exclusivity, on the other.

In brief, the length of marketing exclusivity is contingent on whether or not the drug is considered a 'new chemical entity' (NCE). The Hatch-Waxman Act defines an NCE drug as an approved drug that consists of active ingredients, including the ester or salt of an active ingredient, none of which has been approved in any other full NDA.[53] If the approved drug is not an NCE, then the FDA may not approve an ANDA for a generic version of the approved drug until three years after the approval date of the pioneer NDA.[54] In contrast, if the approved drug is an NCE, then a would-be generic manufacturer cannot submit an ANDA until five years after the date of the approval of the pioneer NDA. The effect of this provision is to restrict a potential generic manufacturer from bringing a product to market for five years plus the length of the FDA review of the ANDA.[55]

2.2.7 Generic marketing exclusivity In order to encourage challenges of pharmaceutical patents, the Hatch-Waxman Act provides prospective manufacturers of generic pharmaceuticals with a potential reward. That reward consists of a 180-day exclusivity period awarded to the first ANDA applicant to file a paragraph IV certification.[56] Once a first ANDA with a paragraph IV

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50 35 U.S.C. § 156 (2006).
51 *Id.*
52 35 U.S.C. § 156(c)(3) (2006).
53 21 U.S.C. § 355(j)(4)(D)(i), (ii) (2006).
54 21 U.S.C. § 355(j)(4)(D)(iii) (2006).
55 21 U.S.C. § 355(c)(3)(d)(ii) (2006).
56 21 U.S.C. § 355(j)(5)(B)(iv) (2006). Section 505(b)(2) applications do not qualify for the 180-day generic exclusivity period. CTR. FOR DRUG EVALUATION &

certification has been filed, the FDA cannot issue marketing approval to a subsequent ANDA with a paragraph IV certification on the same drug product for 180 days. Because market prices could drop considerably following the entry of additional generic competition, the first paragraph IV ANDA applicant could potentially obtain more handsome profits than subsequent market entrants – thereby stimulating patent challenges in the first instance.[57]

The 180-day generic exclusivity period is intended to ameliorate collective action problems that may arise with regard to pharmaceutical patent challenges.[58] Stated less technically, an independent generic firm that challenges a patent must bear the expensive, up-front cost of litigation. If the independent generic firm is successful, however, the challenged patent is declared invalid with regard to the entire pharmaceutical industry. Any firm – not just the one who challenged the patent – could then introduce a competing product to the marketplace. Understandably, this forced sharing may undermine the incentives any one independent generic firm would possess to challenge an innovative firm's patent. The award of 180 days of generic exclusivity is therefore intended to allow a successful patent challenger to capture an individual benefit for its effort, in turn encouraging such challenges in the first instance.[59]

3 Current controversies surrounding the Hatch-Waxman Act

In the quarter-century since the passage of the Hatch-Waxman Act, generic pharmaceuticals have entered the U.S. market in increasing numbers. As the Federal Trade Commission (FTC) reported in 2002, nearly half of the prescriptions filled in the United States are for generic drugs.[60] Yet many new drugs have also been invented, developed, and brought to the market since 1984. The Hatch-Waxman Act would therefore appear to have been highly successful in both encouraging the generic drug industry and promoting the discovery and development of new drugs by innovative firms.[61] Despite these successes, the legal framework created by the Hatch-Waxman Act has,

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RESEARCH, FOOD AND DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY, LISTED DRUGS, 30-MONTH STAYS, AND APPROVAL OF ANDAS AND 505(B)(2) APPLICATIONS UNDER HATCH-WAXMAN, AS AMENDED BY THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 5 n.14 (Oct. 2004).

57 *See generally Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

58 *Id*.

59 *See generally* Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH L.J. 667 (2004).

60 FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION i (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

61 *See* Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 586 (2003).

throughout its history, generated controversy and numerous proposals for reform. This chapter next reviews three current controversies involving the Hatch-Waxman Act.

3.1 Authorized generics

An 'authorized generic' is a pharmaceutical that is marketed by or on behalf of an innovative drug company, but is sold under a generic name.[62] The innovative firm may distribute the drug under its own auspices or via a license to a generic drug company. The price of this 'authorized copy' is ordinarily lower than that of the innovative drug.[63] Authorized generics are thus similar to 'private label' products that are manufactured by one firm but sold under the brand of another. Although private label products are commonplace in food, cosmetic, and other markets, they have only recently attracted attention in the pharmaceutical industry.[64]

Current interest in authorized generics is largely due to a shift in corporate strategies that has been traced to the early 1990s. Until that time, many entrants in the pharmaceutical industry engaged exclusively either in selling innovative drugs or in selling generic drugs. Several other innovative firms began to market authorized generics shortly before patents on their products were due to expire. Among such products were Nolvadex® (tamoxifen), authorized by the Stewart Pharmaceutical Division of ICI Americas (now AstraZeneca) and sold by Barr Laboratories; Dyazide® (triamterene/hydrochlorothiazide), marketed by SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline); and Ventolin® (albuterol), authorized by GlaxoSmithKline and sold by Dey LP.[65]

Many innovative firms did not continue to sell authorized generics at that time, however, reportedly due to a lack of profitability.[66] One reason for the 'resurgence' of authorized generics in the early 2000s is that physicians, pharmacists and patients more rapidly switch to generic drugs upon their introduc-

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[62] Some sources refer to authorized generics as 'branded', 'flanking' or 'pseudo' generics. *See Blockbuster Drugs with Expiring Patents Gain New Hope: Generic Drugs*, DRUG WK., Apr. 15, 2005, at 352.

[63] *See* Leila Abboud, *'Authorized Generics' Duel Grows*, WALL ST. J., Mar. 25, 2004; Leila Abboud, *Drug Makers Use New Tactic to Ding Generic-Drug Firms*, WALL ST. J., Jan. 27, 2004.

[64] *See* John Schmeltzer, *Upscale Generics Make Gains: 'Private Label' Items Battling Brand Names*, MONTGOMERY COUNTY HERALD, May 19, 2006.

[65] *As brand-generic alliances grow, opponents cry foul*, DRUG STORE NEWS, Aug. 23, 2004.

[66] Sanda Levy, *Why Authorized Generics are Making a Comeback*, DRUG TOPICS: THE ONLINE NEWSPAPER FOR PHARMACISTS, *available at* http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111159.

tion to the marketplace than a decade ago.[67] Because the rate of generic adoption is much greater now, innovative firms reportedly are more willing to 'genericize' their own brands in order to capture a share of that market.[68]

Authorized generics practice has proven controversial due to the Hatch-Waxman Act's architecture and incentive structures. Some commentators have voiced concerns that the introduction of authorized generics, particularly during the 180-day market exclusivity granted to the independent generic firm that brought a paragraph IV challenge, thwarts the policy goal of encouraging the introduction of generic pharmaceuticals.[69] In particular, the use of authorized generics may discourage firms from filing paragraph IV patent challenges if their litigation expenses cannot be recouped through the 180-day market exclusivity period.[70] As antitrust attorney David A. Balto explains:

> The bounty from challenging a patent is very important. Pharmaceutical patent litigation is a multimillion-dollar proposition. But for the potential reward of six-month exclusivity that represents the vast majority of potential profits from generic entry, many firms might forgo challenging patents.[71]

For example, the FDA ruled that the generic manufacturer Apotex was entitled to 180-day exclusivity for its version of the anti-depressant drug Paxil® in 2003. The innovative drug company, GlaxoSmithKline, introduced an authorized generic version of Paxil®. Although Apotex anticipated sales of up to $575 million during the 180-day generic exclusivity period, its sales were reported to be between $150 million and $200 million.[72] In a 2004 filing with the FDA, attorneys for Apotex asserted 'that the authorized generic crippled Apotex's 180-day exclusivity – it reduced Apotex's entitlement to about two-thirds – to the tune of approximately $400 million'.[73]

In line with current trends, a number of successful paragraph IV ANDA applicants have faced competition from authorized generics during the 180-day

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67 *Id.*

68 *Id.*

69 *See* Beth Understahl, *Authorized Generics: Careful Balance Undone*, 16 FORDHAM INTELL. PROP., MEDIA, & ENT. L.J. 355 (Autumn 2005).

70 Tony Pugh, *Loophole may Dampen Generic-drug Boom*, SAN JOSE MERCURY NEWS, May 3, 2006, at A1.

71 David A. Balto, *We'll Sell Generics Too: Innovator Drug Makers are Gaming the Regulatory System and Harming Competition*, 39 LEGAL TIMES no. 12 (Mar. 20, 2006).

72 *See* Jenna Greene, *The Drug Industry has Figured Out a Way to Best Generic Competition, and Pharmaceutical Patent Litigation Could Free-Fall*, 183 NEW JERSEY L.J. 217 (Jan. 23, 2006).

73 *See* Pugh, *supra* note 70.

generic exclusivity period. These independent generic firms include Barr, for the product Allegra® (fexofenadine);[74] Eon, for the product Wellbutrin SR® (bupropion SR);[75] and Teva, for the product Glucophage®.[76] Some industry analysts believe that authorized generics will be an increasingly prominent feature of the U.S. pharmaceutical market in the future.[77] Other commentators believe that this time has already arrived: according to one account, since 2004 'authorized generic versions have appeared for nearly all drugs with expiring U.S. patents'.[78]

In addition, innovative firms commonly introduce authorized generics on the eve of generic competition. Without an independent generic patent challenger in the first instance, innovative firms may themselves make diminished, or delayed, use of the authorized generic strategy. As a result, the procompetitive benefits of authorized generics may be postponed, or not realized at all, should independent generic rivals become less willing to challenge patents held by innovative firms.[79]

On the other hand, authorized generics potentially offer several benefits both to drug companies and to consumers. Authorized generics are commonly less expensive than the innovative drug. The introduction of an authorized generic therefore allows a lower-cost product to be made available to the consumer.[80] As the FDA opined in a statement issued in July 2004:

> Marketing of authorized generics increases competition, promoting lower prices for pharmaceuticals, particularly during the 180-day exclusivity period in which the prices for generic drugs are often substantially higher than after other generic products are able to enter the market.[81]

In addition, once a generic version of a drug becomes available following patent expiration, innovative firms may lose considerable market share. Without being a participant in the generic market, innovative firms may not be

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74 *See* Understahl, *supra* note 69.

75 *Id.*

76 *See* Tara Croft, *Building Teva*, DAILY DEAL (Oct. 25, 2004).

77 *See* James Richie, *Prasco's Market Share Rx: Authorized Generic Drugs: Firm Helps Pharmaceutical Companies Retain Profits*, CINCINNATI BUS. COURIER, Feb. 6, 2006.

78 Tony Pugh, *Drug Companies Battle Generics with their Own Copies*, DULUTH NEWS-TRIB., Apr. 30, 2006.

79 *See* Narinder Banait, *Authorized Generics: Antitrust Issues and the Hatch-Waxman Act*, MONDAQ, Nov. 4, 2005.

80 Morton I. Kamien and Israel Zang, *Virtual Patent Extension by Cannibalization*, S. ECON. J., July 1999.

81 Food and Drug Admin., U.S. Dep't. of Health and Human Servs., *FDA Supports Broader Access to Lower Priced Drugs*, FDA TALK PAPER, July 2, 2004.

able to take advantage of investments they previously made with respect to their manufacturing facilities. Authorized generics therefore allow innovative firms to continue to employ their manufacturing facilities at or near peak capacity even following patent expiration.[82] Authorized generics also potentially provide the innovative firm with an additional income source, which is commonly a royalty on sales made by its generic subsidiary or contracting partner.[83]

Authorized generics may also be a means for settling patent infringement suits between innovative and independent generic firms. A judicial holding of patent invalidity often severely impacts an innovative firm in terms of its lost revenue. Patent litigation is a notoriously uncertain venture. By settling patent litigation, and allowing an ANDA applicant to produce an authorized generic, innovative firms better manage risk. This technique provides a more stable revenue stream, both in support of the innovative firm's research and development activities and for its investors. The generic company making an authorized generic can also benefit by not having to pursue an ANDA at the FDA, expanding its product line, acquiring manufacturing experience, and gaining the first-mover advantage in the generic market.[84]

The use of authorized generics as a litigation settlement mechanism also impacts consumers, but in a manner that is both less certain and likely varies on a case-by-case basis. On one hand, particular settlement agreements may provide for the sale of authorized generics years before the disputed patent is set to expire. As a result, consumers may gain early access to a lower-cost alternative to the innovative drug. On the other hand, had the generic firm refused to settle and ultimately prevailed in the litigation, then the market would have been open to full competition even earlier. The impact upon competition of a litigation settlement likely depends upon a number of complex factors, including the strength of the patent, the number of potential generic competitors, and the precise terms of the litigation settlement agreement.

The policy debate concerning authorized generics has been accompanied by legal challenges before the FDA and the courts concerning this practice. Opponents of authorized generics have contended that the Hatch-Waxman Act's 180-day generic exclusivity period should be understood as applying to

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82 Jon Hess & Elio Evangelista, *Authorized Generics: Lifecycle Management's Compromise in the Patent Wars*, CUTTING EDGE INFO., Aug. 23, 2005, at 4.

83 *Id.*

84 Christopher Worrell, *Authorized Generics*, presentation given at The 5th Generic Drugs Summit (Sept. 27–9, 2004) and David Reiffen and Michael R. Ward, *'Branded Generics' as a Strategy to Limit Cannibalization of Pharmaceutical Markets* (May 2–4, 2005), *available at* http://www.uta.edu/faculty/mikeward/brandedgenerics.pdf.

authorized generics.[85] The FDA and two courts of appeal have taken the opposite view, however, reasoning that the Hatch-Waxman Act does not require an innovative pharmaceutical company to file any sort of application in order to market the drug as an authorized generic.[86] In turn, the 180-day period of generic exclusivity provided by the Hatch-Waxman Act only applies to ANDA or § 505(b)(2) applications with paragraph IV certifications. Under this view, the 180-day generic exclusivity period does not bar authorized generics from entering the market.

The FTC is currently studying the authorized generics issue, and is expected to release its findings in 2009.[87] The FTC project has not deterred the introduction of legislation that would ban this practice.[88] Congress was not the only entity to be surprised by how readily private actors might potentially defeat one of the primary purposes of the Hatch-Waxman Act, the encouragement of prompt pharmaceutical patent challenges. One court described authorized generics as a 'gaping black hole' in the Hatch-Waxman Act, *en route* to confirming the legality of the practice.[89] Authorized generics have not been the only instance in which the firms push the limits of the Hatch-Waxman scheme, however, as this chapter explains next.

3.2 Reverse payment settlements

A generic firm's filing of a paragraph IV ANDA commonly results in a patent infringement suit brought by a innovative drug company. In such litigation, if the NDA holder demonstrates that the independent generic firm's proposed product would violate its patents, then the court will ordinarily issue an injunction that prevents the generic drug company from marketing that product. That injunction will expire on the same date as the NDA holder's patents. Independent generic drug companies commonly amend their ANDAs in this event, replacing their paragraph IV certifications with paragraph III certifications.[90]

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[85] *See* GENERIC PHARMACEUTICAL ASS'N, COMMENT IN SUPPORT OF CITIZEN PETITION DOCKET NO. 2004P-0075/CP1 (May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p_0075_c00003_vol1.pdf.

[86] *See Mylan Pharms Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006); *Teva Pharmaceutical Industries, Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

[87] FTC, Notice, 71 FED. REG. 16779-02 (Apr. 4, 2006).

[88] In the 109th Congress, two bills (S. 3695 and H.R. 5993) proposed to ban the marketing of authorized generics prior to the expiration of the 180-day generic exclusivity period.

[89] *See* Brian Porter, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177 (2005) (citation omitted).

[90] 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(i) (2006).

On the other hand, the courts may decide in favor of the independent generic firm. The court may conclude that the generic firm's proposed product does not infringe the asserted patents, or that the asserted patents are invalid or unenforceable. In this circumstance, the independent generic firm may launch its product once the FDA has finally approved its ANDA application.

In addition to the issuance of final judgment in favor of either the innovative drug company or the generic firm, another resolution of pharmaceutical patent litigation is possible. This legal situation leads to a number of cases with varying details, but a common core fact pattern. Upon filing a paragraph IV ANDA, a generic firm would be sued for patent infringement as provided by the Hatch-Waxman Act. The NDA holder and generic applicant would then settle their dispute. The settlement would call for the generic firm to neither challenge the patent nor produce a generic version of the patented drug, for a period of time up to the remaining term of the patent. In exchange, the NDA holder would agree to compensate the ANDA applicant, often with substantial monetary payments over a number of years.

Opinions about the effects of reverse payment settlements upon social welfare have varied. Some commentators believe that such settlements are anticompetitive. They believe that many of these agreements may amount to no more than two firms colluding in order to restrict output and share patent-based profits.[91] Such settlements are also said to eliminate the possibility of a judicial holding of patent invalidity, which may open the market to generic competition and benefit consumers.[92]

On the other hand, some commentators have found nothing inherently troublesome about reverse payment settlements. Among their observations is that there is a general judicial policy in favor of promoting settlement. The settlement of litigation both serves the goal of resolving disputes in a peaceful manner, and also preserves scarce judicial resources.[93] Second, any settlement of litigation between rational actors necessarily involves an exchange of benefits and obligations. As Judge Richard Posner has explained:

> [*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements.[94]

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[91] *See* John E. Lopatka, *A Comment on the Antitrust Analysis of Reverse Payment Patent Settlements: Through the Lens of the Hand Formula*, 79 TUL. L. REV. 235 (2004).

[92] *See* M. Lave, *supra* note 36.

[93] *See* Stephen McG. Bundy, *The Policy in Favor of Settlement in an Adversary System*, 44 HASTINGS L.J. 1 (1992).

[94] *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003) (emphasis in original).

Third, certain reverse payment settlements have allowed for the introduction of generic competition prior to the date the relevant patent expires. It is possible, for example, for the innovative and generic firms to 'split' the remaining patent term, with the generic firm being allowed to market a competing product prior to the running of the full patent term. Such agreements may potentially benefit consumers, certainly in comparison to a judgment that the patent is not invalid and infringed.[95]

Finally, the dispute settlement procedures established by the Hatch-Waxman Act may themselves promote the use of reverse payment settlements of pharmaceutical patent litigation. In patent litigation outside the Hatch-Waxman Act context, the accused infringer is ordinarily using or marketing the patented technology. A judicial finding of infringement would expose the accused infringer to an injunction, along with damages award for past uses and sales. As a result, the accused infringer may well be willing to compensate the patent proprietor in order to avoid the risk of such a holding.[96]

Some observers believe that the structure of the Hatch-Waxman Act alters the traditional risk profile between the plaintiff-patentee and accused infringer. As explained by one federal district court:

> [I]n creating an artificial act of infringement (the ANDA IV filing), the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from infringing commercial sales. . . . Because of the Hatch-Waxman scheme, [the generic firm's] exposure in the patent litigation was limited to litigation costs, but its upside – exclusive generic sales – was immense. The patent holder, however, has no corresponding upside, as there are no infringement damages to collect, but has an enormous downside – losing the patent.[97]

As a result, some commentators believe that it is entirely predictable that the unique procedures of the Hatch-Waxman Act have resulted in the new phenomenon of reverse payment settlements.

To date, the primary mechanism for addressing the legality of reverse payment settlements has been the antitrust laws. Unfortunately, uniformity of results has not been a hallmark of judicial treatment of these settlements.[98]

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[95] *See* Marc G. Schildkraut, *Patent-splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004).

[96] *See* Kristopher L. Reed, *A Return to Reason: Antitrust Treatment of Pharmaceutical Settlements under the Hatch-Waxman Act*, 40 GONZ. L. REV. 457 (2004).

[97] *In re Ciprofloxacin Antitrust Litigation*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

[98] *See generally* Larissa Burford, *In re Cardizem* & *Valley Drug Co.*: *The Hatch-*

The Court of Appeals for the Sixth Circuit has held that one reverse payment settlement constituted a *per se* violation of the antitrust laws.[99] The Courts of Appeals for the Second and Eleventh Circuits have declined *per se* treatment to reverse payment settlements, employing a more permissive mode of analysis based upon the traditional rule of reason approach.[100] Notably, the different cases considered by these courts have each involved their own, distinct set of facts. Nonetheless, the difference between the *per se* rule on one hand, and alternative approaches similar to the rule of reason on the other, have plainly contributed to different judicial outcomes. It should also be noted that the trend is certainly toward more lenient judicial supervision of reverse payment settlements.

As with authorized generics, the phenomenon of reverse payment settlements demonstrates that innovative firms are not only the only market entrants willing to expose gaps in the Hatch-Waxman Act. Generic firms will participate in such conduct too, if such acts further their own interests in the marketplace. As Congress contemplates the outright prohibition of reverse payment settlements,[101] it may wish to reflect upon the considerable degree that the entirety of the Hatch-Waxman Act attempts to achieve public goals through private actions – actions that do not always present the most advantageous alternative for members of the pharmaceutical industry. The current controversy over declaratory judgments, which this chapter discusses next, provides a third example of this glaring reality.

3.3 Declaratory judgment actions

The Hatch-Waxman Act goal of achieving the prompt introduction of generic drugs is in part achieved through timely challenges of pharmaceutical patents in federal court. But under the Hatch-Waxman architecture, such challenges may occur only if the innovator files infringement charges against a paragraph IV ANDA applicant. But suppose that the innovative firm opts not to sue? In such a case, assuming the generic applicant's filings are in order, the FDA will

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Waxman Act, Anticompetitive Actions, and Regulatory Reform, 19 BERKELEY. TECH. L.J. 365 (2004); Richard D. Chaves Mosier & Steven W. Ritcheson, *In re Cardizem and Valley Drug: A View from the Faultline Between Patent and Antitrust in Pharmaceutical Settlements*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 497 (2004).

[99] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[100] *See, e.g., Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003); *In re Tamoxifen Citrate Antitrust Litigation.*, 429 F.3d 370 (2d Cir. 2005).

[101] In the 110th Congress, S. 316 and H.R. 1432, both styled as the Preserve Access to Affordable Generics Act, propose to declare such agreements an act of unfair competition.

grant final marketing approval once 45 days have passed.[102] Yet the generic firm may not wish to manufacture and distribute its product in view of the unresolved intellectual property issues.

Under these circumstances, many generic firms have attempted to pursue a so-called declaratory judgment action against the patent proprietor. Under U.S. law, the usual roles of the litigants are reversed in a declaratory judgment action. The generic firm becomes the plaintiff in search of a judicial declaration of patent invalidity, with the patent proprietor finding itself the defendant.

In support of such efforts by generic firms, Congress incorporated provisions into the Hatch-Waxman Act that expressly contemplate declaratory judgment jurisdiction. As amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[103] the Hatch-Waxman Act provides for a 'civil action to obtain patent certainty' consisting of a 'declaratory judgment absent infringement action'.[104] The effectiveness of this provision was initially unclear. As it had prior to the 2003 amendments, the Federal Circuit took a cabined view of the availability of declaratory judgments in pharmaceutical patent cases.

The nub of the problem was that the existence of declaratory judgment jurisdiction is predicated upon 'actual controversy'.[105] As the U.S. federal courts do not issue advisory opinions,[106] the declaratory plaintiff must demonstrate that an actual controversy exists. In order to fulfill this standard, the Federal Circuit formerly held that the patentee must have made an explicit threat, or otherwise engaged in conduct that created an objectively reasonable apprehension on the part of the plaintiff that the patentee will commence suit if the activity in question continues.[107] Mere ownership of a patent does not

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102 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

103 Pub. L. No. 108-173, 117 Stat. 2066 (2003).

104 21 U.S.C. § 355(j)(5)(C)(i) (2006). *See also* 35 U.S.C. § 271(e)(5) (2006).

105 *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) ('The [Declaratory Judgment] Act, paralleling Article III of the Constitution, requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment.').

106 *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997) ('the federal courts do not sit to render advisory opinions'); *GAF Building Materials Corp. v. Elk Corp.*, 90 F.3d 479, 482 (Fed. Cir. 1996) ('the dispute was purely hypothetical and called for an impermissible advisory opinion.').

107 As described in *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 n. 2 (Fed. Cir. 1992):

> The test for determining whether an actual controversy exists in a declaratory judgment suit in a patent case is two-pronged. First, the defendant's conduct must have created on the part of the plaintiff a reasonable apprehension that the defendant will

by itself subject its proprietor to declaratory judgment actions. Although the additional step of listing of the patent in the Orange Book has been taken in this class of cases, it should be noted that the Hatch-Waxman Act requires NDA holders to do so.[108] An action compelled by federal law hardly seems an appropriate basis for developing a reasonable apprehension of being sued for patent infringement in any particular case. As a result, without further conduct on behalf of patent proprietors, the Federal Circuit rejected the use of declaratory judgment jurisdiction in Hatch-Waxman Act cases where the patent proprietor failed to file infringement charges against the paragraph IV ANDA applicant.[109]

In 2007, the ability of generic drug companies to commence declaratory judgment actions in keeping with 35 U.S.C. § 271(e)(5) abruptly improved. This change in circumstances was due to the release of the Supreme Court opinion in *MedImmune, Inc. v. Genentech, Inc.*[110] Although *MedImmune* did not involve the Hatch-Waxman Act, the Supreme Court took the opportunity to overrule the Federal Circuit's 'reasonable apprehension of suit' test that had served as a predicate for declaratory judgment jurisdiction. The Court instead explained that a justiciable dispute must be 'definite and concrete, touching the legal relations of parties having adverse legal interests', and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be under a hypothetical state of facts'. The Court further stipulated that the lower courts should determine 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment'.[111]

The Federal Circuit's first opportunity to apply the *MedImmune* standard within the context of the Hatch-Waxman Act arose in *Teva Pharmaceuticals USA, Inc. v. Novartis Phamaceuticals Corp.*[112] In that case, five Novartis patents were listed in the Orange Book in connection with its product FAMVIR®. One of the listed patents, U.S. Patent No. 5,246,937, was directed to famciclovir, the active ingredient of FAMVIR®. The other four patents

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initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the device or have prepared to produce that device.

108 21 U.S.C. §355(b)(1) (2006).

109 *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

110 *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007).

111 *Id.* at 771 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

112 *Teva Pharmaceuticals USA, Inc. v. Novartis Phamaceuticals Corp.*, 482 F.3d 1380 (Fed. Cir. 2007).

claimed method of therapeutic use of FAMVIR®. The '937 patent will expire in 2010, while the other patents will expire in 2014 or 2015.[113]

In accordance with the provisions of the Hatch-Waxman Act, Teva filed an ANDA that included a paragraph IV certification with respect to each of the five patents. Novartis responded by bringing an infringement suit against Teva based upon the '937 patent alone. Novartis did not assert infringement of the four method patents. In turn, Teva filed a declaratory judgment action in order to establish 'patent certainty', in keeping with the 2003 amendments to the Hatch-Waxman Act. Applying the then-applicable standard that there must be a 'reasonable apprehension of imminent suit' for jurisdiction to exist, the district court dismissed Teva's declaratory judgment action.[114]

On appeal, the Federal Circuit acknowledged that the Supreme Court had rejected the 'reasonable apprehension' test in *MedImmune*. Writing for himself and Judge Mayer, Judge Gajarsa instead identified five circumstances that, in combination, suggested that Teva had a justiciable controversy under Article III. These circumstances were:

1. The listing of five Novartis patents relating to FAMVIR® in the Orange Book.
2. Teva filed an ANDA certifying that it did not infringe the patents listed in the Orange Book, or that the patents were invalid.
3. The 'civil action to obtain patent certainty' established by the 2003 amendments to the Hatch-Waxman, as well as the purpose of the Hatch-Waxman Act.
4. The charge of infringement brought by Novartis against Teva based upon the '937 patent.
5. The possibility of future litigation based upon the four method patents.[115]

Judge Gajarsa further explained that three particular circumstances would suffice to establish declaratory judgment jurisdiction in future cases:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.[116]

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113 *Id.* at 1334.
114 *Id.* at 1334–5.
115 *Id.* at 1341–5.
116 *Id.* at 1344.

Senior Judge Friedman concurred in the result, but explained that he would have taken 'a somewhat different, and shorter, path than the court does in reaching that conclusion'.[117] Judge Friedman explained that because (1) Novartis had listed its patents in the Orange Book and (2) Teva had filed paragraph IV certifications for each of those patents, these circumstances in combination established that there is an 'existing controversy between the parties over whether Teva's generic version of FAMVIR® would infringe the four other FAMVIR® patents listed in the Orange Book, and whether those patents are valid'.[118] According to Judge Friedman, the fact that Novartis had filed an infringement suit based upon the '937 patent 'confirms that the controversy between the parties is continuing'.[119]

The distinction in approaches between the majority and concurring opinions is of considerable moment to the Hatch-Waxman Act's patent dispute resolution system. Because Novartis had sued on one of its Orange Book-listed patents, *Teva v. Novartis* presented an easy case. But suppose Novartis had opted not to bring a charge of infringement under 35 U.S.C. § 271(e) at all? In this circumstance, Judge Friedman would conclude that the requirements for declaratory judgment jurisdiction were satisfied. In contrast, the majority would look to additional facts and circumstances to see whether a justiciable case or controversy existed.[120]

Until the Federal Circuit faces an appropriate fact pattern, we won't know whether the 2003 amendments to the Hatch-Waxman Act will further the goal of encouraging prompt patent challenges or not. Yet this experience once more suggests the unintended consequences of this statute upon the behavior of pharmaceutical firms. When Congress promulgated the Hatch-Waxman Act, it contemplated that pharmaceutical patent holders would continue their pattern of aggressive enforcement against their competitors. Many innovative firms have instead reacted by becoming remarkably less litigious, at least during the dawning moments of generic market entry. This ironic response to the Hatch-Waxman Act's structure of incentives is one of several experiences from which broader themes may be drawn, as this chapter discusses next.

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117 *Id.* at 1346.

118 *Id.* at 1347.

119 *Id.*

120 Such factors as the patent proprietor's infringement charges against other ANDA applicants, with respect to the product in dispute and perhaps other products; the history of litigation between the declaratory judgment plaintiff and the patent proprietor; and possibly a more general appreciation of the economics and marketplace realities of pharmaceutical patent litigation would appear to be relevant in such cases.

4 The challenges of an industry-specific patent law

A quarter-century of experience with the Hatch-Waxman Act allows us to reach some broad conclusions about the ability of a legislature to tailor intellectual property law to specific industries. First, the Hatch-Waxman Act teaches that the private sector cannot always be neatly cajoled into achieving public aspirations. Second, pharmaceutical patent law exists as a partially closed system, a design choice that holds implications both for the Hatch-Waxman Act and the patent system more generally. Finally, despite lingering questions about the need for the Hatch-Waxman Act, Congress continues to supplement this statute in order to encourage new technological pursuits. Although such extensions are predictable, they should be done with care in view of their impact upon the public domain.

4.1 Private sector pursuit of public goals

The lesson that our experience with the Hatch-Waxman Act most forcefully conveys is that the legislature cannot always encourage specific private actors to work towards public goals. The framers of the Hatch-Waxman Act sought to achieve a discrete point of balance between the often competing goals of encouraging pharmaceutical innovation and promoting public access to medicines. Yet the intentions of this industry-specific statute have at times been thwarted by the very actors that it regulates. The different players within the pharmaceutical industry have persistently behaved in ways that the framers of the Hatch-Waxman Act did not anticipate.

This experience provides an important insight for future intellectual property policy makers: that the pharmaceutical patent system may accomplish more when it aims to achieve less. A purported strength of the patent system is that it is indifferent to the ways in which innovation is achieved. In this vein, the U.S. obviousness statute stipulates that 'patentability shall not be negatived by the manner in which the invention is made'.[121] Many technological pathways, ranging from an exhaustive research project to serendipitous discovery, may result in a patented invention. The patent system's lack of reference to the origins of an inventive discovery has furthered the ease of its application to distinct innovation environments, the universality of its regulatory impact, and its lack of ready manipulability by private actors.

Counterintuitively, the more specific objectives of the Hatch-Waxman Act seem to be more readily manipulated by both innovative and generic firms. In particular, the incentive provided by the generic marketing exclusivity has at times been thwarted due to both unilateral and bilateral conduct by pharmaceutical firms. The Orange Book provides a second example, for its history as

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121 35 U.S.C. § 103(a) (2006).

a patent clearinghouse has been a troubled one. The goal of prompt patent challenges has also been thwarted by the simple unwillingness of innovative firms to place their patents before fora that might invalidate them. These and other experiences suggest that the inducements provided by an intellectual property work best when they are framed broadly. More specific incentives must be framed with great care, if at all, lest they lead to activity that can defeat the public aims the statute seeks to achieve.

4.2 Pharmaceutical patent law and system closure

In 1984, Congress opted to establish a specific intellectual property regime for both seminconductor chips and pharmaceuticals. For the former the legislators enacted a *sui generis* statute.[122] Like most of its industry-specific peers, covering such subject matter as boat hulls and plant species, the Semiconductor Chip Protection Act has led a quiet and isolated existence.

Congress chose differently for the drug industry, fashioning a permeable system situated within both the patent and food and drug laws. This design choice has proven on balance to be a wise one. Pharmaceutical patent law continues to track broader movements in intellectual property law, remaining subject to judicial course corrections to the general patent system without the need for legislative activity. As discussed previously, the ruling in *MedImmune, Inc. v. Genentech, Inc.*[123] formally had nothing to do with the Hatch-Waxman Act. By easing the prerequisites for establishing declaratory judgment jurisdiction, however, the *MedImmune* ruling furthers congressional intentions in enacting the 2003 MMA amendments. The statute's open architecture also allows pharmaceutical patent law to interface with peer systems abroad and to some extent escape problems of regulatory capture.

Lack of predictability is one negative consequence of the statute's open structure. Some generalist patent law rulings may increase the value of the Hatch-Waxman Act's specialized provisions. For example, the well-known decision in *eBay, Inc. v. Mercexchange, L.L.C.*[124] made permanent injunctions more difficult for patentees to obtain after prevailing in enforcement litigation. Given that the Court's opinion called attention to business method patents and trolling practices, however, the *eBay* holding likely will be of little moment to innovative drug companies. To the extent that *eBay* does limit the remedies provided to them, the ruling effectively increased the value of marketing exclusivities and probably the thirty-month stay of marketing approval as well.

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122 Semiconductor Chip Protection Act of 1984, Pub. L. No. 98620, 98 Stat. 3347.

123 *MedImmune, Inc. v. Genentech, Inc.*,127 S.Ct. 764 (2007).

124 *eBay, Inc. v. Mercexchange, L.L.C.*, 126 S.Ct. 1837 (2006).

On the other hand, some rulings may decrease the value of pharmaceutical patents. When the Supreme Court recently raised the bar for patentability in *KSR International Co. v. Teleflex Inc.*,[125] many observers opined that the pharmaceutical patent field will serve as that decision's sounding board. Some went so far as to predict specific product lines that would soon fall prey to generic competition.[126] With generalist judicial holdings and patent legislation playing a sizeable role in the balance struck by the Hatch-Waxman Act, it is no wonder that pharmaceutical firms devote considerable efforts towards lobbying the legislature and promoting international agreements.

Sometimes the role of the drug industry is dynamic. Innovative pharmaceutical firms were the most forceful advocate of the insertion of intellectual property law into the international trade agenda with the advent of the WTO. Other times the pharmaceutical industry promotes stasis, however, as we can observe in the contemporary patent reform discussions currently before Congress. No matter what the current mood of the leading drug companies, however, their perceived intellectual needs and particular industry structure continue to play a dominant role in the shaping of general patent law and policy both in the United States and abroad.

4.3 Embracing and extending Hatch-Waxman

A decade ago, Alfred Engelberg posed a question that remains cogent today: is the Hatch-Waxman Act truly necessary?[127] Engelberg deemed the patent-term extensions and the *Bolar* experimental exemption as largely negating each other in terms of their practical marketplace impact. Engelberg also questioned the fairness of government encouragement of challenges to issued patents in one particular field of endeavor. For it is the government that issues the patent in the first place, and as experience with the *sui generis* pharmaceutical patent regime consistently demonstrates, patent challenges remain a private matter done for business reasons despite their significant public externalities.

Despite these lingering challenges, Congress has nonetheless augmented the Hatch-Waxman Act to create other focused innovation incentives. For example, Congress developed a pediatric exclusivity that extends an existing intellectual property right by six months.[128] The pediatric exclusivity is awarded to innovative firms that complete pediatric studies on an approved drug. Contemplated additional extensions appear to be gaining more traction. Congress has considered patent term extensions and marketing exclusivities

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125 *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

126 George E. Jordan, *Patent Law Change to Effect N.J.: 'Obviousness' is Redefined, Pharma Industry Cringes*, NEWARK STAR-LEDGER, May 27, 2007.

127 Engelberg, *supra* note 26.

128 21 U.S.C. § 355a (2006).

for the development of biological, chemical, and radiological countermeasures used for homeland security.[129] Current discussion of creating an expedited marketing approval pathway for follow-on biologic products has also raised the prospect of a twelve-year marketing exclusivity and an extraordinary elaborate patent dispute resolution system.[130]

It is easy to see why the Hatch-Waxman Act framework has proven perennially popular with the legislator. A significant stumbling block to the omnibus patent reform effort currently before Congress has been the need to accommodate the general patent system to diverse industries. This obstacle is removed in the case of industry-specific marketing exclusivities. Since the advent of the TRIPS Agreement, what was once merely a legislative convenience has become a legal necessity. Although the TRIPS Agreement identifies both patents and marketing exclusivities as intellectual property rights that fall within its aegis, marketing exclusivities are far less extensively regulated. The result is that national legislatures enjoy considerably greater discretion in crafting this sort of quasi-patent with its more narrowly oriented incentives.

In addition to perpetuating some of the disconnects between public goals and private endeavors, increasing congressional resort to marketing exclusivities seems troubling. As Professor Mark Janis has explained, traditional justifications for such 'second tier patent protection' are that they are more accessible to small enterprises and that they provide intellectual property rights to subject matter that falls without the traditional patent regime.[131] Both of these rationales seem wholly inapplicable here. The innovative pharmaceutical industry has long been dominated by sophisticated multinational enterprises, while the phrase 'patent medicine' suggests the longstanding use of the patent system by drug companies.

That each of the existing marketing exclusivities potentially protects wholly routine, non-innovative efforts suggests an additional concern about extending this concept to new subject matter. As the Supreme Court recently observed in the *KSR* case,[132] granting intellectual property rights to subpatentable subject matter may retard progress and ultimately stifle innovation. Our experience also suggests the difficulty of calibrating the terms of marketing exclusivity precisely. Many critics view the grant of pediatric exclusivity to have been an undeserved windfall for innovative firms, for example, which in their view obtain far greater revenues from six months of

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129 *See, e.g.*, Project BioShield II Act, S. 975, 109th Cong. (2005).

130 *See, e.g.*, Biologics Price Competition and Innovation Act, S. 1695, 110th Cong. (2007).

131 Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151 (1999).

132 *KSR*,127 S.Ct. at 1727.

marketing exclusivity than they expend on pediatric studies.[133] For both reasons, Congress would do well to approach further extensions of the Hatch-Waxman Act with some caution.

5 Conclusion

Achieving the appropriate balance between pharmaceutical innovation and access to medicines is a pressing social issue. Patients rely upon innovative drug companies to discover new drugs, but they also depend upon generic firms to increase access to such medications once they have been developed. The Hatch-Waxman Act established the patent and food and drug laws as the primary mechanisms through which these competing demands will be mediated in the United States. Policy makers would do well to reflect upon a quarter-century of experience with a *sui generis* pharmaceutical patent regime.

[133] The views of these critics are presented in Robert Steinbrook, *Testing Medications in Children*, 347 NEW ENG. J. MED. 1462 n. 18 (Oct. 31, 2002).

24 Current controversies concerning patent rights and public health in a world of international norms

Cynthia M. Ho

1 Introduction

Patents are often touted as important and even essential to promoting innovation in the area of drug discovery, but the potential benefits may be illusory or even non-existent. In particular, to the extent that patent rights entitle their owner to exclude others from the making of the invention, the patent owner may price a patented drug at levels that are beyond what some can afford. Pharmaceutical companies that obtain patents emphasize that patents promote research that helps all of society and that higher costs for patented drugs are an unfortunate, but necessary reality to funding expensive research and development of drugs. Such companies point to sunk costs such as extensive clinical testing of drugs, including those that never reach the marketplace. Human rights advocates and developing countries, on the other hand, emphasize that giving corporations rights to control access to medicine is inhumane where due to patent protection, treatment is available, but not affordable.

Can patent rights be reconciled with public health? Technically, every nation has the ability to decide whether or not to grant patents, including patents on pharmaceutical compounds. Historically, many nations elected not to provide any patents, or only limited patent rights as one method to promote greater access to medicine. However, while this option technically still exists, it is increasingly an illusory option in light of other realities. In particular, many countries of the world, including less developed countries, are members of the World Trade Organization (WTO).[1] One of the benefits of membership is access to global markets. However, the privilege of membership also carries certain obligations, including a commitment to comply with all related agreements to the WTO. One such agreement is the Trade-Related Intellectual Property Agreement ('TRIPS'), which established the first-ever minimum

[1] WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO: THE ORGANIZATION: MEMBERS AND OBSERVERS (last visited Feb. 2007), *at*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (listing 150 member states).

levels of patent rights on a global scale.[2] Essentially, TRIPS requires every WTO member to provide minimum levels of patent rights, including restrictions on what must be patentable subject matter, as well as permissible exceptions. Accordingly, under TRIPS, nations no longer have unfettered flexibility to decide how best to balance patent rights against other goals, such as providing nutrition, or accessible health care.

This chapter aims to highlight some current global controversies concerning the appropriate balance between patent rights and public health. First, a brief background to TRIPS is provided, including its genesis, an overview of the patent provisions, and its place in the international world order. Second, current controversies concerning national attempts to address domestic interests while adhering to TRIPS are analyzed. Third, this chapter discusses heightened standards of patent rights that have been imposed by international agreements since the conclusion of TRIPS. Finally, this chapter discusses counter-movements to the general global trend towards ever-increasing patent rights.

2 TRIPS

2.1 Background

2.1.1 Genesis Although TRIPS is now considered a cornerstone of international law, as well as a principal influence on national patent laws, its existence importantly does not reflect a uniform consensus amongst nations concerning the appropriate scope of patents. The negotiation of TRIPS was highly contentious; whereas wealthy countries with substantial intellectual property interests pressed for TRIPS, it was opposed by countries that previously had provided no patent protection, or only limited patent protection. The conclusion of TRIPS was substantially aided by the fact that it was part of a larger 'package deal' with the negotiation of the WTO. In particular, any country desiring greater access to markets through the WTO was required to accept related WTO agreements, such as TRIPS. The linkage of TRIPS to the WTO enabled wealthier countries to succeed in raising levels of global intellectual property protection because they were able to use market access as a bargaining chip; prior attempts to negotiate international agreements that simply raised intellectual property standards failed since developing countries had nothing to gain by acceding to such requirements.[3] Another impetus for

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2 TRIPS (1994).

3 *See, e.g.*, Gana (1996: 334) (noting that 'the TRIPS Agreement accomplishes,

developing countries to agree to the TRIPS provisions was a belief that they would no longer be subject to unilateral pressure and economic sanctions by wealthier countries demanding increased protection of intellectual property.[4]

Although the minimum standards under TRIPS clearly benefited the wealthy countries, they suggested that the new requirements would benefit all countries by setting the stage for increased foreign direct investment, as well as an environment that fostered innovation. This suggestion was not backed by empirical data and indeed, many policy institutes suggested that countries at different levels of developments should have different types of intellectual property laws.[5]

The conclusion of TRIPS may also have been aided by the fact that developing countries initially believed that TRIPS would not be unduly invasive on sovereign interests because of language concerning social policy goals beyond patent rights within TRIPS. For example, article 7, entitled 'Objectives', explicitly states that intellectual property rights should contribute 'to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare'.[6] Article 8, entitled 'Principles', similarly refers to values beyond promoting innovation and explicitly states that members may adopt measures to protect public health and nutrition; however, the scope of such measures has always been controversial since only measures that are 'consistent' with TRIPS are permissible.[7] Exceptions from the default standards for patentability as well as patent rights also have language concerning social norms. For example, one permissible exception from the default standard of patentability is for diagnostic and therapeutic treatments.[8] Another exception to patent rights notes not only the interests of the patent owner, but

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through the potential threat of economic ostracism, what could not be accomplished through negotiations independent of the international economic framework'); Helfer (2004: 2–3) (noting that TRIPS is defended as a package deal); Reich (2004: 362) (noting that the WTO negotiations succeeded where prior WIPO negotiations failed, because TRIPS was presented as a package deal to which countries could not resist if they wanted access to global markets).

4 *See, e.g.*, Correa (2000: 11).

5 *See, e.g.* , U.N. Doc. E/C.12/2001/15 (2001: 15), (noting that uniform rules may be inappropriate for nations at different levels of development); Commission on Intellectual Property Rights (2002: 8) (noting that '[d]eveloping countries should not be deprived of the flexibility to design their IP systems that industrialized countries enjoyed in earlier stages of their own development'); Correa and Musungu (2002: 23) (noting that industrialized countries had varying evolutions of their patent systems that enabled them to take into account the competitive strength of their industries).

6 TRIPS, art. 7.

7 TRIPS, art. 8(1).

8 TRIPS, art. 27(3). In addition, 'ordre public or morality' is referenced in a different exception from patentability. Ibid., art 27(2).

also the 'legitimate interests of third parties', which have been speculated to include an interest in a quicker supply of low-cost generic drugs.[9]

Despite such language concerning social norms, the ability of member states to balance patent rights against other social interests has been an ongoing issue since the conclusion of TRIPS. Countries have raised a number of disputes under TRIPS concerning the scope of patent rights, including issues concerning public health. Indeed, concern over the impact of TRIPS on public health gathered increasing momentum and led to the conclusion of the Doha Public Health Declaration in 2001, which provided some clarification on the interpretation of TRIPS.[10] Although the Declaration was unanimously agreed to at the time, it was signed in the wake of a globally recognized AIDS epidemic. In addition, the unanimous declaration did not quell all disputes since some statements could be ambiguously interpreted – just as with TRIPS itself. For example, although the Declaration proclaimed that 'TRIPS does not and should not prevent Members from taking measures to protect public health', it did not provide much detail on how TRIPS should – or should not – be implemented to achieve this goal.[11] The Declaration did clarify a few discrete issues, including the fact that the grounds upon which compulsory licenses are issued are within the discretion of national governments. However, even this clear statement has not prevented continuing disagreements as later discussed within the section on compulsory licenses.

2.1.2 Overview TRIPS not only mandates that patents exist for all WTO member countries, but also sets forth certain minimum requirements for the patent systems of each country. In particular, TRIPS provides a general standard for patentable subject matter that effectively prohibits nations from limiting patents based upon social goals – other than those permitted under TRIPS. For example, countries can no longer unilaterally decide to bar patents on drug compositions because of their domestic preference for widespread access to drugs; so long as the new drug satisfies the patentability standards, there is no wholesale exception for banning patents on inventions that impact health. TRIPS also provides general standards for the scope of patent rights, including both the activities that constitute infringement, as well as what exceptions from patent rights are permissible. TRIPS also establishes the patent term, as well as additional rights that may effectively extend exclusivity for owners of drug patents through a new international norm regarding secrecy of information provided for regulatory approval.

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9 TRIPS, art. 30.
10 Doha Public Health Declaration, paras 5(a), (c).
11 Doha Public Health Declaration, para. 4.

PATENTABLE SUBJECT MATTER TRIPS requires that patents be generally available for all 'inventions' in all fields of technology if they comply with the technical patentability requirements of being novel, have industrial application and an inventive step.[12] In particular, TRIPS specifies that patents must be available for products and processes.[13] This is a major change for dozens of countries that had previously provided no patents, or excluded drugs from the scope of product patents to improve the accessibility of drugs. TRIPS provides some exceptions to patentability; for example, members retain the right to exclude methods of medical treatment, as well as inventions that would violate morality if commercial exploitation were permitted.[14]

Countries maintain some flexibility regarding what must be patented based on the lack of definition of key terms. For example, while TRIPS requires patents to be granted for all inventions, the term 'invention' is not defined under TRIPS; similarly, what constitutes a 'field of technology' is not defined. Accordingly, TRIPS does not demand that member states provide patents on isolated or purified compounds, or provide patents on methods of doing business – national discretion on such subjects may continue. In addition, countries also retain some flexibility in denying patents for inventions that they deem to lack novelty, industrial application, or inventive step. In particular, although these must be criteria under national patent acts, TRIPS similarly provides no definitions of these key terms.

PATENT RIGHTS In addition to requiring that patents be granted, TRIPS also dictates the scope of patent rights. Under TRIPS, a patent owner is entitled to exclude others from making, using, selling, offering to sell, or importing the patented invention into the country for the term of the patent.[15] The term of patent rights 'shall not end before the expiration of twenty years counted from the filing date'.[16] Unlike some prior patent regimes that provided a fixed patent term calculated from the date of issuance, TRIPS does not specify when the patent term should begin and only states the earliest time that patent protection may expire. Although the only benchmark given is the filing date, TRIPS does not require that protection begin with the filing date of the patent application; accordingly, nations may continue to provide protection only from grant of an issued patent, or publication of an application. What is important, however, is that the term may not end before twenty years from filing. In particular, the WTO dispute process found Canada's patent act in violation of

12 TRIPS, art. 27(1).
13 Ibid.
14 TRIPS, art. 27(2)–(3).
15 TRIPS, art. 29.
16 TRIPS, art. 33

this provision because its term of seventeen years from date of grant (for applications filed before 1989 – prior to TRIPS) did not always provide a term that would last twenty years from filing.[17] Canada argued that given the fact that examination of patent applications typically took five years, its absolute grant of seventeen years from patent issuance was effectively the same and in some cases provided a longer term than a grant of twenty years from issuance minus the period of examination. The WTO panel and the Appellate Body concurred that TRIPS requires that the term be provided as a matter of legal certainty.[18]

EXCEPTIONS FROM PATENT RIGHTS As with granting of patents, there are permissible exceptions to patent rights under TRIPS – with respect to either the exclusive rights over the patented invention or the patent term.[19] The first exception, under article 30, explicitly states that it is a 'limited exception' and has been narrowly interpreted by a WTO panel to have three separate and cumulative conditions that substantially restrict the ability of member states to deviate from the standard patent rights.[20] The second exception, under article 31, essentially permits compulsory licenses, but only if a dozen procedural criteria are satisfied.[21] The exception for compulsory licenses has been highly contentious, and will be discussed in greater detail below.

DATA PROTECTION In addition to demanding that patents be provided, TRIPS also mandates the first-ever international norm for trade secrecy. The trade secret right required under TRIPS is only for information that is provided to governmental agencies, but otherwise 'undisclosed' to third parties.[22] In other words, TRIPS provides protection from 'unfair competition' for information that must be submitted to obtain approval of the marketing of a pharmaceutical or agricultural compound. Although the type of information covered is clear, the scope of the provision is less clear since TRIPS does not define what constitutes the impermissible 'unfair competition'. In addition, TRIPS also does not state how long the protection from unfair competition should last.

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17 *See* WTO, *Canada – Term of Patent Protection*, WT/DS170/R (May 5, 2000), *aff'd*, WT/DS170/AB/R (Sept. 18, 2000).

18 WTO, *Canada – Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000), para. 90. The ruling resulted in an extension of the patent term of some blockbuster drugs and concomitant delay of related generics onto the market.

19 TRIPS, arts. 30–31.

20 WTO, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000). The panel noted that the three separate elements must be 'presumed to mean something different' from each other or else there would be redundancy. *Id.* ¶¶ 7.20–7.21.

21 TRIPS, art. 31

22 TRIPS, art. 39.

The interpretation of these terms would be important in assessing whether and when a generic manufacturer could rely on the submission of a pioneering drug company to obtain approval for its own product. Although there have been disputes, there has thus far not yet been an official determination by a WTO panel concerning the scope of this provision.[23] On the other hand, this right may be irrelevant for the many countries subject to heightened requirements under TRIPS-plus agreements discussed in a later section.

2.1.3 Enforcement One important aspect of TRIPS lies in the enforceability of its provisions. Although some countries were given a transition period to fully comply with TRIPS in light of their developmental stage, all requirements, including transitional provisions, are ultimately enforceable under the WTO framework. TRIPS is enforceable pursuant to the Dispute Settlement Understanding (DSU) that governs all WTO agreements.[24] The DSU is considered the most powerful enforcement mechanism of any international agreement because decisions pursuant to the DSU are backed by the WTO. Nations who do not comply may lose WTO benefits.[25]

One result of the DSU is that TRIPS provisions tend to dominate over not only domestic interests, but also competing international agreements and norms. Because other international instruments and organizations do not have the same enforcement ability, their interests are effectively not promoted. For example, the universally recognized rights to health, and right to life, as recognized by UN agreements, are not easily definable, let alone enforceable. In contrast, patent criteria under TRIPS are clearly defined and have strong enforceability under the DSU. WTO panels that consider TRIPS violations pursuant to the DSU must take into account international norms when interpreting WTO rules, such as TRIPS.[26] However, international norms also dictate that where a treaty's terms are clear, there is no need to look beyond

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[23] The United States brought a formal case against Argentina for alleged failure to comply with this provision, but the case failed to produce clear rules since it was ultimately settled after two years of discussion. *See* World Trade Organization, Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 (June 20, 2002). For an interesting review of the background leading to the TRIPS provision, including limitations to its interpretation, see Reichman (2004).

[24] DSU, art. 23

[25] Dreyfuss & Lowenfeld (1997: 276–7); Helfer (2004: 22).

[26] DSU, art. 3(2). Customary rules include at least the interpretative rules under the Vienna Convention, which requires that a treaty be interpreted in 'good faith' in accordance with the 'ordinary meaning' of the treaty terms in their context and in light of the object and purpose of the treaty. Vienna Convention on the Law of Treaties, art. 31(1).

the text.[27] Moreover, even if a WTO panel were to consider human rights norms in interpreting TRIPS, that would be a far cry from enforcing international norms *beyond* TRIPS. For example, UN resolutions suggesting that fundamental human rights, such as a right to health, be given 'primacy' over TRIPS, are not enforceable under the WTO framework and also lack independent enforceability.

Since each international regime provides its own rights and enforcement provisions, the regime with the strongest enforcement ability – WTO/TRIPS – effectively dominates over other international norms. Outside of specific cases of TRIPS violations, there is no separate mechanism to consider the extent to which TRIPS conflicts with or even nullifies other international norms. There is no official requirement that TRIPS not impinge on other international treaties and even in the event of such an arguable conflict, it would not constitute a justiciable action under the WTO.

2.2 Current issues

2.2.1 Patentability As noted earlier, TRIPS mandates patent protection for all 'inventions' that satisfy the criteria of patentability, but does not define what constitutes an invention, thereby allowing some domestic differences and flexibility. However, the limits of that flexibility may be challenged by India's current patent act because it provides a new gloss to the limits of patentable subject matter. Although India's 2005 amendments to its patent act did extend patent protection to products in all fields of technology, notably including drug patents for the first time, it did so with a major caveat. In particular, the current law excludes certain products from the scope of patent protection where they are considered to be variations of existing compounds. Section 3(d) of the present Indian patent law provides that:

> Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [can not be patented].[28]

In addition, an explanation to this provision clarifies that chemical derivatives, such as salts, esters, isomers, and other combinations, shall be consid-

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[27] Vienna Convention on the Law of Treaties, May 23, 1969, 8 I.L.M. 679, art. 31.

[28] India Patents (Amendment) Act, 2005 ¶ 3(d).

ered to be the same substances, unless they differ significantly in properties with regard to efficacy.[29]

India's provision is unique in excluding subject matter from the scope of patentability that would generally be considered – if at all – under other patentability criteria. Other countries do not exclude compounds from consideration as patentable subject matter based on the similarity to prior compounds. Rather, most other countries consider similarity to prior compounds only under the other requirements of whether a compound is new and has an inventive step. In addition, although a related compound might seem likely to be considered to lack an inventive step, many patent laws construed this requirement in a manner that in fact considered chemically similar products to often satisfy the test. Whether or not something is more efficacious is more akin to a question typically considered by an agency concerned with sale of drugs. However, even then, the question typically only focuses on whether the new drug is safe and effective, but not necessarily *more* effective than other products, let alone one that is chemically similar.

The Indian law limiting patentability of modified compounds was done with the specific intention of avoiding a practice common within the pharmaceutical industry of obtaining a portfolio of patent protection based upon a single drug that essentially enables a company to obtain exclusivity far beyond the term of a single patent. Often referred to as 'life cycle management' or 'evergreening', this occurs when multiple patents are obtained related to a single commercial product based upon slight variations after an initial patent on the underlying chemical compound. For example, subsequent patents issued to the same patent holder may be for new uses of the same compound or new dosing mechanisms. Although criticized by generic drug companies and patients' rights groups, evergreening is an established practice in many industrialized countries. India, however, apparently was not interested in simply following suit.

The scope of India's exception to patentability has already been the subject of one globally watched dispute surrounding the denial of a patent on a cancer drug to Novartis for its drug Glivec, alternatively marketed as Gleevec. In particular, the above exception was the focus in two related petitions brought by Novartis after denial of its patent application.[30] Novartis not only sought judicial relief from the denial of its patent application, but also a declaration

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[29] Ibid.

[30] The denial of its patent application also terminated its exclusive marketing right, a right that WTO member states were required to provide if they did not immediately provide patent protection. *See* TRIPS, art. 70(9).

that the Indian law was invalid.[31] Novartis asserted that section 3(d) of the Indian patent law was invalid as inconsistent with TRIPS; it suggested that the exclusions established 'new hurdles for pharmaceutical innovation, unjustifiably and illegally narrowing what is patentable'.[32] In addition, Novartis asserted that the provision was also invalid as arbitrary, illogical and vague, such that it was unconstitutional under article 14 of India's constitution.[33]

The Novartis case was closely watched by both patent holders and public health advocates worldwide. For multinational pharmaceutical companies such as Novartis, the case was essential to determining its patent rights not only in Glivec, but in other compounds as well.[34] Such companies also believed that challenging India's patent law was essential to ensuring strong global patent rights. On the other hand, public health advocates were concerned that if the Indian law was found invalid, access not only to Novartis' Glivec drug, but other medicines would be affected. In particular, such advocates saw the case as a small window of opportunity to prevent patents on variations that were not sufficiently inventive to justify extended monopoly terms.

Novartis disputed that its possible success might negatively impact access to medicine. Novartis asserted that protecting patent rights is essential because patents 'save lives by stimulating innovation'.[35] Novartis also asserted that its litigation was only about the fundamental legal principles and would not have an impact on access to Glivec since 99% of patients in India currently receive it without cost from Novartis.[36] Novartis also suggested that generic versions of Glivec would not improve access to medicine because factors other than drug cost impede access.

Novartis was pressured repeatedly to withdraw its case. The U.S. Chair of the Congressional Committee on Oversight and Government Reform wrote to Novartis to suggest that it reconsider its position for fear that its suit would have a severe impact on worldwide access to medicine.[37] Similarly, five members of the European Parliament issued a declaration asking Novartis to

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31 *See, e.g.*, Gentleman (2007).

32 Novartis (2007).

33 *See, e.g.*, *Novartis v. Union of India*, para. 1 (Madras H.C., June 8, 2007)

34 Although the Novartis case was of primary interest to multinational pharmaceutical companies, the challenged Indian provision was also questioned by some Indian pharmaceutical companies. In particular, some believed that most innovations of current Indian companies are primarily incremental and might thereby be denied patent protection whereas multinational companies would be the only companies with adequate resources to develop patentable products.

35 Novartis (2007).

36 Ibid.

37 Statement by Henry Waxman (2007).

drop the case.[38] The German Minister of Economic Cooperation and Development also asked Novartis to drop the case.[39] However, Novartis resisted all these pressures and persisted in its legal challenge.

Whether Novartis deserved an Indian patent on Glivec is an interesting question since the drug is recognized as an important cancer drug. Novartis highlights the fact that the drug is a medical breakthrough that is recognized worldwide and patented. However, Novartis does not emphasize that its contested application is not for the fundamental breakthrough drug – which has already been patented – but, rather, for a variation on that drug that would essentially enable Novartis to continue to have a monopoly in the marketplace for the drug beyond the original patent term, thereby preventing lower-cost generics from entering the marketplace. The application at issue here is for a new beta crystal version of Glivec. Although one opinion of the patent office suggested that the beta crystal version was previously known, the controversy focused on whether the crystal version, if not known, would be barred under section 3(d). According to some, even the new beta crystal version should have met India's standard because the new version is more stable at room temperature and has a 30% improvement in bioavailability.[40] Arguably, an increase in bioavailability could constitute an improvement of efficacy; however, what constitutes efficacy is not explicitly defined, let alone how the efficacy should be proven.

Although the Indian High Court ultimately rejected Novartis' challenge, the narrow scope of the opinion suggests that is not the final chapter to this controversy. The court held that Novartis had no standing to challenge whether India's patent act complied with TRIPS and suggested that any such issue should be subject to resolution within the WTO system.[41] In addition, the court rejected the constitutionality challenge since it found that the term 'efficacy' is well known to those in the pharmaceutical field and that a law is not necessarily arbitrary and vague simply because it sets out a general framework.[42] Even though it agreed that the current language could result in arbitrary application by the patent office, the court contended that the appropriate remedy was not invalidation of the statute, but appeal of individual cases denied by the patent office.[43]

Although Novartis cannot bring a case before the WTO, it may petition a WTO member country to do so. In addition, if India rejects additional patent

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38 Statement by Anne Ferreira et al. (2007).
39 Gerhardsen, 15 Feb. 2007.
40 Bate (2007).
41 *Novartis v. India,* para. 8.
42 *Novartis v. India,* paras 13–14.
43 *Novartis v. India,* paras 11, 16–18.

applications of interest to multinational corporations and/or WTO members, a challenge before the WTO may be likely. However, unless and until a WTO panel rules on the Indian patent law, the Indian law remains on the books and the TRIPS question remains outstanding.

In the meantime, as this book goes to press, there is a new legal controversy that may implicate section 3(d) of the Indian Patent Act once again. This time the provision is being raised as a defense to a patent infringement action brought by Roche against Indian generic maker Cipla; moreover, Cipla is seeking to have the patent revoked on this ground.[44] The Delhi High Court has heard arguments by the parties concerning whether to impose an injunction against Cipla for marketing the patented drug Tarceva, which is used to treat cancer.[45] Cipla apparently asserts that the active ingredient in Tarceva is a derivative of an earlier substance called gefatinib, such that a patent is impermissible unless increased efficacy is established.[46]

2.2.2 Patent rights – 'limited exception' The scope of the 'limited exception' to patent rights may also be reconsidered in the near future. One possible dispute concerning what constitutes a 'limited' exception to patent rights may focus on a provision of India's patent laws that limits patent rights for some owners. Although India is the only country that currently has this law, it may be important since India is the source of many generic drugs and supplies the majority of generic AIDS medications.

India took a novel approach to limiting patent rights for patents filed under the 'mailbox' provision of TRIPS. Those countries that did not allow product patents at the time TRIPS was concluded were required to immediately adopt a procedure whereby owners of patents in other countries could file applications in India to be reviewed once product patent protection was authorized in the order in which they were received.[47] In other words, although the patent applications would not immediately be examined, once product patent protection existed, they would be reviewed in the order in which they were received and the Indian filing date, or any applicable earlier priority date, would be utilized with respect to prior art. The questionable aspect of India's patent law is that it does not provide the same rights to patents issued from mailbox applications as other applications. In particular, the owner of a patent based on a mailbox application may only recover 'reasonable royalties' against companies that were using the invention prior to January 1, 2005. Moreover, the

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44 Shrivastava (Feb. 9, 2008).
45 Ollier (Jan. 28, 2008).
46 Ollier (Jan. 28, 2008); Shrivastava (Feb. 9, 2008).
47 TRIPS, art. 70(8).

patent owner is powerless to enjoin such companies from continuing to make and sell the invention.[48] The law technically only limits the patent owner from obtaining full remedies against those who 'have made a significant investment', were producing the product prior to January 1, 2005, and continue to manufacture the product.[49]

The effect of this provision is to enable generic manufacturers of inventions subject to mailbox applications to continue to do so with a *de facto* compulsory license, so long as they had the foresight to begin their production before January 1, 2005 and subject only to the caveat a 'significant investment' (undefined in the law). Practically, this means that although product patents are permissible under Indian law, the generic drug industry may continue to exist at least for drugs that were produced prior to January 1, 2005. This generic production would be *in addition* to production of any drugs denied patentability under India's novel section 3(d) of its patent laws barring patents on variations of existing compounds that are more efficacious.

The issue is whether India's *de facto* compulsory license could be considered a 'limited exception' under TRIPS. After all, TRIPS states that all patents must be entitled to the same scope of rights without discrimination based on technology. In addition, article 28 clearly states that the patent owner is entitled to bar third parties from making, using, offering for sale, selling or importing the patented invention. Such a right is facially compromised by a provision allowing unauthorized use of the patented invention, subject only to payment of a reasonable royalty. Also, the 'limited exception' under article 30 has been interpreted very narrowly in the single WTO case considering the exception. The first requirement is that the exception be a 'limited' one in scope and the unlimited making and sale of a patented product seems far from limited.[50] Indeed, in the Canada Generic Medicines case, the WTO panel rejected a far more limited use; in particular, it rejected Canada's claim that so long as the patentee had the exclusive right to sell, the other rights could be restricted.[51] Here, even that right is not exclusive to the patentee.

2.2.3 Compulsory licensing The scope of compulsory licenses under article 31 has recently been at issue in the wake of licenses issued by Thailand and Brazil. Although Brazil quickly withdrew its single compulsory license after obtaining a favorable reduction in price, Thailand has thus far resisted pressure

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48 India Patents Act 2005, §11A(7).

49 Ibid.

50 WTO, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

51 Ibid., para. 7.33.

to withdraw its licenses.[52] Over the course of a few months, Thailand issued three licenses on both HIV treatment, as well as on the heart drug Plavix. More recently, on the eve of a change in administration, Thailand approved compulsory licenses on four cancer drugs.[53] The new administration has stated that it will review all the licenses in light of pressure from patent owners, as well as other nations.[54] However, regardless of whether Thailand bows to political pressure, its licenses, as well as the controversy concerning them, serve as a useful example to clarify what actually is required under TRIPS. In particular, this section will address the contention that the licenses were inappropriate in view of the patented subject matter, as well as whether prior negotiation with the patent holder was required before issuing the licenses. This section also uses the Thailand situation to illustrate that there are additional issues beyond TRIPS that implicate the feasibility of actually using such licenses to improve access to medicine.

Article 31 applies to national legislation that permits unauthorized use by the government, or third parties authorized by the government, in situations that do not fall under article 30 *and* satisfy a long list of procedural requirements. Generally, a state must attempt to negotiate for a license directly from the patent holder before imposing a compulsory license.[55] However, this negotiation may be waived in cases of 'national emergency', or other circumstances of 'extreme urgency', or 'public non-commercial use'.[56] Regardless of whether a country is entitled to avoid an initial consultation with a patent owner prior to compulsory licensing, that country must always satisfy a number of other conditions according to TRIPS.[57] For example, conditions governing the grant of a license include that use shall be 'considered on its

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[52] In one case, a compulsory license was deemed not necessary when patent holder Novartis agreed to give its cancer drug Glivec for free to Thai patients below a certain income level. *Thailand Giant Drugmaker Novartis (Thailand) To Give Free Cancer Drug to Thai Patients* (Feb. 4, 2008).

[53] Ministry of Public Health and National Health Security Office of Thailand (2008).

[54] *Thailand Public Health Minister to Review Thai Compulsory Licensing* (Feb. 11, 2008); *Thailand Health Ministry Change Could Mean Fewer CLs* (Feb. 8, 2008).

[55] TRIPS, art. 31(b) (noting that compulsory use should not be permitted unless the proposed user has first 'made efforts to obtain authorization' for use from the patent owner on 'reasonable commercial terms' and those efforts have 'not been successful within a reasonable period of time').

[56] Ibid. Even in cases where waiver of negotiations with the patent owner is applicable, the patent owner must be notified of the use 'as soon as reasonably practicable'. Ibid.

[57] In addition, other grounds include non-commercial use, dependent patents, and anti-competitive practices. *See* TRIPS, art. 31(a)–(l).

individual merits',[58] and that the scope and duration of the use must be 'limited' to the authorized purpose.[59] Additional mandatory procedural safeguards also exist in the form of judicial or other independent review of the use authorization.[60] Even if the use is authorized, it is contingent on 'adequate remuneration' being paid to the patent holder. Such remuneration must take into account the 'economic value of the authorization'.[61] As with the review of the use authorization, remuneration decisions are subject to judicial or other independent review.[62]

PERMISSIBLE SUBJECT MATTER What constitutes appropriate subject matter for compulsory licensing has been a key point of contention with the Thai licenses. In addition, because it has been an issue since the conclusion of TRIPS, exploring this issue is important. As with all analyses of TRIPS, the proper place to begin is with the text of TRIPS itself. The negotiation history should be consulted only when the text is ambiguous, or to confirm a meaning. As will be shown, all analyses point to a conclusion that there is no limit on the type of subject matter that may be subject to compulsory licensing under TRIPS.

Article 31 is a lengthy provision that has many procedural requirements, but no explicit provision limiting the type of subject matter for which it applies. To the contrary, the only provision mentioning subject matter relates to additional requirements for the scope and duration of licenses only in the case of semiconductor technology.[63] The mention of only one type of technology and only for one sub-section of article 31 requirements suggests that there is no general restriction on what subject matter may be licensed.[64]

In addition, although some member states continue to contest whether there should be limits to what subject matter may be licensed, the Doha Public Health Declaration is very clear on this point. In particular, it states that 'each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted'.[65] Indeed, part of

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58 TRIPS, art. 31(a).

59 TRIPS, art. 31(c).

60 TRIPS, art. 31(i).

61 *Ibid.* For example, Thailand considers a royalty rate of 0.5% of the total sale value to be compliant. *See, e.g.*, Khwankhom (2006).

62 TRIPS, art. 31(j).

63 Whereas the general requirement for scope and duration of compulsory licenses is that 'use be limited to the purpose for which it was authorized,' for semiconductor technology, use 'shall only be for public non-commercial use or to remedy a practice determined . . . to be anti-competitive' TRIPS, art. 31(c).

64 Watal (2001: 321).

65 Doha Public Health Declaration, para. 5(b).

the impetus for negotiating this declaration was that some developing countries were concerned that anticipated compulsory licenses would be considered in contravention of TRIPS.[66]

In addition, the negotiating history confirms that there should be no restrictions on the type of subject matter considered permissible since such restrictions were actually contemplated and specifically rejected. For example, the additional limitations on the licensing of semiconductor technology were previously proposed by the U.S. to apply to all compulsory licenses.[67] In addition, while most of the procedural requirements in the final version of article 31 are similar to the initial draft in 1990,[68] one major distinction is that the initial draft contained a specific list of permissible subject matter that could be subject to licensing.[69] In addition, even these limitations disappeared in the next draft of the provision. Accordingly, subject matter limitations were previously considered and *rejected* before the final text of TRIPS article 31 was concluded.

In addition to differences in the draft text based upon the input of all parties, the final version of article 31 is notably different from prior U.S. proposals that attempted to restrict compulsory licenses solely to adjudicated violation of competition laws or to address a declared national emergency. The U.S. attempted to distinguish compulsory licenses, which it disfavored, from government use, for which it wanted wide discretion in subject matter. The U.S. negotiating position was intended to ensure that TRIPS would not require any modification to existing U.S. law which enables the government – or those authorized by the government – to use any patent without authorization of the patent owner, subject only to subsequent suit for reasonable

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66 *See, e.g.*, Draft Ministerial Declaration (2001: pmbl) (noting the 'vulnerability of developing and least developed country members to the imposition or the threat of imposition of sanctions . . .').

67 Watal (2001: 244).

68 Both require a presumption of negotiation with the patent owner prior to compulsory license, yet both waive this requirement in the case of a national emergency. *Compare* TRIPS, art. 31 *with* WTO (1990: para. 5A.2.1–5A.2.4) (qualifying language with 'except in the case of a manifest national emergency'). Both require consideration of the individual merits, limitation in scope to the initial purpose, non-exclusive use, supply predominantly for the domestic market, judicial review, as well as some type of remuneration.

69 In contrast to the current article 31, the 1990 draft stated that 'compulsory license may only be granted for the following purposes', Gervais (2003: 248). In particular, the six permissible subjects suggested as appropriate to compulsory licenses include a remedy of an adjudicated competition law, to address a national emergency, national security or critical peril of life, overriding public interest or the possibility of exploitation by the government or third parties, dependent patent, or failure to work an invention *see* Gervais (2003: 246–7).

compensation.[70] During negotiations, the U.S. explicitly denied that its laws were limited to government defense; rather, it stated that its use was unlimited in subject matter.[71] After failing to persuade other members of any real distinction between government use and compulsory licenses, both were combined in one text that provides no subject matter restrictions.[72] Although the negotiating strategies of individual countries are not technically part of the supplemental record that is pertinent to interpretation of treaties, it does suggest that at least the U.S. believed that article 31 covered a broad range of subject matter. This is consistent with the prior interpretation and useful background with regard to subsequent controversy between the U.S. and Thailand regarding whether the Thai licenses were improper.

IS A 'NATIONAL EMERGENCY' REQUIRED? Considering the explicit declaration of the Doha Public Health Declaration in 2001, the continuing misperception that a national emergency is required deserves further discussion. Part of the problem may be that the Doha Public Health Declaration addressed a number of different topics, such that differing provisions may be improperly conflated. For example, while it clearly states that members have the freedom to determine the grounds upon which licenses were granted, a more frequently remembered provision is for a different topic relating to when initial negotiation with the patent owner may be waived. In particular, as will be discussed in more detail in the next section, although there are no limits on the types of subjects that may be licensed under article 31, certain situations may permit a government to avoid an initial consultation with the patent owner. One of these situations, a national emergency, was expressly discussed in the Doha Public Health Declaration. In particular, it clarified that '[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS . . . and other epidemics can represent a national emergency or other circumstances of extreme urgency'.[73]

Past situations involving use of compulsory licenses may have reinforced a perception that compulsory licenses are limited to national emergencies simply because of the attention devoted to use of licenses in such circumstances. For example, Brazil has repeatedly threatened to issue compulsory licenses for HIV

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70 See 28 U.S.C. 1498.

71 *See, e.g.*, United States Review of Legislation in the Fields of Patents, IP/Q3/USA/1, at 12 (May 1, 1998) (denying that 1498 was limited to activities within the national security sector and claiming that any 'noncommercial use by or for the government' would qualify).

72 Watal (2001: 320–21).

73 Doha Public Health Declaration, para. 5(c).

drugs to address AIDS. Indeed, the Doha Public Health Declaration was prompted by the concern of developing countries that their ability to issue compulsory licenses to address AIDS epidemics might be unduly challenged; they sought an express clarification from all WTO countries.[74]

PRIOR NEGOTIATION The next disputed issue is when – if ever – a country is permitted to waive the usual requirement of prior negotiation with the patent owner prior to issuance of a compulsory license. Criticism of the Thai licenses suggests that some believe prior negotiation is always required. For example, patent owner Merck suggested that it was always entitled to negotiation prior to the issuance of a compulsory license under TRIPS.[75] This section will show that this is incorrect based upon a proper analysis of TRIPS that begins with the text of TRIPS itself.

Article 31 states that a compulsory license 'may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'.[76] Importantly, however, this is not the end of the provision. Rather, the very next sentence states that '[t]his requirement may be *waived* by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.[77] In other words, prior negotiation with the patent owner is *not* required by TRIPS in three situations – a national emergency, a 'circumstance of extreme urgency' or public non-commercial use. Although discussion often emphasizes that prior negotiation may be waived for a national emergency, this is only one of three possible situations where prior negotiation is not required.

Turning to the controversy concerning Thailand, there are actually two conflated issues. First, there was the erroneous perception by some that a national emergency is always required. However, as just noted, although a national emergency may be relevant to compulsory licenses, it is never a requirement for issuance of such a license. Rather, it is only of possible relevance if a country wishes to *waive* the prior negotiation requirement. As noted in the last section, compulsory licenses are not limited to situations of national emergency since there is no subject matter requirement. The second, and more pertinent, issue is whether Thailand's issuance of the licenses was consistent with the prior negotiation requirement. There is actually a factual dispute

74 *See, e.g.*, Draft Ministerial Declaration (2001).
75 Kazmin Jack (2006: 9).
76 TRIPS, art. 31(b).
77 Ibid.

concerning whether Thailand did in fact conduct prior negotiations. If Thailand did so, then there is no need to consider whether its actions fell within one of the three permissible waivers of the negotiation requirement. However, given that this requirement has engendered so much confusion, further analysis is needed to better understand the requirement.

Assuming that there were no prior negotiations between Thailand and the patent owners, could Thailand qualify for a waiver of negotiation for its compulsory licenses? The actual licenses each stated that they were issued based upon public non-commercial use, which is one of the three situations that permits waiver of prior negotiations. However, to distinguish the differences amongst the waiver situations, this section will analyze not only whether public non-commercial use was proper (as well as what it means), but also whether Thailand could have avoided negotiation based upon the national emergency condition. The licenses can be analyzed as two separate groups – the licenses for antiretrovirals versus licenses on Plavix, a heart drug medication. The national emergency exception to prior negotiation is discussed first, followed by public non-commercial use.

NATIONAL EMERGENCY The first question is whether any of the licenses could have been issued based upon a national emergency. There should be no serious question regarding the two patented antiretrovirals since there is global recognition that AIDS can be a national emergency. WTO member countries specifically included AIDS as an example of what would constitute a permissible national emergency or situation of extreme urgency under the unanimously agreed Doha Public Health Declaration in 2001.[78] However, some controversy erupted over whether the Plavix license reflected Thailand's belief that there was a national emergency concerning heart disease.[79] Thailand never asserted such a belief and the controversy seemed to surround a misunderstanding concerning another basis upon which prior negotiation may be waived; namely, whether there was a public non-commercial use. Indeed, the next section explicitly considers whether Thailand's license of Plavix constitutes a public non-commercial use, such that prior negotiation with the patent owner was unnecessary under TRIPS. Although there has thus

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78 Doha Public Health Declaration, para. 5 (c).

79 *See, e.g.*, Gerhardsen (Feb. 16, 2007), (noting that Sanofi-Aventis was surprised by the Plavix compulsory license since lack of access would not constitute an 'extreme emergency'); *Bangkok's Drug War goes Global* (Mar. 7, 2007) (noting that 'heart disease isn't a "national emergency"'); Cass (Mar. 13, 2007) (suggesting that if treatment for heart disease is considered a national emergency, Thailand not only starts down a 'slippery slope', but also sets a 'dangerous precedent' for TRIPS that threatens 'all intellectual property').

far been less news concerning reports of licenses of anti-cancer drugs, perhaps in light of current Thai reconsideration of such licenses, the analysis for such licenses would be the same.

PUBLIC NON-COMMERCIAL USE According to customary principles of international law for interpreting treaties, such as TRIPS, the ordinary and customary meaning of terms should be used. Only if the terms are ambiguous should supplementary text, such as prior drafts, be used. In addition, although supplementary texts may be used to confirm a meaning, prior history is fairly minimal in this case such that this is not much of an issue.

What is the plain meaning of 'public non-commercial use'? The term is not defined in TRIPS or the Doha Public Health Declaration. The lack of direct guidance in the Declaration concerning the scope of public non-commercial use simply means that the text of TRIPS – albeit limited – is the primary focus for analysis, together with any ordinary and customary meaning.

So, the question remains, what is the ordinary and customary meaning of 'public non-commercial use'? Many sources concerning TRIPS give scant attention to the scope of this definition.[80] However, the ones that do suggest that the term could be broadly interpreted. One resource book on TRIPS suggests that 'public' may broadly refer to either use by the government, or use that is for the public benefit.[81] However, what constitutes 'non-commercial use'? Can use by a private company ever constitute non-commercial use, even if it is for public benefit? Some have suggested that a commercial enterprise could qualify if the licensed product is sold without a profit, such that it is not functioning as a typical commercial enterprise.[82] This interpretation is also reinforced by the fact that the term was intended – at least by U.S. negotiators – to allow the U.S. to continue to grant government contractors the ability to use patented technology.[83] During the negotiation of TRIPS, the U.S. stated that this ability was not limited to inventions relating to national security, but could include any patented invention, even though it has most often been used

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[80] For example, the Gervais book on TRIPS generally provides detailed analyses of provisions, but does not attempt to define public non-commercial use. Rather, its 'comment' concerning this term only addresses the fact that the right holder must be notified if it has reason to know that the technology is patented. *See* Gervais (2003: 251).

[81] UNCTAD-ICTSD (2005: 471).

[82] Watal (2001: 328); UCTAD-ICTSD (2005: 471). Moreover, one resource book goes so far as to say that the phrase is a 'flexible concept, leaving governments with considerable flexibility in granting compulsory licenses without requiring commercial negotiations in advance' UNCTAD-ICTSD (2005: 471).

[83] One commentator suggests that the phrase 'public non-commercial use' was coined to encompass the type of use that is permitted by the U.S. under section 1498. *See* Gorlin (1999: 34).

for things such as creating planes and missiles.[84] In addition, during the brief anthrax scare, the U.S. contemplated a compulsory license under the same provision to enable a company to produce greater quantities of the antibiotic ciprofloxacin to ensure an adequate supply. Moreover, permitting a broader interpretation of public non-commercial use could be consistent with reading article 31 in light of the objectives and principles of TRIPS, as required pursuant to the Doha Public Health Declaration. In particular, article 7 provides that 'intellectual property rights should contribute to . . . dissemination of technology, to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare'.[85] In the case of Thailand, the third party would be making low-cost quantities of HIV drugs to ensure that Thai citizens have access to essential medicines as required by law.

Based upon the above discussion, another examination of some of the criticisms of the Thai license on Plavix suggests that the criticisms are not well-founded under TRIPS. For example, some have suggested that the Plavix license was suspect because it was issued by a military-based government to a for-profit entity.[86] TRIPS expressly permits the government to authorize a third party to use a compulsory license. Moreover, the fact that the authorized party is a for-profit entity would not necessarily preclude its licensed use from qualifying as public non-commercial use if done for the benefit of the public. So, what about the fact that the license is from a military-based government? Is the political leaning of a government an issue under TRIPS? There is nothing under the terms of TRIPS article 31 about the type of government entitled to use a compulsory license, let alone any suggestion that use of licenses by a military-based government should be subject to increased scrutiny. In fact, other provisions of article 31 suggest that discretion is given to the national authority – without regard to how it is organized. For example, the decision of what constitutes permissible subject matter is one that is within the province of the national government.

COMPULSORY LICENSES UNDER TRIPS AS A NON-EXISTENT OPTION Although the above discussion shows that Thailand's licenses should be permissible under TRIPS, there are other important factors that may impact whether Thailand

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[84] United States Review of Legislation in the Fields of Patents, WTO, IP/.Q3/USA/1 (May 1, 1998), at 12 (denying that 1498 was limited to activities within the national security sector and claiming that any 'non-commercial use by or for the government' would qualify).

[85] TRIPS, art. 7.

[86] *See, e.g., Lonely Thailand*, May 23, 2007 (suggesting that Thailand was 'exploiting vague language' in the context of suggesting that use by a military-based government can not constitute public-non-commercial use).

continues its licenses, as well as whether other countries will follow suit. In particular, despite the fact that Thailand took the unprecedented step of issuing a ninety-page document to explain the TRIPS-consistency of its licenses for antiretrovirals, as well as Plavix, controversy has not abated.[87]

NO NEW DRUGS Patent owner Abbott announced that it was withdrawing registration of half a dozen new drugs in Thailand even after Thailand issued its explanatory report.[88] Despite widespread condemnation of and protests against Abbott's actions by patient rights groups and doctors, Abbott thus far has not backed down from its decision to blacklist Thailand, although it did capitulate after public pressure to register the HIV drug Alluvia.[89]

Abbott's actions underscore that issuing a TRIPS-complaint compulsory license may have the unintended effect of *worsening* overall access to medicine. Abbott's decision not to register certain drugs is not governed by TRIPS because TRIPS only governs whether a certain country provides patent rights. It does not govern whether drug manufacturers must seek patent rights or registration of patented drugs.[90] Nonetheless, if countries are practically precluded from using the 'flexibility' under TRIPS for fear of retaliation beyond the scope of TRIPS, such flexibility is essentially non-existent. After all, what good is a compulsory license of one drug for a relatively small population of 50,000, if it results in seven other drugs not being available for any citizens?

Although Abbott is the only patent owner of the three owners of licensed patents to have taken retaliatory action, the unexpected and drastic measure of removing additional drugs from the Thai market may make Thailand as well as other countries wary of exercising their right to authorize compulsory licenses in the future. The fact that retaliation through removal of drugs from the registration process is not governed by TRIPS or any other international agreement means that a country such as Thailand is without any international legal recourse to challenge Abbott's actions.

US RETALIATION In addition to suffering retaliation from Abbott, Thailand may also suffer broader economic losses as a result of its compulsory licenses.

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87 Ten Burning Issues (Feb. 2007).

88 *See, e.g.*, Gerhardsen (Mar. 3, 2007); Hookway and Zamiska (2007).

89 Abbott's decision was not a positive one for public relations as it resulted in worldwide protests, as well as protests at the annual shareholder meeting. *See, e.g.*, Jaspen (2007).

90 If a company does seek to sell a drug, TRIPS does require that the information submitted to the regulatory agency be protected from unfair competition under article 39. However, there is nothing under TRIPS that mandates a company to submit such information in the first instance.

In particular, the most recent Special 301 Report issued by the U.S. Trade Representatives Office lists Thailand as a priority watch country.[91] The listing is the first step towards possible economic sanctions unilaterally determined and imposed by the United States.

In addition, the listing of Thailand as a priority watch country emphasizes that TRIPS compliance does not provide a country with immunity from sanction under the U.S. Trade Act. Technically, the U.S. could list any country that it believes is in violation of an international trade agreement, such as TRIPS. However, the fact that the recent report failed to note any specific provision of TRIPS that Thailand has violated suggests that there is no provision at issue. Rather, the report noted the licenses as cause for 'serious concern' and as 'indications of a weakening respect of patents'.[92] While this may seem odd, the U.S. trade laws behind the Special 301 priority list do not require any actual violation of international laws.[93] Rather, the U.S. may initiate proceedings against any 'unjustifiable' act of a foreign government that 'burdens or restricts' U.S. commerce.[94] Failure of other countries to provide desired IP laws has been deemed to suffice. The U.S. has previously used this procedure to force other countries to agree to standards beyond those required by TRIPS. Although Special 301 may not be compliant with the WTO and has in fact been previously subject to a review under the WTO, the U.S. has not shied away from using this trade act.[95]

2.2.4 Issues on the horizon The current challenges to balancing public health interests against patent rights required under TRIPS are likely only to become more severe. In particular, as the scope of WTO member countries continues to increase, there are fewer places for nations to find low-cost

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[91] Office of the USTR (2007). This report is an annual report by the United States Trade Representatives office concerning global intellectual property issues that is conducted pursuant to section 301 of the U.S. Trade Act of 1974. The report not only describes perceived deficiencies in the protection or enforcement of intellectual property, but also designates different priority status to countries. A country designated as a priority watch is given heightened attention over one that is merely listed as a watch country.

[92] Office of the USTR (2007: 12). The same document claims that the United States 'is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow countries . . . to address the serious public health problems that they face'.

[93] *See* 19 U.S.C. § 2411(a)(1). Although violation of U.S. rights under trade agreements may be grounds for retaliation under special 301, those are not the only grounds.

[94] 19 U.S.C. § 2411(a)(1)(B)(ii).

[95] Appellate Body Report, *United States Sections 301–310 of the Trade Act of 1974*, WT/DS152/R, art. 23 (Dec. 22, 1999).

generic drugs. The changing landscape of full patent protection of TRIPS will be a particular concern to the global AIDS crisis in developing countries. While some countries such as Brazil have been able to make substantial inroads in treating HIV through low-cost generic medicines, many HIV patients are now becoming resistant to 'first-line' HIV treatments and need access to newer, and likely patented drugs. The 'second-line' treatments used to treat drug-resistant AIDS patients can cost from seven to twenty-eight times the price of the unpatented generics on an annual basis.[96] To the extent that such drugs are patented and countries prohibited from using compulsory licenses – either because of narrow interpretations of TRIPS, or because of challenges beyond TRIPS, there could be a serious public health crisis.

The ability of India to continue to make generic drugs is of particular concern. Presently, India provides the majority of generic HIV medications, but its ability to continue to do so is unclear. India actually has several provisions under its current patent law that soften its transition to providing patents on products, as opposed to solely processes of making drugs. First, as previously discussed, some generic manufacturers can continue to make generic versions of drugs that they were making prior to 2005 subject to a compulsory license if they have made a 'substantial investment' *and* if the Indian law permitting them to do so remains unchallenged by a WTO panel. Perhaps of greater importance for new drugs subject to patent applications after 2005 is the long-term status of section 3(d) of India's patent law that currently prohibits patents on slight variations of prior patented compounds unless they show improved efficacy. The *Novartis* decision allows this provision to remain in effect, but given the significance of this law to patent owners, it will likely be subject to future challenges. While the law remains effective, the Indian patent office has a powerful weapon to deny patents on variations of old HIV compounds that do not show increased efficacy, which can then enable the Indian generics drug industry to continue to be a major supplier for developing countries worldwide.[97]

Moreover, for developing countries that do not have the ability to manufacture lower-cost drugs, even if they could issue a compulsory license, the issue is of particular concern. While there is technically a 'solution' under TRIPS to enable such countries to import patented drugs from a different country, the solution involves complex procedures that make the normal

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[96] Médicins Sans Frontières (2005).

[97] For example, prior to the *Novartis* court ruling, MSF suggested that if Novartis succeeded, Abbot's request to patent new forms of lopinavir and ritonavir would similarly be entitled to patents and thereby negatively impact access to medicine. *See* Médecins Sans Frontières (2006).

requirements for compulsory licenses pale by comparison.[98] In the four years since this option has been available, only two developing countries, Rwanda and Nepal, have attempted to use this option, with the results still unclear.[99]

PARALLEL IMPORTS Controversy may also move away from compulsory licensing and towards discussion of whether to permit parallel imports. This is sometimes also referred to as a question of whether to recognize international exhaustion of patent rights. TRIPS does not explicitly state whether a nation must also exclude others from importing the patented invention *if it has been previously sold under patent in a different country*. Rather, TRIPS simply states that parallel imports shall not be the subject of dispute settlement proceedings under TRIPS.[100] In addition, the Doha Public Health Declaration technically affirms the right of each country to use this principle; in particular, it states that TRIPS is intended to 'leave each Member free to establish its own regime for such exhaustion without challenge'.[101] However, since other affirmed 'rights' under the Doha Public Health declaration have been challenged, such as the right of each nation to determine what subject matter is appropriate for compulsory licensing, this right may be as well.

The controversy focuses on whether a country may preclude importation of patented products that were previously sold in a different country subject to patent rights. If a country recognizes international exhaustion of patent rights that means that it considers a patent owner's rights in a patented product to be 'exhausted' by the first sale of the product anywhere in the world. For example, if a patented product was first sold in Canada, the patent owner could not then try to claim that its importation right in India was infringed if India recognized international exhaustion. On the other hand, for a country that does not recognize international exhaustion, such as the United States, the fact that a patented product was subject to an authorized sale in Canada would not bar the patent owner from also exercising its rights at the border of the United States to prevent importation.

Permitting parallel imports is touted as consumer-friendly since it enables drugs to be sold at a lower price in the second country. Pharmaceutical companies, on the other hand, assert that parallel imports are dangerous since counterfeiting might be involved. Moreover, even if the parallel imports are from a legitimate source, such companies also object to exhaustion of patent rights

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98 WTO General Council Decision of Aug. 30 2003.

99 Gerhardson, July 20, 2007; MacInnis (2007); Anderson, Feb. 20, 2008; Allen, Feb. 27, 2008.

100 TRIPS, art. 6.

101 Doha Public Health Declaration, ¶ 5(d).

since their current business model relies on price discrimination amongst different markets. If consumers are free to buy the cheapest product that is globally available, the differing national prices set by drug companies become irrelevant.

The utility of parallel imports may be diminished in a world where most countries provide patent protection, but it would not be entirely eliminated. In particular, even if patent protection existed in all countries, that does not mean that drug costs would be uniform. Indeed, even among developed countries that currently provide patent protection, there is a great differential in prices. This is largely a function of whether national governments demand lower prices for drugs. But, regardless of the reason, to the extent that there is any differential, there still remains some utility to parallel imports. However, given the controversy of this topic at TRIPS, continued controversy is likely if countries attempt to use this option more aggressively.

3 Beyond TRIPS

3.1 TRIPS-plus agreements

The most significant development in the decade since TRIPS was signed is the proliferation of 'TRIPS-plus' agreements that require member countries to embrace standards of intellectual property that go beyond TRIPS. In general, these are bilateral or regional free trade agreements (FTAs) negotiated between a major industrialized country (such as the U.S. or Canada) and a developing country.[102] As with the WTO Agreement, these subsequent agreements involve countries agreeing to higher intellectual property standards as part of a bargain for increased market access. This part highlights some typical requirements of FTAs regarding patentability, patent rights, and data protection.[103]

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[102] To a lesser extent, there are also bilateral investment agreements that require intellectual property standards or condition trade benefits on the level of intellectual property rights in force. *E.g.*, Andean Trade Preference Act, 19 U.S.C. § 3202(d)(9) (2000); Caribbean Basin Economic Recovery Act, 19 U.S.C. § 2702(c)(9). In addition, a committee under the auspices of WIPO is negotiating a draft treaty on standards of patentability, the Substantive Patent Law Treaty ('SPLT'). WIPO (2003); GRAIN (2002: 3) (noting that if successful, the SPLT 'could make . . . TRIPS . . . obsolete' to the extent that TRIPS only provides the minimum, whereas the SPLT 'will spell out the top and the bottom line'). However, discussions have largely stalled on that agreement. *E.g.*, WIPO (2004: ¶ 7).

[103] *See, e.g.*, Free Trade Agreement, art. 17.9; Chile FTA, art. 15.9; U.S.–Morocco. In addition, some agreements do not set specific requirements, but rather mandate adoption of the 'highest international standards' of intellectual property rights. *See, e.g.*, Euro-Mediterranean Agreement, art. 39; Eur. Cmty.–S. Afr., art. 46, Oct.

PATENTABILITY Whereas TRIPS allowed countries some flexibility in defining the terms of patentability to meet their individual needs, subsequent FTAs further infringe on that limited flexibility. For example, whereas TRIPS allows countries to define what constitutes 'new' and 'patentable', some TRIPS-plus agreements explicitly limit national discretion to define these terms. Some agreements specify that a new use of a previously known compound is *per se* patentable subject matter, thereby nullifying prior flexibility under TRIPS.[104] In addition, some agreements provide that an invention may be considered novel even if it was publicly disclosed prior to the patent application by the inventor.[105] While this is consistent with United States law, it is a more permissive standard, resulting in more patents – which could negatively impact public health – than what TRIPS requires.[106]

National ability to assess patentability is also limited in some FTAs through provisions that limit the ability for thorough review of patent applications. In particular, some FTAs specifically restrict countries from permitting third parties to oppose the issuance of patents until after the patent is granted.[107] In contrast, TRIPS only dictates that enforcement provisions exist for granted patents. Since India is not a signatory to any FTA, India is able to permit third parties to bolster the patent review process by filing oppositions both prior to patent issuance as well as after patent issuance. The pre-grant oppositions seem to be particularly important; indeed, the denial of an India Glivec patent seems to have been prompted by a pre-grant opposition filed by the Cancer Patient Aid Association of India.[108]

PATENT TERM The patent term in many TRIPS-plus agreements goes beyond the TRIPS requirement that the term not end before twenty years from the date

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104 *See, e.g.*, U.S.–Oman (2006), art. 15.8(1)(b) (stating that the agreement 'confirms that . . . patents [are] available for . . . known product[s] . . . for the treatment of particular medical conditions'); U.S.–Korea FTA, art. 18.8,], (stating that the 'Parties confirm that patents shall be available for any new uses or methods of using a known product').

105 *See, e.g.*, United States–Panama Trade Promotion Agreement, art. 15.9(7) (noting that public disclosures by the inventor within one year of application shall not be considered in assessing whether the invention is novel or has inventive step); U.S.–Korea FTA, art. 18.8(7) (noting that public disclosures 'made or authorized by, or derived from, the patent applicant' within one year of the patent application shall be disregarded in assessing novelty and inventive step).

106 *See* 35 USC 102(b) (providing a grace period for disclosures that exist one year prior to the patent application).

107 *See, e.g.*, US–Korea FTA, art. 18.8(4) (noting that if opposition proceedings are provided to third parties, 'a party shall not make such proceedings available before the grant of the patent').

108 *See, e.g.* MSF (2006).

of application. In particular, many agreements allow for extension of the patent term if there are 'unreasonable delays' in the patent examination.[109] 'Unreasonable delays' may be as few as four years from the date of filing or two years from the request for examination.[110] Some agreements also allow for a further extension of a patent term for activity that occurs outside the patent office. For example, some require an extension of the patent term if marketing approval for sale of a patented drug results in 'unreasonable curtailment' of the effective patent term.[111] The rationale for extending the patent term of such patented drugs is that marketing approval is based upon clinical data that often do not exist at the time of the patent application, such that marketing approval is often not granted until after patent issuance; because the patented drug can not be sold without marketing approval, the *effective* patent term may be shortened.[112] The required patent term extensions under TRIPS-plus agreements for marketing approval delays essentially provide protection to pharmaceutical patent owners that the WTO panel considered beyond the scope of patent rights in the *Canada – Patent Protection of Pharmaceutical Products* decision. Although that decision focused on whether generic manufacturers were liable for making the patented invention during the patent term for regulatory approval, in the course of addressing this ultimate issue, the panel found that there was no 'legitimate interest' for pharmaceutical patent owners to maintain an effective patent term equivalent to that of patent owners who did not need regulatory approval to make use of their inventions.[113] However, for countries that are members of TRIPS-plus agreements, this panel finding is *de facto* inapplicable.

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[109] *See, e.g.*, US–Oman FTA, art. 15.8(6)(a); Trade Promotion Agreement, U.S.–Peru (2006), art. 16.9(6)(a); US–Australia FTA, art. 17.9(8)(a); US–Korea FTA, art. 18.8(6)(a) (defining 'unreasonable delay' as including a period of more than four years from the date of filing of an application).

[110] *See, e.g.*, Peru TPA, art. 16.9(6)(a). Alternatively, others define unreasonable delay as four years from filing or two years from a request for examination, whichever is later. *See, e.g.*, Australia FTA, art. 17.9(8)(a); Oman FTA, art. 15.8(6)(a).

[111] *See, e.g.*, Free Trade Agreement, U.S.–Singapore (2003), art. 16.8(4)(a); US–Chile FTA, art. 17.10(2)(a); CAFTA, art. 15.9(6)(b); Korea FTA, art. 18.8(6)(b). Similarly, where countries allow marketing approval based upon approval in another country, a patent term extension may be required in some cases based upon a delay in that other country's approval process. *See, e.g.*, US–Singapore (2003) FTA, art. 16.7(8).

[112] *See, e.g.*, Cong. Budget Office (1998: ch. 4) (noting that the average 'effective' patent term is about eleven to twelve years).

[113] The panel noted that '[o]n balance . . . the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized *that it could be regarded as a "legitimate interest" within the meaning of Article 30*'. WTO Report, *Canada Generics*, para. 7.82 (emphasis added).

LIMITED COMPULSORY LICENSING FTAs also limit compulsory licensing beyond TRIPS. Whereas TRIPS does not specify the grounds under which compulsory licensing may be permitted, and the Doha Public Health Declaration purports to leave this matter within the discretion of national authorities, currently negotiated TRIPS-plus agreements limit circumstances under which developing nations may issue compulsory licenses authorizing generic manufacturers to produce lower cost versions of patented drugs.[114] The Singapore agreement, for example, limits compulsory licensing to remedying anti-competitive behavior, public non-commercial use, and national emergencies.[115] Moreover, some FTAs entirely omit any provision that is analogous to the compulsory licensing provision of TRIPS article 31; rather, the only exception to patent rights is a provision similar to TRIPS article 30, which only provides 'limited exception' from patent rights.[116]

Even for FTAs that do not have provisions explicitly governing compulsory licensing, other provisions may impede use of patented inventions. In particular, compulsory licensing may be a non-issue if a generic drug company cannot obtain the regulatory approval necessary to sell a drug because of rules that prevent the generic company from relying on the data of the patent owner. Although TRIPS does provide protection for information submitted by a patent owner to government agencies for regulatory approval, it is only against 'unfair commercial use'.[117]

In subsequent agreements, the scope of protection for data is more explicit and expansive. Whereas TRIPS does not provide any timing requirements, most subsequent agreements mandate that no one other than the originator of the information can use it for five to ten years.[118] During this time, the patent

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[114] In particular, the agreement stated that '[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted', Doha Public Health Declaration, para. 5(b).

[115] Singapore FTA, art. 16.7(6)(a) (anticompetitive practices); Singapore FTA, 16.7(6)(b) (public non-commercial use or national emergencies).

[116] *See, e.g.*, Korea FTA, art. 18.8(3), Panama TPA, art. 15.9(3) *and* Columbia FTA art. 16.9(3) (providing for 'limited exceptions' to the patent rights in a manner similar to TRIPS article 30, but without any mention of other uses similar to TRIPS article 31).

[117] TRIPS, art. 39(3).

[118] *See, e.g.*, North American Free Trade Agreement (1992), art. 1711(6) (requiring member states to provide protection to test data for a 'reasonable' time, which is explicitly defined as lasting at least five years); Chile FTA, art. 17.10(1) (requiring five years of data protection for pharmaceutical products that use a 'new chemical entity'); Singapore FTA, art. 16.8(2) (requiring five years of protection for test data of pharmaceutical products – a category perceived as broader than new chemical entities); CAFTA, art. 15(10) (providing five years of protection for pharmaceutical products); FTAA, ch. XX, subsec. B.2.j, art. 1.2 (providing for at least five years of non-reliance

owner *de facto* becomes the only possible manufacturer and seller of patented drugs, with the concomitant result of higher priced drugs to consumers. In addition, the period of *de facto* monopoly to the patent owner may be increasing. For example, in one of the most recent agreements, Russia appears to have agreed to protect undisclosed test data for at least six years. This agreement also suggests that the data are barred from public non-commercial use, although TRIPS explicitly requires only that such information be protected against unfair *commercial* use.[119]

While large pharmaceutical companies allege that data protection is necessary to recoup the investment in creating the clinical data they submit, the data protection necessarily delays the availability of generic drugs if manufacturers of generic drugs are not permitted to rely on similar data.[120] The patent owner and originator of the data suggest that generic manufacturers are not impeded since they could create their own clinical data. However, generic manufacturers typically operate on slim profit margins since they do not own patents, but rather, they manufacture and sell off-patent drugs in open competition with other generic companies, as well as the patent owner. From a public health perspective, permitting a second company to rely on existing clinical data on efficacy, rather than forcing the second company to generate its own expensive data would enable a generic manufacturer to enter a market and provide lower cost drugs to consumers.[121]

Some FTAs entitle the patent owner to a commercial monopoly if the patent term expires before the period of data protection.[122] In addition, other FTA provisions delay the approval of generic drugs by precluding reliance on information submitted for marketing approval during the term of the patent.[123]

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on test data for marketing approval); Oman FTA, art. 15.9(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Peru TPA, art. 16.10(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Australia FTA, art. 17.10 (providing at least five years for new pharmaceutical products and ten years for agricultural chemical products).

[119] *See, e.g.*, Office of the U.S. Trade Representative (Nov. 19, 2006); *Russian Accession: New Potential Hurdle with EU* (2006).

[120] This is particularly significant given that developing and marketing a new drug costs an average of 800 million dollars and takes ten to fifteen years to complete. *See* INT'L FED'N PHARM. MFRS. & ASS'NS (2005).

[121] In addition, it may be arguably unethical to even require patients to undergo duplicative tests where scientific protocol would require some patients be precluded from obtaining known therapeutic treatment if they were in a 'control' group.

[122] *See, e.g.*, Korea FTA, art. 18.9(3); Columbia FTA, art. 16.10(2).

[123] *See, e.g.*, Peru FTA, art. 16.10.3(a); Columbia FTA, art. 16.9.6; Panama FTA, art. 15.9.6.

NO PARALLEL IMPORTS In addition to limiting compulsory licensing, some countries have utilized TRIPS-plus agreements to obtain a clear bar against use of parallel imports. Some of these agreements prohibit developing countries from importing patented drugs from countries that sell them at the lowest price; that is, they prohibit parallel importation and reject the principle of international exhaustion. For example, the U.S.–Singapore and U.S.–Morocco Free Trade Agreements limit parallel importation by requiring member countries to provide patent holders with the means to block importation of patented drugs if it violates a distribution agreement.[124]

3.2 Counter-movements

Although FTAs continue to be negotiated, there are some signs that the tide is turning, or that there are at least alternative approaches being discussed and proposed. This section highlights some of these alternative approaches. In particular, shifting public support and scrutiny of FTAs are discussed. In addition, contrary paradigm proposals to TRIPS-plus agreements are also highlighted. Although the competing paradigms are a long-shot for adoption in their current form, discussion and consideration of these approaches may help to shift the focus away from ever-increasing rights for owners of intellectual property.

FTA – SHIFTING TIDE One remarkable shift is that the breadth of some previously negotiated FTAs may actually be limited. For example, the United States Trade Representatives announced new trade rules for FTAs with developing countries that aim to strike a better balance between promoting innovation and public health rights.[125] Although the actual language of the FTAs remains to be both crafted and approved by Congress (as well as the other countries), Congress did provide a bilateral agreement of principles, including the fact that the 'side letter' currently included as part of the noted FTAs

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[124] Singapore FTA, art. 16.7(2)–(3); Morocco FTA, art. 15.9(4); *see also* FTAA, ch. XX, subsec. B.2.e, art. 7.1 (technically permitting parallel imports, but requiring members to review their domestic laws 'with a view to adopting at least the principle of regional exhaustion' within five years).

[125] Letter to Susan Schwab from Charles Rangel and Sander Levin, May 10, 2007. The new rules are to apply to pending agreements with Peru and Panama; but not to Korea and Russia. Office of the United States Trade Representative (May 2007) (noting that modified provisions relating to medicines and health only apply to 'developing country partners'). In addition, the pending agreement with Colombia may ultimately join Peru and Panama, but is currently stalled because of violence against trade unionists. *See* Letter to Susan Schwab from Charles Rangel and Sander Levin, May 10, 2007.

should be made a part of the text of the FTA.[126] In addition, the EU Parliament separately adopted a resolution that called on the EU Council to prevent negotiations of drug-related TRIPS-plus provisions that impact public health and access to medicines, with specific reference to data exclusivity, patent extensions and limits on grounds of compulsory licenses.[127]

ACCESS TO KNOWLEDGE – PROPOSED TREATY There is a separate movement to promote a treaty that embodies a norm contrary to the one in TRIPS. In particular, there is a proposed Treaty on Access to Knowledge ('A2K') that aims to ensure a true balance between intellectual property owners and users; A2K has been subject to continued discussion since it was first proposed in 2005.[128] While TRIPS has language concerning balance, the interpretation of TRIPS thus far tilts predominantly in favor of rights holders. The A2K framework, on the other hand, utilizes a minimum standards framework, but for a contrary purpose to TRIPS. Whereas TRIPS requires all members to adopt certain minimum levels of protection, A2K suggests all members adopt certain minimum standards of *access*.[129]

A2K directly challenges the scope of patentable subject matter as well as patent rights under TRIPS. For example, A2K suggests excluding higher life forms from patentability.[130] This is in direct contravention to TRIPS article 27(3)(b) as well as the law of many industrialized countries that require higher life forms to be patented. With respect to patent rights, A2K suggests a safe harbor from infringement for improvement inventions, as well as 'compas-

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[126] The document states that parties '(1) would affirm their commitment to the Doha Declaration, (2) clarify that the Chapter does not and should not prevent the Parties from taking measures to protect public health or from utilizing the TRIPS/health solution, and (3) include an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation'. Peru & Panama FTA Changes, at 8 (May 10, 2007: 8).

[127] European Parliament Resolution of 12 July 2007 on the TRIPs Agreement and Access to Medicine, para. 11.

[128] For example, Yale Law School has hosted two major conferences on A2K that brought together academics as well as activists. *See* Yale Access to Knowledge Conference, http://research.yale.edu/isp/eventsa2k.html (last visited Feb. 16, 2007). Additional information about the substance of the conference and subsequent discussions is available on a wiki at http://research.yale.edu/isp/a2k/wiki/index.php/Yale_A2K_Conference (last visited February 16, 2007).

[129] Draft Treaty on Access to Knowledge (2005), arts 1–2. On the patent dimension, A2K echoes the Doha Public Health Declaration by reinforcing that TRIPS does not and should not prevent member states from adopting measures to protect public health. *See also* Draft Treaty on Access to Knowledge, arts. 1–3(c).

[130] Draft Treaty on Access to Knowledge, art. 4-1(a)(viii).

sionate use' of medicine and medical technology.[131] Although the phrase 'compassionate use' may lead to a quagmire of interpretive problems, the suggestion that patents be used for promoting public health is important and a novel suggestion in the international framework. Indeed, domestic laws may allow far less than compassionate use. For example, in the United States there is no statutory safe harbor, and common law exclusions for experimental use have been narrowly interpreted.[132]

Specific suggestions on how to balance health issues with patent rights were also embraced in a draft text for a 'Paris Accord', discussed at a meeting of the Transatlantic Consumer Dialogue ('TACD') in June 2006.[133] The goal of the Accord echoes that of A2K in aiming to provide a balanced approach. In particular, it declares that 'science depends upon access to knowledge' and that intellectual property rules 'should not prevent experimental use'.[134] In addition, it sets forth specific proposals that stand in contravention of most TRIPS-plus rules regarding data exclusivity. The proposal suggests that 'methods of protecting investments in clinical trials for new medicines should not prevent governments from making medicines available at affordable prices or require unethical or unnecessary replication of human experiments'.[135] In other words, rules providing data exclusivity that are premised on the necessity to protect financial investment in clinical trials should not function in a way that would interfere with public access to medicine. The more difficult question is how to *achieve* this goal – especially in light of TRIPS-plus agreements that may already interfere with public health. In addition to supporting A2K goals, the draft text also supports a global agreement to better support financing of drug research[136] and specifically rejects the traditional business

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131 Draft Treaty on Access to Knowledge, art. 4-1(b)(ii), (iv).

132 *E.g. Madey v. Duke Univ.*, 307 F.3d 1351, 1360–62 (Fed. Cir. 2002). *But see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (providing a slightly expanded interpretation of a limited statutory provision exempting certain activity from the scope of infringement). The lack of exceptions to patent infringement has been repeatedly noted as a problem, but despite repeated discussion of the issue, there has been no change thus far to the patent laws. *See generally*, Eisenberg (1989: 1017); O'Rourke (2000: 1177).

133 Draft Paris Accord, June 17, 2006. The TACD is comprised of over sixty U.S. and EU consumer organizations that aim to propose joint recommendations to their respective governments. *See* TACD, About TACD, http://www.tacd.org/about/about.htm (last visited February 16, 2007).

134 Draft Paris Accord, 2.

135 Ibid.

136 Ibid. (noting that '[g]overnments must support global agreements to share in the costs of evaluating new medicines').

model of multinational pharmaceutical companies that uses high drug prices to finance research.[137]

Most recently, some A2K goals entered mainstream political discussions within the World Intellectual Property Organization (WIPO). In particular, WIPO members agreed to 'initiate discussions on how, within WIPO's mandate, to further facilitate access to knowledge and technology for developing countries and LDCs'.[138] In addition, the member states agreed that WIPO should 'promote norm-setting activities related to IP that support a robust public domain'.[139] While the WIPO discussions lack the detail of prior proposals of A2K, the inclusion of A2K principles is nonetheless noteworthy and seen as a major step forward.[140] Although the WIPO general assembly must still approve the report, the consensus is considered a major achievement; one report suggested that the discussion 'potentially rewrote the UN Body's mandate'.[141]

RESEARCH AND DEVELOPMENT – PROPOSED TREATY Beyond the aspirational goals embodied in A2K-type proposals, there are additional proposals to radically modify current systems in order to achieve a better balance between patents and public health. These proposals involve both systems for promoting health research and systems to address intellectual property barriers. For example, some have suggested global research and development treaties that would ask countries to adopt a variety of different mechanisms to support all diseases, rather than those deemed most profitable by pharmaceutical companies.[142] Some proposals suggest that countries should provide differing amounts of support for research based upon their national income levels. Others suggest giving trade credits to countries that foster projects promoting social or public interest objectives. One of the boldest suggestions for addressing the TRIPS-plus movement lies in the Medical Research and Development Treaty Proposal of 2005, which suggests that countries not only develop alternative means for supporting research, but also forego dispute resolution and trade sanctions under various trade agreements. Rather, countries would utilize the treaty framework to support innovation.[143]

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137 Ibid. (suggesting that 'when possible and appropriate' the current system of stimulating research and development through high prices 'should be replaced with new systems that reward developers . . . for improved health care outcomes').

138 *See, e.g.*, Gerhardsen, June 14, 2007.

139 Ibid.

140 *See WIPO Members Agree on Development Agenda*, June 20, 2007.

141 New, June 18, 2007.

142 *See, e.g.*, Hubbard and Love (2004).

143 Medical Research and Development Draft Treaty (2005: art. 2.3).

An interesting recent development is the resolution by the World Health Organization to take a greater role in promoting development of research and access to drugs. At the annual WHO summit, member states adopted a resolution that not only encouraged the organization to provide support to countries that 'intend to make use of the flexibilities' in TRIPS, but also to 'encourage the development of proposals for health-needs driven research and development' that would include a range of incentive mechanisms.[144] The resolution is particularly noteworthy since just one month previously, members were divided with respect to the WHO's appropriate role both with respect to TRIPS, as well as with respect to proposals to foster research and development.[145]

4 Conclusion

The final chapter of how patents and public health are balanced is still not written. However, this chapter hopefully at least provides an outline of current issues that are important to understanding the current framework, as well as possible competing frameworks. While the trend towards TRIPS-plus agreements and aggressive enforcement of patent rights may be troubling, the bold and creative actions of countries such as India and Thailand in the face of this environment suggest that the battle is far from over. In fact, the idea that a balance is necessary seems to have captured the attention of stakeholders beyond patent owners such that the future may hold a more balanced calibration.

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144 World Health Assembly (2007). Despite the resolution, the U.S. has disassociated itself from the decision. *See WHO Members Adopt Resolution on Pharmaceutical Innovation*, May 23, 2007.

145 *See, e.g., WHO Members Divided over Plan for Promoting Pharmaceutical Innovation*, Apr. 25, 2007 (noting controversy over whether WHO should deal with TRIPS and bilateral trade agreements, as well as controversial funding mechnisms for pharmaceutical innovation).

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25 Biotechnology patent pools and standards setting

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Introduction

Diagnostic genetic tests are increasingly used to identify specific human genetic mutations (for example, in the BRCA-1 human gene) in an attempt to assess the risks of a given disease (for example, breast cancer). There are often multiple mutations correlated with a particular disease; we will refer to such situations as *polymutational correlations*. It often arises that the diagnostic correlations between disease and individual gene mutations in a polymutational test are patented by different patent holders. This may give rise to the phenomenon known as a *patent thicket*, where a potential market entrant needs to seek and obtain licenses, which may not always be available, from the different patent holders in order to broadly test for the disease.[1]

Problems associated with patents on diagnostic genetics

Many diseases can be correlated with a genetic variation such as a nucleotide sequence permutation, known as single nucleotide polymorphism (SNP), within an individual's makeup.[2] The International Haplotype Mapping Project estimates that there are close to ten million commonly occurring SNPs in the human genome.[3] The use of specific SNPs in diagnostics, or of the probes useful for their detection, have been the subject of patents. Thus, to accurately study or test for a particular disease that is correlated to multiple patented SNPs or SNP fragments, it may be necessary to obtain a license from each of several patentees of the multiple SNP-based tests. The transaction costs of investigating and obtaining multiple licenses to multiple mutations, SNPs and diagnostic tests in such a situation can quickly become prohibitively expensive – and has been referred to as a 'nightmare'.[4]

* The author wishes to thank Christine Norris for her able assistance in the preparation of this chapter.

1 J.H. Barton, *Patents, genomics, research and diagnostics*, 77 ACAD. MED. 1339 (2002).

2 International HapMap Project, http://snp.cshl.org/ (last visited June 27, 2007).

3 *Id*.

4 R.F. Service, *DNA analysis: will patent fights hold DNA chips hostage?*, 282 SCI. 397 (1998).

The numbers of genetic tests and laboratories offering them have grown explosively in the last seven years. In late 1999 it was estimated that genetic testing was available for more than 300 diseases or conditions in over 200 US laboratories.[5] By early 2003 there were about 900 available genetic tests in the US,[6] and by mid 2007 the numbers had grown to 622 laboratories doing clinical testing for 1127 diseases.[7] One can quickly see that the problems of thickets arising out of multiple patents on SNPs, for example, will become worse as the technology matures. The problems of patent stacking appear particularly acute in the area of multiplex arrays. This technology provides the ability to simultaneously detect genes or proteins which are expressed in a single tissue at a given point in time. In June 2007, the US Food and Drug Administration (FDA) issued nonbinding recommendations to provide guidance for preparing and reviewing pre-market approval submissions for such multiplex tests.[8] If, for example, an array-manufacturing company like Affymetrix wants to develop a chip using proprietary platform technology (for example, their GeneChip®[9]) in a test for a disease correlated with 20 mutations, Affymetrix or its client diagnostic laboratory may first have to obtain licenses from multiple patentees of one or more of the recommended 20 mutations. These licensing and marketing problems led Affymetrix in 2002 to call for an end to gene patenting.[10]

Additional concerns have been raised about thickets and stacked patents in diagnostic genetics. For example, clinicians and hospitals are said to be inhibited and/or prevented by gene patents from diagnosing their patients with certain diseases. Researchers are said to be hindered in their ability to develop and advance medicine by preventing and/or delaying the identification of new

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[5] Sec'y's Advisory Comm. On Genetic Testing, Nat'l Inst. of Health, A public consultation on oversight of genetic tests: December 1, 1999–January 31, 2000 (1999), available at http://www4.od.nih.gov/oba/sacgt/reports/Public%20Consultation%20Summary.pdf (last visited September 15, 2004).

[6] F. COLLINS, WORLD ECONOMIC FORUM, A BRIEF PRIMER ON GENETIC TESTING (2003), *available at* http://www.genome.gov/page.cfm?pageID=10506784 (last visited June 27, 2007).

[7] *See* http://www.genetests.org/ (last visited June 27, 2007).

[8] CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMIN., US DEP'T OF HEALTH AND HUMAN SERVS, GUIDANCE FOR INDUSTRY AND FDA STAFF – PHARMACOGENETIC TESTS AND GENETIC TESTS FOR HERITABLE MARKERS (June 19, 2007), *available at* http://www.fda.gov/cdrh/oivd/guidance/1549.html (last visited June 27, 2007).

[9] *See*, *e.g.*, http://www.affymetrix.com/products/index.affx (last visited June 27, 2007).

[10] T. ABATE, COUNCIL FOR RESPONSIBLE GENETICS, DO GENE PATENTS WRAP RESEARCH IN RED TAPE? (2002), *available at* http://www.gene-watch.org/programs/patents/red-tape.html (last visited June 27, 2007).

mutations for certain diseases.[11] In turn, several solutions have been proposed to address these concerns, including compulsory licensing[12] or certain US legislative approaches, such as exempting diagnostic testing from patent enforcement[13] or abolishing patents on genetic sequences altogether.[14]

I suggest in this chapter, as I have suggested earlier,[15] that the use of carefully crafted patent pools is reasonably likely to make patents pertaining to the diagnosis of polymutationally correlated diseases available to the industry at reasonable royalties.

Existing patent pools in biomedicine and biotechnology

A *patent pool* is an arrangement in which two or more patent owners agree to license certain of their patents to one another and/or to third parties.[16] Patent pools have been used in a variety of industries from sewing machines and aircraft in the early years to software and consumer electronics products such as DVDs, Blu-Ray discs and high definition DVDs.[17]

Several commentators have recommended patent pools as a solution to general patent thickets in biotechnology.[18] In fact, a number of so-called biotech pools have been established or are in the process of being established. I will demonstrate, however, that none of these established or planned biotech arrangements meets the requirements of a classic patent pool.

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11 *See generally*, D.G.B. Leonard, *Medical practice and gene patents: a personal perspective*, 77 ACAD. MED. 1388 (2002); M.K.Cho et al., *Effects of patents and licensing on the provision of clinical genetic testing services*, 5 J. MOLECULAR DIAGNOSTICS 3 (2003).

12 *See supra* note 1.

13 Genomic Research and Diagnostic Accessibility Act, Office of Legislative Policy and Analysis, H.R. 3967, 107th Cong. (2002), *available at* http://olpa.od.nih.gov/legislation/107/pendinglegislation/9gene.asp (last visited June 27, 2007).

14 Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007), *available at* http://becerra.house.gov/HoR/CA31/Issues/genepatents.htm (last visited June 27, 2007).

15 T. Ebersole et al., *Patent pools as a solution to the licensing problems of diagnostic genetics*, 17 IP TECH. L.J. 1 (2005); J.A. Goldstein, et al., *Patent pools as a solution to the licensing problems of diagnostic genetics, United States and European perspectives*, DRUG DISCOVERY WORLD, Spring 2005, at 86.

16 US DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (April 6, 1995).

17 *See*, *e.g.*, http://www.mpegla.com (last visited June 27, 2007).

18 D.B. Resnik, *A biotechnology patent pool: an idea whose time has come?*, 3 J. PHIL. SCI. L. (2003), *available at* http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html (last visited June 27, 2007); L.M. SUNG, GREATER PREDICTABILITY MAY RESULT IN PATENT POOLS (2004), *available at* http://www.ftc.gov/opp/intellect/020417lawrencemsung1.pdf (last visited June 27, 2007).

One-stop-shop pools Take for example, the case of Green Fluorescent Protein (GFP). This is a fluorescent reporter molecule used in drug discovery to create a detailed picture of how drug candidates affect the distribution, trafficking and function of proteins within a cellular environment. GE Healthcare has entered into strategic alliances with institutions including BioImage A/S, Aurora Biosciences and Columbia University so as to pool several GFP patents. These patents cover different mutations which together dramatically improve the yield of correctly folded GFP molecules. Thanks to the aforementioned strategic alliances, GE Healthcare is a convenient 'one stop shop' for these multiple patents.[19] Another example of a single source for multiple biotech patents is stART Licensing, a joint venture formed by Geron Corp. and Exeter Life Sciences. stART will actively and broadly license the two companies' contributed patented technology, including the foundational nuclear transfer cloning technology that was developed at the Roslin Institute for cloning Dolly the Sheep and the technology for producing proteins in the milk of animals.[20]

Humanitarian pools On or about 2000, Dr Ingo Potrykus of the Swiss Federal Institute of Technology succeeded through genetic engineering in enriching rice grains with ß-carotene, a precursor of Vitamin A. As a result of this research, the rice, now known as Golden Rice, became a promising nutritional supplement for populations suffering from endemic Vitamin A deficiency. After the work was complete Dr Potrykus discovered that in order to commercialize the rice he might need licenses to 70 different patents held by 40 different organizations. He assigned all of his patent rights to Astra Zeneca (now Syngenta), who acquired the rights of other third party entities. Syngenta in turn granted Dr Potrykus a humanitarian license with the right to sublicense public research institutions and low-income farmers in developing countries. The assignee retained commercial rights so as to produce Golden Rice as a nutraceutical in the developed world, although at the time of writing, it has no plans to commercialize it.[21]

Preemptive pools In 2005, the Fred Hutchinson Cancer Research Center, Pacific Northwest National Laboratory, Dana-Farber Cancer Institute, University of Southern California/Norris Comprehensive Cancer Center and Hospital, the Institute for Systems Biology, the Broad Institute of MIT and

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19 http://www.bioimage.com/pdf/Patent%20Portfolio%20v4.1.pdf (last visited June 27, 2007).

20 http://www.geron.com/pressview.asp?id=709 (last visited June 27, 2007).

21 http://www.goldenrice.org/Content2-How/how9_IP.html (last visited June 27, 2007).

Harvard, and The University of Texas M. D. Anderson Cancer Center formed a consortium to carry out a joint research effort to identify breast cancer biomarkers. The plans call for all intellectual property (IP) to be pooled and made available to consortium members and to third parties.[22] Efforts toward a similar pool have been initiated in the case of the SARS Corona virus IP. Several contributing laboratories involved in the discovery of the SARS virus have agreed to pool their patent applications so as to facilitate research and development in the field.[23]

Attempted pools Some pools are but attempts, like the heroic efforts by Essential Inventions to set up a therapeutic pool containing five HIV/AIDS drugs whose five patents are owned by Glaxo Wellcome, Bristol-Myers Squibb and Hoffman La-Roche. This effort is motivated by the crisis in access to essential treatment for AIDS and is aimed at providing anti-retroviral medicines, medical devices and testing regimens to countries working with the World Health Organization.[24]

In sum, these examples of biotechnology patent 'pools' whether established or imagined include loose aggregates of diverse IP, one-stop-shopping, 'one-company-buys-all-complementary-IP', and humanitarian pools. In no case, however, are these classic pools, such as those known from the consumer electronics industry, which are pools of standard-driven, essential, blocking and complementary patents held by interdependent players.

Important concepts in the formation of genetic diagnostics patent pools

Let us now define certain basic terms used in patent pool nomenclature. There are four basic types of patents involved in the formation of a pool. *Complementary* patents are for different aspects of the same technology that can be used together, and not just substituted for each other. An example from diagnostics would be two patents each covering a different genetic correlation for the same disease. *Competing* patents are for technologies that substitute for each other. An example from our field would be one patent on a genetic correlation and another on an antibody-based immunoassay for diagnosing the same disease. *Blocking* patents are necessary to practice the technology. An example would be a composition of matter patent on an isolated gene and all its fragments. *Essential* patents claim technologies that have 'no technical alternative' and are critical for the end product. An example would be the

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[22] http://www.fhcrc.org/about/ne/news/2005/10/04/biomarker.html (last visited June 27, 2007), and personal communications.

[23] J.H.M. Simon et al., *Managing severe acute respiratory (SARS) intellectual property rights: the possible role of patent pooling*, 83 WHO BULL. 641 (2005).

[24] http://www.essentialinventions.org/ and personal communication.

patent on the Δ-508 mutation in cystic fibrosis – which is *the* crucial mutation involved in the disease.[25]

My concept for a genetic diagnostics patent pool follows a basic principle: in a case where multiple mutational correlation patents for the same disease are owned by different owners, then one pool should contain only one set of polymutational correlations for that disease.[26] Other characteristics of such a pool are:

- The pool should include only the essential, blocking and complementary mutational correlation patents for the disease, but no competing patents.
- The pool should not include patents on non-DNA technology, such as chips, software, detection devices, reagents, thus avoiding multiple platforms in same pool.
- The pool should be formed and supervised by an independent expert committee who will choose the patents.
- Licenses offered to the pool by members should be nonexclusive. Pool members need to be free to offer individual licenses outside the pool so as to avoid illegal tying.
- Licenses from the pool need to be nondiscriminatory to all licensees.
- Narrow grant backs should be allowed from licensees for any of their improvements that are essential to the pool.
- By establishing a 'reasonable royalty', the pool will not foreclose competition in the downstream markets by users of the pooled technologies. Downstream players may include reference laboratories, clinicians, research/clinical laboratories, chip manufacturers, or hospitals.
- And, most critically for our purposes, a *standard* should be established so as to decide which mutational correlations are necessary for a state-of-the-art diagnostic assay for the disease involved, and which correlations are not. By establishing a standard it will be easier for the independent expert committee to decide which patents belong in the pool (blocking, complementary or essential patents with claims that read on the standard) and which ones do not (competing patents with claims that do not read on the standard).

Most successful patent pools in consumer electronics (for example, the MPEG-2 and DVD pools) are combinations of essential and complementary IP held by interdependent players. The pools generally organize around industry

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25 Tsui et al., US Patent 6,984,487 claim 7 (issued January 10, 2006).

26 *See supra* note 15.

standards. Such standards inform the universe of patent holders as to the essentiality and/or complementarity of patents to be added to the pool. The standards are arbitrary and not functional in the sense that, for example, there is nothing *a priori* functional about the diameter of a CD disk being 120 mm, or its standard sampling rate being 44.1 kHz. Consumer electronics manufacturers need each other in order to create a market for their products (for example, CD players that will play standard CDs). These manufacturers will therefore cooperate with each other, form standard-setting organizations and then follow the standards set forth by such organizations.

The question for biotechnology patent pools is whether similar standards could be agreed upon in this field. I believe that the answers are both yes and no.[27] Yes, standards can be determined and agreed upon in certain biotech fields such as genetic diagnostics, but, no, these are not the same types of arbitrary industry standards used in the highly interdependent computer electronics industry. In the genetic diagnostics field it is useful to refer to medically driven 'best practices' as the standards to be used in the formation of a patent pool. That is because an important inquiry to be addressed before performing any genetic testing is to determine which mutations are significant for diagnosing the disease or for identifying a carrier, and therefore which combination of mutations should be considered the 'best practice' when performing such testing.

I believe that policy or consensus statements issued by a government agency such as NIH or WHO, or a medical organization such as the American College of Medical Genetics (ACMG) will be useful in creating a legal standard to determine patent essentiality in pool formation. The ACMG routinely issues laboratory standards and guidelines for disease testing. For example, in 2001 it issued a policy statement recommending a 'standard' panel of 25 mutations for identifying carriers of Cystic Fibrosis (CF), consisting of all CF-causing mutations with an allele frequency of $\geq 0.1\%$.[28] In addition, the ACMG over the past decade has issued policy statements with 'standards' for the significant mutations to be employed in and genetic testing of a variety of other diseases including Alzheimer's Disease, Breast Cancer, Canavan Disease, Colon Cancer, Factor V Leiden, Fragile X Syndrome, Newborn Hearing Screening, Prader-Willi and Angelman Syndromes and Uniparental Disomy.[29]

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[27] T. Ebersole et al., *Patent pools and standard setting in diagnostic genetics*, 23 NATURE BIOTECHNOLOGY 1 (2005).

[28] W.W. Grody et al., *Laboratory standards and guidelines for population-based cystic fibrosis carrier screening*, 3 GENETICS MED. 149 (2001); *see also* M.S. Watson et al., *Cystic fibrosis population carrier screening: 2004 revision of American College of Medical Genetics mutation panel*, 6 GENETICS MED. 387 (2004).

[29] http://www.acmg.net/resources/policy-list.asp (last visited June 27, 2007).

The World Health Organization is another international authority on biological standards and has as its goal to develop, establish and promote international standards with respect to biological and other products. It recently announced the approval of the first international standard for a human genetic test, that is, Factor V Leiden.[30] It consists of a Reference Panel of three human genomic DNA samples that serve as reference materials for laboratories carrying out genotyping for Factor V Leiden: 03/254 (FV wild type); 3/260 (FVL homozygote) and 03/248 (FVL heterozygote).[31]

Standard panels for the genetic testing of many other diseases could, and most likely will, be set by the scientific community and medical organizations in the next few years. In fact, there may already exist diseases that have a few mutations which are routinely tested for and recognized informally as the standard, but have yet to be officially endorsed by a medical organization. Such medical organizations could carry out a critically important role in the recommendation of standards for diagnostic genetics. Once such standards are accepted they, in turn, can become organizing principles around which pools can be formed. And, they can also become an important factor in dealing with the so-called *holdout* problem in pool formation.

The holdout problem in biotech pools

A holdout is a patent holder of an essential, blocking or even complementary patent who believes it can go it alone, in other words that it need not contribute its patent to those of others in the pool, but instead can negotiate bilaterally with pool licensees to do its own deal, hoping to receive a higher royalty.[32] I believe that establishment of a medically driven standard for diagnostic testing of polymutationally correlated diseases will decrease the propensity of patent holders to play holdout. Even though such a standard does not play the same role as an arbitrary industry standard in consumer electronics, I do believe that most if not all diagnostic labs will still want to offer the 'best' test possible if it is recommended by respected medical authorities. Such laboratories would then not have as strong an incentive towards going it alone, and may decide to license their patents to the pool instead.

Another incentive to ameliorate the holdout problem might be the recent (2006) decision of the US Supreme Court in *eBay, Inc. v. MercExchange,*

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30 http://www.who.int/mediacentre/news/releases/2004/pr84/en/ (last visited June 27, 2007).

31 E. Gray et al., *Establishment of the first international genetic reference panel for factor V Leiden, human gDNA*, 96 THROMB. HAEM. 216 (2006).

32 G. George, *What is hiding in the bushes? eBay's effect on holdout behavior in patent thickets*, 13 MICH. TELECOMM. & TECH. L. REV. 557 (2007).

L.L.C.[33] eBay is the well-known operator of an online auction service. MercExchange is a provider of online services, and holds a patent on an online auction method.[34] MercExchange sued eBay, seeking a permanent injunction. The lower district court denied the injunction, almost automatically. The US Court of Appeals for the Federal Circuit reversed and granted the injunction, also almost automatically. Granting *certiorari*, the Supreme Court reversed and remanded the case, but disagreed with both the Federal Circuit and the district court. In so doing, it stated that injunctions under US patent law should neither be automatically granted nor automatically denied. Analyzing the need for an injunction in patent law should be done in accordance with the traditional four-factor test applied by the courts when considering whether to award permanent injunctive relief in other areas of US law. Under the four-factor test, a successful plaintiff must demonstrate: (1) that, absent an injunction it will suffer irreparable injury; (2) that remedies available at law (for example, money damages) are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a permanent injunction is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[35]

Therefore, public policy and fairness now need to be regularly and carefully considered by a court before deciding on the entry of a permanent injunction in patent cases. After the decision in *eBay*, permanent injunctions in US patent law are no longer automatic. In certain instances money remedies will be enough and patent holders who do not manufacture or license may not readily get injunctions. Since the public health is a major 'public interest' it would also follow that patent holders in the health sciences who do not work or actively license their inventions are now vulnerable to not getting injunctions.[36] Potential holdouts who are patentees of essential or complementary polymutational diagnostic correlation patents – especially non working patent holders – need to carefully consider this uncertainty when planning whether to join a genetic diagnostics pool or try disrupting its formation and implementation by threatening lawsuits against licensees.

Conclusion

In spite of the description of many past patent-sharing arrangements in

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33 *eBay, Inc. v. MercExchange, L.L.C.*, 126 S.Ct. 1837 (2006).

34 MercExchange, *Generating Changes in Dynamic Markets*, http://mercexchange.com/index.html (last visited June 28, 2007).

35 *See eBay*, 126 S.Ct. at 1839.

36 There has not yet been a post-*eBay* decision of a lower court in the health sciences. In areas such as electronics, the lower court decisions after *eBay* have been mixed: some have entered permanent injunctions, others have not.

biotechnology as 'pools', only recently has there been a rigorous application of classic pool definitions and concepts to the field. The area of diagnostic genetics especially is one where thickets have appeared and where careful analysis and application of well-established pool principles are warranted. Medically driven standards set by international medical bodies should be considered when creating a patent pool in genetic diagnostics. Such standards assure the legal acceptability of the pool by providing an objective test for which patents read or do not read on the standard. The existence of a medically accepted standard also provides potential holdouts with a 'best practice' that would give them an incentive to join the pool rather than go it alone. When coupled to the lack of automatic injunctions after *eBay*, a passive IP holder in genetic diagnostics in the United States may well decide that their best strategy for maximizing profits is not to hold out from, but to join, a pool. Such a result will ultimately benefit the public by providing state-of-the-art diagnostics unencumbered by thicket concerns.

26 Patenting industry standards

Vincent F. Chiappetta

Introduction

Patents and industry standards are economic double-edged swords. Properly wielded they enhance efficient market performance, but when deployed with inadequate care they become powerful engines for monopoly profits. When patents control access to an industry standard, achieving the proper balance becomes an extremely complex and challenging task.[1] This chapter examines the evolving legal effort to help get that outcome 'just right'.[2]

Two key considerations guide the appropriate legal response to patent capture of an industry standard. First, patents and standards inherently conflict. Standards generally contemplate benefits from widespread adoption, which patent law intentionally constrains to foster its objectives. Legal regulation of their co-existence, therefore, must distinguish between the patent system's legitimate competitive costs and those that go beyond. Second, standardization can come about in different ways – *ex post* from accumulated market transactions over time or *ex ante* as either the intentional joint creation of industry participants or in the form of a government mandate. These varying sources raise distinct practical and policy concerns, and so a one-size legal approach does not fit all.

[1] The same issues arise with regard to other kinds of intellectual property rights, such as copyrights on software code or trade-secret enhancements of related processes. *Cf.* Pamela Samuelson, *Questioning Copyrights in Standards*, 48 B. C. L. REV. 193 (2007) (discussing the capture problem when governments adopt privately drafted standards subject to copyright protection). Patent law's uniquely powerful exclusionary right makes patent capture of particularly significant concern.

[2] *See, e.g.*, U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING COMPETITION AND INNOVATION (2007), http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf [hereinafter Joint Report]; Mark A. Lemley, *Intellectual Property Rights and Standard Setting Organizations*, 90 CAL. L. REV. 1889 (2002) [hereinafter Lemley IP Rights]; Mark A. Lemley. *Ten Things To Do About Patent Holdup of Standards (and One Not To)*, 48 B. C. L. REV. 149 (2007) [hereinafter Lemley Ten Things]; Janice M. Mueller, *Patent Misuse Through Capture of Industry Standards*, 17 BERKELEY TECH. L.J. 623 (2002).

The following sections discuss how the law can properly distinguish between appropriate and undue costs of patent capture in each of the three standard-setting contexts. The first, addressing market-generated standards, provides the clearest example of the basic tension between realizing on patent law's goals and achieving standardization's efficiencies. When competitive market forces freely select a validly patented option as the 'best', the overall system is operating as intended. Despite capture's clear harms, the law should provide no special relief. Legal intervention should be limited to the same antitrust and patent misuse principles applicable to any acquisition or exercise of market power.

The 'nothing special' legal response to patent capture of market-generated standards presupposes, and thus emphasizes, the need for a properly functioning patent regime. The unavoidable costs inherent in the standards interaction add another powerful reason to push ahead with current reform efforts aimed at ensuring issued patents reflect true innovation and providing effective post-issuance mechanisms that allow ready correction of inevitable errors. The standards context also makes clear that claims to patent 'property' rights should not create artificial barriers to rectifying public interest harms, making compulsory licensing and even non-enforcement very real remedial options once a violation is found.

Cooperative *ex ante* standardization by industry competitors through standard-setting organizations (SSOs) requires the law take a more active role, affirmatively facilitating informed, expert decision-making while constraining opportunism. SSO private ordering best permits the tailoring required to maximize participation, pre-decision patent disclosure and full assessment of the related costs and benefits under specific circumstances. Contract and tort law should encourage that activity by limiting the uncertainties and risks of too readily implied legal obligations, while reliably and effectively enforcing not just the letter but the purpose of express SSO undertakings. As with implied duties, the extraordinary power of antitrust and patent misuse regulatory law should be circumspectly deployed to minimize its chilling effects. That requires rigorous application of existing doctrinal requirements in private actions (standing and requiring antitrust injury harm to competition not to competitors) rather than stretching to provide supplemental remedies for every breach of an SSO commitment. Government action should be restricted to addressing collusive participant misuse of the standard-setting process and circumstances posing significant market harms unlikely to be effectively remedied by private contract claims.

The mandatory nature of government standards requires a different legal response. Those standards' genesis in government action will generally limit post-adoption legal redress to traditional antitrust/patent misuse violations, making careful attention to inadvertent capture during the standard-setting

process key. Unlike private SSOs, however, government standard-setters cannot readily resolve the issue through disclosure and licensing obligations. Imposing such requirements would not only seriously interfere with First Amendment free speech/government petitioning rights and raise significant government taking concerns, it would trigger substantial adverse political reaction. Traditional public notice and comment procedures provide some useful assistance in obtaining necessary information. Their usefulness, however, can be enhanced by a generous reading of the 'corruption of process' exception to antitrust law's *Noerr-Pennington* government-petitioning exemption, permitting recourse against misrepresentations by patent holders. Use of requests for licensing proposals can improve information about patent holder intentions as well as licensing terms regarding identified patents by generating competitive bidding. Three additional 'process' tools can further reduce the risk of capture: scrupulous attention to articulating promulgated standards in terms of required 'outcomes' rather than specific technological means; institutionalized post-adoption monitoring and adjustment when capture occurs; and, most importantly, prior to acting carefully considering whether industry or market-generated standards might not be better-suited to the task.

Finally, the proper legal solution requires looking beyond the boundaries of a single jurisdiction. The increasing interconnectedness of markets emphasizes that the exercise is not an individual sport. Reaching a truly satisfactory outcome must take into account the proposed solution's benefits and costs not just at home, but in the greater international economic and social context.

Market-generated standards

Pure market-generated standards are by their nature 'efficient' and, therefore, desirable in a market economy. They reflect consumer demand, specifically, buyers' preference for the resulting standard's particular functionality-price relationship. In addition, market-generated standards result from, and self-adjust over time based on, three interrelated kinds of competition. First, they emerge from head-to-head rivalry among alternative offerings. Second, as a specific standard emerges, providers will continue to reduce prices and enhance functionality in an effort to become the dominant provider. Finally, existing standards remain subject to displacement through paradigm-shifting innovation.

In the real world, of course, inefficiencies do exist. The competition forming and evolving market-generated standards can be significantly impaired by barriers to change. Sunk costs in an existing standard will slow or prevent the shift to new, more desirable alternatives.[3] The gasoline automotive engine

[3] Joint Report, *supra* note 2, at 35 nn.11–12.

provides an example. The enormous related manufacturing, distribution, support and learning curve/familiarity investments make the market highly resistant to change, even when the existing paradigm is clearly extremely problematic. A successful alternative must not merely merit the investments in its own creation and implementation on purely competitive terms, but its benefits must be sufficient (actually, and as perceived) to overcome the powerful producer, distributor and consumer vested interests in the present system.

In addition, market-generated standard formation and transition can be adversely affected by network effects.[4] For example, when interoperability (technical or otherwise) with other users or equipment is a crucial requirement, a particular alternative's value rises as the number of adopters increases. When a particular offering reaches sufficient market penetration, this 'network' value can drive it to become the industry standard independent of its stand-alone price-functionality merits. And once entrenched, those same network effects pose a substantial barrier to alternatives, requiring they offer not only superior function-price benefits, but sufficient extra value to offset the lost network benefits.

The *de facto* market standardization on the Microsoft Windows personal computer operating system demonstrates the operation and power of network effects. As the Windows system installed base increased, the related ability to seamlessly integrate with those users became a significant new purchaser consideration, eventually overcoming even substantial price-functionality merits of alternatives. Additionally, increased user numbers generated market opportunities for infrastructure providers such as independent application developers, peripheral manufacturers and service and support companies. Those activities in turn further enhance the platform's 'network' consumer value, independent of its individual merits. The overall result is significant barriers to change, going well beyond those of sunk costs.

Although sunk costs and network effects can reduce the efficiency of market-generated standards (at least over the short term) there is little basis for legal complaint or special intervention. As United States courts evaluating antitrust cases have long held, it is not improper for a competitor to prevail based solely on its superior product, operating efficiency or natural advantage.[5] If it were otherwise, the legal system would punish winning on the merits, an outcome hardly conducive to robust competition – the central engine of economic efficiency. Such victories, therefore, must be accepted as

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[4] *See, e.g.*, Mueller, *supra* note 2, at 634.

[5] Judge Learned Hand's seminal opinion in *United States v. Aluminum Co. of Am.*, 148 F.2d 416 (2d Cir. 1945), eloquently explains the reasoning briefly outlined in the text.

an unavoidable artifact of the market system. Legal intervention requires something more, specifically, actions which create or maintain monopoly power by artificially impairing consumer choice.[6] As a result, a market-generated standard arising from free consumer choice among competing alternatives will generally be immune from legal challenge. Any displacement of a dominant provider or change in the standard must come on the merits – competitors offering lower prices or improved performance sufficient to overcome any resistance to change.

Patents substantially affect the competitive market framework. As an incentive to invest in innovation in the face of a substantial public goods problem,[7] patent owners receive powerful legal rights to prevent others from using the covered invention for a fixed period of time.[8] However, the mere existence of a patent and the related exclusionary rights do not automatically create market power concerns.[9] To obtain that power – through standardization or otherwise – a patent holder must first prevail over alternatives in the market.[10] So in that regard at least, patent-based standards are no different than other market-generated standards.

Special concerns do arise, however, once a patent-based alternative actually becomes the *de facto* standard. Unlike other market-generated standards, patent rights permit the holders to significantly constrain competition within the standard through licensing terms adversely affecting third party offerings'

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[6] Requiring more than a demonstration of monopoly power – that the defendant also engaged in inappropriate exclusionary (predatory) behavior to obtain or maintain that power – is standard U.S. antitrust doctrine. *See United States v. Grinnell Corp.*, 384 U.S. 563 (1966). An illuminating discussion of what exclusionary/predatory activity entails can be found in *United States v. United Shoe Mach. Corp.*, 110 F.Supp. 295 (D. Mass. 1953), *aff'd per curiam*, 347 U.S. 521 (1954).

[7] *See, e.g.*, Vincent Chiappetta, *Defining the Proper Scope of Internet Patents: If We Don't Know Where We Want to Go, We're Unlikely to Get There*, 7 MICH. TELECOMM. & TECH. L. REV., 289, 307–8 (2001–2) (describing the regime's focus on overcoming the 'free-riding' disincentive to investment in innovation).

[8] U.S. law prohibits virtually all making, using, offering to sell or selling of the patent invention. *See* 35 U.S.C. § 271(a). The term of a U.S. patent, consistent with international treaty obligations, generally extends for 20 years from the date of application. *See* 35 U.S.C. § 154(a)(2).

[9] The U.S. Supreme Court decision in *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 37–40 (2006), contains an interesting recent visitation of the proposition that patent exclusionary rights do not by themselves create a 'monopoly'. *See also* Joint Report, *supra* note 2, at 22.

[10] Patents may actually create an impediment to a market victory on the merits by making buyers wary of the resulting control; at least if they think about it (*cf. Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451 (1992)).

price, functionality or availability (including preventing them entirely).[11] This 'patent capture' substantially increases the likelihood of additional inefficiencies, including the worst case possibility that a single dominant supplier/monopolist will emerge. Although patent-controlled standards do remain vulnerable to alternatives, they will only be displaced during the patent term if an offering outside the scope of the patent provides sufficient benefits to overcome sunk cost/network effects barriers to change.

Despite these potential substantial negative effects, the basic legal analysis does not change. A patent-controlled standard reflecting consumer preferences is still a victory on the competitive merits. Moreover, by definition such a patent-based, market-generated standard reflects an innovation highly valued by the marketplace. The resulting exclusionary costs, therefore, merely reflect society's intended patent bargain; in this case the price of having encouraged a highly productive investment with the lure of surplus return, including the prospect of monopoly profits.

In such circumstances, using the law (antitrust, patent misuse or otherwise) to limit or withdraw the promised returns and mandate open competition within the related standard would substantially undermine the patent system – an undelivered incentive being no incentive once the ruse is exposed.[12] This, unsurprisingly, is precisely the conclusion reached in the April 2007 Joint Department of Justice–Federal Trade Commission Antitrust Enforcement and Intellectual Property Rights Report[13] which expressly confirms that a patent holder's refusal to license does not (alone) raise antitrust concerns:

> Antitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections. Antitrust liability for refusals to license competitors would compel firms to reach out and affirmatively assist their rivals, a result that is 'in some tension with the underlying purpose of antitrust law [footnote omitted[14]].'

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[11] It has been argued that patent capture provides beneficial control over a standard by allowing the patent owner to prevent fragmentation (or 'forking'), which undermines the uniformity benefits. There are, however, other less harmful ways to avoid this concern. *See* Lemley IP Rights, *supra* note 2, at 1963–4.

[12] Eliminating patent law merely to avoid patent capture is not a viable option; at least if one accepts the value of the investment incentives it provides. *See* Lemley Ten Things, *supra* note 2, at 151; Mueller, *supra* note 2, at 651–2. *See also* Chiappetta, *supra* note 7, at 291 n.11.

[13] Joint Report, *supra* note 2.

[14] The omitted citation is to the U.S. Supreme Court decision in *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004), which discusses the tension noted in the Joint Report quotation in the text, and which in dicta indicated that, as a consequence, an antitrust 'essential facilities claim' would be unfavorably received. *See* Mueller, *supra* note 2, at 656–7 (discussing the essential facili-

> Moreover, liability would restrict the patent holder's ability to exercise a core part of the patent – the right to exclude.[15]

Similarly, the Patent Act, at 35 U.S.C. § 271(d)(4), expressly exempts a refusal to license from patent misuse claims.[16]

Successful patent holders, however, do not receive an entirely free pass. Generous legal treatment of the patent standard 'monopoly' presumes that related market power was properly obtained and is being legally maintained. Improper conduct in obtaining a patent (such as intentionally withholding material information during prosecution) may give rise to both inequitable conduct relief and *Walker-Process*[17] antitrust liability. The former doctrine would prohibit enforcement of the improperly obtained patent's claims, thus permitting competitive standard compliant offerings.[18] That relief does not, however, eliminate first mover or other market-based advantages which may have arisen from the patent prior to the unenforceability determination. *Walker-Process* antitrust violations[19] somewhat mitigate those latter concerns through the deterrence of treble damages, but will not fully undo the market harm caused by those who decide to 'take the risk'.

Additionally, although holders of valid patents (including those who draft or amend claims during prosecution expressly to read on subject matter essential to an emerging standard[20]) are free to prevent others from using the invention, the law actively polices against efforts to improperly maintain or extend

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ties doctrine in the patent capture context as well as noting that the European Union might be more receptive in connection with an abuse of a dominant position claim). *See also* Joint Report, *supra* note 2, at 27–31.

15 Joint Report, *supra* note 2, at 6.

16 Section 271(d)(4) reads as follows: 'No patent owner . . . shall be . . . deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . (4) refused to license or use any rights to the patent'. The U.S. Supreme Court has (arguably) read this statutory language as applicable only to patent misuse, but found it nonetheless provides important interpretative guidance in the antitrust context. *See Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006). *See also* Joint Report, *supra* note 2, at 25–6.

17 *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

18 *See, e.g., J.P. Stevens & Co., Inc. v. Lex Tex, Inc.* 747 F.2d 1553 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985).

19 *See* Mueller, *supra* note 2, at 654–5 for a discussion of the doctrinal requirements.

20 The Court of Appeals for the Federal Circuit has expressly found that drafting or amending claims to read on market activity is not inequitable conduct. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988), *cert. denied*, 409 U.S. 1067 (1989). *But see infra* note 61 (discussing the potential liability for such actions when under a duty to disclose).

patent-based power.[21] Specifically, antitrust law prevents predatory actions used to hold onto even properly acquired monopoly power.[22] Because the predicate monopoly power will likely exist when a patent affords substantial control over a market-generated standard,[23] antitrust law will be available to constrain patent holder behavior going beyond competition on the merits,[24] preventing the exercise of related patent rights in ways which unduly entrench or expand control over the standard. For example, a patent holder could be prohibited from requiring licensee grant-backs of standard-related intellectual property rights[25] or from refusing to deal with applicants under a licensing program absent specific justifications.[26] Beyond the deterrence of treble damages, related antitrust remedies could include compulsory licensing or even non-enforcement as necessary to rectify the resulting competitive harm.[27]

Patent misuse goes further, prohibiting license terms which 'impermissibly broaden the "physical or temporal scope" of the patent grant'[28] whether or not the patent holder holds, or has a dangerous probability of obtaining, monopoly

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21 *See* Joint Report, *supra* note 2, at 30–31 (explaining the somewhat paradoxical point that while refusing to deal at all is generally exempt from antitrust law, once the decision to license is made implementation will be closely scrutinized for related competitive harms, citing *Motion Picture Patents Co. v. Universal Film Mfg. Co. et al.*, 243 U.S. 502 (1917)). *See also* Joint Report, *supra* note 2, ch. 4.

22 *See* 15 U.S.C. § 2.

23 *Cf. In re Rambus*, Opinion of the Commission, 2006 WL 2330117 (F.T.C. 2006) (finding adequate sustained power in the relevant market for a Sherman Act Section 2 violation when patents controlled implementation of an industry-generated standard). Section 2 also sanctions improper efforts to obtain monopoly power under a claim of attempted monopolization. However, attempt is likely only to apply very late in the standard-setting process, when the predicate dangerous probability of success (capture) exists. Additionally, such cases are extremely difficult to prove. *See infra* note 31 and accompanying text.

24 Microsoft discovered this inconvenient legal reality about acquired market power in connection with the monopoly it had obtained via the Windows operating system; antitrust law applied to its market activities despite (and arguably because of) its related copyright protection and rights to exclude. *See Microsoft Corp. v. United States*, 253 F.3d 34 (D.C. Cir. 2001), *cert. denied*, 534 U.S. 952 (2001).

25 *See* Joint Report, *supra* note 2, ch. 4.

26 *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) (imposing a duty to deal on a monopolist who had chosen to deal in the past).

27 Although not a fully litigated result, the settlement in *Microsoft* reflects this wide-reaching remedial approach, requiring Microsoft to make its interoperability protocols available to third parties. *See United States v. Microsoft Corp.*, No. 98-1232, 2002 WL 31654530 (D.D.C. 2002), *superseded by* 2006 WL 2882808 (2006).

28 *Windsurfing Intern. Inc. v. AMF Inc.*, 782 F.2d 995, 1001 (1986) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971)). *See* Mueller, *supra* note 2, at 671–3.

power. For example, licensing terms limiting competition after the patent's expiration (including required continued payment of royalties) are prohibited. Remedially, misuse may also prove more advantageous in terms of access to the standard, prohibiting any enforcement of the patent until the adverse effects of the misuse have dissipated.

These antitrust and misuse legal limitations do not, however, preclude many patent holder actions that severely limit standard-compliant competition. For example, imposing geographic and product restrictions during the term of the patent or charging exorbitant royalty rates are likely legal, and no liability attaches to an outright decision not to license at all. Moreover, attacking all but the most clearly abusive licensing terms could prove practically counter-productive. Real or perceived high risks of licensing could strongly bias patent holders in favor of the more secure no-license approach, thus eliminating all competition.

Finally, one specific behavior requires brief mention in light of its importance to the industry-generated standard context discussed below. It might be argued that concealing potential future patent capture while the market is determining the standard deserves special legal treatment, perhaps as an attempt to monopolize under Section 2 of the Sherman Act.[29] For example, a patent holder might intentionally ignore competitive but infringing offerings while consumer market transactions lock in the patented alternative as a *de facto* standard. Once that occurs, the patent holder could then sue and eliminate infringers, permitting it to raise its prices to monopoly levels. Although (perhaps) ethically offensive, aside from individual estoppel or fraud claims based on express patent holder misrepresentations or possible laches claims, such 'ambush' behavior will not generally support legal relief.[30] A non-enforcing patent holder facing strong competition does not have sufficient market power to trigger antitrust liability,[31] nor does failing to enforce consti-

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[29] 15 U.S.C. § 2. Enforcement of patent rights during this period would also be subject to attempt claims, but only if the other requirements of the cause of action can be demonstrated. *See infra* note 31.

[30] As the courts have noted, the antitrust laws are not a code of professional conduct for business; they exist to ensure vigorous (even no-holds barred) competition is not unduly impaired. *Cf. E.R.R. Presidents Conference v. Noerr Motor Freight*, 356 U.S. 127, 140–141 (1961).

[31] Attempt cases are notoriously difficult to win, requiring proof not only of predatory acts but a dangerous probability of success and specific intent to monopolize. *See Spectrum Sports v. McQuillan*, 506 U.S. 447 (1993). Thus even if a failure to enforce relevant patents was found to be a predatory act, liability would only attach if the patent holder then held a significant market share – generally requiring a showing in the 40–50% range – and, perhaps, a demonstration that non-enforcement was not motivated by other considerations, such as convincing the market to adopt the related standard on its merits.

tute patent misuse. Such patent holders will be treated like other competitors vying for market victory – meaning they are legally entitled to make whatever decisions they deem most appropriate regarding their patents to enhance their competitive position. Only if and when they actually obtain sufficient market power to trigger antitrust law will their actions be legally constrained, and then only to the same extent as any other potential or actual monopolist.

The central role of patent law

For the reasons discussed above, antitrust and patent misuse constraints do not – and should not – eliminate all the inefficiencies patent capture can impose. As legal sanctions only reach egregious conduct by the patent owner, the proper operation of the patent regime constitutes a vital part of the industry standards legal mix – with costs directly proportional to the quality of the patents it produces.

The current recalibration of the United States patent bargain is, therefore, an important move in the right direction. Recent adjustments to the 'invention' requirement promise a laudatory reduction in inappropriately issued patents thus substantially reducing the risk of undue standards capture. Congress, the Patent and Trademark Office and third parties continue to invest significant resources and energy in improving prior art identification during examination; a process further enhanced by the requirement that many applications must now be published prior to final approval. Additionally, the United States Supreme Court has tightened the reach of the doctrine of equivalents[32] and, more recently, effectively raised the non-obviousness bar by taking a more generous view of what advances would be obvious to the person of ordinary skill in the art.[33]

Other changes can reduce opportunities for strategic patenting designed to increase standards capture. No legal prohibition prevents an applicant from drafting or amending patent claims to cover essential standard requirements.[34] However, revitalizing the Federal Circuit's 'on again – off again' use of the written description requirement to limit post-filing claim amendments could substantially constrain the ability to make adjustments targeting subsequent standard-setting decisions.[35] Additionally, the motivation for

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[32] *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

[33] *See KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

[34] *But see infra* note 61 (discussing potential liability if under an obligation to disclose).

[35] *But see* Mueller *supra* note 2, at 637–42 (arguing the Court of Appeals for the Federal Circuit may be moving in the 'wrong' direction, at least with regard to patent capture concerns).

alacrity in prosecution provided by running the fixed 20-year term from the date of filing (in lieu of starting the term clock on issuance) can be reinforced by expanding the 'laches' doctrine and statutory and regulatory efforts constraining abusive continuation practice.[36] This would minimize tactical prosecution delays while waiting for an unclear standard to stabilize or become locked in. Finally, switching from first-to-invent to first-to-file would further reduce opportunistic behavior.[37] Specifically, by determining 'novelty' based on the application filing date, not an earlier asserted date of invention, standards publication would serve as prior art cutting off all subsequent patent claims.

Regarding patent rights themselves, the recent shift in the infringement 'balance of power' substantially mitigates the costs of 'bad-patent' standards capture. Those seeking to offer compliant products by challenging and eliminating invalid patents are increasingly able to do so without having to bet their business. Declaratory judgment actions can now be brought based on the patent holder's assertion that a prospective course of action (specifically, a standard-compliant offering) may infringe, thus eliminating the substantial risk of having to show a reasonable apprehension of a (perhaps imminent) lawsuit as a result of having actually engaged in the challenged conduct.[38] Further serious consideration should be given to enhancing third-party administrative options for challenge, including reducing the burden of overcoming the presumption of validity from 'clear and convincing' to a 'preponderance of the evidence' in such instances.

Finally, the United States Supreme Court pronouncement in *eBay v. MercExchange*[39] concerning injunctive relief in patent infringement cases offers important cost-mitigating opportunities. The Court's holding that traditional equitable factors must be applied in determining whether an injunction is appropriate focuses attention in the standards capture context beyond the patent holder's 'property' rights to include the larger public policy considerations. Specifically, courts should explicitly consider whether on the facts the public interest would be better served by limiting relief to market-rate-royalty compulsory licenses, thus permitting additional standard-compliant offerings.[40]

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36 *See, e.g., Symbol Technologies, Inc. v. Lemelson Med., Educ. & Research*, 422 F.3d 1378 (Fed. Cir. 2005); Lemley Ten Ideas, *supra* note 2, at 163–4.

37 *See* Mueller, *supra* note 2, at 642–5.

38 *See Sandisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377–83 (citing *MedImmune, Inc. v Genetech*, 127 S.Ct. 764 (2007), for the proposition that the Article III case or controversy requirement does not require the plaintiff to 'bet the farm' by acting first, and also holding that on the facts not even the patent holder's stated intent not to sue eliminated the justiciable controversy).

39 547 U.S. 388 (2006).

40 Limiting automatic injunctive relief has the further positive effect of encour-

Applied to patent capture of market-generated standards, compulsory licensing is, however, far from a certainty. It can be convincingly argued that absent improper behavior by the patent holder, compulsory licensing conflicts with the basic patent bargain – reneging *post facto* on society's promise of protected monopoly profits in return for taking investment risk whenever it produces significant positive results. Avoiding this undesirable outcome requires careful attention to the specific facts. When the patent holder is actively exploiting the invention by offering standard-compliant products which ultimately capture the market, a very strong connection exists between injunctive relief and accomplishing patent law's incentive objective. However, when a non-producer seeks to enforce patents only after *others'* actions have created the related standard, limiting relief to market-rate royalties is far more appropriate.[41] That remedial approach discourages patent holders from 'gaming' the system, waiting to make capture claims until standard lock-in has artificially enhanced the threat-of-injunction 'hold-up' premium they can command. The limitation forces a salutatory election between obtaining value by producing (or by licensing/transferring for production as discussed immediately below) in the face of competition or receiving market-rate royalty returns based on the patent's contribution (as discussed further below) once a related standard is in place.

The active-passive analysis applies equally to post-standard acquisition of patents specifically for licensing purposes. The Patent Act contemplates inventors may be poorly positioned to realize on their innovations themselves by expressly authorizing patent transfers as an alternative means to obtain a return on investment.[42] Pre-standard acquisitions, therefore, should generally be treated as outlined above – injunctive relief turning on whether the acquirer engaged in active pre-standard exploitation or only in *post hoc* licensing as a non-producer. Acquisitions by non-producers after a standard exists, however, will generally be driven by the prospect of related capture premiums.[43] Such acquirers should presumptively be governed by market-rate royalty compulsory

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aging voluntary market-based licensing programs, giving such programs the significant allure of avoiding the costs and uncertainties of judicial enforcement, not the least of which is a judicial determination of the appropriate royalty rate. *See infra* notes 44–5 and accompanying text.

41 Justice Kennedy drew this distinction and the related potential for abuse point in his *eBay* concurrence. *See eBay*, 126 S.Ct., at 1842 (Kennedy, J., concurring).

42 *See* 35 U.S.C. § 261. Nor is it a legal violation merely to accumulate patents. *See Automatic Radio Mfg. Co. v. Hazeltine Res.*, 339 U.S. 827, 834 (1950) (dicta).

43 *Cf. In re Negotiated Data Solutions LLC*, 2008 WL 258308 (F.T.C. 2008) (majority, in a three–two decision, expressing concern over patent assignment to non-market participant, resulting in exploitation of industry lock-in and requiring compliance with assignor's SSO licensing commitments by its assignee).

licensing. That approach ensures innovators will obtain purchase prices reflecting the patent's actual market value, not artificial premiums arising from the *in terrorem* effect of possible post-standard injunctive relief.

Finally, the observation that not all patents contribute equally to an outcome[44] applies with special force to standards capture.[45] When determining reasonable royalties (and damages), the specific patent's contribution should be carefully assessed, reflecting its role in light of everything required for standard-compliant implementation. Additionally, level of 'contribution' serves as a further consideration regarding withholding injunctive relief in the first instance. Injunctive relief should be routinely available to protect active exploitation when the patent-holder's portfolio forms the core of the standard. However, public policy considerations forcefully argue for compulsory licensing when minor contributor hold-outs threaten general implementation.

Industry-generated standards

The value of standards is not disputed. As the Joint Report succinctly states:

> [Industry standards] . . . are widely acknowledged to be one of the engines driving the modern economy. Standards make products less costly for firms to produce and more valuable to consumers. They can increase innovation, efficiency, consumer choice; foster public health and safety; and serve as a 'fundamental building block for international trade.'[46]

That many of these benefits redound to manufacturers has not escaped their notice. It has become increasingly common for producers to collaboratively establish industry standards through an existing or *ad hoc* trade SSO. Unlike pure market-generated standards, which arise in response to consumer choice among alternatives in the marketplace, competing producers make industry-standard determinations *ex ante*. Consequently, although industry-generated standards take existing consumer preferences into account, they can create rather than reflect the market outcome.

That 'preemptive action' increases both the likelihood and costs of error. Unlike market-generated standards which arise slowly over time in response to consumer need and desires, industry-driven standardization specifically contemplates rapid, broad-based adoption in anticipation of demand. That

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[44] Justice Kennedy's *eBay* concurrence notes the importance in infringement-remedial determinations of considering the relative contribution of the patent to the actual product (in the instant situation, the standard). *See eBay*, 126 S.Ct. at 1842 (Kennedy, J., concurring).

[45] *See* Lemley Ten Ideas, *supra* note 2, at 151–4 and 165–7 (noting the problems of patent royalty stacking and inattention to actual contribution).

[46] Joint Report, *supra* note 2, at 33.

means sunk costs and network effects barriers to change will arise more quickly and powerfully, locking in improper decisions despite possible ultimate market preference for alternatives.[47] Despite this risk, prevailing opinion (including among government regulators) is that collaborative, industry 'expert' standard-setting will on net produce significant efficiency benefits.[48] Therefore, the law generally treats good faith errors in such standard-setting as an acceptable price for obtaining positive outcomes, not a matter for regulatory intervention and adjustment.

Deliberate abuse of the SSO decision-making process, however, is viewed quite differently.[49] Manipulation of the standard-setting process by SSO participants to enhance their individual competitive positions triggers serious legal response. Many such 'standardizing' agreements, such as price fixing or bid rigging, constitute *per se* antitrust violations carrying significant sanctions, civil and criminal.[50] Other agreements (for example overly enthusiastic information sharing among participants or standardized selling practices) may be struck down as facilitating improper behavior or impairing already problematic market performance.[51] Agreed prohibitions on using alternatives, in effect mandating adoption of an agreed standard, are also subject to legal attack. Although such undertakings help prevent 'fragmentation', which is essential to preserving the efficiency benefits of standardization, they also can adversely affect competitive development and adoption of alternatives. Therefore, although SSO agreements may legitimately prohibit untrue or misleading compatibility assertions, absent extraordinary circumstances, an undertaking to use only the adopted standard should be treated as an illegal restraint of trade.[52]

SSO industry standard-setting offers special benefits and raises serious concerns regarding possible patent capture. As noted above, consumers' failure

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47 *See* Lemley Ten Ideas, *supra* note 2, at 154–5.

48 *See* Joint Report, *supra* note 2, at 34 and 55–6.

49 *See id.*

50 *See* Joint Report, *supra* note 2, at 37 and 55. It is, of course, necessary to prove the conspiracy. *See Golden Bridge Tech., Inc. v. Nokia, Inc.*, 2007 WL 2688487 (E.D. Texas 2007) (Sherman Act Section 1 violation by SSO participants, as all such violations, requires evidence excluding the possibility of independent action).

51 *Cf. United States v. Container Corp. of Am.*, 393 U.S. 333 (1969); *Fed. Trade Comm'n v. Cement Inst.*, 333 U.S. 683 (1948).

52 *See Allied Tube & Conduit Corp. v. Indian Head*, 486 U.S. 492 (1988), and *Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656 (1961); Joint Report, *supra* note 2, at 35 n.10. *But see Golden Bridge Tech., Inc. v. Nokia, Inc.*, 2007 WL 2688487 (E.D. Texas 2007) (when alleging a concerted refusal to deal – SSO participants in this case refusing to support a proposed standard – the plaintiff must offer evidence excluding the possibility of independent action).

to anticipate and incorporate patent consequences can substantially reduce competition within a market-generated standard. The *ex ante* cooperative nature of SSO standard-setting offers a considerable advantage over market-generated outcomes in avoiding the problem. Participating industry members more likely know about, and are in a significantly better position to discover, understand and appropriately take into account patent effects on the desirability of the various options than are consumers. However, that same cooperative decision-making process also offers substantially enhanced opportunities for capture. Unlike market-generated standards which gradually emerge from industry competition, after SSO agreement the industry rapidly moves toward general implementation. The prospect of quick lock-in not just of consumers but also of competitors provides significant incentives for disingenuous patent owners[53] to encourage unwitting industry-wide adoption of the alternative they control (or less charitably – engage in patent 'hold-up' or 'ambush' behavior).[54]

These capture benefits and risks require SSOs to find ways to maximize pre-decision identification, assessment and minimization of patent effects while encouraging participation and constraining opportunism. Those dual objectives require finding an appropriate balance under the particular circumstances between participant obligations and the resulting time/resource commitments and liability risks. The law plays an important role in facilitating this outcome, providing explicit support for private ordering while independently monitoring for and regulating actions posing otherwise irremediable harm to the public interest. Regarding the former, contract and tort law offer a foundation on which SSOs can construct individually tailored, reliably and effectively enforceable information disclosure and patent access commitments from the participants. Concerning the latter, when properly applied, antitrust and patent misuse law impose salutatory external restraints on anti-competitive actions which fall beyond the reach of private undertakings because they either involve participant collusion or are not readily enforceable or resolvable through private suits.

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[53] Including groups owning complementary patents or those holding patents being abetted by other participants with preferential licensing positions.

[54] *See* Joint Report, *supra* note 2, at 35. The practical viability of standards hold-up is the subject of lively debate. Some, not unconvincingly, argue that the business penalties such behavior will trigger in future dealings with the victims makes such tactics unprofitable in the long run and, therefore, of little consequence. *See id.* at 40–41. The *Qualcomm*, *Dell*, *Unocal*, *Rambus* and *Negotiated Data* cases (discussed *infra* at notes 95–100 and accompanying text), however, provided ample evidence that although those considerations may reduce the problem, it is clearly more than theoretical.

Ensuring that contract and tort law provide a useful platform for SSO agreements requires close attention to their doctrinal requirements. Specifically, both regimes only offer relief for breaches of duties owed. In the SSO context, such legal duties might be implied from the circumstances.[55] For example, participation might give rise to a contractual duty of good faith and fair dealing superseding the typical 'arm's-length' relationship among parties negotiating an agreement. Or tort 'fraud' doctrine could sanction not only affirmative misrepresentations, but imply a duty to speak, thus imposing liability for misleading omissions. Reliance on implied duties is, however, extremely unwise. Such claims generate notoriously complex and costly implementation issues while producing, at best, uncertain, if not affirmatively counter-productive, outcomes. Implied contract and tort duties are factually driven, equitable overlays on an economically preferable negotiation among parties generally well-positioned to look out for themselves. Claims, therefore, will only effectively (albeit expensively) reach egregious behavior – intentional deception regarding a fact clearly known to be material in circumstances creating both the need and the legitimate expectation of disclosure despite other participants' expertise and ability to otherwise discover the information.[56] Equally importantly, overly generous legal recognition of implied duties (or even frequent SSO enforcement attempts) may generate undesirable long-term outcomes. At best, such duties create strong incentives for participants to avoid liability by limiting knowledge through deliberate non-inquiry. At worst, their inherently ambiguous nature poses significant risks even to those acting in good faith, pointing away from participation in SSO standard-setting to the detriment of all.

SSO participant duties are, therefore, generally best limited to those arising from explicit agreements clearly defining the obligations and liabilities.[57] One common undertaking requires participants to disclose all potentially relevant patents and applications in their own portfolios and, in some instances, also extending to include those held by others of which the participant is aware.[58]

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[55] *See* Lemley IP Rights, *supra* note 2, at 1909–27 and 1935–6; Mueller, *supra* note 2, at 657–60.

[56] *See Rambus Inc. v. Infineon Technologies Ag*, 318 F.3d 1081 (Fed. Cir. 2003) (reversing jury findings of fraud and breached duty to disclose).

[57] Obviously careful attention must be paid to ensuring these agreements are legally enforceable. *See* Lemley IP Rights, *supra* note 2, at 1909–11 (discussing the enforcement problems when the obligation only appears in the SSO bylaws or policy statements).

[58] As noted at the outset of this chapter, patents raise the most significant concerns; however, other forms of intellectual property rights can pose problems. Many SSO undertakings, therefore, cover a variety of such rights. *See* Lemley IP Rights, *supra* note 2, at 1973 (containing a survey/summary of SSO participant undertakings and related requirements) [hereinafter Lemley Summary].

Relying on the public availability of patents only takes the SSO so far. There is no way to discover as yet unpublished applications and, more importantly, independent review and analysis of the public records would be an enormously expensive task producing at best uncertain results. The affirmative disclosure obligation not only enlists the expertise of the participants but reveals important information about whether they view their patents or applications as relevant to the various alternatives under consideration. Such obligations, by themselves, raise no legal concerns.[59] The requirement provides information necessary to the SSO decision-making process, a clearly legitimate purpose making antitrust or other challenges unlikely.

Despite the theoretical attractiveness of disclosure obligations, the approach has two significant drawbacks. The first involves the related costs and risks borne by SSO participants. For a disclosure undertaking to provide helpful information it must go beyond blanket submissions of all patents and require specific indications of relevance. Participants must, therefore, carefully assess their portfolios to avoid liability. Many will have large patent portfolios[60] and significant employee rolls requiring considerable time and resources to search and query. Relevance determinations will involve complex assessment of patent claims, further complicated by the participants' natural reluctance to disclose internal activities (including pending applications[61]) and thinking to competitors.[62] Moreover, every change in portfolio, employees or standard-setting direction will require new iterations of the process. As a consequence even seemingly straightforward disclosure requirements can dissuade participation, particularly by those most critical to the task.

SSOs mitigate these cost concerns by fine-tuning the disclosure commitment. Each limitation, however, inevitably reduces the obligations efficacy. For example, a seemingly logical limitation might require disclosure only of relevant patents in a participant's own portfolio. But that restriction produces a substantial information gap regarding patents held by non-participants as well as a useful cross-check on other participants' disclosures. Similarly, eliminating the affirmative search requirement (as many SSOs do[63]) carries even

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59 *See id.* at 1943–4.

60 This is particularly true in patent-intensive industries. *See* Lemley Ten Ideas, *supra* note 2, at 151.

61 The ongoing *Hynix Semiconductor* case against Rambus is, in part, based on Rambus' alleged drafting of patent claims in pending applications covering the standard which it did not disclose *See, e.g.*, *Hynix Semiconductor, Inc. v. Rambus Inc.*, 2007 WL 3284069 (N.D. Cal. 2007) (containing a description of the complaint).

62 Although disclosure can and should be covered by confidentiality provisions, that expedient does not eliminate the practical risks of giving such sensitive information to competitors.

63 *See* Lemley Summary, *supra* note 59.

more adverse information consequences. Not only does the approach significantly limit the available data; it encourages participants to avoid 'knowing' relevant information.

Second, even a disclosure obligation imposing maximum coverage and relevance assessment fails to fully address the patent capture problem in a number of important respects. At the most fundamental level, ironically, even the hoped for 'no patents' response suffers from a serious shortcoming when it matters most – in the event of breach. Specifically, such an undertaking suffers from serious remedial shortcomings in dealing with false statements.[64] Contract law generally limits the remedy to expectation damages, good news to a frustrated potential participant (perhaps) but hardly a satisfactory public policy outcome when patent rights prevent competitive implementation of an industry standard. Estoppel and uniqueness/inadequacy of monetary damages arguments could be made in support of compulsory licensing. However, as the breach involves only a failure to disclose, not denial of agreed access, legal and practical obstacles will likely bar such relief. A court is unlikely to be legally sympathetic absent a compelling showing of both (1) that if disclosure had been made the standard would only have been adopted with a related waiver of rights or licensing undertaking and (2) defendant's bad faith (an intentional effort to obtain individual advantage, thus providing little help in inadvertence or even negligent oversight cases). However, even a willing court faces serious practical implementation issues. Determining the appropriate licensing terms requires constructing the 'what if' world in which disclosure was made.[65] That requires not only identifying and assessing the contribution the patent makes to the adopted standard, but the other factors (including alternative standards) which would have affected the licensing terms had the SSO and the patent holder reached a negotiated agreement. Finally, contract law's prohibition on punitive damage awards provides little deterrence to participants who decide these uncertainties make doing less than a full search or affirmatively limiting their disclosures worth the risk.

Beyond these intra-SSO shortcomings, reliance on contractual disclosure obligations also does little to improve access by non-participants. A disclosure obligation running to the SSO or its participants is only enforceable by others if the contracting parties clearly intended to grant them third-party beneficiary

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[64] As discussed *infra* (starting at note 72), these difficulties can be mitigated, if not entirely resolved, by modifying the disclosure undertaking. *See also* Lemley IP Rights, *supra* note 2, at 1917 and 1921–2.

[65] *See In re Rambus, Inc.*, Opinion of the Commission on Remedy, 2007 WL 431524 (2007), currently stayed pending appeal (struggling with the 'what if' problems of how the standard would have come out had Rambus disclosed its patents); *In re Dell*, 121 F.T.C. 616 (1996).

status or the outsider can show justifiable reliance.[66] An SSO could, of course, expressly include third-party rights as part of the required disclosure undertaking. Participants understandably will resist the resulting open-ended exposure (including its possible use as a defense in unrelated infringement actions), to say nothing of the resulting liability.[67] And, of course, even clear third-party rights at best afford outsiders the same discouraging opportunity to plow the above-discussed infertile remedial ground from a more attenuated, even less advantageous position.

Absent third-party beneficiary status, outsiders are left to show estoppel arising from reasonable reliance. Naked appeal to internal SSO undertakings is unpromising absent additional action making external reliance justified – such as a post-adoption SSO public affirmation of free access to the standard. Beyond the unlikelihood that SSOs will make such ill-advised, uncaveated assertions to the world, aggrieved claimants will face the substantial burden of demonstrating they reasonably relied in light of the public availability of patents and their own expertise. And even if reliance can be shown, it would take a truly heroic third-party action to reach beyond the SSO making the statement to the underlying breaching patent holder and obtain the rights necessary to implement the standard – both substantially increasing the costs as well as reducing the likelihood of any useful relief.

The difficulty of obtaining effective contractual relief for breach is not, however, the most significant shortcoming of a disclosure requirement. Most participants will diligently perform their agreed undertakings in good faith,[68] making SSO decision-makers routinely aware of myriad potentially relevant patents. Identification, however, merely raises the capture concern. Without additional information regarding how the related rights might be exercised, SSO standard-setters face an unhappy choice among three undesirable alternatives. They could reject every affected standard regardless of its technical or market merits. Practically, that approach would certainly eliminate many good, and perhaps all, alternatives. Additionally, the joint decision not to deal

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66 Mueller, *supra* note 2, at 658–60. If obligations only run to the SSO, the other participants' reciprocal obligations will generally suffice to give them either third-party beneficiary status or support a reliance claim.

67 Participants may also find the 'no outsider remedy' affirmatively advantageous as it limits competition, thus further intensifying their resistance to expanding third-party rights. Although a joint refusal to deal on that basis would be subject to antitrust attack, individual action is not.

68 They may do so because they honor their word or because of the practical and legal risks. *See supra* note 55 discussing the position that business reputation costs reduce the likelihood of opportunism.

raises antitrust concerns. Despite its blanket applicability to all participants[69] and rational connection to enhancing standardization, there are less restrictive means of accomplishing that outcome.[70] Or they might entirely ignore patent impediments, leaving resolution of any resulting capture to the marketplace. That approach raises serious efficacy concerns; limiting evaluation to the technical merits while ignoring the very real prospect that the resulting standard cannot be widely adopted. Moreover, not only is much of the value of the disclosure obligation destroyed, it arguably becomes affirmatively detrimental. Requiring participant identification of relevant patents puts all on express notice, increasing the likelihood of willfulness treble damages if they subsequently fail to obtain a license.[71] Finally, they could try to estimate the effects of the disclosed patents and consider those costs when making the decision. While that process poses few legal risks, practically it is a largely futile exercise given the wide range of possible patent holder responses.

The obvious, and frequent, solution is to move beyond mere disclosure undertakings, requiring participants to agree that they either will not assert their patents against, or will license them to, anyone implementing the SSO standard.[72] Such undertakings substantially improve the likelihood of injunctive mandatory-licensing relief by expressly tying breach to denial of promised access, rather than a mere failure to disclose. Additionally, because the agreement applies, but is also expressly limited to, all standard adopters, it provides non-SSO participant access while minimizing related patent-holder exposure to spurious claims and defenses. Finally, although a non-assertion/licensing undertaking does not fully eliminate the practical cost and competitive concerns of mandatory disclosure obligations, it can substantially reduce them by allowing each participant to individually calibrate its search-analysis-disclosure investment to the particular circumstances. Those likely to hold no patents of economic consequence can simply commit to blanket non-assertion, avoiding

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[69] It can be reasonably argued that if such undertakings are required before disclosures are made, the related 'veil of ignorance' precludes antitrust exposure because the undertaking cannot reflect concerted action targeting particular patent holders. *See* Lemley IP Rights, *supra* note 2, at 1946. However, that argument is of no avail when (as is very commonly the situation) before joining, prospective participants are aware of the SSO's likely standardization outcomes and others' patent positions.

[70] Notably, as discussed below in the text, requiring undertakings to provide access to the related patents. *See Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332 (1982) (striking down a particular implementation of an accepted pro-competitive justification based on the availability of alternative, less harmful ways of accomplishing that outcome); Lemley IP Rights, *supra* note 2, at 1944.

[71] *Cf.* Lemley Ten Ideas, *supra* note 2, at 164–5 (even under a very relaxed standard of willfulness, prior knowledge is likely sufficient).

[72] *See* Lemley Summary, *supra* note 59.

the costs of an internal search as well as disclosure of their portfolio and related assessments to other participants. Those with relevant patents can tailor their search and disclosure/non-assertion/licensing undertakings to reflect an investment and level of public knowledge consistent with their interest in obtaining licensing returns.

Although highly preferable to pure disclosure obligations, SSO non-assertion/licensing commitments raise two important issues, each triggering related practical and legal concerns. First, the commitment's requirement that participants surrender some or all of their competitive patent advantage makes clear articulation of the obligation both crucial and problematic. For example, a standard might define a communications protocol aimed at maximizing product interoperability. The key scope question is whether the related SSO non-enforcement/licensing obligation extends only to patents essential to implementing a compliant version of the protocol itself or does it also include enhanced operating performance, which while not affecting interoperability, may limit the practical ability of other members to effectively compete.

Practical considerations and legal constraints support using the narrower 'essential to compliance' SSO undertaking. Practically, non-patent holders will seek to avoid or at least minimize the additional market power accruing to those holding 'improved implementation' patents. In response such patent owners may either elect not to participate or withdraw, feeling such demands compel surrender of competitive advantage without offsetting returns generated by standardization.[73] But the latter group is also most likely to hold core patents most relevant to 'best' standard options, so obtaining their licensing commitment on those rights will be vital. Better to encourage their participation and acquiescence on the essential patents, leaving the others to console themselves that they remain free to develop and patent future improvements, in which event the 'essential' limitation will be to their ultimate benefit. Importantly, antitrust law also puts its substantial weight on that side of the scale. The recognized justifications for joint standardization only extend to agreements necessary to accomplish the related objective – in the example, interoperability. Going further eliminates desirable individual competitive incentives to improve performance.[74]

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[73] Despite the fact the undertaking is made prior to actual standardization discussions, participants will generally have a fair idea of how the core and improvement patent issue will affect them, making the conflict and concerns real.

[74] *See* Joint Statement, *supra* note 2, at 48 (noting a similar concern when monopsony power is used to coerce royalty-free licenses) and 53; *infra* notes 78–9 and accompanying text. Extending coverage to 'improved implementation' patents might be defended on the grounds it is essential to obtaining the necessary broad-based participation. *Cf.* FED. TRADE COMM. & DEP'T OF JUSTICE ANTITRUST GUIDELINES FOR

The typical SSO agreement reflects these considerations, covering only patents necessary to a 'compliant implementation' – requiring patent holder participants either to forgo enforcement or agree to license only when no commercially or technologically feasible alternatives exist to implement the adopted standard.[75] Such an undertaking encourages maximum participation by both limiting coverage to patents which read on expressly articulated aspects of the standard (that is, necessary for 'compliant implementation'[76]) and by carving out an exception when feasible alternatives exist. Applied to the above communications protocol example, a patent holder would only be required to waive assertion or license a patent if no feasible alternative exists to implementing a fully interoperable protocol, not merely to remove competitive disadvantages among compliant offerings (such as speed of operation).

Second, a commitment to either waive assertion or license falls considerably short of resolving patent-capture concerns. Such an undertaking does little to meaningfully quantify the actual costs of implementing the related standard, making comparative decision-making highly problematic. Worse, it does not avoid capture in fact. Agreeing to negotiate a license does not guarantee that the process will produce competitive (much less acceptable) royalty rates or other terms, even under an obligation of good faith and fair dealing and the limitations imposed by antitrust and patent misuse law.

A few SSOs have resolved this concern by requiring members to commit to royalty-free licenses.[77] Although all patent holders will undoubtedly view 'free' as an inadequate return on their investment standing alone, some situations will offer sufficient offsetting benefits to make the arrangement acceptable. For example, in patent-intensive industries, royalty-free licenses may merely replace the need for individually negotiated (and essentially free) cross-licenses, clearing away mutually blocking thickets. Or, the standardization may

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COLLABORATION AMONG COMPETITORS, Section 3.36 (April 2000) (noting participant opportunism concerns as a justification for restraints on member competition). That argument is hard to sustain when, as will generally be the case, the SSO participants so 'encouraged' by limiting competition represent a significant share of the prospective licensee market and hold sufficient power to force adoption of an alternative standard. *See id; infra* notes 78–9 and accompanying text. *But see* Lemley IP Rights, *supra* note 2, at 1945 (noting the mitigating effects of the right not to participate on antitrust concerns).

[75] *See, e.g.*, IEEE and VITA standards patent policies described in IEEE Department of Justice Business Review Letter (April 30, 2007) and VITA Department of Justice Business Review Letter (October 30, 2006), respectively.

[76] Clearly, such an undertaking requires SSO participants to carefully consider how they frame adopted standards; that is, explicitly specifying what constitutes a fully compliant offering and, therefore, the patent holder participants' related obligations.

[77] *See* Joint Report, *supra* note 2, at 47 (noting in particular that this is the approach taken by the World Wide Web Consortium).

make the product more attractive, increasing its price or market, thus motivating patent holders who believe their superior expertise and first-mover advantages will permit them to out-compete others for those benefits to agree.

In many cases, however, a 'free' license requirement will face considerable resistance. Non-market participants cannot treat forgone royalties as generating cross-licensing avoidance benefits or as an investment in increased returns generated by their superior competitive position. Other patent holders' relative size and economic strength will expose them to substantial risk that surrendering patent advantage will permit larger rivals to crush them in the marketplace. Practically, these concerns limit the number and kinds of patent holders willing to participate, hampering the effectiveness of SSO decision-making and resulting standardization.

Conditioning participation on foregoing patent rights also raises antitrust concerns.[78] A 'royalty free' requirement may be treated as a joint effort by potential license 'purchasers' to coerce non-market terms. The requirement might be defended as necessary to eliminate patent capture and the related barriers to competitive adoption, particularly as the individual patent holder retains the right not to participate. However, when the SSO participants wield non-*de minimis* market power making non-participation untenable, a 'zero price' requirement raises substantial risk of concerted refusal to deal and buyer-side price-fixing liability.[79] Finally, in addition to these difficulties, even a legal 'free' licensing requirement will only resolve royalty rate hold-up concerns, leaving other perhaps equally, if not more, problematic licensing terms unaddressed.[80]

'Reasonable and nondiscriminatory' (RAND, sometimes also referred to as 'fair, reasonable and nondiscriminatory' or FRAND) licensing requirements substantially reduce these practical concerns and legal risks. Such an undertaking applies not only to royalty rates but to all licensing terms. The right to obtain a reasonable return helps assuage non-market participant and small player concerns. Additionally, the royalty provides a competitive advantage over licensees, further enhancing the ability of the patent holder to capitalize on any expertise and first-mover position they hold with regard to the related industry standard. Legally, the RAND commitments' reliance on individually negotiated transactions reflecting market terms as a vehicle for pro-

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78 *Id.* at 48; Lemley IP Rights, *supra* note 2, at 1944–7.

79 *See supra* note 75.

80 For an interesting listing of ways a patent holder could use other licensing terms to impair a licensee's ability to compete, see Joint Statement, *supra* note 2, at 46 n.69. Such efforts would, however, remain subject to general antitrust and patent misuse limitations discussed in connection with market-generated standards.

competitive elimination of patent capture, all but eliminates related antitrust concerns under a rule of reason analysis.[81]

Despite these improvements, the RAND approach does not fully eliminate the 'terms' hold-up problem. The nebulous nature of the requirement provides ample room for improper conduct.[82] Moreover, even patent holders acting in good faith can generate significant problems. They may subjectively overvalue the contribution of their patents to standard implementation or hold genuine but idiosyncratic views of appropriate licensing terms, reaching well beyond royalty rates. Ironically, these issues may be exacerbated (if not caused) by the very standardization decision a RAND licensing requirement facilitates.[83] Prior to standardization, a patented innovation stands or falls on its own merits in the marketplace, leaving 'reasonableness' to be defined by actual demand. However, publicly anointing a patent-based option as the industry standard diminishes that competitive discipline, particularly as network effects limit or destroy the practicability of using alternatives. As a result, the standard enjoys considerable market power. Patent holders acting in good faith may believe that in such circumstances it is 'reasonable' to require high royalty rates and restrictive licensing terms because limited availability is the optimal way for the industry to maximize its returns (to say nothing of the patent holder's own interests). Finally, a variety of transaction costs may inhibit otherwise desirable licenses, such as licensor inaccessibility or inattention due to unrelated legitimate business issues, a prior unhappy course of dealings between the parties and the like.

Obtaining effective relief against licensing-terms 'hold-out' (in good or bad faith) under a RAND licensing requirement is, at best, problematic.[84] SSOs have shown little interest in direct enforcement of participant licensing commitments (RAND or otherwise),[85] and individual hope-to-be-licensees face daunting legal hurdles. Although breach of a RAND commitment strongly supports compulsory licensing relief, the problem of determining reasonable terms remains. Even if a court determines that RAND terms should

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81 *See* VITA Department of Justice Business Review Letter (October 30, 2006); Daniel G. Swanson & William J. Baumol, *Reasonable and Nondiscriminatory (RAND) Royalties, Standards Selection, and Control of Market Power*, 73 ANTITRUST L.J. 1 (2005). This outcome assumes, as the VITA Business Review Letter indicates, no independent violation exists (such as a buyer/licensee-side price-fixing conspiracy).

82 *See* Joint Report, *supra* note 2, at 47; IEEE Department of Justice Business Review Letter (April 30, 2007). *See also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 314 (3rd Cir. 2007) (noting the problem of determining 'reasonable' licensing terms, but finding it did not bar relief).

83 *See* Joint Report, *supra* note 2, at 47.

84 *See id.*

85 *See id.*

be objectively defined (hardly a forgone conclusion),[86] a time-consuming and expensive inquiry will be required. Although these difficulties are not unique in law or insurmountable,[87] they do seriously affect the costs, timing and uncertainty of RAND licensing outcomes, substantially reducing the commitment's efficacy as a solution to patent capture.

To address these RAND concerns, SSOs may require participants to commit to specific licensing terms, including maximum royalty rates, in advance.[88] That approach helps maximize the selection of the best overall standard in three significant respects. First, it provides extremely useful *ex ante* information about costs to the SSO decision-making process, allowing more accurate non-technical comparisons among the options under consideration. Second, it substantially resolves the risk that post-adoption terms hold-up will bar meaningful access and competition within the adopted standard. Finally, the competition generated by that comparison helps reduce the legitimate costs of patent capture. A specific terms requirement motivates patent holders to price attractively in order to drive adoption of the related alternative, with reduced royalty rates offset by resulting volume (particularly as non-adoption may lead to zero usage) and possible market share capture as a result of the patent holder's greater expertise, first-mover and cost advantages. Consequently, patent holders will frequently have incentives to maximize their offering's attractiveness as compared to both other patented options and alternatives not subject to patent constraints, thus closing the price gap among all possibilities.

Despite these considerable benefits, *ex ante* specific licensing term undertakings can raise significant practical and legal concerns.[89] Practically, the resource- and time-intensive process of generating and comparing proposals substantially changes the dynamics of standard-setting, shifting it from a primarily technical exercise to one requiring business and legal inputs and involvement. The increased investment and longer decision-making cycles may deter participation and, potentially, prevent some beneficial standard-

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86 *See id.* at 46 n.70.

87 *See id*. at 46; *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 314 (3rd Cir. 2007); Joseph Scott Miller, *Standard Setting, Patents, and Access Lock-in: RAND Licensing and the Theory of the Firm*, 40 IND. L. REV. 351 (2007); Swanson & Baumol, *supra* note 81; Damien Geradin & Migeul Rato, *Can Standard Setting Lead to Exploitative Abuse? A Dissonant View on Patent Hold-up, Royalty Stacking and the Meaning of FRAND*, SSRN database at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=946792.

88 *See* Joint Report, *supra* note 2, at 49; IEEE and VITA Business Review Letters, *supra* note 75.

89 *See* Joint Report, *supra* note 2, at 49–56.

setting from occurring at all. The crucial question, however, is whether despite those additional transaction costs the resulting (albeit, perhaps, fewer) standards may nonetheless be net superior to those generated by less well-informed SSO decision-making which can result in much more costly, problematic post-adoption licensing negotiations and lost competition. Perhaps a middle-ground cost solution lies in parallel-track discussions, with either the engineering experts informing business/legal decision-making or vice-versa.

Legally, a patent holder's express willingness to license on specific, quantified terms may lead courts to find compulsory licensing appropriate not only regarding the standard, but in non-standards infringement cases as well. Arguably under *eBay's* case-by-case assessment mandate an SSO commitment should only affect standard-compliance situations as it indicates very little, if anything, about harms suffered by the patent holder in other contexts. Nonetheless, the related risks are real and may chill potential SSO participation if such an undertaking is required. Such agreements can also raise antitrust concerns. Unlike SSO-imposed royalty-free licensing requirements, specific term commitments are best viewed as voluntary unilateral offers to deal by the patent holder, which, standing alone, raise little difficulty.[90] However, subsequent evaluations, negotiations and the ultimate decision to accept or reject particular proposals involve concerted action by the SSO participants who are generally competitors. United States antitrust regulators have taken the sensible position that such arrangements should be evaluated on their specific facts under the rule of reason.[91] Because such undertakings improve information and mitigate hold-up risks leading to better and lower cost standards through *ex ante* competition among alternatives (which also limits individual power and constrains collusion[92]), *bona fide* specific term licensing undertakings and related SSO discussion and decision-making should generally be found pro-competitive.[93] Similarly, SSO joint refusals to deal with patent holders unwilling to participate in the open bidding process (whether SSO participants or not) will likely pass legal muster as reasonably

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[90] *See id.* at 54.

[91] *See id*. at 37 and 52–3. The market power generated by standardization may constrain the actual licensing terms ultimately offered by the patent holder under antitrust law, but that is a separate matter. *See supra* notes 20–28 and accompanying text.

[92] This analysis differs from that applicable to many patent pools. Standard-setting generally chooses *ex ante* among competitive patents, while a pool can involve *ex post* collective pricing decisions. *See* Joint Report, *supra* note 2, at ch. 3 (noting the special concerns raised when pooled patents are substitutes rather than complementary). *See also* Lemley IP Rights, *supra* note 2, at 1950–54.

[93] *See* Joint Report, *supra* note 2, at 52 and 54–5.

related to accomplishing those objectives. That said, the attendant risks, including challenges that the process is a cover for other *per se* violations such as buyer-side price fixing, quite rationally has led some SSOs to avoid the exposure and rely instead on second-best undertakings such as RAND licensing commitments.[94]

The above discussion indicates that SSO undertaking requirements must be carefully tailored to the particular circumstances. Balancing obtaining information and controlling opportunism against related costs and legal risks impeding participation is something sophisticated and knowledgeable industry participants are particularly well-suited to achieve. The law should facilitate rather than hinder that process. It can do so by limiting the chilling effect of poorly defined implied liabilities and by ensuring reliable and effective enforcement of express undertakings. Contract and tort law implied gap-filling duties should be tightly restricted to truly egregious circumstances. Express obligations should, however, be aggressively enforced to maximize their information-generating and opportunism-limiting objectives, including through generous use of compulsory licensing remedies when violations are found.

The need for legal circumspection is especially relevant to properly calibrating the law's regulatory role. Antitrust law's treble damages offer significant disincentives to opportunism, with its criminal sanctions providing especially powerful downside risks regarding *per se* violations. Additionally, the regime's 'market effects' focus goes far toward resolving the problematic relational and remedial limitations of contract law enforcement of SSO undertakings. Any adversely affected party can bring an antitrust action, SSO participant or otherwise, and the regime's focus on rectifying market harm makes compulsory licensing (or even non-enforceability) a ready response to patent-capture abuse.[95]

The regime's power and remedial flexibility are readily apparent in recent regulatory actions. In the *Dell Computer*[96] and, ultimately, the *Unocal*[97] cases, the Federal Trade Commission obtained consent decrees (a royalty-free

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94 *See* Joint Report, *supra* note 2, at 49 and 50–53.

95 *See, e.g., Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3rd Cir. 2007) (permitting a private action for both attempt and monopolization under Sherman Act Section 2) and *Qualcomm Inc. v. Broadcom Corp.*, 2007 WL 2296441 (S.D. Cal. 2007) (analogizing SSO undertaking breaches to inequitable conduct before the Patent Office and finding waiver/non-enforceability an appropriate remedy).

96 *In re Dell*, 121 F.T.C. 616 (1996).

97 *In re Union Oil Co. of California*, 2005 WL 2003365 (F.T.C. 2005) (agreeing to non-enforcement of blocking patents as part of a decree permitting a merger with Chevron to go forward).

license and non-enforcement concession, respectively) based on allegations that patent capture resulting from opportunistic breach of disclosure obligations violated the antitrust laws (specifically, Section 5 of the Federal Trade Commission Act). In an on-going enforcement action against Rambus, Inc. alleging a Sherman Act Section 2 violation based on willful non-disclosure in breach of SSO obligations,[98] the Commission imposed a royalty-bearing compulsory license running in favor of anyone wishing to comply with the standard.[99] Most recently, a sharply divided FTC found that its 'fairness authority' under Section 5 allowed it to enforce (through a consent decree in this case) an SSO licensing commitment made by a patent holder participant against the assignee of those patent rights in order to prevent potential *consumer* harm.[100]

These enforcement actions demonstrate how antitrust law can fill important gaps in SSO undertakings to prevent patent capture. However, as the courts have long noted, over-zealous antitrust intervention can itself impair desirable market activity.[101] The *in terrorem* effect of the regime's uncertain, time-consuming and costly application (regardless of ultimate liability) may unduly chill SSO participation and/or deter adoption of the most effective forms of undertakings. Avoiding these harmful effects requires the regime only be applied when clearly necessary to address significant and otherwise irremediable market harms.

Delivering on that objective means that in private actions courts should closely adhere to the central antitrust distinction between harm to competition and harm to individual competitors[102] as reflected in the related antitrust injury and standing requirements.[103] That means every private plaintiff must prove not only a direct exclusionary effect but a significant threat to proper

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98 *See In re Rambus*, Opinion of the Commission, 2006 WL 2330117 (F.T.C. 2006) (finding the obligation to disclose in a 'fair reading' of the SSO policies).

99 *See id.* and *In re Rambus, Inc.*, Opinion of the Commission on Remedy, 2007 WL 431524 (2007) (currently stayed pending appeal).

100 *In re Negotiated Data Solutions LLC*, 2008 WL 258308 (F.T.C. 2008). The two dissenters in the three–two decision argued that the decree went beyond the Commission's traditional application of its Section 5 authority.

101 *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993); *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). *See also* American Intellectual Property Association Statement regarding the Federal Trade Commission decision in *Dell Computers* at http://www.ftc.gov/opp/global/aipla.shtm.

102 *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993).

103 *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3rd Cir. 2007) (dismissing certain claims based on lack of standing and antitrust injury).

operation of the marketplace as a whole. In the standards context, the sufficiency of that showing should specifically consider whether the harm can be resolved through other less dramatic means – such as enforcing an SSO undertaking in a contract action. If such an alternative is available, the case carries little risk of otherwise irremediable general market harm and likely does not merit the application of antitrust law.

The same considerations should similarly limit government regulatory action. The clearest situations calling for government action involve collusion among the SSO members. The arguments favoring private ordering redress disappear when the participants have strayed beyond legitimate information gathering and limiting individual opportunism. Using the SSO forum to facilitate price-fixing agreements or concerted refusals to deal should be aggressively attacked and severely sanctioned to maintain the basic integrity of the industry standard-setting process.[104]

Government action is also justified when private contract enforcement cannot rectify significant market harms.[105] For example, an SSO may only require disclosure or RAND licensing commitments, meaning market-detrimental patent capture may occur without a predicate breach. Or, when the SSO undertaking does not provide third-party rights, non-SSO participants may be precluded from offering competing implementations of the standard. Or, capture may arise from unidentified patents held by non-SSO participants having no obligations to disclose or license. In such situations, government (and private) antitrust intervention may provide the only effective legal recourse.

The substantial downside risks of overly enthusiastic enforcement means that even when filling a gap the courts should apply traditional antitrust concepts. Consequently, a patent-capture antitrust finding must satisfy the same clear (and difficult) standard of proof required in any attempted or actual monopolization action. Mere opportunistic interference with competition, much less unethical behavior, is not sufficient.

Like antitrust law, patent misuse offers supplemental private enforcement benefits coupled with a risk of over-regulation harms. One scholar has made a compelling argument that public welfare considerations justify the doctrine's expansive application to industry standard capture involving opportunistic

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104 Assuming, of course, an actual conspiracy exists. *See supra* note 51.

105 *In re Negotiated Data Solutions LLC*, 2008 WL 258308 (F.T.C. 2008). The two dissenters in the three–two decision argued that the decree went beyond traditional application of F.T.C. Section 5. Perhaps, most interesting is Commissioner Kovacic's statement in dissent that Commission action was not ordinarily appropriate when the harm could readily be avoided by the victims.

breach of an SSO disclosure or licensing obligation.[106] Such application has the special appeal that it can address situations where antitrust-level competitive harm cannot be shown. However, the chilling effects of the doctrine's considerable vagaries and its draconian unenforceability remedy in the absence of either collusion or market power, risks significantly impairing SSO private ordering decisions, if not participation in the first instance. On balance the better approach is to limit SSO remedial activity to contract and antitrust law.[107] Patent misuse is more appropriately reserved for licensing terms which exceed the scope of the patent bargain; an issue which should remain independent of whether they also breach an SSO undertaking.

Government-generated standards

Government-established standards can reflect a desire to foster the same market efficiencies driving industry-generated standardization. More frequently, however, they reflect other policy objectives such as public health and safety, technology forcing, elimination of barriers to trade or achieving specific distributional outcomes. Before addressing how this important difference provides an important mechanism for mitigating patent capture concerns, it is useful first to consider how the related problems can be magnified in government standard-setting's unique context.

Unlike market- or industry-generated standards, patent capture of a government standard arises from a government edict requiring general adherence to the related standard. Because non-compliance is not permitted, preferred alternatives cannot shift demand and displace the standard in the marketplace. Consequently, potential competitors have no options other than obtaining a license or remaining on the sidelines. Regarding licensing, when the government unilaterally puts the standard in place, legal recourse against the patent holder is limited to antitrust law's prohibition on predatory efforts to maintain the resulting monopoly power (not refusals to deal) and patent misuse which only sanctions the use of licensing terms reaching beyond the physical or temporal scope of the related patents. Because neither legal regime guarantees third-party access, society must bear the related monopoly costs.

Mitigating the costs of patent capture must, therefore, focus primarily on the government standard-setting process. As with industry-generated standards, pre-decision information gathering and assessment of patent effects are

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[106] *See* Mueller, *supra* note 2, at 669–83 (arguing convincingly that the explicit Section 271(d)(4) (*see supra* note 16) exemption for failure to license should not be applicable to patent capture resulting from breach of an SSO undertaking).

[107] Antitrust law can repair the related harms by taking a flexible and aggressive approach to remedies, including non-enforceability of patent rights, eliminating the need to rely on the misuse doctrine merely to obtain that result. *See supra* note 96.

essential to avoid unintended social harms. Despite government's greater coercive powers, its standard-setters are, as a practical matter, frequently much less advantageously positioned to deal with these issues than SSOs. Government decision-makers will generally have less ready access to and be less familiar with the myriad nuances of the related technologies and patent environment than an SSO-assembled throng of active industry participants. Additionally, they will likely be substantially resource constrained, exacerbating the difficulty of acquiring the necessary information.

Addressing these difficulties by imposing participation and information reporting requirements on industry experts or, more directly, by mandating non-enforceability of, or access to, any relevant patent rights are legal and practical non-starters. Mandates raise serious First Amendment compelled-speech and private property 'Takings' concerns, as well as interfering with patent law's incentive objectives.[108] Even such a modest requirement as conditioning rule-making comments or legislative testimony on giving a disclosure undertaking raises substantial right to petition issues. Beyond these legal and policy issues, the certain adverse political reaction and related implementation costs make such an approach, even if otherwise permissible, all but useless. As a consequence, government standard-setting generally must proceed without the benefit of SSO-style express disclosure and access undertakings from patent holders.

A variety of legal and administrative tools can, however, help reduce the likelihood of patent capture in this governmental world of second best. Traditional public notice and comment procedures can provide important and useful information. Patent holders have limited incentives (if any) to disclose information concerning capture possibilities in their own portfolios. However, others will eagerly provide information about such patents, especially when they threaten to impair their ability to compete.

Three problems reduce the efficacy of this process. First, expertise requirements, inattention, bandwidth and related costs will likely leave some relevant patents undisclosed and will provide only incomplete information regarding others. Second, and somewhat ironically, even this incomplete input may provide government standard-setters with too much data and too little useful information. An indiscriminate flood of good, ill-considered, biased, self-interested and irrelevant material may prohibit effectively processing it in a meaningful way.

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108 *See supra* note 12 and accompanying text (discussing the similar problem if patents were rendered enforceable because they interfered with access to a market-generated standard).

One partial solution to the information deficiency/overload problem is to realize that the crucial information will generally come from industry and industry watch-dog or public interest sources. Those sources are, however, prone to overly aggressive advocacy and dissembling, if not worse. That concern can be mitigated practically by cross-checking and follow-up of sources and, legally, by application of the key exception to antitrust law's *Noerr-Pennington*[109] immunity doctrine. That doctrine affords wide First Amendment latitude when petitioning the government, immunizing even explicit efforts to further anti-competitive goals – which arguably includes advocating adoption of a patent standard in order to obtain resulting monopoly profits from patent capture. However, in *California Motor Transport*,[110] the United States Supreme Court explained that although even unethical lobbying for a clearly anti-competitive political outcome is generally immune from the antitrust laws, actions which 'corrupt the administrative or judicial processes . . . may result in antitrust violations'.[111] That language is broad enough to reach knowing misrepresentations to government officials about relevant patent considerations. Although the Court has been very solicitous of petitioning rights, even in adversarial adjudicatory settings,[112] imposing a basic duty of candor in direct governmental dealings is neither unknown nor inappropriate; the inequitable conduct patent law doctrine offering one particularly relevant example. Permitting antitrust attempt or monopolization claims against a petitioner who affirmatively misleads a standard-setting regulatory authority would go far toward constraining such opportunism as well as undoing any resulting competitive harms.

Third, and most importantly, as with SSO disclosure obligations, even if the comment process does identify the critical patent capture concerns, it provides inadequate insight into how the patent holders will react and the related effects on the alternative standards being considered. This issue could be addressed by governmental mimicking of the competitive bidding triggered by SSO specific-terms-licensing undertakings. For example, rather than

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109 The doctrine's name comes from the Supreme Court cases initially establishing the immunity described in the text: *E.R.R. Presidents Conference v. Noerr Motor Freight*, 356 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

110 *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

111 *Id.*, at 512–13.

112 *See Professional Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49 (1993). Although that Court in that case protected a litigant's right to bring any objectively non-frivolous suit even for subjectively improper reasons, it did not address how such a litigant's affirmatively misleading a judicial decision-maker regarding relevant facts would affect the outcome – the more applicable analog to misleading a standard-setter.

moving directly to promulgating a standard based on comment input, government standard-setters could solicit licensing proposals, including from any identified patent holders. That process would not only help quantify and compare the costs of alternatives currently under consideration (and perhaps reduce their overall costs through the resulting competition); it might draw out additional possibilities. And, unlike SSOs, government standard-setters generally need not consider antitrust constraints, including refusing to deal with anyone unwilling to participate.[113] While helpful, the approach does have one very significant shortcoming: it adds very significant administrative expense and time delays to the standard-setting process.

Beyond these information gathering and assessment tools, the likelihood and effects of capture may be further reduced by three 'process' improvements reflecting the unique nature of government standard-setting: deliberate focus on how government standards are articulated in light of the specific goals; post-adoption monitoring and adjustment for capture; and, perhaps most importantly, deciding whether in the circumstances something other than government standardization is the most effective approach.

As noted at the outset of this section, unlike market or industry standards, many (if not most) government standards seek outcomes that do not depend on a particular implementing means. Comparing an industry-generated product interoperability standard with a government automobile fuel efficiency standard provides an illustration. Industry interoperability requires every participant use the identical communications protocol. In contrast, a fuel efficiency standard only requires achieving the targeted level of performance. That means many government standards can be stated in technology-independent terms, focusing on the required output (miles per gallon in the example) rather than the specific means for achieving it, making them far less susceptible to patent capture.

Careful articulation of government standards cannot, of course, fully avoid capture. Not all government standards lend themselves to statement in non-means terms. For example, industry complaints that output requirements are unachievable may be addressed by requiring the use of the 'best available technology'.[114] In other situations, the desired output may not be objectively quantifiable. For example, because there is presently no way to prevent mad cow disease (or even determine for certain if it is present), government safety standards are framed in terms of specific government approved testing

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[113] They may, however, face discrimination claims. Additionally, although the federal and state governments are largely immune from antitrust liability, subordinate government subdivisions are not.

[114] *See, e.g.*, 33 U.S.C. § 1311(b).

methodologies. Additionally, if not properly constrained, the recent expansion of patent law into less crisply defined arenas (such as business methods) threatens increased capture of even 'output' articulated government standards.

Explicitly expanding government standard decision-makers' writ to include on-going post-adoption review and adjustment can also reduce patent-capture costs; in fact the mandatory nature of government standards greatly facilitates such action. Amendments removing what subsequently are revealed to be, or become, unnecessary specific technological requirements or adding newly available alternative implementations are relatively straightforward. When radical changes result, government standards can flexibly deal with the specific situation by grandfathering existing implementations, providing time schedules, offering subsidies or simply mandating that industry absorb migration costs. Such directives, of course, would require careful assessment of related benefits and costs as well as the practical realities, social and political. Even when no practically feasible alternatives exist, other actions can mitigate the adverse social costs of capture. For example, the *eBay* focus on public harms might justify limiting relief to compulsory market-rate licensing when the infringement is the result of complying with a government standard. And, in extreme circumstances, a governmental taking, either through mandatory governmental licensing or outright ownership of the problematic patent, could provide a net lower cost solution by eliminating hold-out premiums or monopoly profits through tax-payer-subsidized competitive access.

Perhaps the most important mechanism for dealing with patent capture in the government context is circumspection before acting. Most government standards do not explicitly target increased market efficiencies. Instead they set baseline social policies, such as safety standards, internalization of specific costs or mandating distributional outcomes, independently of what the market might otherwise produce (at least short term). Consequently, when a government standard cannot be readily articulated in such output terms rather than specific means subject to capture, that may signal the particular matter can be better dealt with, at least presently, by industry standard-setting or by letting the market decide.

In conclusion – the importance of context and the related international implications

The above discussion reveals that viewing 'patent capture' as an epithet elides the complexity of the interaction between patents and standards. It fails to consider the inherent tension between the incentive goals of patent law and the efficiencies that may be produced by widespread adoption of a standard and the importance of assessing 'capture' in the specific context. A 'captured' market-generated standard arises from desirable competitive forces, with the patent generally representing the promised (and intended) reward for the

successful innovator (provided, of course, the resulting power is used in accordance with antitrust and patent misuse law). A 'captured' industry-generated standard requires a close look at the underlying process; does it reflect expert private ordering or collusion and opportunism? A 'captured' government standard must be measured by the public policy objectives it pursues – does the patent-based requirement result from necessity (including political compromise) or implementation error. And, even more fundamentally, does the goal require a government standard at all? Context, therefore, counsels strongly against the impulse to resolve every patent standard capture 'problem' by using law to 'fix' the resulting impediment to widespread access and implementation. On closer analysis, the proper legal response may require not merely restraint, but affirmative assistance to the standard-setting process or, even protecting the captured returns.

This strong context dependency applies equally to decision-makers in other jurisdictions. They may be more or less favorably inclined to patent interests which capture a standard, but their ultimate decision should nonetheless take into account the patent-standard conflicts and related tension as well as the genesis of the particular standard involved.[115]

That common analytical core carries special significance in a global economy. The benefits of standards and patent-capture risks are not isolated to single local markets; they are equally important in the international marketplace. An appropriate legal response to the patent-standard interaction, therefore, requires more than an assessment of the domestic market effects in light of national values and goals. It should take into account the inter-jurisdictional ramifications, including the potential benefits of international consistency and predictability as well as the related distributional consequences.[116] As with standards in the marketplace, there is much to be gained from standardizing standards law, but it is equally important to watch for inappropriate capture by particular points of view and related vested interests.

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[115] For a European Union perspective, *see* Mauritis Dolmans, *Standards for Standards*, *available at* http://www.ftc.gov/opp/intellect/020522dolmans.pdf (2002) (noting the particular importance of standardization to the EU's market integration objectives). The European Commission has recently indicated its intent to investigate both the *Rambus* and *Qualcomm* cases, which may provide interesting insights into the European Union view of, and legal approach to, such situations. For a comparative view from the U.S. perspective, see Brussels IP-Antitrust Conference: Abbott Comments on SSOs, *available at* http://www.techlawjournal.com/agencies/ftc/20070118_abbott.asp (2007).

[116] *Cf.* Vincent Chiappetta, *TRIP-ing Over Business Method Patents*, 37 VAND. J. TRANSNAT'L L. 181 (2004).

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