The Intellectual Property Debate

NEW HORIZONS IN INTELLECTUAL PROPERTY

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Edited by

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Introduction: debating IPRs

Meir Perez Pugatch

Aliusque et idem
Carmen Saeculare, 10
Horace

1. THE LESSONS OF HISTORY: WAVES OF IP DEBATES

If a Martian (or any kind of extraterrestrial for that matter) were to visit earth for the first time and be exposed to some of the debates that are currently taking place in the IP domain, he would undoubtedly think that there is something very peculiar with the system. After all, if something as 'technical' and 'legalistic' as IPRs draws so much attention, then surely there is either more to the system than meets the eye, or the system is relatively new and therefore requires modifications. If the same Martian were to visit earth sooner – say in the 17th century (1623 to be exact) – when section 6 of the *Statute of Monopolies* was passed in Britain, then he would have probably understood that the system is far from new and would thus have eliminated the second explanation.

After all, the Statute of Monopolies – which at the time revoked all rights to private monopolies under the British dominium and established that the British Crown has the sole authority to grant such monopolies, has made an exception with regard to patented inventions.

> Any declaration before- mentioned shall not extend to any letters patents (*b*) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (*c*) to the true and first inventor (*d*) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (*e*), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (*f*): the same fourteen years to be acccounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this act had never been made, and of none other.[1]

But if the system of IPRs is more than five centuries old, what makes it so fraught with emotion that every generation occupies itself with new debates on IPRs, which are often as emotional as they are rational?

Indeed, the current debates on IPRs are vast and diverse, as will hopefully be demonstrated in this book. However, before outlining some of the themes that will be discussed in the ensuing chapters, it may be useful to remember that such debates have been on the agenda for at least two centuries.

In a paper entitled *The Patent Controversy in the Nineteenth Century*,[2] Fritz Machlup and Edith Penrose, two of the most prominent scholars of IPRs in the early 1950s, have described some of the most intense debates over patent protection in the 19th century. It is worth noting what Machlup and Penrose said about the great patent debates of the 19th century when referring to the debates that took place in the US Congress during the 1940s and 1950s:

> In recent publications [in the 1950s – author's note] commenting on these discussions it has been suggested that opposition to the patent system is a new development. A writer of a 'history' of the patent monopoly asserted that 'there never has been, until the present time, any criticism of this type of "exclusive privilege". . . '.
>
> In actual fact, the controversy about the patent of invention is very old, and the chief opponents of the system have been among the chief proponents of free enterprise. Measured by the number of publications and by its political repercussions – chiefly in England, France and Germany, Holland and Switzerland – the controversy was at its height between 1850 and 1875. The opposition demanded not merely reform but abolition of the patent system. And for a few years it looked as if the abolitionist movement was going to be victorious.[3]

The great patent debate of the 19th century sowed the seeds of the debates that followed in the 1950s, 1970s and up to the present. The patent debate of the 19th century covered it all – philosophical, ethical and legal aspects. It was also the time when economic arguments were put to use and from which a whole new specialization in the economics of IPRs emerged. Machlup and Penrose talk about four dimensions in which the patent debates took place: 1. the natural property right in ideas; 2. the just reward to the inventor; 3. the best incentive to invent, and 4. the best inventive to disclose secrets. Each of these dimensions saw argument for and against the patent system.

To note two dimensions: the notion *natural property right in ideas* and the *incentive to disclose secrets*.

The notion of *natural property right in ideas* was probably first manifested in 1791 France, in which patent rights were linked explicitly to the notion of property. Right number 17 of the *Declaration of the Rights of Man and of Citizens*, as adopted by the French Constitutional Assembly, states: 'the

right to property being inviolable and sacred, no one ought to be deprived of it, except in cases of evident Public necessity, legally ascertained, and on condition of a previous just indemnity'.[4] In that year the French Constitutional Assembly also adopted a new patent law which stated that 'every novel idea whose realisation or development can become useful to society belongs primarily to him who conceived it, and that it would be a violation of the rights of man in their very essence if an industrial invention were not regarded as the property of its creator'.[5] Machlup and Penrose tell us that some advocates of IPRs, such as Stanislas de Bouftler went as far as arguing that intellectual property is superior to plain material property: 'invention, the source of arts, is also the source of property: it is primary property, while all other property is merely conventional'.[6] The economist, Henry Macleod, another advocate of patents argues that 'the production of a man's mind are now recognized to be as truly his own property and the fruits of his industry as the production of material wealth' and that 'it is hard to see on what grounds he can be denied the same tenure in one as in the other'.[7]

Critiques of the patent system did not leave unchallenged the notion that intellectual property is equal to physical property. R.A. Macfie, one of the leaders of the patent abolitionist movement, argued that 'if there were any "natural rights" in connection with inventions it would be the inventor's "right to use his own invention" '. Macfie argued that not only is the patent system not a manifestation of a natural right, but rather that under this system 'all too often an inventor find himself barred from using his own idea because someone else has obtained a patent on it'.[8] Opposition to the notion of natural property in ideas also came from the social progress movement which held the view that since social progress is much more important for the creation of inventions than the individual inventor, any system of pecuniary rewards for inventors, such as patents, is completely inadequate. J.L. Ricardo, an advocate of the social progress perspective argued that since 'nearly all useful inventions depend less on any individual than on the progress of society' there is no need for it to 'reward him who might be lucky enough to be the first on the thing (invention) required'.[9] *The Economist*, which at the time sympathized with this line of argument, noted in an 1850 issue that before the inventors

> can establish the right of property in their inventions, they ought to give up all the knowledge and assistance they have derived from the knowledge and inventions of others. That is impossible, and the impossibility shows that their minds and their inventions are in fact, parts of the greater mental whole of society . . .[10]

Another dimension that fuelled the debate in the 19th century focused on the *incentive to disclose secrets*. To some degree this discussion has emerged

from the more fundamental economic debates about the extent to which the patent system provides incentives for and optimizes the rate of inventive activity on the one hand, and the opportunity and social costs that are associated with these activities on the other hand.[11] When addressing the issue of the incentive to disclose secrets, advocates of the patents system described it as a social contract. The social contract argument derived from the teachings of the French philosopher Jean Jacques Rousseau.[12] The Social Contract argument was adapted to the patent system by French economists such as De-Bouffler and Louis Wolowski. The latter, for example, argued that 'the patent system constitutes a genuine contract between society and the inventor. If society grants him a temporary guaranty, he discloses the secret which he could have guarded; quid pro quo, this is the very principle of equity'.[13]

Opponents of the patent system, such as Rogers, Prince Able Smith and Rentzsh had equally persuasive counter-arguments. They have suggested the possibility that if an inventor is able to keep his invention secret for a period longer than that granted by patent term, he would be reluctant to disclose his invention to society (a well-noted example is the case of Coca-Cola, which prefers to keep its formula secret rather than applying for patent protection). They argued that it is likely that an inventor will apply for a patent mainly when he believes that he will not be able to keep his invention secret for a period that is longer than, or at least equal to, that of the patent term. Rogers, for example, attacked the notion of the social contract, as portrayed by patent advocates, and argued that this contract is extremely one-sided since an inventor can choose to disclose his invention to society only if he expects that his profit will exceed the alternative of exploiting his invention in secret. He thus concluded that 'no one can call that a fair bargain which is voluntary on one side, and involuntary on the other'.[14]

The debates of the 19th century did not solve the problems of the patent system. On the contrary, the controversies surrounding the patent system and IPRs as a whole have spilled over to our present century.

The 1950s brought a new wave of IP debates in the United States. During 1957 and 1958 the Subcommittee of Patents, Trademarks and Copyrights, of the Committee on the Judiciary – US Senate, held a series of discussions over the role of the system of IPRs and their impact on the industrial strength of the nation. Distinguished IP scholars, most of which were economists, such as Allen, Machlup, Melman, Palmer, Vernon, submitted to the Subcommittee highly detailed reports on the patent system.[15] These reports (15 altogether) laid out, or at least re-stated, the theoretical and academic foundations for the economic study of IPRs (though economists, such as Arnold Plant and Michael Polanyi provided fascinating discussions about the economics of patents in the 1930s and 1940s).[16]

However, despite their efforts, Machlup and his peers could not reach a definite conclusion about the prospects of IPRs. In the concluding remarks of his 80-page report Machlup apologized before the Subcommittee given that 'the statements winding up the discussion in the preceding section look like a disappointingly inconclusive conclusion of a rather lengthy economic review of the patent system'.[17] After all, it was Machlup who concluded in the same report that 'no economist on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss to society'.[18] Over the years this rather famous conclusion has been quoted repeatedly by different academics. Vernon, who focuses more on the economics of patents in the international system, expressed strong self-criticism about his ability to enlighten the Subcommittee. Vernon considered the lack of sufficient data as one of the most serious problems in economic study of IPRs, stating that 'we plunge into this analysis with one major misgiving. Policy towards the international patents system turns heavily on an appraisal of its economic impact, and much of the data needed in order to consider this impact objectively is lacking or inadequate'.[19] Therefore, he adds, 'the contentions in favour of extending the rights patentees suffer from the basic deficiency, no less than the contentions in favour of curtailing them.'[20]

The 1970s put the third wave of IP debates into the context of the North–South divide. In a series of publications, the United Nations Conference of Trade and Development (UNCTAD), representing the bulk of developing countries, vigorously flagged up the effect of IPRs on developing countries. One can recall publications such as *The Role of the Patent System in the Transfer of Technology to Developing Countries – 1975*; *Major Issues in the Transfer of Technologies to Developing Countries – A Case Study of the Pharmaceutical Industry – 1975*; *The Role of Trade Marks in Developing Countries*, *1979*.[21] However, despite their critical approach to the impact of IPRs on developing countries, the UNCTAD studies did not seem to offer an alternative, practical policy for the IP system. Nor did they extend beyond the scope of an academic discussion (albeit a very interesting one).

It would seem that we are now facing the fourth wave of IP debates, which for lack of a better term we might refer to as the 'Millennium IP debate'. This debate is far from over, and its boundaries are yet to be defined. Its origins, however, can be traced to the TRIPS agreement and its aftermath.

The inclusion of an agreement on trade-related aspects of intellectual property rights (TRIPS) under the auspices of the World Trade Organization was one of the most innovative and controversial elements of the multilateral trading system. Signed in Marrakesh (15 April 1994) as annex 1C to the final act establishing the WTO, the TRIPS agreement represents

a significant increase in the global level of intellectual property protection and is considered to be a 'revolution in international intellectual property law'.[22]

The process of implementing the TRIPS agreement by developing and least developed countries is a painful one, particularly in the area of pharmaceutical patents. Much controversy surrounds the linkage between patents and access to medicines. The debate over the extent to which the internationalization of IPRs affects the ability of poor countries to gain access to affordable medicines has extended beyond the domain of trade policy. This debate has become as emotional as it is rational, and encompasses legal and health issues and even questions of business ethics and morality.

The Millennium IP debate promises to be wide in scope and full of heat. It will encompass issues across the board, such as incentives to innovation, industrial development, trade policy, access to available technologies, and effective commercialization in the age of knowledge-intensive industries. In this wave, like the IP debates that precede it, the virtues and flaws of the system will be emphasized, discussed and celebrated.

2. THE MILLENNIUM IP DEBATE – IS THERE ANYTHING NEW UNDER THE SUN?

Is there any point at all in collecting essays that represent different aspects and perspectives of contemporary IP issues? Given the depth and scope of past debates should we not try to compile a book that focuses on historical debates rather than on contemporary ones? After all it was Machlup and Penrose who had admitted – bravely – that 'despite all the changes in the economic scene, our thinking on the subject has hardly changed over the century'.[23]

There is certainly a need to recall some of the old debates. As argued above, one would only stand to benefit from the lessons history can teach.

However, there is also an equal need to capture some of the issues presently being debated. While many aspects of the IP debates remain the same throughout history (and there is also a considerable chance that they remain so in the future), other elements have been influenced by a natural evolutionary process of creating, distributing and utilizing knowledge and information – the subject matter of IPRs. Four elements are particularly worth mentioning.

First, the unit of analysis has shifted from the individual to the organizational unit (be it a company, a research institution or a University). Consequently, the relationships governing the field of IPRs have become

more complex. It is self- evident that as we progress we are focusing less on the individual inventor and more on the process of 'organized innovation' (or what we simply refer to as R&D). This is not to say that individuals are not important. By all means they are! Inventive activities cannot be done without the ingenuity of the human mind (at least at present). However, as the process of innovation takes place by an organized unit, the importance of one individual (even if he is the undisputed 'brain' behind the technology) is diminishing. This observation is far from being original (and again no one said it was). As far back as 1940 Alfred Khan had already pointed to this change:

> The systematic, planned experimentation which characterizes modern technological method, swifter and surer than the old, has enhanced the interdependent, cooperative nature of invention. Technology has become so vast and so complex that the individual is more than ever dwarfed in relation to it. Invention has in addition become much more consciously cooperative. In the great modern research laboratories, tens, hundreds of men focus upon single, often minute problems. With scientific organization thus systematically mulling over all the well-known problems, inventions become increasingly inevitable. It become[s] more than ever impossible to isolate any one contribution as the invention or any one man as sole inventor and rightful patentee. . . . Hence inventors are for the most part trained salaried professionals, hired to learn and to work in the great laboratories provided by those who can afford them. Patents are automatically assigned to the corporation which pays the salaries and provides the facilities. Because it takes the risks, the business takes the speculative reward.[24]

We should also note that R&D activities that ultimately led to the creation of knowledge-based products are influenced by other factors, such as capital, infrastructure, manufacturing capacity, market presence, logistical abilities and competition. These are as important, and at times more important than the process of knowledge creation as a whole. If semantics are of importance (and they usually are) perhaps it would have been better if, today, we should treat IPRs as OPRs – that is organization property rights. And, without getting into a discussion of what it means to consider IPRs (OPRs) at the organizational level, suffice it to say that the interests and incentives to create, utilize and distribute IPRs by an organization are not necessarily the same as those of the individual. For example, it is sometimes surprising to observe how different debates on the effect of IPRs – say in the corporate world (for example in the pharmaceutical and IT companies) – focus on the 'individual nature' of corporate IP owners, portraying them either as 'benign' or 'malign' (depending on one's perspective). It is in the heat of such debates that we tend to overlook one very significant factor – that all commercial companies, regardless of their orientation, share one common denominator – profit! Therefore, it is

overdue that modern discussions should reflect this change in the unit of analysis.

Second, patents are no longer the only form of IPRs that are worth discussing, especially with regard to policy-making issues. Traditionally, policy-making aspects of IPRs have been equated with patents, as for example with regard to the TRIPS agreement (even this author has committed this unfair act when focusing on patents and trademarks in his previous book). This is not to say that there are no works or writings on other forms of IPRs, especially copyrights and trademarks (one can only look at the writings of Plant, Schechter and Chamberlin on trademarks in the first half of the 20th century).[25] But patents have always been considered the most controversial and sexy subject in the IP domain, and hence have received much more attention. This is no longer the case. Copyrights, trademarks, geographical indications and other forms of sui-generic protection (such as pharmaceutical data exclusivity) are rapidly gaining their rightful place under the sun, not least because they are associated with some of the most intriguing and heated debates in the Millennium era. Their economic rationale, legal manifestation and social uses (and abuses) should be addressed more frequently in policy discussions.

Third, it is a paradox (though a natural one) that as specialization and professionalism in the IP field increase they ultimately lead to a detachment between different elements and themes of IPRs, which are becoming more and more 'divorced' from one another. IPRs today affect the micro and macro levels. They can be thought of or learnt about from various perspectives and schools of thought, including economics, law, finance, management, entrepreneurship and accounting. Expertise in the field of IP is a hot commodity in many areas, such as trade policies, industrial policies, technology transfer, product development, health care, music, films the webspace, traditional knowledge and many others. However, as each subject develops naturally into its own micro-cosmos, the field as a whole is becoming increasing fragmented. Therefore, it is very important to try inducing and to reintroduce an interaction between different IP themes, as this would allow us to obtain a more comprehensive view on the IP field as a whole.

Finally, contemporary debates on IPRs are predominantly influenced by external factors, the result of the age in which we live. It is these events that influence our perceptions of IPRs and not vice versa. Had the internet not been developed, the entire conflict of downloading and copyright infringement would not have become an issue. This is also the case with regard to pharmaceutical IPRs and the issue of access to medicines in least developed countries. It is the disastrous state of poverty and disease in sub-Saharan Africa (and obviously the fact that we know about it) that brings

about the heated debates about IP policies in this field. This was not the case 50 years ago. Regardless of how trivial and banal this may sound, IPRs are but one of many factors that affect a particular situation. And no matter if we view them as part of the solution or as part of the problem, IPRs are never the only factor – the silver bullet – and sometimes not even the most important factor. This should be taken into account and remembered even when focusing solely on IPRs, as this book does.

3. THE STRUCTURE OF THIS BOOK

Grouping various IP contributions into distinct and homogeneous categories is not an easy task, not least because each contribution touches upon different aspects of IPRs. Nevertheless, an attempt has been made to structure this book in a manner that would allow readers to be exposed to some of the thematic and topical aspects of the contemporary discussions in the field.

The book comprises five broad sections, two of which are thematic (trade investment and enforcement policies; valuation, commercialization and public–private partnerships) and three are topical (patents, pharmaceuticals and biotechnology; access, competition and antitrust in the information society as well as geographical indications).

Section one – trade, investment and enforcement policies of IPRs – deals with the international aspects of IPRs. Michael Blakeney provides an analysis of the 10-year-old TRIPS agreement, focusing on the promise of 'promoting technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users in a manner conducive to social and economic welfare' (TRIPS, Article 7). He is critical of the veracity of this promise, particularly with regard to developing countries. Brian Hindley discusses the economics of IPRs and considers the case for an international IP system, such as that established by the TRIPS agreement. He concludes, that 10 years after its coming into force, the TRIPS agreement is still much more beneficial to developed right-holder countries than to developing ones. Douglas Lippoldt considers the empirical linkage between national IP environments, international trade and foreign direct investment (FDI). He finds that, overall, stronger IPRs tend to boost trade, FDI and licensing activities in developing countries, while also emphasizing that IPRs cannot be treated as a 'silver bullet' development solution. Paul Vandoren and Pedro Velasco Martins provide a right-holder perspective on the issue of global IP enforcement, focusing on the new enforcement strategy of the EU. They argue that in the coming years the EU is likely to adopt a more proactive enforcement strategy of IPRs outside its borders.

Section two – IPRs, business and public–private partnerships – focuses on the business aspects of IPRs across different media. Richard Rozek and George Korenko outline the different methods of evaluating the dollar worth of IP (knowledge) assets – that is the cost, market and income approaches. They identify the income approach as one that is accepted across most forums, and illustrate two methods for its application that will help companies prepare robust valuations of their IP assets. Grant Isaac provides a critical assessment of the scale neutrality of IPRs, and enumerates the different factors that affect the ability of companies to engage in successful exploitation of IPRs, particularly small and medium-sized enterprises (SMEs). He concludes that, from a broader policy perspective, the lack of scale neutrality in the patent policy instruments negatively affects the innovative and commercial abilities of SMEs. Richard Rozek and Bridget A. Dickensheets discuss the complementary functions performed by academic, government and private industry scientists and provide examples of market-based methods that are used to transfer technology among the three sectors. To facilitate cooperation between sectors, they conclude that public policy should focus on the protection of IPRs and free market principles rather than price regulation or other controls. Robin Blatt provides an overview of US technology transfer policies within the university setting. She explores the contemporary opportunities, challenges and conflicts that have emerged as a result of the goal towards privatization and commercialization of early stage government-funded R&D within the university setting. She argues that Universities in the US have reached an historic juncture where contemporary technology transfer policy issues require active re-examination.

Section three – IPRs, pharmaceuticals and biotechnology – covers some of the heated issues that are currently being debated in these fields. David Goren discusses the question of achieving a new balance between rewarding innovative pharmaceutical research, while meeting the needs of a growing public demand for innovative health care solutions at lower prices. He argues that any solution to the current health care IP crisis requires that society maintain the appropriate profit motive in rewarding innovation and allows the free market to operate properly, while balancing public interest. Eric Noehrenberg provides a right-holder analysis to the question of patents and access to medicines in developing countries, particularly with regard to the patentability of essential medicines, the prices of generic drugs and the criticism of the TRIPS agreement and access to medicines. He concludes that for too long IPRs (and patents in particular) have been blamed for the on-going health crisis in poor countries, while other, more significant factors, have been overlooked and ignored, sometimes intentionally. Trevor Cook discusses the issue of gene patents and gene-sequence patents from

the perspectives of European and United States patent laws. He argues that the 'Ginny' of gene patenting is far from being evil, or unusual for that matter. He suggests that one should be wary of legislation that is based either on anecdotal concerns that have been inadequately analysed, or on historical considerations that have little relevance for the future.

Section four – IPRs, competition, access and antitrust in the age of the information society – considers some of the tensions and disputes arising from the regulation and protection of IPRs in the era of rapid and dramatic digital, electronic and web-based technological developments. Duncan Curley provides a critical assessment of the European approach towards balancing the protection of IPRs on the one hand and safeguarding EU competition law, including the use of antitrust mechanisms, on the other hand. He finds that the recent EU actions in this field, such as in the case of Microsoft, run the risk of eroding the exclusivity granted to IP owners and may even upset the delicate balance between competition law and the need to preserve incentives to innovate offered by IPRs. Uma Suthersanen considers how technological development affects different stakeholders and influences their policy-orientated behaviour towards the design of IPRs. She finds that the emergence of new technologies in the digital and internet media, as in the case of file sharing, is usually accompanied by a sense of hysteria concerning the threat of copyright infringement. She argues that demands to impose penalties and remedies on those who create and provide these technologies should be carefully balanced against their overall contribution to the economy as a whole. Guido Westkamp analyses the extent to which the technological changes in the information society affect and alter traditional structures of copyright law and exclusive rights in general. He finds that the current inherent tensions in copyright law are now subject to a novel evaluation, which places more emphasis on control over information than the requirement for a substantive analysis of copyright infringement. Nevertheless, he argues that although the inherent architecture of copyright might have shifted towards an all-embracing control right over information, it remains doubtful whether such shift will, in future, be upheld.

Section five – IPRs and geographical indications (GIs) – focuses on this fascinating form of intellectual property, which thus far has not received adequate coverage in the literature (at least in terms of volume). Michael Blakeney provides an historical overview of the evolution of GIs from a very basic form of trademark to a stand-alone IP right, which is regulated and standardized by the TRIPS agreement. Considering the merits of GIs for developing countries, he suggests that although an expansion of the products covered by GIs arguably serves the interests of EU countries, overall in the package of TRIPS norms, GI protection comes closest to

developing countries' policy interests, and could also boost the protection of traditional knowledge. David Vivas Eugui and Christoph Spennemann consider the international regulation of GIs in recent regional and bilateral free-trade agreements. They find that the EU and US regional trade agreements serve as good illustrations of the recent shift in international IP policy-making away from the multilateral (WTO/WIPO) forum to the regional and bilateral levels. They suggest that developing countries should be wary of this phenomenon and that these countries should carefully assess whether the ensuing GI obligations under these agreements correspond to their economic and societal priorities. Phil Evans provides a consumer-perspective analysis of GIs in general and of the tension between GIs and trademarks in particular. He argues that in analysing the phenomenon of GIs, one should also adopt a competition policy perspective, which would allow one to deconstruct the incentive structures that GIs create in agricultural markets and to discuss the impact that GIs have on competition in product markets. He concludes that the WTO TRIPS regime that allowed the present anti-competitive nature of the GI system to impose itself globally, would also be to the detriment of consumers in Europe and elsewhere.

4. LIMITATIONS OF THIS BOOK

In the epilogue of his highly controversial book, *The Secret Agent*, which was first published in 1907, Joseph Conrad says the following: 'I have always had a propensity to justify my action. Not to defend. To justify. Not to insist that I was right but simply to explain that there was no perverse intention, no secret scorn for the natural sensibilities of mankind at the bottom of my impulses.'[26]

It is in the same light, and without being apologetic, that self-criticism should be expressed about the methodological constraints and the limitation of substance that are part of this book.

Methodologically speaking, the book may, at times, be viewed as having an imbalance, in the sense that it does not reflect all the views that may be expressed on a given subject or debate. For example, it is possible to argue that the discussions on pharmaceutical IPRs reflect a more positive perception while the discussion on GIs tends to emphasize negative views on the subject.

There are three explanations for this. First, like any publication that is based on contributions, this book also reflects the Editor's ability to approach authors and secure contributions. To this extent, any criticism on the non-objectivity of the book should ultimately be attributed to the

shortcomings of the Editor, not the authors. Second, to some extent this book seeks to emphasize views which are not as frequently mentioned and expressed as other themes. For example, it would seem, at least to this author, that criticism of pharmaceutical IPRs appears more frequently in the academic literature than right-holders' perspectives, which usually appear in more professional publications. Finally this book is not objective as it reflects the views of the person who envisaged this project. After all Conrad begins his epilogue by saying that 'the Origin of the Secret Agent: subject, treatment, purpose and every other motive that may induce an author to take up his pen, can, I believe, be traced to a period of mental and emotional reaction'.[27] This book is no different. Nevertheless, and in spite of the above, it can be argued with a degree of certainty that, overall, this book does provide a balanced or at least comprehensive picture of different IP debates. Moreover, it is also possible that the cross-subject linkage that is created in this book – for example the linkage between the thematic issue of trade policy of IPRs and topical issues, such as pharmaceutical IPRs, copyrights and GIs, enhances the overall balance of this book, as some views that are not expressed in one section are expressed in other sections.

With regard to limitations of substance, arguably this book could have covered many other topics, as well as much more ground on each topic. That other subjects and issues of disputes do not appear in this publication does not suggest that they are unimportant. Some may also argue that the book should have focused on issues other than those covered here. That is all true. Yet no book is perfect and this one certainly does not presume or intend to be. And, be that as it may, it is hoped that the 'plat du jour' presented in the book will be attractive enough to open up and develop the appetite of those who take an interest in the field.

NOTES

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PART I

Trade, investment and enforcement policies of IPRs

1. A critical analysis of the TRIPS agreement

Michael Blakeney

1. INTRODUCTION

Signature of the TRIPS agreement is one of the obligations which members of the WTO are obliged to undertake. The ostensible reason why this agreement was included in the constellation of undertakings which comprise the charter of a global free trade regime is that the infringement of intellectual property rights is claimed to be trade distorting. Intellectual property was included as a negotiating subject in the Uruguay Round of the GATT, largely on the evidence which was compiled by the USA that annual losses to US traders caused by the trade in infringing items totalled some $US60 billion, which represented an annual loss of some 200 000 jobs.[1] These figures appear to have been compiled from evidence presented to Congressional hearings about the losses sustained by businesses from counterfeiting and piracy. There is an understandable tendency for traders to exaggerate the sales which they might have made if not for the presence of factors over which they have no control.

Similarly large figures have been reported in Europe. For example, in its proposal for a counterfeiting Directive, the European Commission refers to a survey carried out in France in 1998 by KPMG, Sofres and the Union des Fabricants, which reported that the average loss to the businesses that replied to the survey was put at 6.4 per cent of turnover. It also refers to a 2000 study by the Centre for Economics and Business Research (CEBR) on behalf of the Global Anti-Counterfeiting Group (GACG), which quantified that the average annual reduction in profits was: EUR 1266 million in the clothing and footwear sector; EUR 555 million in the perfumes and cosmetics sector; EUR 627 million in the toys and sports articles sector; EUR 292 million in the pharmaceuticals sector. Finally it reported a study carried out by the International Planning and Research Corporation (IPR), on behalf of the Business Software Alliance (BSA) which quantified the losses in western Europe (EU + Norway + Switzerland) from software piracy in 2000 to be more than USD 3 billion. Again for each of these

surveys, enterprises were asked what their sales would have been, if not for counterfeiting and piracy.

Despite the looseness of these figures, it is unquestionable that counterfeiting and piracy has an impact upon world trade. The question that this chapter addresses is whether the TRIPS agreement is the appropriate instrument with which to deal with this problem.

Although the agreement began as an initiative to deal with the trade in infringing products, which was reflected in the inclusion of 'counterfeiting and piracy' in the original title, it deals with much more. The agreement prescribes a comprehensive range of intellectual property norms which have to be implemented by all WTO Members. The advantage to the USA in the institution of an effective global regime for the enforcement of intellectual property rights is undoubted. An interesting question is how the nation, which is the largest exporter of intellectual property rights, was able to persuade the rest of the world to adopt a global regime providing for the enforcement of those rights. En route to this solution, the US also had to persuade the international community of nations that an inter-governmental agreements on tariffs and trade had more to offer than the specialized agency of the United Nations which was set up to deal with intellectual property.

Part of the answer lies in the very effective lobbying by US trade interests in Geneva to secure the TRIPS agreement.[2] Part of the answer lies in the fact that intellectual property in the WTO context is part of a package of agreements in which intellectual property could be bargained for, say, the reduction in protectionist agricultural subsidies. Part of the answer also lies in the promise of economic benefit which is made to countries which are obliged to implement the agreement. Article 7 of the TRIPS agreement, which is headed 'Objectives' states that

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare . . .[3]

This chapter also examines the veracity of this promise, and looks at the rationale of the TRIPS agreement from the perspective of developing countries.

2. INTELLECTUAL PROPERTY AS THE HANDMAIDEN OF DEVELOPMENT

Even before intellectual property rights became trade related, WIPO had been very successful in assisting developing countries in promulgating

intellectual property laws. The assumption of the relationship between intellectual property rights and economic development is generally accepted as an article of faith. For example an entire division of the World Intellectual Property Organization (WIPO) is concerned with 'cooperation for development'. The United Nations Conference on Trade and Development (UNCTAD), which became representative of the views of developing countries, has produced a number of studies calling for the improvement of the ways in which patent and trade marks laws operate in the transfer of technology.[4] The assumption of these studies was that with the removal of impediments and abuses in the operation of intellectual property laws, the resultant flow of technology would lead inexorably to economic development.

However, even in industrialized countries, the evidence that intellectual property rights are a handmaiden of economic development is equivocal. In his celebrated 1969 study of the patent system in the United States, Fritz Machlup concluded that 'no economist on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society'.[5] Since that time a number of empirical studies have been undertaken to ascertain the industrial significance of patent protection. In his 1971 study, Firestone found that competition was reported by US firms as the principal factor influencing R&D expenditure.[6] On the other hand, the 1973 study of British firms by Taylor and Silbertson asserted the importance of the availability of intellectual property protection as a reason for invention.[7] On the other hand a British study 10 years later found that among 50 small and medium enterprises, intellectual property protection tended to be a low priority largely because of the perceived expense of enforcing intellectual property rights.[8] In a study published in 1986, Mansfield inquired among a random sample of 100 firms from 12 industries in the USA, about the proportion of their inventions that were introduced between 1981 and 1983, which would not have been commercially developed if patent protection had not been available.[9] He discovered that there were sectoral differences in attitude to intellectual property protection. In the pharmaceutical and chemical industries patent protection was considered essential for the commercialization of about one third of inventions. In the petroleum, machinery and fabricated metal products industries the proportion was between one tenth and one fifth. Mansfield found industrial property protection to be considered of little significance in the electrical, office equipment, motor vehicle, instrument, primary metals, rubber and textile industries. Similar results to these had been found by Llewellyn's 1981 study of the R&D activities of Australian firms.[10] An interesting observation in Mansfield's study was that in the chemical and pharmaceutical industries 80 per cent of the patentable

inventions were patented, but even the firms in industries where patenting was not considered to be essential, he reported that over 60 per cent of patentable inventions were patented. This suggests the use of intellectual property rights to establish market power.

The tension between intellectual property issues and competition policy was highlighted by the Senate Standing Committee on Science and the Environment in its 1979 report on *Industrial Research and Development in Australia*,[11] in which it expressed the view that 'Australia's present patent system may well be acting against the country's best interests'.[12] The Industrial Property Advisory Committee, commissioned to examine how this situation might be improved, suggested amendments to the Patents and Trade Practices Acts.[13] The issue of the economic effects of the Australian patent system was addressed by the 1982 study of Mandeville, Lamberton and Bishop.[14] They concluded that 'the economic benefits of the patent system to the innovative process in Australia are not only small, but extremely subtle'. They suggested that:

- The patent incentive is not an important determinant of measured domestic R&D activity, but plays a small role for the small inventor.
- Patents apparently play a subtle role in connection with investment expectations and the transfer of technology to Australia.
- Patent information is a relatively unimportant source of R&D/technological information for domestic industry, small inventors and professional engineers. However, it is regarded as having some importance by large overseas-based multinational firms.
- The majority of patents held by domestic firms are said to produce a return but the absence of a patent system would be unlikely to affect production significantly.

Mandeville *et al.* identified many of the negative effects which have been attributed to the patent system by commentators on the operation of that system in developing countries. These negative effects included:

- The high direct and compliance costs of the system which 'acts as a deadweight to the innovative process by distracting resources from more useful activities'.
- The occurrence of restrictive practices in patent licensing which has 'the effect of dampening the already small domestic industrial R&D effort'.
- 'Patent monopolies imply higher prices for consumers and industry as well as distortions in the allocation of resources'.

- '. . . the mystique of the patent system can distract attention from the more important phases of the innovative process such as development and marketing'.

This study concluded with the assessment that there was 'little room for doubt that the benefit/cost ratio of the patent system in Australia is negative, or at the very best, in balance'. However, these costs and benefits were considered to be outweighed by the negative economic effects to Australia's international commercial relations, should the system be abolished.

A number of developing countries had noted the tension between the technology transfer objectives of the TRIPS agreement and the way in which the agreement made it possible for rights owners to impose unreasonable terms for technologies.[15] Given that technology transfer to facilitate economic development is stated as the objective of the TRIPS agreement, WTO Members are urged to 'examine as part of the Article 71.1 review the impact of implementing the TRIPS Agreement on the transfer and dissemination of technology and the related trade and development prospects of developing countries', with a view to 'operationalizing these provisions'.[16] For example, The South Centre has suggested that in relation to Art. 66.2, developed countries should 'provide more specific information on any existing schemes including the precise incentives, number of applying firms, and the effectiveness of these measures.'[17] To the extent that intellectual property rules do not promote technology transfer, it is suggested that

> WTO Members should consider the establishment of additional mechanisms to facilitate access by developing and least-developed countries to technologies on a reasonable basis in order to fully implement the TRIPS Agreement, and to harmonize its operation with the broader objectives of the WTO Agreement.[18]

India, noting the difficulties faced by developing countries to obtain access to foreign technology, has indicated the need to address that issue under the several provisions of the TRIPS agreement, such as articles 7, 8, 30, 31, 40, 66.2 and 67. It has argued that 'prospective technology seekers in developing countries face serious difficulties in their commercial dealings with technology holders in the developed countries' and that 'the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them'.[19]

A typical catalogue of the sorts of things to be included in a general review is that contained in Venezuela's 6 August 1999 communication to the Council for TRIPS,[20] namely:

1. Include the principles of the United Nations Convention on Biodiversity in the TRIPS Agreement, . . . to prohibit the granting of patents to those inventions made with foreign genetic material that are inconsistent with Article 15 of the CBD relating to the recognition of sovereignty and access to genetic resources.
2. Establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders.
3. Extend the list of exceptions to patentability in Article 27.3(b) of the TRIPS Agreement to include the list of essential drugs of the World Health Organization, in order to develop the principles established in Article 8 of the Agreement.
4. Extend the incentives mentioned in Article 66.2 of the TRIPS Agreement in favour of developing country Members. Review the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement with the aim of making them effective and operational.
5. Establish mechanisms of support for developing and least-developed countries through electronic commerce which involve strengthening development strategies and modifying the productive structures, as well as facilitating open technology transfer on a reasonable commercial basis.

3. INTELLECTUAL PROPERTY, TRADE AND INVESTMENT

Most developing countries are net importers of technology from developed countries. The World Bank estimates that most developed countries would be beneficiaries from the TRIPS agreement from the enhanced value of their patents. For example, the benefit to the USA was estimated to be $19 billion per annum.[21] In 1999 the World Bank estimated a net outflow from developing countries of $7.5 billion on royalties and licence fees.[22]

There is an extensive and growing literature which questions the thesis that intellectual property protection is a necessary pre-requisite for economic development.[23] Japan and South Korea are often cited as examples of intellectual property-driven economic development. On the other hand, the economic histories of these countries, as well as the rest of the industrial world, is one of imitation and plagiarism, which is replaced by the propertization of innovation, once the imitator has something to lose. Thus

even the USA, which was the architect of the TRIPS agreement, commenced its industrial life by imitating the industrial innovations of the UK. There is another thesis, which surprisingly has not yet been tested, that the industrial development of countries necessarily commences with a phase of imitation, during which the technological skills which underpin indigenous industrial innovation are developed.

Certainly the strengthening of intellectual property rights has been associated with the decline of indigenous industries based on imitation.[24] On the other hand, it is argued that developing countries with appropriate intellectual property regimes have access to those proprietary technologies previously withheld because of a lack of intellectual property protection. This access, however, comes with significant costs, which may limit the extent of these imports.

Research on the extent to which a stronger intellectual property regime encourages foreign investment is inconclusive. Certainly the significant investment in East Asia and Latin America occurred prior to the introduction of the TRIPS regime.[25] The UK Commission on Intellectual Property Rights concluded in its 2002 report *Integrating Intellectual Property Rights and Development Policy*:

- There is some evidence that trade flows into developing countries are influenced by the strength of IP protection, particularly for those industries (often high technology) that are 'IPR sensitive' (for example, chemicals and pharmaceuticals), but the evidence is far from clear.
- These flows may contribute to productive capability. But they may also be at the expense of domestic output and employment in local 'copying' and other industries. Developing countries with no or weak technological infrastructure, may be adversely affected by the higher prices of importing IP protected goods.
- The evidence that foreign investment is positively associated with IP protection in most developing countries is lacking.
- For more technologically advanced developing countries, IPRs may be important to facilitate access to protected high technologies, by foreign investment or by licensing.
- Achieving the right balance may be difficult for some countries such as India or China where some industries have the potential to benefit from IP protection, but the associated costs for industries that were established under weak IP regimes as well as consumers are potentially high.
- Most of the evidence concerning the role of IP in trade and investment relates to those developing countries which are more technologically advanced. For other developing countries, we conclude that any beneficial trade and investment effects are unlikely to outweigh the costs at least in the short and medium term.

4. INSTITUTIONAL CAPACITY

In the majority of developing countries there is considerable dependence on technical assistance provided by WIPO and other bodies. In order to meet the TRIPS implementation deadlines many developing countries accepted the legislative drafting assistance which was provided by these bodies. For the most part, model laws were provided off the shelf and adopted irrespective of their appropriateness for client countries. Often outside legal drafters were made available, invariably from the legal systems of developed countries. This was because of the lack of people in developing countries with the specialized technical skills of legislative drafting combined with an expertize in intellectual property law.

An illustration of the difficulties for developing countries to engage with their TRIPS obligations is illustrated by the TRIPS implementation and review processes. Developed country members of the TRIPS agreement were obliged by Art. 65(1) to implement its provisions within one year of the coming into force of the agreement, namely by 31 December 1995. Developing country members were granted a further four years' grace by Article 65(2). A number of developing countries found the five-year deadline for implementation to be rather too brief to permit their effective compliance. As for some, the TRIPS disciplines and the nature of the enforcement obligations within the agreement were rather unfamiliar.

A number of developing countries have also questioned what they consider to be unreasonable pressures by developed countries to ensure their compliance with the TRIPS agreement. Thus the Dominican Republic and Honduras observed that

> Ever since the end of the Uruguay Round, all countries, developed and developing alike, have been racing against time to ensure due compliance at the national level with the provisions of this Agreement. However, during the transition period granted to the developing countries, we have seen selective unilateral pressures unleashed against countries that have tried to exercise their legitimate rights in full compliance with the letter and spirit of the Agreement.[26]

Developing countries have contrasted the pressure imposed on them to implement the TRIPS agreement with the failure of developed countries to provide incentives for the transfer of technology to them, as required by Art. 66.2, and to provide technical assistance to developing countries, as required by Art. 67.[27]

A number of developing countries (for example Cuba, Dominican Republic, Egypt, Honduras) have indicated that the transitional implementation period of five years, granted under Art. 65.2, has been insufficient to undertake the complex and costly administrative tasks required under the

TRIPS agreement, such as the modernization of their administrative infrastructure (intellectual property offices and institutions, the judicial and customs system), as well as the promulgation of new intellectual property laws.[28]

Opposed to the desire of developing countries to delay the implementation of the TRIPS agreement are pressures from developed countries to initiate the review of the implementation of the Agreement under Art. 71.1.[29] The European Union has reminded negotiators that the TRIPS agreement establishes minimum intellectual property standards 'from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods'.[30] Similarly Japan has declared that 'We should not discuss the TRIPS Agreement with a view to reducing the current level of protection of intellectual property rights. To the contrary, the TRIPS Agreement should be improved properly in line with new technological development and social needs'.[31]

Exacerbating this situation is the fact that the TRIPS agreement has a built-in reform agenda for the review of the provisions concerning geographical indications (article 23.4), the patentability of biological inventions (article 27.3.b) and to 'non-violation' cases (article 64), which required their review prior to the deadline for the implementation of the agreement by developing countries. Thus these countries were obliged to engage in a review process which concerned provisions that had not yet been implemented in their countries. Thus they were obliged to participate in a review process concerning matters of which they had no practical experience.

5. COSTS OF IMPLEMENTING TRIPS

A 1996 study by UNCTAD estimated the institutional costs of compliance with TRIPS in a number of developing countries.[32] Thus for example, in Chile, additional fixed costs to upgrade the IP infrastructure were estimated at $718 000, with annual recurrent costs increasing to $837 000. In Egypt, the fixed costs were estimated at $800 000 with additional annual training costs of around $1 million. To some extent these costs could be defrayed from registration fees, but it is questionable whether resources should be diverted from over-burdened health and education budgets to subsidize the administration of intellectual property rights. Scarce engineers and lawyers have to be employed as patent and trademark examiners. Resources have to be devoted to their training. The registration statistics indicate that this infrastructure is largely devoted to the registration of overwhelmingly foreign-owned intellectual property rights.[33]

One practical example will suffice. Article 27.3(b) of the TRIPS agreement requires countries to introduce a system for the protection of plant variety rights. The typical UPOV-type system requires testing stations for the evaluation of proposed varieties, to ascertain their distinctiveness, stability and the transmissibility of their particular traits. These stations would have to be staffed by appropriate scientists. A measure of the perceived relevance of such a system is the fewness of developing countries which joined the UPOV system while it was voluntary. Given the dominance of northern companies in seed breeding, it is probable that these testing facilities will be for the benefit of foreign enterprises.

6. FOOD SECURITY

For developing countries food security is a policy priority, followed closely by public health. Plant Variety Protection laws were developed in response to industry calls for *sui generis* protection for agricultural and horticultural innovation. The inclusion of a seed saving exception for farmers was a public policy safeguard, which was an early reflection of food security concerns. This safeguard does not exist in patent statutes and this absence was an inducement for seed companies to shift their attention to the patent system as a means of protecting their innovations. In the USA for example, the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc*.[34] The defendants objected that Pioneer had obtained both patent protection and certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter in the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that 'when two statutes are capable of co-existence, it is the duty of the courts . . . to regard each as effective'.

The impact of patenting on food security is illustrated by the recent Canadian Federal Court of Appeal case of *Monsanto Canada, Inc. v. Schmeiser*.[35] This case concerned the cultivation by a farmer of canola, which contained chimeric genes conferring tolerance to glyphosphate herbicides, which Monsanto had patented. Monsanto had marketed these genes in its product 'Roundup Ready Canola'. Schmeiser had cultivated canola derived from plants on his land which he claimed had developed this tolerance from wind-borne genetic pollution. The trial court had found that cultivation of a plant was not an infringement of patented genes contained

in that plant, however, the majority of the Federal Court of Appeal agreed with Monsanto that this was infringing use.

Counsel for Schmeiser raised the moral question of whether it was right to manipulate genes in order to obtain better weed control or higher yields. The Federal Court of Appeal ruled that his was a question for Parliament to consider and that the court's job was to 'interpret the Patents Act as it stands'.

The relevance of these developments to the debate on the TRIPS agreement is that all countries are obliged to introduce plant variety protection laws. Modern biotechnological developments suggest that patent protection is going to be increasingly significant for the protection of plant varieties. This will enable the global privatization of food sources. Food security is arguably too important to be sterilized by the intervention of private intellectual property rights. A related concern is that the propertization of genetic resources has resulted in the concentration of proprietary biotechnologies in a few corporations.[36] The Nuffield Council in its report on bioethics and genetically modified crops observed that there were 'six major industrial groups who between them control most of the technology which gives the freedom to undertake commercial R&D in the area of GM crops.[37] In its report on *EC Regulation of Genetic Modification in Agriculture* (1998) the Select Committee of the British House of Lords also warned of the problem of cartels and monopolies in the agrochemical/seed sector, pointing out that the degree of consolidation was already much greater than in the pharmaceutical sector.

The proprietization of enabling technologies, as well as genetic resources raises concerns about the capacity of the public agricultural research system to fulfil its public good mission in contributing to the elimination of food insecurity. As Drahos observed, 'in biotechnology and agriculture it is likely that much research will end up as an international rather than public good and that it will be distributed according to complex licensing structures.'[38]

Many resource-poor farmers cultivate minor food crops that enable them to meet the nutritional needs of rural communities much better than if major crops such as wheat, rice and maize alone are cultivated. However, plant variety protection generally does not encourage breeding related to minor crops with small markets. This is because the returns on breeders' research investment will be quite small. Rather, they encourage breeding targeted at major crops with significant commercial potential. Moreover, protected varieties of plants may not even be food crops. In Kenya, for example, until very recently, about half the protected new varieties were foreign-bred roses cultivated for export.

It is conceivable, then, that plant variety protection may contribute to a trend whereby traditional diverse agro-ecosystems, containing a wide range

of traditional crop varieties, are replaced with monocultures of single agrochemical-dependent varieties, with the result that the range of nutritious foods available in local markets becomes narrower.

7. HEALTH

The impact of the TRIPS agreement on the availability of pharmaceutical products has generated considerable controversy and is examined elsewhere in this book. The pharmaceutical industry was one of the main lobbyists for the global extension of intellectual property rights. Developing countries were particularly concerned about the impact of the TRIPS agreement on the availability of those products. At the TRIPs Council meeting held on 2–6 April 2001, Members agreed to hold a special session of the Council in June 2001 to discuss the relationship between intellectual property rights and access to medicines. This discussion was prompted by the lawsuit brought by the Pharmaceutical Industry Association and 39 of its affiliate pharmaceutical companies against the Government of South Africa, regarding the compulsory licensing provisions of its Medicines and Related Substances Control Amendment Act. The notoriety surrounding that action, which was discontinued by the plaintiffs, prompted, in April 2001, Resolution 2001/33, of the 57th Session of the United Nations Commission on Human Rights on 'Access to Medication in the Context of Pandemics such as HIV/AIDS'. The Resolution recognized access to medicines in the context of pandemics as an essential human right.

As the TRIPS agreement is implemented, the supply of generic copies of new drugs will be prevented. It is the threat of international competition from generics which restrains prices. The inhibiting effect of the TRIPS agreement on low-cost alternatives has been recognized in the first instance in the Declaration on the TRIPS agreement and Public Health at the 4th Ministerial Conference in Doha on 14 November 2001. The Doha Declaration recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. It stressed the need for the TRIPS agreement to be part of wider national and international action to address these problems. It reaffirmed that the TRIPS agreement does not and should not prevent measures to protect public health and that the TRIPS agreement should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all.

The main problem was that the compulsory licensing provisions of the TRIPS agreement were of little practical use to countries with little or no

pharmaceutical manufacturing capabilities, since developing countries could not import from other Members with manufacturing capacity until the second Member had also invoked a compulsory licence and that even then the second Member would fall foul of Article 31(f) because the compulsory licence would have to be 'predominantly for the supply of the domestic market' of the Member granting the licence. In recognition of this problem, paragraph 6 of the Doha Declaration explicitly recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement. In an attempt to resolve the issues identified in paragraph 6 of the Doha Declaration, negotiations between WTO Members, meeting within the TRIPS Council, took place throughout 2002 and 2003, culminating in the agreement endorsed by the General Council of the WTO on 30 August 2003. The decision provided for a temporary waiver of Members' obligations under Article 31(f) until such time as that article is amended.

8. COPYRIGHT

Underpinning economic development is an important role of copyright and the copyright-based industries in the production and dissemination of knowledge. Publishing and the computer and communications industries are important both for general education and for scientific research. The principal problem for developing countries is in getting access to protected works at prices which their students and teachers can afford. The cost of protected software and textbooks is often beyond the means of all but the most wealthy.

In the context of the development of indigenous copyright industries, it is interesting to note that the USA in the nineteenth century sought to aid the development of its domestic publishing industry by declining to recognize the rights of foreign copyright owners. Indeed it was not until 1989 that it acceded to the Berne Convention. The UK Intellectual Property Rights Commission observed that

> although the potential benefits from the development of copyright-based industries in some developing countries may be enticing in some cases, it is hard not to conclude from looking at the evidence from the developing world overall that the negative impacts of stronger copyright protection are likely to be more immediate and significant for the majority of the world's poor.[39]

Attempts had been made since 1967 to modify the international copyright regime to reflect the interests of developing countries. The Stockholm

Conference of the Berne Union in that year had addressed the critical issues of translation rights and compulsory licensing, but consensus could not be reached. The Paris Berne Revision Conference of 1971 incorporated the Protocol concerning developing countries, which had been formulated in Stockholm in an Appendix to Convention. However, few developed countries adopted it and few developing countries included these provisions in their national law.

The TRIPS agreement obliges WTO Members to adopt the first 19 articles of the Berne Convention, which will probably have the effect of locking students and researchers in poor countries out of the global information system.

9. LEAVING THE FIELD

The TRIPS agreement was heralded by the USA as a global intellectual property charter. It was grounded on the twin principles of national treatment and MFN. However, within a few years of its promulgation, the USA appears to have abandoned the agreement in preference for bilateral arrangements. The engine for this bilateralism is section 301 of the US Trade Act which provides for the imposition of trade sanctions upon those nations which are regarded by the US Trade Representative as having deficient intellectual property laws or enforcement regimes. The enforcement of s.301 may be regarded as an indication of the lack of faith by the USA in the TRIPS regime.

Parallel to the enforcement of s.301, the USA has linked its Bilateral Investment Treaties and its Free Trade Agreements to the acceptance of prescribed intellectual property standards.[40] These standards are invariably 'TRIPS plus' in that they add to the obligations which nations accepted under the TRIPS agreement. Typical of these obligations are: narrowing the grounds of exclusion from patentability, for which TRIPS provides; an obligation to provide for an extension of patent term to compensate patent owners for regulatory delays in being able to exploit the patent; a redrafted compulsory licensing provision which confines the use of compulsory licences to specified cases; the requirement that each Party give effect to UPOV; and the obligation to implement the WIPO Copyright Treaty and the Performers Rights Treaty, which postdate TRIPS.

Associated with these agreements is a Memorandum of Understanding On Issues Related to the Protection of Intellectual Property Rights (MOU). This MOU contains further prescriptions and standards on intellectual property which signatories have to meet. For example, in the Jordan FTA the exclusion of mathematical methods from patentability is clarified

to avoid the exclusion of business methods and computer-related inventions. This has the effect of recasting Jordanian patents law, which, being based on an English model, would otherwise exclude these matters from patentability. Similarly the MOU prescribes the level of criminal penalties for infringements.

A contemporary mantra of intellectual property globalization, exemplified by the TRIPS agreement is the harmonization of standards and enforcement. The problem with the US bilateral enterprise is that the harmonization will be undermined, as countries extort preferential intellectual property deals.

NOTES

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22. World Bank, *World Development Indicators 2001*, World Bank, Washington DC, 2001, Table 5.11.
23. See e.g. the authorities cited in R. Dunford, 'Is the Development of Technology Helped or Hindered by Patent Law?' (1986) 9 *University of New South Wales Law Journal* 117.
24. See K. Maskus 'Intellectual property rights and foreign direct investment', Policy Discussion Paper No. 0022, University of Adelaide, Adelaide, 2000, p. 113
25. See K. Maskus 'Intellectual property rights and foreign direct investment', Policy Discussion Paper No. 0022, University of Adelaide, Adelaide, 2000, 2–3.
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27. E.g. see communications to the Council on TRIPS by Egypt (WT/GC/W/109), India (WT/GC/W/147) and the African Group (WT/GC/W/302).
28. E.g. see WT/GC/W/209.
29. E.g. the USA, WT/GC/W/115.
30. WT/GC/W/193.
31. WT/GC/W/242.
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2. The TRIPS agreement: the damage to the WTO

Brian Hindley

INTRODUCTION

The WTO presumably exists to increase world economic welfare. It follows that its rules and processes should be structured to ensure that the outcomes of negotiations between its members achieve that end – or, at worst, can plausibly be claimed to achieve it.

From that standpoint, the TRIPS agreement represents a failure of the negotiating processes of the GATT, the predecessor of the WTO, which in this respect operated in a similar way to the WTO. The claim that the TRIPS agreement increases world welfare rests on foundations that are much too shaky to support an agreement so strong and prescriptive.

The belief that the TRIPS agreement creates, or will create, a transfer of substantial wealth from the residents of poor countries to the residents of rich countries has a much firmer basis. That transfer of wealth plays a major role in justifying the suspicion with which developing countries now view the WTO, a suspicion that has plagued that institution from Seattle to Cancun, and which its supporters should deeply regret.

In what follows, I elaborate on these propositions. I then turn briefly to the questions of what can be done and what should be done.

ECONOMIC CASE FOR PATENTS

There is a broad range of intellectual property rights. They serve different purposes and offer different ownership rights, and each therefore requires its own analysis. In this chapter, in the interests of brevity, I shall discuss patents. Much of the analysis applies without great difficulty to some other intellectual property rights – copyright, for instance. It has little in common, though, with economic analysis of yet other intellectual property rights – for example, trademarks (Grossman and Shapiro, 1988, analyse trade in counterfeit products).

The economic case for patents is an exercise in second-best economics. First-best economics deals with outcomes that cannot even in principle be bettered. Second-best economics identifies the best *available* option when, for some reason, the absolute best cannot be achieved.

There are in fact two economic arguments for a patent system: one applying when the nature of an invention can be kept secret and the other when it cannot. The latter is the more important case in the modern world, and also the one that has more in common with other intellectual property rights. I shall concentrate on it here.

When the nature of an invention cannot be kept secret, inventors, in the absence of a patent system, are likely to have difficulty in obtaining a return on resources they invest in making an invention. As soon as the invention appears on the market, imitators can discover its secret; and in the absence of a patent system can offer their version for sale, limiting or eliminating the means by which the original inventor can profit from the invention. Hence, in the absence of a patent system, the socially valuable activity of invention is likely to be under-rewarded, and therefore to be under-supplied, in comparison with an ideal allocation of resources.

A patent in some degree corrects this situation. A patent gives an inventor a temporary right to prevent others from making commercial use of the invention. Hence, the owner of a patent can set a price for his invention knowing that a legal basis is available for action against the entry into the market of imitators.

Take as an example, a person who believes that she can invent a pill that would prevent the occurrence of some deadly illness in those who take it – AIDS, say. I take it that the social value of such an invention is beyond dispute. Its private value to its prospective inventor, however, is problematic. As soon as the pill is marketed, others will be able to analyse its contents and produce their own version of it. When these versions are marketed – as in the absence of a patent will be legally possible – their competition will push the price of pills towards their physical cost of production: say $2.

At that price, though, the inventor will have no excess of revenue over the physical cost of production of pills to provide a return to resources she used in *creating* the new product. If she anticipates that situation, she may well decide not to proceed with the invention. For an investment of $1 million, a new product with a social value of many millions or billions might be created. But in the absence of a patent system or some alternative, the potential inventor may not even be able to recoup $1 million.

A patent, however, by protecting her against competition from imitators, allows her to charge a price that maximizes her returns, say $50, as against the $2 for which the pill would sell in the absence of a patent. Invention

becomes more profitable; the incentive to invest resources in innovative activity is increased; and probably there will be more inventions.

Are Patents Good or Bad from an Economic Standpoint?

Yet the different price of pills with and without patents – $50 with patents versus $2 in their absence – raises the question of whether society might be better off without a patent system. At the higher price, people will use fewer pills than they would at the lower price. The consequence will be a greater prevalence of AIDS. But from a social point of view, to choose to have more AIDS rather than more pills is foolish. It would be better to use more pills and have less AIDS: it would be better if pills were sold at their resource cost of $2.

It may be that society would prefer the pill to be invented and sold at $50 to not having it at all. Best of all, though, would be to have the pill and have it sold for $2.

The invention might be made in the absence of patents. Imitators might take a long time to discover the secret of the pill – long enough to persuade the inventor that she can recoup her investment. She may be willing to finance the invention, or be able to find others who will finance it, for the pure prestige of it. In the absence of a patent system, prizes and rewards for socially useful inventions would probably multiply. Whatever the motivation of inventors, there is no question that inventions appear even where there is no patent system.

The availability of patents, though, in effect eliminates the possibility of the best option of the pill being invented and sold at $2. If there is a patent system, inventors are likely to patent their inventions, and to act in such a way as to maximize their returns from those inventions. While the patent lasts, therefore, the pill will sell for $50 not $2.[1]

So will the institution of a patent system increase social welfare? That depends on how many more inventions it will induce than would appear in its absence. For social welfare to increase, however, it isn't enough merely that there will be more inventions with the patent system than without. That is because the patent system will cause all the inventions that would have been made in its absence to be sold – so to speak – at $50 rather than $2, which is socially costly. To improve on the patentless state, a patent system must give rise, not just to more inventions, but to enough new inventions to compensate for this cost.

In a comparison between a patentless state and a patent system, many people think it is plausible that this condition will be met. They may be right, though it would be difficult to assemble cogent evidence. The basic indeterminacy identified by this analysis, however, dogs easy answers to

almost every question about the social value of the patent system, including two that are relevant here. The first is: Is a patent term of $t + 1$ years better than a t-year term? The second, a related question, is: Will the world be economically better off if the patent system were enforced in all countries, rather than in just a subset of them?

I return to these questions below. It is more important first to explain why the problem appears.

Public Goods and Private Goods

Economists often say with great confidence that where there are no property rights, establishment of them will improve the allocation of resources. Why don't they have the same confidence about the transition from a patentless state to a patent system – about the institution of *intellectual* property rights?

The answer lies in a distinction between two types of good. *Private goods*, such as bread, have the characteristic that what one person consumes another cannot. With *public goods*, on the other hand, one person's consumption of the good does not reduce the amount available for others to consume. Public goods are like the beam from a lighthouse or a television signal: one person's reception of it does not reduce the possibility of consumption by others.

Economists' paeans about the benefits of exclusive private property rights apply to private goods. Consumption of private goods *must* be restricted by one means or another, and private property rights are a means of doing that with many desirable properties. Consumption of public goods, on the other hand, need not be restricted: one person's consumption does not reduce the amount available for anyone else. Ideally, therefore, no price should be charged for the use of public goods, and their production should not be subject to property rights.

The purpose of a patent, though, is to allow a price to be charged for a public good: knowledge. In an ideal social state, no price would be charged for knowledge: the price of the prophylactic AIDS pills *ought to be* $2 – the physical cost of making the pill and of its private-good constituents. A price of $2, however, leaves no margin for a reward for the inventor, which also cannot be optimal. The patent system remedies the latter problem by allowing a charge for knowledge, which should ideally be free. It fixes – or partially fixes – one problem by creating another. That is why the social benefits of the patent system are problematic.

Financing the production of public goods is typically a problem. If no price is charged for a public good, as is optimal from one standpoint, there won't be private production of them: not, at least, by profit-maximizing

persons. It is widely assumed, therefore, that government must itself provide public goods, or subsidize their production.

Governmental provision, though, is an unattractive solution to the public-good problem in the production of material that is currently patented or copyrighted. Inventions and literary and musical works are quintessentially individual; and they often challenge the status quo, which governments are typically under pressure to maintain. It is difficult to conceive of good and genuinely original inventions or works of art emerging from government-owned workshops, or being selected for public support in their inception stages by official committees. The government-provision or government-support model of public-good production is therefore deeply problematic for production that is now supported by patents and copyrights.

Patents, therefore, may well be the best *available* means of addressing the problem of insufficient returns to invention. That does not mean, however, that formulation of public policy should ignore their deficiencies and problematic features.

Optimal Patent Term

Why do we only have a 20-year patent term? If the patent system is as valuable as its proponents insist, why not a 50-year term or a 100-year term? Advocates of the system sometimes talk about 'trade-offs', but often leave the nature of the trade-off poorly specified.

Some proponents, moreover, say merely that more invention is better than less. That position tends to point in the direction of a very long patent term, and certainly one longer than is enshrined in current legislation. As already noted, however, it is a fallacy to believe that more invention is necessarily better than less when more invention is induced by means of patents. The line of argument that exposes that fallacy also says that a 25-year term may be worse than a 20-year term (and a 20-year term worse than a 15-year term and so on).

The problem is that an extension of the term from 20 to 25 years implies that all of the inventions that would have been invented under a 20-year term will now have an additional five years of protection, which, by definition, is not necessary to induce their invention. AIDS prophylactic pills will sell at $50 for an extra five years rather than going to $2: and as a consequence those five years will see more AIDS than is necessary. That is a social cost. Social welfare will only increase if the longer patent term induces *enough* new inventions to compensate for this cost.

Will it do so? The question is empirical, but we do not have the data needed to answer it.

An increase in the patent term, though, tries to induce invention by promising further income after the end of the old patent term. In its nature, that pushes additional rewards further and further into the future. But a promise of a dollar in the future is worth less than a dollar in hand now, and less the further in the future is the promised delivery. We can be confident, therefore, that there is some term $t + 1$ that is socially inferior to term t. We just don't know what number t represents: whether it's five or fifty (or zero).

Extending Geographical Coverage of the Patent System

The TRIPS agreement forced or will force countries without systems of IP protection, or with weak systems, to adopt a strong one. It therefore raises the question of whether an increase in the geographical coverage of IP systems is economically good or bad. But the basic indeterminacy that makes it impossible to say whether a patent term of $t + 1$ years is better than one of t years also makes it impossible to give a decisive answer to the question of geographical extension.

The extension of the patent system to more countries will certainly increase the returns to invention, and therefore will increase the incentive to invent. Probably, therefore, it will lead to more inventive activity. Considered by itself, that is a social gain. But the extension will also restrict the use of inventions under patent by residents of countries that adopt the system. That is a social cost. Whether cost or gain is larger is an empirical question. In practice, however, as with patent term, we have no means of answering it; and therefore no way of knowing whether the extension will increase or decrease world economic welfare. Deardorff (1990) provides a formal proof of the indeterminacy in this context.

Of course, many factors other than those mentioned in the text might affect the level of costs and benefits. None is so large or so certain in effect, however, as to override the basic indeterminacy.

One factor that is frequently mentioned is the cost of setting up and running a system for the enforcement of intellectual property rights in countries that have no such system. That cost is likely to be high in poor countries, and, of course, makes it all the less likely that they will gain from adopting strong systems of intellectual-property protection.

Another lies in the contention that adoption of a patent system makes it more likely that a country will receive inward investment in industries where intellectual property is important. If inward investment generates external benefits, such an effect would tend to offset losses from other aspects of the agreement (though insofar as such investment is diverted from other developing countries, it does not offset the costs on them as a group).

A related issue is technology transfer. The adherence of a nation to the patent system, it is said, will facilitate the purchase by its residents of the technology and knowhow associated with a patented invention. There is little doubt that this is true. The other side of the equation, however, is that this knowledge is purchased. A firm in a country that does not adhere to the patent system and that wishes to use the technology and knowhow may have only the information embodied in the patent, and must acquire the knowhow by other means. But there is no a priori ground on which to assume that this is impossible; or even that it is more costly than purchase from the patentee.

Transferring Wealth from Poor to Rich

We cannot be confident about the direction of the effect on world welfare of an extension in the geographical extent of the patent system. We *can*, however, be confident that extension of the patent system to developing countries will result in a substantial increase in the value of licence payments from residents of those countries to the owners of patents, who typically reside in rich countries.

Indeed, we can be confident that rich countries gain, in aggregate, from the TRIPS agreement.[2] Their residents get more inventions as a result of payments made by the residents of poor countries; and they get increased royalty payments too.

It follows that the probability that developing country welfare will increase as a result of the TRIPS agreement is less than the probability that the world as a whole gains. Rich countries gain in all circumstances, even if the world as a whole loses. Poor countries therefore might lose even if the world in aggregate gains.

Why did Developing Countries Accept it?

There are, no doubt, many reasons why developing countries accepted an agreement so disadvantageous for them. Two factors call for special mention, however.

The first is that the US was prepared, under its 'Special 301' legislation to take unilateral action against countries that in its view offered too little protection for intellectual property rights. The baseline against which developing countries had to judge TRIPS, therefore, was not the status quo as it existed prior to Special 301. Their choice was between facing unilateral US action or accepting the TRIPS agreement and the WTO protection that such an agreement appeared to offer against self-authorized US action. Not unreasonably, they opted for the WTO option.

That choice, however, does not allow the inference that developing-country governments preferred the TRIPs agreement to the status quo ante: the state that existed before the US prepared for attack. It cannot be inferred that they were better off, or thought they were better off than that state. They thought they were better off with the agreement than under unilateral US attack; but that is a different matter (and they may have been wrong).

Second, when the Uruguay Round ended, the great bulk of its outcome was presented as a single undertaking, to be accepted or rejected as a whole. Faced with this requirement, some developing-country governments accepted agreements, including TRIPS, that they intensely disliked, and that they knew would bring them serious domestic political problems. But why did these governments accept that the agreements they disliked were part of an indivisible single undertaking, so that acceptance of them was a condition of membership of the WTO?

Part of the answer lies in the Agreement Establishing the World Trade Organisation. Article II(4) says that GATT 1994 (which contains the relevant outcomes of the Uruguay Round) is legally distinct from GATT 1947. A country could therefore reject the WTO and remain a party to GATT 1947, and a country that followed this course would be protected by the provisions of GATT 1947 *with respect to the actions of trading partners that also remained parties to GATT 1947*.

But a country is entitled to withdraw from GATT 1947 on six months' notice, as the US subsequently did. A country that had rejected the single undertaking and GATT 1994 would then have found itself without a multilateral treaty on trade that was common to itself and the US. Such a country would therefore have found itself without multilateral legal protection against US trade-policy actions. Hence, even countries that deeply disliked parts of the single undertaking had a major incentive to accept it.[3]

Summing Up: What is Wrong with the TRIPS Agreement?

The TRIPS agreement was aggressively pursued by the US, supported by the EC and Japan; and there are grounds for a strong presumption that their residents will gain from it. Indeed, all countries that already possessed patent systems – that is to say, by and large, rich countries – will probably gain from the agreement.

There is, however, a corresponding presumption – weaker, but still true – that the agreement will force losses upon the residents of countries forced to adopt the system – by and large poor countries. They will certainly lose as a result of the royalty payments they must now make. Their hope for gain lies in the possibility that these payments will induce additional inventions

that have a value to them that exceeds the payments. That is not impossible, but it is not an outcome to bet on.

There is no basis for any presumption that the gains of rich countries exceed the loss to poor countries. There is no basis, therefore, for a presumption that the agreement has increased, or will increase, world welfare.

To say that the US (and the EC and Japan) should not have pursued these gains is not cogent. However, since the gains could be achieved only by threats of trade-policy action against the exports of countries deemed by the US to offer insufficient protection for intellectual property rights, getting them necessarily involved the GATT/WTO. That is a problem. The WTO has other and more important functions, and its performance of those functions is likely to be impaired by a perception that the WTO is a vehicle for the exploitation of poor countries by rich ones.

The position could have been rectified in the Uruguay Round, by trade-policy shifts in rich countries that would have benefited poor countries. Agriculture and textiles, for example, are areas in which benefits to poor countries would also have produced benefits for the residents of rich countries, and disproportionately for poor residents of rich countries.

But while the Uruguay Round showed progress in both areas, it was not enough. Finger and Nogues (2002) provide a detailed assessment.

WHAT OUGHT TO HAPPEN NOW?

The TRIPS agreement is an established fact. To suggest recantation is not useful. Besides, just as it may not have increased world welfare, it may also have increased it. Agnosticism about the effects of change speaks for the status quo, and against impassioned attempts to change it, which, because the grounds for agnosticism exist, are likely to be driven, as happened in the TRIPs negotiation, by ulterior motives.

The agreement, though, is not a static thing. In the first place, means to enforce it must be put into place and maintained – a major expense for countries that have not previously had systems for the enforcement of intellectual property rights. The governments of such countries have strong ethical grounds for requiring technical and financial assistance for the construction and maintenance of their systems of enforcement from developed countries. Indeed, they have a strong ethical case for calling upon developed countries to finance all of those expenses.

In the second place, there will be attempts to amend the agreement in one direction or another. A notable amendment – or clarification – was the *Doha Declaration on the TRIPS Agreement and public health* and the *Decision of the WTO of 30 August 2003* on the implementation of paragraph 6 of that

declaration. The decision allowed WTO members without the capacity to manufacture generic versions of pharmaceutical products needed to combat public health problems to import generics from elsewhere.

Developing countries regarded this as a victory, and in an area in which developing country success is hard to find, one can sympathize with that view. Yet, in line with the basic indeterminacy noted earlier, it carries a problem.

The decision allows use of pharmaceuticals that have already been developed at lower prices than would otherwise be available. It is still true, though, that if inventors cannot reap a return for developing pharmaceutical products aimed at health problems in developing countries, their incentive to develop new ones is blunted. This is a cost: potentially a heavy one, which, in time, may outweigh the current benefits of the declaration and decision. When this outcome threatens, developing countries should press for alternatives to patents as a means of financing the development of pharmaceutical products that are relevant to their special needs.

In general, governments of developing countries have every right to require a demonstration that amendments to the TRIPS agreement will not further damage their interests, and to reject the amendment if this is not shown. There should be no hesitation about this. The US and other developed countries played a rough game to obtain the TRIPS agreement. Developing countries should not be shy about insisting that their interests be fully taken into account in its future development.

NOTES

1. A similar effect on price appears when the nature of an invention *can* be kept secret. That situation is most likely to be approximated for an invention relating to the process of production. Consider, therefore, an invention that reduces the costs of production of a good by x per cent. Were the invention freely disseminated, and if the industry producing it contains many firms, the price of the product would fall by something like x per cent, and there would be no scope for the inventor to profit from his invention. In either the absence of a patent system, or the presence of one, however, the effect on the price of the product is likely to be much smaller than x per cent. In the absence of a patent system, the inventor's problem is that if he sells his secret, he will lose control of its further dissemination. It is therefore quite possible that the invention will be put into effect in one firm only, with only a small effect on the price of the product, if any. A patent system allows the invention to be sold without loss of control over its dissemination. Rather than allowing the price of the product to fall by x per cent, however, the inventor will prefer to take as much as possible of the reduction in costs of production as a reward for himself. Once again, the effect of the invention on the price of the product will be small.
2. If there is ground for lack of confidence, it lies in the fact that the TRIPS agreement mandated a minimum patent term of 20 years – longer than the pre-existing term in most developed countries. Since the effect on welfare of this increase in patent term is indeterminate, it follows that the effect of the Uruguay Round package on the welfare of rich countries is also indeterminate.
3 Stegemann, (2000), gives a good account of the issues underlying the negotiations.

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3. Can stronger intellectual property rights boost trade, foreign direct investment and licensing in developing countries?

Douglas Lippoldt

INTRODUCTION

In recent decades proponents of strengthened intellectual property rights (IPRs) have argued their case from a variety of angles, often including an emphasis on the potentially positive effects for economic growth in developing countries. Stronger patent rights, for example, might encourage foreign rights holders to trade, invest directly or license intellectual property in developing countries.[1] Yet, as Maskus (2000) and others point out, theoretical models are ambiguous on some dimensions of the relationship between the strength of IPRs and indicators of economic activity. An examination of the empirical evidence is needed to untangle the complex relationships among these variables.

Why does this issue matter for economic development? The economic well-being of a nation is linked closely to the availability of resources and technology. Progress in the latter plays a central role in boosting output per worker and is an important determinant of income levels.[2] Developing countries, particularly in the earlier stages of development, may face limitations in resources and the ability of domestic sources of innovation to respond adequately to the incentives from stronger IPRs. Where a developing country is lagging in one of these areas, foreign sources may play an important role in closing the gap (Park and Lippoldt, 2003). If inward trade, direct investment and licensing can be influenced by the strength of IPRs in an economy, then governments may be able to exploit IPR policy to enhance these flows and stimulate development. Inflows of goods, direct investment and licences embody various types of intellectual property and represent a form of technology transfer.

Intellectual property has particular characteristics that differentiate it from physical goods. Unlike a material resource, the same bit of intellectual

property can be made available simultaneously and repeatedly on a non-exclusive basis to multiple users, generally at a low marginal cost. New ideas embodied in intellectual property, being non-rivalrous, cannot only contribute to technical progress but can also have 'disproportionate' impacts on economic growth due to big returns to scale when one idea is applied many times (Jones, 2004). Given this economic potential, policy makers may be particularly motivated to boost development of new domestic intellectual property and access to existing intellectual property from abroad.

There is a growing body of literature pointing to a positive relationship between a nation's openness or progressive integration into the world economy and its growth or economic development (OECD, 2001; WTO, 2003). At the same time, the absolute size of the stock of relevant and available intellectual property also appears to be a related and important factor particularly in relation to productivity. As Jones (2004) notes, 'Because of the non-rivalrous nature of ideas, output per person depends on the total stock of ideas in the economy instead of the per capita stock of ideas'. Since intellectual property can cross borders easily, the scope of the available stock can be nearly global, subject to an appropriate international framework and the willingness of rights holders to facilitate access. Singapore and Hong Kong–China are examples of economies that have overcome scale limitations in their domestic stocks of intellectual property, in part, through their integration into the global economy; among other initiatives in this regard, they have undertaken commitments with respect to the international framework agreements governing intellectual property.

IPR STRENGTH AS AN ECONOMIC POLICY LEVER

Why would strengthening of IPRs influence merchandise trade, foreign direct investment (FDI) and licensing? The answer is bound up in the nature of intellectual property. The non-rivalrous, non-exclusive nature of intellectual property presents a challenge to the original innovator (or subsequent rights holder) wishing to appropriate an economic benefit from the intellectual property. Weak IPRs in a particular market may discourage the foreign rights holder from making the intellectual property available there through trade, direct investment or licensing. This is because the potential inability to enforce IPRs means rights holders could face greater difficulty in appropriating returns from the use of the intellectual property; this could be doubly damaging to the rights holder in the event that a competitor makes use of the intellectual property. Here, it is worth noting that the starting point for many developing countries, especially prior to the 1990s,

tended to be relatively weak systems of IPR protection sometimes based on poorly adapted systems dating from a former colonial era or sometimes, in effect, non-existent systems.[3]

The importance of IPR protection to rights holders may vary depending on the ease with which the ideas can be imitated. An exporter of speciality steel with a unique manufacturing process may not be especially concerned about patents in a particular destination market if the exported good cannot be reverse engineered. On the other hand, a software producer whose code can be easily copied by anyone with a laptop computer may hesitate to sell into a market where piracy is commonplace. An apparel firm may hesitate to invest and manufacture in a country where trademark protection is ineffectual. While a goods producer in a competitive and free-wheeling market may get paid the full amount of his/her marginal product, in the absence of a mechanism to protect IPRs there is a risk of little or no return to the originators of ideas and hence insufficient incentives to innovate. In order to correct such shortcomings in the marketplace, key players in the international community have worked to rebalance things and ensure that those who create ideas have incentives to continue to do so. The result is an international system of treaties and institutions that has evolved over a number of decades to help protect various aspects of intellectual property, subject to certain conditions (for example one condition for the granting of a patent of limited duration is that the applicant make public the idea to be protected).

The past 15 years have witnessed substantial change and strengthening in the web of international treaties that governs IPRs in conjunction with national laws. The World Intellectual Property Organization (WIPO) administers a series of international IPR agreements developed over many years. During the 1990s, many developing and transition countries moved to strengthen their IPR regimes through adherence to these WIPO-administered agreements (Park and Lippoldt, 2005). For example, during the 1990s, 59 nations became parties to the Berne Convention for the Protection of Literary and Artistic Works, bringing the total membership to 157 countries; 60 nations became parties to the Paris Convention for the Protection of Industrial Property, bringing the total membership to 168.[4] This is a considerable burst of activity in a relatively short period, given that both treaties date originally from the 1880s. In part, the expanded adherence to WIPO agreements was propelled by the launching of economic transition in former socialist states and by the advent of the WTO and the Agreement on Trade-Related Intellectual Property Rights (TRIPS). The TRIPS agreement built on the existing framework of WIPO agreements, but was negotiated within the GATT/WTO, coming into effect on 1 January 1995. It resulted in a strengthened application of minimum IPR standards in many developing countries,

albeit with implementation extended over a number of years due to transitional periods.

A number of relatively recent regional trade agreements (RTAs) go beyond the TRIPS agreement in establishing additional minimum IPR requirements (Lippoldt, 2003). Some of these involve one or more developing countries. According to the TRIPS agreement, WTO Members may implement IPR protection that is more extensive than the minimum required under the agreement, provided that this does not contravene the agreement. In a review of 15 selected regional accords, Lippoldt found that they often included one or more provisions going beyond the strict requirements of the TRIPS agreement. Often these additional requirements concerned conformity with, or accession to, other relevant international agreements. There are also examples of RTAs that have special provisions concerning shortened transition periods, enforcement or cooperation, among other issues.

Developing country perspectives vary on the importance of IPRs in their economic policy frameworks. Public debate in these countries is sometimes caught up in emotive issues such as implications for public health and access to medicine[5] or the need to prioritize among many competing demands for limited government resources. Implementation costs of IPR commitments undertaken in the various international agreements can be significant.[6] On the other hand, some developing countries have sought to exploit strengthened IPRs strategically as a development tool. For example, they may see IPR policy as a means to draw in investment and to encourage innovation, with the potential to boost development on both the extensive dimension (overall size of the economy) as well as the intensive dimension (that is, the value-added per employee). Government officials from a wide range of economies have pointed to strengthened IPRs as a plank in their strategies to enhance FDI inflows and trade.[7] For example, experts in some poor developing countries have seen the institution of trademark protection as a vehicle for reassuring investors in manufacturing industries that they can combat illegal copying. For wealthier countries, enhancement of IPRs is seen as a means to draw in high technology that can boost worker productivity and contribute to intensification of growth.

THE SCALE OF TRADE AND INVESTMENT FLOWS

Table 3.1 presents an overview of developing country trade and investment flows for selected years. Trade embodies technology and is an important vehicle for technology transfer, with tangible impacts on the importing economies. As underscored in a recent World Trade Report (WTO, 2003),

Table 3.1 Developing country FDI inflows and imports of goods and services, selected years

Region	Foreign direct investment, net inflows (BoP, current US$, millions)				Imports of goods and services (BoP, current US$, millions)	
	1992	1997	2002	2003	1997	2002
East Asia & Pacific	21 402	62 138	54 834	54 400	468 213	620 489
Latin America & Caribbean	14 800	66 718	44 682	36 400	372 804	399 939
Middle East & North Africa	2 270	6 294	2 653	1 800	159 482	178 855
South Asia	746	4 897	4 164	5 100	88 532	115 016
Sub-Saharan Africa	1 538	8 428	7 822	8 500	105 358	110 384
Total (these regions only)	40 756	148 475	114 155	106 200	1 196 386	1 426 685

Source: World Development Indicators database.

'Empirical research has found a positive relationship between the size of trade flows and a country's level of total factor productivity'. The effectiveness of trade as a vehicle for transfer and diffusion of technology depends in part on the composition of imports; the same WTO report points out that in 2000 some 30 per cent of developing countries imports were classified as 'high-tech' products, whereas only about 10 per cent of imports by least developed countries (LDCs) fell into this category; the share for developed country imports of these products was a bit more than 20 per cent. As can be seen from the table, imports into developing country regions are substantial, increasing between 1997 and 2002; however, they still amount to less than a third of the world total of more than 5000 billion in 2002 (excluding intra-EU trade).

As with trade, FDI constitutes an important channel for technology diffusion. A WTO (2002) secretariat report cites four main channels for this to occur via FDI: 1) backward and forward linkages (for example, as foreign affiliates push local suppliers to adopt new technologies or assist them to upgrade, which may benefit other local firms through spillovers); 2) demonstration effects (for example. as local firms learn to imitate technologies or business processes); 3) competition effects (for example, as the expanded presence of foreign firms may stimulate competing local firms to improve their technological performance); and 4) learning-by-doing that builds human capital (for example, employees of the foreign affiliates acquire knowledge through formal training and informal channels, which

may be subsequently shared or applied elsewhere). Table 3.1 shows the large net inflows of foreign direct investment into developing regions. East Asia and the Pacific and Latin America and the Caribbean attract the bulk of these flows, with the other three regions lagging. Although the flows are substantially larger now than they were in the early 1990s, they are down somewhat from their peak. The decline in flows provides an indication of the tough environment in which developing countries now must compete to attract investment.

EMPIRICAL EVIDENCE

Economists are still assessing the impacts to date of strengthened IPRs resulting from increased adherence to key WIPO-administered treaties and the WTO TRIPS agreement, increasing numbers of RTAs, and reforms in national law. Two recent OECD studies contribute to this work in progress and are summarized below. At the heart of both studies is regression analysis whereby indicators for selected types of economic activity are related to indicators of the strength of particular IPRs (controlling for other factors that influence the corresponding economic activity). This OECD work focuses primarily on patents, copyrights and trademarks.[8]

International Trade and FDI

The first OECD study presented here (Park and Lippoldt, 2003) considered the relationship of patent rights to trade and foreign direct investment in developing countries. Among other issues, the study estimated the relationship of changes in an Index of Patent Rights with change in indicators of trade and FDI.[9] The index measures the strength of patent rights based on objective conditions such as membership in relevant international treaties, restrictions on rights, available means of enforcement, duration of protection and sectoral coverage of patent rights, but does not directly cover actual effectiveness of rights in practice. However, this index was also found to correlate well with survey measures of intellectual property laws in practice.[10] The results of the analysis in the study may also be relevant for trademarks and copyrights in that similar indices employed in the study for those types of intellectual property exhibited fairly high correlation with the Index of Patent Rights (with correlation coefficients greater than 0.7). The analysis covered the period from 1990 to 2000, focusing on a sample of developing and OECD countries.[11] The dependent variables were trade and the stock of FDI, each considered as a ratio to GDP. The regression analysis controlled for various other factors that influence trade and FDI.

With respect to trade, the strength of patent rights was found to modestly influence total imports, but this was not generally significant for exports from developing countries and LDCs. Table 3.2 presents selected data from the analysis. For the developing countries, a fairly significant relationship was found in the strength of IPRs and import flows generally, and particularly in some sectors such as textiles, pharmaceuticals and industrial chemicals. In some other sectors, such as computer and office equipment, patent rights appeared to be important primarily where there

Table 3.2 The relationship between import flows and patent protection, 1990–2000

Sector	Destination	Coefficient estimate	p-value	N	R^2
All industries	All countries covered	0.315**	1.1%	154	0.46
	Developing countries	0.243*	14.4%	83	0.55
	LDCs	Insignificant		17	0.35
Textiles	All countries covered	0.439**	4.3%	154	0.53
	Developing countries	Insignificant		83	0.65
	LDCs	6.313**	4.6%	17	0.81
Drugs	All countries covered	0.436**	2.0%	154	0.44
	Developing countries	0.372*	6.6%	83	0.56
	LDCs	Insignificant		17	0.74
Industrial chemicals	All countries covered	0.319**	2.0%	154	0.17
	Developing countries	0.274*	10.4%	83	0.23
	LDCs	Insignificant		17	0.49
Computer & office equipment	All countries covered	0.356*	9.9%	154	0.48
	Developing countries	Insignificant		83	0.54
	LDCs	Insignificant		17	0.71

Notes: The coefficient estimate measures the response of trade flows to the importing country's level of patent rights. The estimates represent the percentage change in the respective sector's imports to GDP ratio per 1 per cent change in the importing country's index of patent rights. Here and in the following tables, N denotes number of observations and R^2 the fraction of the variation in the data explained by the model. ** indicates statistical significance at conventional levels (for p-values 5 per cent) and * indicates modest significance (for 5 per cent < p-values < 20 per cent). The p-value is the probability of incorrectly rejecting the hypothesis of no effect (or of incorrectly concluding an effect). The coefficient estimates were obtained via a regression equation which controlled for other determinants of trade (including GDP per capita, tariff rates, and country risk) and controlled for unobserved factors (that is., *individual fixed effects*). To conserve space, coefficient estimates of the other variables are not reported.

Source: Derived from Park and Lippoldt (2003), Table 8.

was a threat of imitation. The estimates for LDCs were generally not statistically significant.

The study found that the patent rights as described by the index were generally associated positively with FDI (Table 3.3). A 1 per cent increase in the patent rights index was associated with a 0.5 per cent increase in the stock of FDI. The results indicate that variation in FDI in relation to strengthened patent rights is largest for the least developed nations (where IPR regimes are weakest), and second largest for the developing nations (where IPR regimes are next weakest). Thus, patent rights may have a positive but diminishing association with increased FDI as the strength of those rights increases.

Table 3.4 presents results of a similar analysis using data for outward US FDI by sector. A statistically significant relationship exists, but with notable variation by sector. This may be in part related to variation in the ability of investors to appropriate the returns on the intellectual property embodied in the FDI. If firms operate in sectors where they are able to ensure returns even in environments with weak IPRs, this weakness may be less dissuasive to investment than in other sectors where firms might be more vulnerable. For example, some sectors may employ technologies that are difficult to imitate or reverse engineer. Firms may also have other advantages that reduce the importance they place on IPR strength in

Table 3.3 Estimates of relationship between inward FDI stock and patent protection, 1990–2000

	All countries covered	Sample of developing countries	Sample of LDCs
Change in inward FDI (ratio to GDP) associated with a 1% change in the Patent Rights Index	0.49** *(p-value = 4.4%)*	0.73** *(p-value = 1%)*	2.76** *(p-value = 2%)*
% of data explained	34%	31%	25%
Number of observations	239	135	61

Notes: ** indicates statistical significance at conventional levels (for p-values 5 per cent). In the interests of space, the empirical results are abridged to present only the relationship of inward FDI to patent rights, along with some sample information. For developing countries, the controlling variables including GDP per capita, tariffs, country risk are not shown. For LDCs, GDP per capita is not shown, but tariffs and country risk were dropped as control variables due to lack of data for least developed countries.

Source: Derived from Park and Lippoldt (2003), Table 6.

Table 3.4 Estimates of relationship between US outward FDI and patent protection

Sector of origin	Country of destination	Coefficient estimate	p-value	N	R^2
All industries	All countries	0.568*	9.2%	224	0.13
	Developing countries	0.708*	10.5%	127	0.12
Chemicals	All countries (d)	0.311*	17.8%	164	0.07
	Developing countries	0.384*	12.9%	84	0.16
Computer services	All countries	1.680**	0.1%	127	0.60
	Developing countries	1.467**	3.4%	57	0.52
Finance	All countries	2.043**	1.6%	134	0.31
	Developing countries	2.272*	5.8%	68	0.30
Food & kindred	All countries	Insignificant		134	0.34
	Developing countries	0.536*	6%	78	0.49
Petroleum	All countries	1.046**	4.4%	147	0.08
	Developing countries	1.063*	8.65%	79	0.10
Pharmaceuticals	All countries (d)	0.242*	13%	153	0.12
	Developing countries (d)	0.361*	11.3%	77	0.16
Services	All countries	1.639**	2.6%	134	0.28
	Developing countries	1.706*	11.3%	66	0.19

Notes: The coefficient estimate measures the response of US outward FDI to the destination country's level of patent rights. The estimates are in percentage terms (that is the percentage change in the respective sector's outward FDI stock to GDP ratio per 1 per cent change in the destination country's index of patent rights). The coefficient estimates were obtained after controlling for other determinants of FDI (such as GDP per capita) and for unobserved country-specific factors, except where noted by (d) to indicate that tariffs and country risk were *dropped* as control variables.

Source: Derived from Park and Lippoldt (2003), Table 7.

making investment decisions. For example, they may have a strong lead-time advantage or an ability to protect their interest through trade secrecy. As Park and Lippoldt note, 'In these cases, given the costs of acquiring intellectual property rights, firms may forgo seeking IPRs and rely on "natural" protections.' This may have contributed to the results in the analysis, whereby FDI in certain industries (such as metals, machinery and transportation) was found to be insignificantly associated with the index of patent rights in the host country. On the other hand, the strength of patent protection (as measured by the index) appears to matter more for FDI in certain other sectors such as computer services, finance, chemicals, petroleum and pharmaceuticals; this may be due to the relative ease with which competitors can imitate the technology embodied in those sectors.

Fink and Primo Braga (1999) provide some insights which are relevant to the results presented in Tables 3.3 and 3.4. Based on an analysis of data for 89 countries in 1989, they found a positive link between IPRs and trade flows for total non-fuel trade, but a weak link between IPRs and high technology trade (such as chemicals, electrical and office machinery, telecommunications apparatus). They noted several possible explanation for this variation: the effect of market power could well dominate in high-technology sectors (whereby the rights holders are able to charge comparatively high fees for access to technology or withhold technologies); other mechanisms such as first-mover advantages or reputation may enable technology exporters to appropriate returns even where IPRs are comparatively weak, or stronger IPRs could encourage firms to switch from exporting to FDI.

The literature also points to differences in the importance of IPR strength for different types of FDI. Smarzynska (2002) conducted an analysis using firm-level data from a world-wide survey of companies conducted by the EBRD in 1995 concerning FDI undertaken in Eastern Europe and the republics of the former Soviet Union. She found that weak IPR regimes tended to discourage foreign investors in technology-intensive sectors that rely heavily on IPRs. Moreover, in all sectors, weak IPR regimes tended to deter investors from undertaking local production and rather focus on distribution of imported products. In addition, she notes that there is some evidence that weak IPR protection may discourage investors generally (that is, not just those in sensitive sectors). In an earlier study of intellectual property managers from 100 major US firms, Mansfield (1994) and Lee and Mansfield (1996) present an empirical analysis revealing that IPRs mattered little for protecting sales and distribution outlets, but mattered importantly for protecting production and research and development (R&D) facilities. The proportion of FDI invested in production and R&D facilities was positively and significantly related to the perceived strength of IPRs.

In a further study on these issues, Nunnenkamp and Spatz (2003) also

find that the importance of IPRs as a determinant of FDI flows varies according to the sector and host country, especially as those factors relate to the imitative capacity. They 'find that host countries can not only attract more FDI, but also derive more benefits from FDI by strengthening IPR protection. R&D expenditure by US affiliates as well as the value added and exports created by them tend to rise with stronger IPR protection'. At the same time, they note that the extent of these positive effects tends to be limited and subject to the specific conditions more broadly in the sector and country concerned. Other factors, such as market scale, often play a determinant role and may attract investment despite shortcomings in the IPR environment. Also, as more countries raise their standards for IPR protection, the harder it becomes for a country to derive particular advantage from moves to strengthen the protection afforded to rights holders.

In an investment issues survey of the world's largest 1000 firms conducted by the consulting firm A.T. Kearney (2003), business leaders characterized the most critical risks to their corporations as they invest abroad. At the top of the list were such issues as government regulation, country financial risk, currency risk, or risk of political and social disturbances (each of which cited by 60 per cent or more of respondents). Theft of intellectual property was cited by 17 per cent of the respondents and ranked 12th on the list of concerns.

Another parameter influencing the importance of IPRs as a determinant for FDI is the host countries' capacity for local imitation. If the latter is low (that is, IPR infringement risk was not big to begin with) and other factors more important in dissuading investment, a strengthening of IPRs may not be sufficient incentive to attract FDI. In a similar vein, a strengthening of IPRs in a developed country where the level of IPR is already high would not necessarily have a positive impact on FDI, since firms may then prefer to use licensing rather than FDI (for example, if contracting costs are thereby reduced).

Licensing

The second OECD study referenced here (Park and Lippoldt, 2005) concerns the relationship between international licensing and the strengthening of IPRs in developing countries. International licensing activity is considered to be part of services trade, but is given separate consideration in this chapter because of its central role in technology transfer.

Licensing transactions are a means by which technology and expertise can be acquired by licensees, saving them the expense of independent research and development. At the same time, licensors not only derive fees and royalties, but may also be able to capitalize on the licensee's local reputation and

knowledge. As a mode of market entry, licensing can offer firms strategic advantages under certain circumstances. Some companies (particularly small ones) may use licensing as a means to test a market before engaging in FDI or to overcome a lack of capacity to penetrate a market on their own. Also, as Park and Lippoldt note, licensing can involve relatively minimal commitment and make it easier for firms to enter and exit a market, whereas other means of entry may be less flexible (for example, export sales may face tariff and non-tariff barriers and FDI may be costly or may face local restrictions). In addition, businesses may be increasingly looking to licensing as a means of earning an early return on their research and development efforts, rather than depending exclusively on internally-developed end products as the sole source of return on their investment in R&D.[12]

As with trade and FDI, theoretical reflections generally do not lend themselves a priori to absolute statements as to the relationship between stronger IPRs and licensing activity (Maskus et al. 2004). Stronger IPRs may be expected to reduce the costs of reaching and enforcing contracts thereby encouraging expanded licensing activity. However, depending on the initial level of protection, ever stronger IPRs could eventually reach a level where they confer excess market power, risking to constrain licensing as rights holders boost licence fees or refuse to license. Moreover, weak IPRs may prompt a defensive reaction whereby some rights holders are willing to license to local producers in order to have a local interested party to safeguard against infringement.

The OECD study on IPRs and licensing uses two analytical approaches. In the first, four quantitative indexes (similar in construction to the Index of Patent Rights mentioned above) are used to characterize the strength of intellectual property regimes with respect to patent rights, copyrights, trademark rights and enforcement effectiveness. Regression analysis is then employed to estimate the relationship between indicators for licensing and indicators for the strength of IPRs, while controlling for other factors. In this case, the dependent variable is licensing receipts of US enterprises and their foreign affiliates. The regression analysis is conducted first using aggregate data and then using firm-level data.

The study finds general support for the proposition that the strengthening of IPRs has a net positive effect on technology transfer via licensing.[13] Controlling for other factors (such as gross productivity, corruption, tariff rates and country risk), patent rights and effective enforcement of statutes in particular are positively associated with licensing. This may be due to the contribution that stronger patent rights and more effective enforcement make in enhancing the ability of rights holders to appropriate the returns to innovation and hence increase the value of the intangible asset to be licensed.[14]

In addition, stronger patent rights were found to increase licensing relative to foreign direct investment (FDI) in developed regions and at the same time to increase FDI relative to licensing in developing regions. This finding may indicate that a critical level of patent protection is needed before firms have an incentive to relinquish direct control and engage in licensing (as opposed to FDI). The less developed economies tend to have weaker initial IPRs when they launch reforms. Therefore, even after the first stages of IPR reform they may not yet extend sufficient IPR protection to encourage licensing.[15] The effects of IPRs on licensing were found to vary by industry group as well. Patent rights are found to be influential in the services, electrical and electronic, and transportation industries, while not influential in the machinery and wholesale trade industries. Copyrights are important for the licensing of books, trademarks, franchising, and broadcasting. Enforcement effectiveness is especially important in the chemicals, electrical and electronic, and services industries.

The second analytical approach used by Park and Lippoldt (2005) drew on the Securities Data Corporation database on *Joint Ventures and Strategic Alliances* to focus on international licensing transactions between firms in a developed country and firms in a developing or emerging economy (for example Korea, Singapore, Brazil) during the period 1989 to 2002. Overall, for the purposes of the analysis, the database included transactions involving 28 developing or emerging market nations.[16, 17] A large number of these deals involved Asian economies.

Table 3.5 shows the change in licensing transactions between two periods: 1989–1994 versus 1997–2002. As can be seen, developing countries which least strengthened their patent regimes experienced a modest overall reduction in the count of licensing deals. In contrast, developing countries which most strengthened their patent regimes experienced an overall increase of 28 deals over the same time period. Countries with a medium degree of patent reform saw an increase of two more licensing deals. The table points to a positive correlation between changes in licensing deals and changes in patent regimes. Further disaggregation, however, found some exceptional cases where either low patent reform nations obtained more licensing deals than the medium reform nations, or where the medium reform nations obtained more than the high reform nations. However, it was never the case that low reform nations fared better than high reform nations in attracting deals. The overall perspective remains that stronger patent rights are generally associated with increased technology inflows via licensing transactions. The developing nations that reformed their patent regimes the most enjoyed the greatest increases (or in some categories the smallest declines) in licensing agreements with developed nations.

Maskus et al. (2004) provide some complementary information on the

Table 3.5 The relationship between patent reform and high-tech licensing transactions into developing countries

Strengthening of patent regime	Number of licensing transactions		
	1989–94	1997–2002	Change
Low	55	53	−2
Medium	24	26	2
High	33	61	28

Notes:
1. Each row in the table shows the levels and changes over time in the volume of licensing transactions between developing nation licensees and developed nation licensors, as experienced by the developing nations with the specified degree of patent reform. The change in the volume of transactions is for the developing nations in the reform group as a whole.
2. The strengthening of patent regime refers to the change in the index of patent rights of the recipient (licensee) nation. The strengthening of patent rights is considered low if the index grew by less than 7 per cent over the period 1989–2002, and medium if the index grew by more than 7 per cent but by less than 20 per cent over the same period.
3. All deals are 'high-tech' licensing transactions (involving computer equipment and software, communications including telecommunications, biotechnology or electronics).

Source: Park and Lippoldt (2005).

relationship of strengthened IPRs to FDI and licensing. They note that there is evidence to support the notion that stronger IPRs would reduce contracting costs and encourage a shift from FDI towards licensing. However, they find that the 'standard prediction holds only in sectors with rapid innovation rates, which presumably are higher-technology industries'. In lower-technology industries, they find it more likely that 'stronger patents would induce firms to shift toward greater use of FDI and lesser use of licensing'. This is because in lower-technology industries a strengthening of patent rights would reduce the risk of imitation thereby encouraging FDI, whereas presumably the demand for access to new technology via licensing is less pressing in those industries.

CONCLUSION

Technological progress is a fundamental condition for economic development. To the extent that technology is embodied in traded goods and services (including licences) and FDI, developing countries may be able to accelerate technology transfer by enhancing their IPR regimes (which also can help to stimulate domestic innovation). Enhancement of IPR systems

may contribute to the eventual strategic shift from static competition based on low wages and existing technologies, to dynamic competition based on innovation and application of new technologies. From the evidence cited above, it appears that recent strengthening of IPRs in some developing countries has had a positive influence on FDI and licensing and a moderate influence on merchandise trade. These effects vary across sectors and countries, depending on such factors as the risk of imitation and the importance of other factors to rights holders (such as market scale).

Firms holding intellectual assets may enter markets abroad via three main channels: trading in goods or delivering services that embody the intellectual property; investing directly via wholly owned entities or joint ventures; or licensing technology to local firms. All modes may increase in response to stronger IPRs under certain circumstances, but firms may also switch their mode of supply in a given market, moving from exporting to producing locally through affiliates or licensing. In such cases, trade may actually decline or expand more slowly than might otherwise be the case. Where protection of intellectual property is relatively effective and contracts enforceable, firms may opt for licensing and transfer of technology to unaffiliated partners, such as in cases where there are other risks that may dissuade direct investment (for example currency risk) or cases where the licensor lacks the capacity to operate in the market. Further complicating this picture are the cases where firms agree to license as a defensive measure despite a weak IPR environment in a particular market.

There may be a sort of progression with increasing technology transfer associated with increasing effectiveness of IPRs in the partner country, other conditions being equal. However, other conditions are rarely equal. In practice, market entry decisions are influenced by a variety of factors. FDI and trade have been drawn historically in some cases to countries with weak IPRs in Latin America and Asia where markets are fairly large, or in Southeast Asia where labour costs are low. Moreover, the risk of imitation varies by sector or host-country conditions (for example, depending on the local skill base). In addition, complementary factors to the IPR system such as the quality of legal institutions and infrastructure may influence enterprise strategies. Thus, the efficacy of intellectual property reform on trade, FDI and licensing is ultimately subject to the environment in which the enterprises operate and the importance to the rights holders of IPR issues in relation to other non-IPR factors. Intellectual property reform alone will not suffice to close the technology gap between developed and developing nations. In order to reap the full benefits from IPR reform and ensure the capacity to absorb technology inflows, developing countries must also move to develop a coherent policy framework that provides complementary conditions such as appropriate regulation, an environment conducive to enter-

prise, essential physical infrastructure (for example, for communications), and effective educational systems, among other elements.

Can stronger IPRs boost trade, foreign direct investment and licensing in developing countries? In this review of the developing country context, the answer tends to be 'yes'. Patent rights, in particular, have become a prerequisite in enabling firms in developing nations to fully access and exploit technologies and know-how, especially through FDI spillovers and licensing.[18] The results do not imply that stronger protection for patents or other IPRs will always increase trade and FDI and the associated transfer of technology. IPR protection is not a 'silver bullet' development solution, but a general policy implication of the OECD studies for developing economies is that IPR reform should be one part of a broad strategy for promoting economic development. In view of the increasing globalization of markets and the establishment of international standards for IPR protection, competitive pressures leave developing countries little choice but to take action in this regard.

NOTES

1. Under the international statistical framework, royalties and licence fees paid in relation to use of intellectual property fall under the current account heading 'trade in services'. However, given the particular importance of licensing for technology transfer, it is treated separately in this chapter. For further details on the classification of licensing, see: IMF (1993), *Balance of Payments Manual*, 5th edition, International Monetary Fund, Washington, DC.
2. For example, see WTO (2002) for a discussion and bibliographic references.
3. It is possible that IPRs could be made too strong, conferring excessive market power on the rights holders and thereby unduly limiting access to technologies. For a discussion of this issue with respect to patents and an extensive reference list, see Encaoua et al. (2003).
4. Membership figures refer to the situation as of 24 September 2004 and are drawn from the WIPO Internet site: http://www.wipo.org.
5. At the Doha Ministerial Conference in 2001, WTO members issued the *Declaration on The TRIPS Agreement and Public Health*, to make clear their intention for the TRIPS agreement to contribute positively to public health; this document is available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
6. Finger and Schuler (2001) provide an overview of costs related to the implementation of WTO Uruguay Round commitments with respect to IPR reform, customs valuation and sanitary and phytosanitary standards.
7. For example, Cambodia, China and Singapore have integrated IPRs in their national economic strategies and affirmed the importance of IPRs on their national intellectual property office websites: http://www.moc.gov.kh/laws_regulation/development_of_cambodia's_ipr.htm, http://www.sipo.gov.cn/sipo_English/gysipo_e/fzgh/ t20020430_33893.htm, http://www.newiplaws.org.sg/index_about.htm.
8. International accords also cover geographical indications (concerning the origins of goods), industrial designs, layout designs of integrated circuits and undisclosed information (trade secrets). Discussions are underway in the context of the WTO's Doha Development Agenda concerning other dimensions such as the relationship of the TRIPS agreement to protection of traditional knowledge and folklore.

9. The index builds on earlier work by Ginarte and Park (1997).
10. Indicators based on business experience with IPRs were developed using the Global Competitiveness Ratings of the World Economic Forum and the National Trade Estimates of the Office of the US Trade Representative. These each had correlation coefficients of greater than 0.7 with respect to the Index of Patent Rights. See Park and Lippoldt (2003).
11. Some developing countries receive substantial amounts of FDI due to their status as tax havens or centres for 'offshore holding companies' rather than as the ultimate destination or host for these funds. To reduce the impact of such measurement concerns, Park and Lippoldt excluded economies such as Bermuda, the Bahamas and Netherlands Antilles from the sample.
12. This point is sometimes made by representatives of multinational enterprises. For example, it was raised at the *High-Level Workshop on Intellectual Property Rights and Economic Development in China: Meeting Challenges and Opportunities Following WTO Entry*, Beijing, China, 20–21 April 2004, organized by the OECD in cooperation with the State Intellectual Property Office and the Development Research Centre of the State Council, China. The proceedings of this workshop and a related event are scheduled for public release by the OECD. Further information is available at the following web page: http://www.oecd.org/document/49/0,2340,en_2649_34269_31505201_1_1_1_1,00.html.
13. Detailed results are not reported here; instead readers are referred to the original paper.
14. Licensing fees and royalties were found to vary positively with stronger patent rights and more effective enforcement. Copyrights and trademark rights can also influence technology transfer, but were found to exercise comparatively weak influences once patent protection was controlled for. This may be due to the fact that most licence fees are derived from licensing industrial processes. On the other hand, trademark protection can potentially have a negative impact on licensing by increasing firms' abilities to exercise market power.
15. In another analysis of the implications of strengthened IPRs, Nicholson (2003) shows that when wages in destination or host countries are relatively low, a foreign multinational firm is likely to choose production abroad via FDI over exporting. Moreover, if the level of IPRs is not too strong, FDI dominates licensing. Firms may perceive a greater risk of imitation from licensees defecting than from competitors imitating the affiliate producer. However, as IPRs strengthen further, and risks of defection are reduced further, firms may eventually switch to licensing.
16. Licences granted by a developing country firm to a developed country firm or to another developing country firm were excluded as were transactions among developed nations (the latter transactions account for the vast majority of licensing deals).
17. Since fewer than 10 per cent of the transactions in the database report the initial licensing fee, the analysis instead focused on 'counts' or numbers of licensing deals.
18 While much of the foregoing discussion has focused on patents, it was also interesting to note that businesses often rely on the use of trade secrecy to protect their intellectual assets. In some cases, protection for trade secrets can be more important than patents. However, trade secrecy is not a perfect defence. Sometimes, there is abuse of trade secrets, such as when a competitor poaches employees with knowledge of trade secrets and then exploits the knowledge thus acquired. In such cases, access to injunctive relief under IPR protections can be critical to the rights holder.

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4. The enforcement of intellectual property rights: an EU perspective of a global question

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One of the main problems with adopted rules is that they must be implemented and enforced, in order to remain credible and effective. In many instances, and in particular when such implementation is complex, costly and resource-intensive, it would certainly help if the institutions called upon to carry out such tasks were convinced of the overall beneficial effect of their efforts for the community in general. In this chapter, we will describe why the enforcement of intellectual property rights (IPR), and in particular the fight against violations of such rights, is important for the European Union. But, perhaps most importantly (and in a way more difficult) we will endeavour to explain why it should be equally important for others, including many developing countries where piracy, counterfeiting and other IPR infringements are currently widespread and systemic, to contribute to such efforts. Furthermore, we will present the 'Strategy for the enforcement of intellectual property rights in third countries',[1] a paper setting the guidelines for the action of the European Union in the coming years to address the problem outside its borders.

At a time when we are celebrating the 10th anniversary of the TRIPs agreement,[2] we must face the fact that levels of piracy and counterfeiting continue to increase every year and have grown to industrial proportions, becoming a serious threat to national economies and governments. This has happened in spite of the fact that, by now, most members of the World Trade Organisation (WTO) have adopted legislation implementing the minimum standards of IPR enforcement contained in TRIPs.[3] It is, therefore, understandable that those most affected by this problem, and notably the European Union, are increasingly turning their attention, and resources, towards a vigorous and effective implementation of the legislation enforcing IP rights in order to prevent violations of those rights.

WHAT IS THE PROBLEM?

IPR infringement spreads to most types of rights and to virtually any product that can be pirated or counterfeited. One frequent misconception is that violations of intellectual property rights affect mainly luxury brands such as sports and clothing, music and software CDs/DVDs, and little else. The reality is that virtually every IP is being violated on a considerable scale and that the variety of fake products ranges from bottled water to plants and seeds, from aeroplane spare parts to sunglasses, from cigarettes to medicines, from AA batteries to entire petrol stations. Big software producers are as likely to be harmed as small producers of a certain type of tea.

In a survey conducted by the European Commission at the end of 2002 covering the enforcement of IPR in countries outside the European Community,[4] the most frequently reported types of IPR violations were the following:

- **Copyright:** Widespread piracy in all forms, with particular focus on digital media, from CDs to VCDs, to DVDs. There is also extensive illegal digital distribution of films, music, pictures, texts and software over the Internet.
- **Trademarks:** There is counterfeiting of almost every conceivable product, including fake clothes, footwear, leather goods, watches, toys, cigarettes, pharmaceutical products, car parts, electronic devices, lighting products, small electrical appliances, semiconductors, large industrial machines, lubricants and even entire petrol stations. In some countries, a noticeable pattern was identified whereby former business partners continued to use trademarks or designs of the right-holders after the end of a legitimate business relationship.
- **Technical designs:** Reports of design infringements for products like eye glass frames, wine glasses, sliding doors, toys, textiles, and so on.
- **Patents:** There were several reports of infringements on pharmaceutical products, electrical domestic appliances, industrial machinery, and so on.
- **Geographical Indications:** Certain countries allow the registration by local producers of trademarks that in reality are geographical indications originating in other countries or regions.
- **Data protection:** Deficient or even total lack of protection for information provided to national authorities in the framework of the patent lodging or registration of pharmaceutical and agrochemical products processes.

WHY DOES IT MATTER . . .

. . . To Developed Countries?

Innovation is one of the crucial elements of economic prosperity for developed markets, and is a key vector of success in today's business environment. Businesses must constantly create, improve or renew their offer if they wish to keep or capture market shares. Violations of IPR have a very negative impact in a number of different areas for those economies which traditionally invest heavily in IP-protected goods and services and receive considerable added-value for this effort. The most immediately perceived adverse effects of IP violations are as follows:

Economic and social

Sustained inventive and innovatory activity, leading to the development of new products or services, puts businesses at an advantage in technological terms and is a major factor in their competitiveness.

If businesses, universities, research organizations and artists are to be able to innovate and be creative under good conditions, by the same token creators, researchers and inventors must be sure of benefiting from an environment favourable to the development of their activities. IPR violations deprive right-holders of the revenue from their investment in R&D, marketing, creative effort, quality control, and so on. They negatively affect market share, sales volume, reputation, employment and ultimately the viability of certain IP-based activities/companies. High levels of IPR violations also discourage foreign investment and transfer of technology, hence harming economic progress.

These violations also give rise to infringements of labour legislation when the counterfeit or pirated products are manufactured in clandestine workshops by unregistered workers, or sold on the street by clandestine workers.

Lastly, this phenomenon is a genuine threat to the economic equilibrium of the market, since it can lead to the destabilization of certain, sometimes very fragile, sectors, where small and medium sized companies are predominant (textiles, for instance).

Health and consumer protection

It is the basic duty of any public authority to strive for a high level of protection of its citizens, particularly as regards their health and safety. Counterfeiting and piracy, and infringements of intellectual property in general, frequently have dangerous and sometimes even fatal consequences for consumers.

Counterfeiting and piracy often go hand in hand with deliberate cheating of the consumer as to the quality he/she is entitled to expect from a product bearing, for instance, a famous brand name. This is because counterfeit or pirated products are usually produced by anonymous entities which do not respect health, safety and quality requirements. When a consumer buys counterfeit or pirated products, he/she does not in principle benefit from a guarantee, after-sales service or effective remedy in the event of damage. But, more seriously, his/her purchase may pose a real threat to health (counterfeit medicines, adulterated alcohol, food) or to safety (electrical appliances or parts for cars or aircraft).

Public order and security

A growing concern in recent years has been the increased involvement of criminal organizations, and sometimes even of terrorist groups,[5] in major international trafficking of counterfeit and pirated goods. What were once small-scale craft activities have become businesses of industrial proportions, financed and controlled by professional criminals at a multinational level, and taking advantage of the countries with lower levels of enforcement. This evolution is inevitable in view of the particularly lucrative nature of such activities, in conjunction with the relatively low risk compared with other criminal activities. In many countries, crimes like drug trafficking carry significant risks (even the death penalty) and are tackled with considerable resources, while the trafficking of fake goods is seen as a relatively harmless practice. Illustrative of the dimension of the problem is the fact that an increasing number of national police forces, as well as international entities like Interpol and Europol, have recently created departments dealing specifically with it.

Fiscal

Counterfeiting and piracy is an illegal and clandestine practice by nature. As such goods are frequently offered at lower prices, the state is deprived of tax revenue (VAT, revenue taxes, customs duties). This issue is particularly sensitive in countries where economic sectors, such as tobacco, alcoholic drinks, fuel, and so on, are under strict state control.

. . . To Developing Countries?[6]

Why should third countries with little traditional interest in the IPR field, a restricted number of right-holders, and sometimes with a significant share of its industry and commerce benefiting from the violations, care?

The answer to this question is in many aspects the same as the one proposed for developed countries. Indeed, the threats posed by IPR violations

in terms of consumer and health protection, links with organized crime and loss of fiscal revenue are obvious, and directly felt both by developed and developing countries. No country, rich or poor, more or less industrialized can afford to leave an entire sector of its society in the hands of criminal organizations, particularly when the production of goods that have a direct impact on the health, safety and security of its citizens is concerned, neither can any country allow part of its industrial and commercial resources to become a 'parallel economy'. This is why all countries have a direct interest in combating piracy and counterfeiting.

With regard to the first point, however (economic and social consequences), some will say that by enforcing the protection of IP rights held predominantly by entities from developed countries, developing countries will only incur high costs without obtaining direct benefits. It would appear, on the contrary, that they are using their resources to protect the investment of foreign entities.

To counter this reasoning, it must be stressed that effective enforcement of IP rights (even if these belong to third parties) is an essential tool to attract foreign investment and the transfer of technology and know-how, as well as to protect local right-holders in developing and least-developed countries who are already suffering the misappropriation of their intellectual property.[7] Here, issues of good governance and international credibility are at stake, as well as the need to comply with WTO and other international and bilateral commitments. In the medium to long term, it also encourages domestic authors, inventors and investors and contributes to the development of these countries. This is particularly the case for emerging economies.

It is obvious that IPR alone will not do the job. It is only one contributor to innovation, growth and development, and it must be harnessed by rules, accompanied by appropriate national policies and monitored by international institutions, all in a coherent action. But, more importantly, it will only be able to contribute to development and investment if integrated in a system of good governance, respect for property and rule of law.

In the case of least developed countries, one may argue that the benefits are less certain. The longer term benefits in terms of domestic creativity and innovation may not compensate the high short- and medium-term costs of implementing legal and institutional protection and enforcement mechanisms. Furthermore, these requirements may stretch the capacities of least developed countries beyond their limits, since their resources have to be allocated to more pressing basic needs. For these countries only time, in conjunction with technical assistance and capacity building to be provided by developed countries and international organizations may make the case for an effective IP system.

Underestimating the value of intellectual property rights contributes to ineffective enforcement. In order to enhance this aspect of the intellectual property rights system, it might be useful for some (fast) developing countries to assess the value of their industries based primarily on intellectual property rights. This could lead to a better appreciation of the value of intellectual property rights in terms of a country's economic environment, as well as with respect to economic, social and cultural growth and development.

There are, however, recent examples of countries, such as Singapore, Malaysia, South Korea and even China, where the emergence of a competitive and increasingly sophisticated economy is becoming more strongly linked to the need to efficiently protect IP against domestic and external violations. In these countries, the authorities appear to be fully aware of the importance of IPR for development.[8] Furthermore, domestic right-holders demand enforcement of IPR as vigorously as foreign right-holders. The problem is that the piracy/counterfeiting industry is still an important element of the economy. A broader picture therefore emerges, which cannot be tackled merely from an IP angle. Only a comprehensive policy involving authorities at national, regional and local level can provide a solution.

WHAT IS THE SITUATION AROUND THE WORLD?

Once more, the above-mentioned 'Enforcement Survey' provides a diagnosis of the situation of IPR enforcement around the world, both in its negative and positive aspects. The main obstacles to an effective enforcement of IPRs are the following:

- in general, deficient enforcement of the domestic and international IPR regulations: lack of real political will or resources (in the case of poorer countries) to go beyond the publication of TRIPs compatible legislation and to make the fight against IPR violations a real priority. The protection of IPRs is still frequently seen by authorities as an exclusive concern of the right-holders.
- more specifically, there are often no deterrent punishments for infringers, making it economically attractive to be involved in the piracy/counterfeit trade: Violations of IPR are seen as low risk–high profit activities. Whilst there is frequently a reluctance to apply criminal sanctions, administrative penalties are also often insufficient to dissuade pirates/counterfeiters from pursuing their very profitable practices. Other legislative sanctions usually available, such as the seizure of production machinery or the closing of production

facilities, are not systematically used, thus encouraging the continuation of the criminal activities.
- lack of a strong coordinating authority at central level and of a clear strategy: the management and enforcement of IPRs is generally fragmented among a considerable number of entities, from legislative bodies to ministries, from registration agencies to the courts, from customs to the police. There is frequently an absence of structured coordination.
- slowness, inefficiency and/or high cost of the judicial system: reports of slow, uncoordinated, costly trials, with long delays, minimal positive results, and lack of uniformity of the jurisprudence (mainly with regard to the definition of vague concepts often present in the law like 'substantial damages', 'serious offence', and so on.)
- in certain countries, such as Brazil, India, the South Mediterranean countries or even the US, IPR violations result from a different interpretation of multilateral rules. This is particularly relevant in the case of data protection and patents for pharmaceuticals or that of geographical indications. In these cases, violations of rights are often considered as legitimate practices by the national authorities.
- local protectionism of infringing industries and corruption of the authorities in charge.
- lack of human, financial and material resources. In particular, insufficiency of trained officials at all levels: legislators, customs officials, judges and prosecutors, police, and so on.
- ineffective custom controls for export of pirated/counterfeit goods to third countries. Even when the law provides for them (it is a rule that goes beyond TRIPS requirements), these controls are mostly ineffective.
- insufficient public awareness of the problem. Violations of IP rights are not regarded as an offence. Often, people are even unaware of the fact that using a protected brand, trademark or sign constitutes an infringement of the law.

On the other hand, the following points were identified by the respondents to the Enforcement Survey as positive steps towards improving global enforcement of IPR:

- at the higher levels, certain national authorities seem to be increasingly aware of the existence of the problem, and of the commitments undertaken in the framework of multilateral agreements like TRIPS. This is frequently translated into an effort to improve legislation and to adapt it to higher standards of protection and enforcement.

- in some countries with high levels of IPR violations such as China, Thailand and the Ukraine, the human and material resources dedicated to enforcement have recently been improved. Measures adopted include the creation of coordination entities, government task-forces, special police units and specialized courts, participation in training programmes (frequently supported by foreign countries or international organizations and/or right-holders), and the launch of state sponsored public awareness campaigns, and so on.
- the authorities of some countries are willing to accept the cooperation of right-holders in criminal investigations. Such 'partnerships' can lead to positive results, including seizures of large amounts of goods and the dismantling of criminal networks.
- the introduction of measures such as the 'optical disc regulation' offers a cost-effective way to tackle this particular piracy problem at the source. Unlike most enforcement measures, optical disc laws work proactively against infringements of intellectual property rights. Properly implemented, these rules can make it much more difficult for rogue elements to manufacture pirated optical discs, and can do so without placing undue regulatory burdens on legitimate plants. This type of measure has produced immediate positive results in countries where it was recently introduced.

WHAT ARE THE INSTRUMENTS AVAILABLE IN THE EUROPEAN UNION?

Generally speaking, the European Union and its Member States are acknowledged for protecting and enforcing IPR to very high standards. The most 'operational' responsibilities and the majority of the means and resources in the field to fight against piracy and counterfeiting are the responsibility of the individual Member States. The most visible and immediate results in this fight will always be achieved by the national customs authorities, police, courts, and administrations, and are regulated by the different national legislations. This is why the level of enforcement within the Community is different among Member States, and also why some of them still need to do more towards improving the present situation, cutting down the remaining production and sale of pirated or counterfeit goods.

The European Union has a crucial role to play in the harmonization of laws and procedures and the creation of cooperation and information exchange mechanisms at Community level. The responsibilities attributed to the EU have paved the way for several important initiatives in recent years which make a valuable contribution to improving the situation.

As long ago as 1994, the EC adopted the Customs Regulation (Regulation (EC) No 3295/94), allowing border control of imports of fake goods. Later, in 1998, the European Commission issued a green paper on combating counterfeiting and piracy in the single market. As a result of responses to the green paper, the Commission presented an action plan, on 30 November 2000. This action plan is now being implemented, namely in the form of a Directive harmonizing the enforcement of intellectual property rights within the Community,[9] of a Regulation improving the mechanisms for customs action against counterfeit or pirated goods[10] set by the previous Customs Regulation, the extension of Europol's powers to cover piracy and counterfeiting, and the launching of a study on a methodology for the collection, analysis and comparison of data on counterfeiting and piracy. Furthermore, the presidency conclusions of the Spring European Council 2003[11] called for the fight against piracy and counterfeiting to be greatly stepped up. As a result, the Commission intends to launch a legislative initiative with a view to harmonizing the national legislations of the Member States insofar as criminal sanctions on counterfeiting and piracy[12] are concerned.

The situation is, however, different regarding the enforcement of IPR outside the Community borders. The internal instruments available to EU right-holders if their rights are violated inside the Community, or if fake goods are imported into the EU, cannot be applied in cases where such violations occur in third countries and where the resulting goods are either consumed domestically or exported to other third countries. Although such violations occur outside, they directly affect Community right-holders. This is why the European Commission recently presented a strategy paper setting out priorities and optimizing the use of resources to obtain the most effective results in terms of IPR enforcement in third countries, that is in countries that are not members of the EU.

THE ENFORCEMENT STRATEGY

The 'Strategy for the Enforcement of Intellectual Property Rights in Third Countries'[13] (the Enforcement Strategy) was adopted by the European Commission on 10 November 2004. It focuses on the effective implementation and enforcement of existing IPR laws. The Enforcement Strategy proposes to identify priority countries where the efforts and resources of the EU should concentrate. Stress is put on technical cooperation and assistance to help third countries but equally it is foreseen to use bilateral and multilateral sanction mechanisms available against countries involved in systematic violations. The European Commission also proposes a more systematic

promotion of IPR mechanisms in multilateral, bi-regional and bilateral frameworks, as well as to foster awareness-raising of users and consumers in third countries and to establish partnerships with private entities as well as with international organizations and countries sharing its concerns.

The Enforcement Strategy aims to contribute to improving the situation in third countries by ensuring that right-holders are effectively protected against the misappropriation of their property, and citizens in general are protected against the dangers of piracy and counterfeiting. It is the logical consequence of recent EU initiatives such as the above-mentioned Enforcement Directive, which in its turn aims to harmonize enforcement legislation within the European Union, and the revision of the Customs Regulation, which provides for action against counterfeit or pirated goods at the Community's border.

The purposes of the Strategy are defined by the European Commission as follows:

- To provide a long-term line of action for the Commission services with the goal of achieving a significant reduction of the level of IPR violations in third countries;
- To describe, prioritize and coordinate the mechanisms available to the Commission services for achieving their goal;
- To inform right-holders and other entities concerned of the means and actions already available and to be implemented, and raise awareness as to the importance of their participation.

The Commission has also stressed that the following objectives should not be attributed to the Strategy:

This new approach does not aim to impose unilateral solutions to the problem. It is clear that, ultimately, any proposed solutions will only be effective if they are prioritized and considered to be important by the targeted countries.

Furthermore, the Strategy does not seek to impose a one-size-fits-all approach to promoting IPR enforcement. It recognizes the importance of adopting a flexible approach which takes account of different needs, levels of development, membership or not of the WTO, and main problems in terms of IPR (country of production, transit or consumption of fake goods) of the countries in question.

Finally, the Strategy must not be simplistically interpreted either as a copy of other models of IPR enforcement,[14] or as an attempt to join forces with some (developed) countries against those (mostly developing) countries where the problems are more acute. If one of the objectives mentioned in the paper is indeed to improve cooperation and to create synergies with

countries sharing EU's concerns and facing similar problems, it is nevertheless important to note that the Strategy remains primarily focused on positive and constructive efforts, with the EU proposing to create the conditions, in close cooperation with the recipient countries, for the prosecution of such efforts.

The lines of action proposed are the following:

1) Identifying the Priority Countries

The human and financial resources allocated to the enforcement of IPR being limited, it is unrealistic to claim that the European Commission can extend its action equally to all, or even most, of the countries where piracy and counterfeiting occur. A mechanism is therefore foreseen to periodically assess which are the most problematic countries/regions, or those where the action of the Community is most urgently required. This will consist of a questionnaire distributed to entities such as the EC Delegations, Embassies of Member States, right-holders and associations, Chambers of Commerce, and so on. The replies will then be analysed and the results made available to the public. These results, in conjunction with other reliable sources of information available to the Commission,[15] should constitute the basis for the renewal of the list of priority countries for the next period.

It is important to stress that the identification of 'priority' countries in this manner is by no means an attempt to put in place a 'black list', or some kind of pre-selection method for the imposition (or threat) of sanctions. It is first and foremost an exercise that will allow the Commission to allocate its limited resources and to concentrate its efforts where they are most needed.

2) Multilateral/Bilateral Agreements

The TRIPS agreement has a detailed and extensive chapter dedicated to the setting of minimum standards of IPR enforcement and technical cooperation. It also provides for a structure responsible for monitoring the implementation of the provisions of the agreement and for consultation between Members: the TRIPS Council. Finally, it puts in place a mechanism to prevent and settle disputes. These characteristics make TRIPS one of the most adequate and effective instruments to address problems related to IPR violations.

The numerous bilateral agreements (free trade agreements, association agreements, Europe agreements, and so on) established by the European Community typically contain a chapter dedicated to IP. This chapter usually aims for a very high standard of IP protection (and enforcement). Most agreements also include a clause allowing for technical cooperation

in this field. These clauses must be carefully monitored and effectively implemented, notably with respect to the more 'problematic' countries.

The institutional structures of these (and other) multilateral and bilateral agreements (TRIPS Council, Association Councils, the World Intellectual Property Organisation – WIPO, and so on) can be used to monitor and discuss legislation and enforcement problems at a very early stage. They allow for a structured political dialogue and can be forums to submit new initiatives or to act as 'early warning' for problems which may occur, before there is a need to adopt stricter measures.

The European Commission also envisages making the enforcement clauses in future bilateral or bi-regional agreements more operational, and aims to clearly define what the EU regards as the highest international standards in this area, as well as the efforts it expects from its trading partners. Instruments such as the Enforcement Directive and the new customs Regulation on counterfeit and pirated goods may be an important source of inspiration and a useful benchmark, without prejudice to a careful consideration of the level of development and the capacity of our partners.

3) Political Dialogue

The Commission considers that effective protection of IP, at least at the level set in TRIPS, is absolutely essential. Indeed, the first step for fighting piracy and counterfeiting is an adequate level of enforcement at the source, that is in the countries where the goods are produced and exported. This message will be increasingly conveyed at the political level. The Commission is willing to assist third countries in raising their level of enforcement, but it will not refrain from using the instruments at its disposal in cases where deficient enforcement is harming its right-holders. It will also emphasize that effective enforcement is, in many cases, of mutual interest, be it for health, safety or security reasons.

In addition, the Commission is proposing to increase cooperation with countries heavily affected by these types of practices, and which share the Community's concerns, by establishing an exchange of information and even in participating in joint initiatives in third countries. Furthermore, such 'joint ventures' should enable resources to be rationalized where countries share similar concerns and pursue parallel initiatives.

Finally, officials of the EC Delegations in the 'problematic' countries will receive basic training enabling them to offer a minimum of information to entities contacting them with enforcement problems. They can in this way establish close links with the local enforcement entities, with the Community right-holders operating in these countries and with the embassies of EU Member States and other countries concerned by deficient IPR enforcement.

4) Incentives/Technical Cooperation

Most of the countries with deficient enforcement will claim a lack of resources and the existence of more pressing priorities than protecting IP rights. IP enforcement is a complex and multi-disciplinary activity. It involves drafting of legislation, training of judges, police forces, customs officials and other experts, the setting up of agencies or task forces, public awareness raising, and so on. Most of these needs can be, and to some extent already have been, addressed by the Commission through technical cooperation programmes, but it is possible to do more and better.

Technical assistance is an activity favoured by the EU for its contribution towards poverty alleviation and development. The Commission considers that adequate IPR enforcement can contribute to this goal by making a link with investment opportunities, transfer of technology and know-how, protection of traditional knowledge, improvement of health and safety standards, and so on.

The Strategy points out the need for a flexible approach that takes into account the recipient country's different needs, level of development, membership or not of the WTO, and main problems in terms of IPR (country of production, transit or consumption of fake goods). This is because cooperation efforts will only be effective if they are felt to be as important in the recipient country.

Another proposal is to share information and to ensure a minimum level of synergy between the main providers of technical assistance, such as WIPO, the individual EU Member States and third countries such as Japan, the US and others.

5) Dispute Settlement/Sanctions

No rule can be really effective without the threat of a sanction. The Strategy, therefore, also includes the possibility of resorting to the dispute settlement mechanisms provided for in multilateral and bilateral agreements.

For this purpose, a mechanism is available to private right-holders, the so-called Trade Barriers Regulation (TBR) mechanism.[16] TBR is a legal instrument that gives Community enterprises and industries the right to lodge a complaint, obliging the Commission to investigate and evaluate whether there is evidence of violation of international trade rules resulting in adverse trade effects. The procedure will lead either to a mutually agreed solution to the problem, or to recourse to the dispute settlement mechanism.

The TBR has a broad scope of application, covering not only goods but also, to some extent, intellectual property rights and services, when the

violation of rules concerning these rights has an impact on trade between the EC and a third country.

In addition to the WTO dispute settlement mechanism, the EU also includes similar mechanisms in an increasing number of bilateral agreements. These mechanisms can be triggered in cases of non-compliance with the required high(est) standards of IP protection.

It is, nevertheless, important to bear in mind that deficient enforcement derives more frequently from the way the rules are (not) de facto implemented by the competent authorities than from an absence of legislation or a blatant contradiction of legislation with TRIPS requirements. Such specificity makes it often difficult to use dispute settlement mechanisms to address cases of poor protection against deliberate IP violations, since these are mainly designed to correct situations where the national law itself is not in line with international commitments. However, when these de facto deficiencies become systemic, they can be used to substantiate a dispute settlement case.

6) Creation of Public–Private Partnerships

A large number of companies and associations are very active fighting against piracy/counterfeiting. They are both an important source of information and a key partner for any awareness-raising initiatives. Some of these entities are already present, and very operational, in most problematic countries.

The European Commission is proposing to take advantage of this presence by supporting the creation of local IP networks involving companies, associations and chambers of commerce, and by enhancing cooperation with companies and associations that are already active in the fight against piracy/counterfeiting. This can be achieved *inter alia* by exchanging information about future initiatives, and ensuring the cross-participation of experts from the Commission and from private entities in events organized by the other party. Furthermore, the Commission proposes to create the conditions for the set-up of regular dialogue mechanisms between EU right-holders and national authorities of relevant third countries, with a view to establishing a better understanding and possible cooperation towards constructive solutions.

7) Awareness-raising

Providing better information to the public is another relevant dimension of the Strategy. Although the European Commission does not have the resources to pursue on its own extensive awareness-raising campaigns

in third countries, it proposes to include such activities in existing technical cooperation programmes and in those carried out by public–private partnerships.

The Commission has also sponsored the drafting of a 'Guidebook on Enforcement of Intellectual Property Rights'. The main objective of this Guidebook is to assist public authorities of developing and least developed countries in their efforts to establish systems and procedures for the effective enforcement of IPR. The guidebook specifically considers the most common difficulties faced by these countries and provides guidance on how to achieve efficient and long-lasting protection for such rights. It also lists useful resources which may be of assistance to authorities and right-holders faced with such difficulties. The Guidebook will be made publicly available through the Commission website.

Awareness-raising must tackle different elements:

(i) Users/consumers in third countries. This must be done from two perspectives: (a) to promote the benefits of IPR in terms of encouraging of creativity, investment, transfer of technology, protection of traditions and quality; (b) to inform about the dangers of IPR violations to public health, consumer protection, public security, and so on.
(ii) Right-holders. Again from two different perspectives: (a) the risks incurred by trading in certain countries where IPR enforcement is ineffective and the minimum precautions that must be adopted, such as registering IP rights in those countries (frequently, small and medium sized companies do not even apply for the protection of their intellectual property in third countries where they are producing or selling their goods); (b) the need to use the means available in these third countries to enforce their rights. Countries which are members of the WTO (with the exception of least-developed countries) had the obligation to implement minimum standards of IP protection and enforcement in 2000. It is clear that the first steps to protect and enforce IPRs must be taken by the right-holders themselves, and that they must use, to the extent possible, the available mechanisms before being entitled to legitimately complain about the effectiveness of such protection and enforcement.

8) Institutional Cooperation

Different Directorates-General (DGs) of the Commission are responsible for the different aspects of IPR enforcement. These services must step up their coordination and cooperation with a view to enhancing the role of the Commission in the fight against piracy and counterfeiting. The Strategy,

moreover, proposes to simplify the identification of and the access to the service responsible for external entities (right-holders, third country authorities, and so on) concerned about a specific issue.

CONCLUSION

The Enforcement Strategy does not propose to re-invent the wheel, but rather aims to demonstrate that the European Union Commission is willing to work more and better on the basis of legislation that is for the most part already in place in the different countries. It is essential to accompany the commitments agreed to in the framework of TRIPS with a view to combating IPR violations with a genuine willingness to tackle the problem at the borders, in the courts, and in the streets. The European Commission, for its part, must ensure that EU right-holders are effectively protected against the misappropriation of their property, and EU citizens against the dangers of piracy and counterfeiting.

NOTES

* Respectively Director *ad interim* in charge of 'Textiles, New Technologies, Intellectual Property, Public Procurement and Trade Analysis' and Administrator responsible for 'IPR Enforcement and IPR in bilateral Trade Agreements', at the Directorate General for Trade of the European Commission. Both were involved in the elaboration of the Enforcement Strategy. The views expressed in this chapter are those of the authors and cannot be attributed to the European Commission.

1. The complete version of the results of the 'Strategy for the enforcement of intellectual property rights in third countries' is available at: http://europa.eu.int/comm/trade/issues/sectoral/intell_property/pr 010704_en.htm.
2. Agreement on Trade-Related Aspects of Intellectual Property, Annex 1C to the Agreement establishing the World Trade Organisation (TRIPS, Marrakesh 1994).
3. Pursuant to article 65 TRIPS, the deadline for the adoption of national legislations up to TRIPS standards expired in 2000 for developing countries (with some exceptions in areas like patents). Least developed countries have until 01/01/2006, at least (01/01/2016 in the case of patents for pharmaceutical products), to adapt their legislation to the TRIPS requirements.
4. 'Survey on enforcement of intellectual property rights in third countries'. The complete results, including a detailed report per country, for all the countries for which sufficient information was received, are available at: http://europa.eu.int/comm/trade/issues/sectoral/intell_property/survey_en.htm.
5. For instance, in 1995, the Royal Ulster Constabulary confirmed that counterfeiting and piracy, particularly in relation to counterfeit videos, was a major source of funding for the IRA. Source: Website of Alliance http://www.aacp.org.uk/cost/casestudies.html.

   In its Threat Assessment Report 2002, The Organised Crime Task Force in Northern Ireland established a direct link between IP theft activities and paramilitary and terrorist groups in the region. In its Newsletter of September 2002, Interpol stated that 'extensive evidence is now available that [. . .] organised criminals and terrorists are heavily involved in planning and committing these (IPR) crimes.'

6. For more detailed reflections on the position of the European Commission concerning the more general relation between IPR and development, see a summary of the Conference Commemorating the 10th Anniversary of TRIPS – held in Brussels on 23/24 June 2004, and in particular the conclusions by Commissioner Pascal Lamy: http://europa.eu.int/comm/trade/issues/sectoral/intell_property/pr110604_en.htm.
7. Cf. the cases of counterfeits of certain brands of rice wine in China or of a well-known local fish sauce brand in Vietnam.
8. China's commitment to step up IP protection has been publicly stated by its Prime Minister on a number of occasions throughout 2004. The Chinese Government has declared the fight against IPR infringement a priority issue and has established a State-Council level working group for the fight against piracy and counterfeiting, under direct supervision of its Vice Prime Minister.
9. The Enforcement Directive was formally adopted in April 2004. The text is available at: http://www.europa.eu.int/comm/internal_market/en/intprop/piracy/index.htm.
10. COM (2003) 20 final, of 20/01/2003, available at: http://europa.eu.int/comm/taxation_customs/customs/counterfeit_piracy/files/counterfeit_en.pdf.
11. Spring European Council 2003: Presidency Conclusions: '37. The European Council calls upon the Commission and Member States to improve exploitation of intellectual property rights by taking forward measures against counterfeiting and piracy, which discourages the development of a market for digital goods and services; to protect patents on computer implemented inventions. . . .'
12. The competence to legislate in penal matters belongs mostly to Member States. The European Union has limited, albeit increasing powers in this delicate field of national sovereignty.
13. The complete version of the results of the 'Strategy for the Enforcement of Intellectual Property Rights in Third Countries' is available at: http://trade-info.cec.eu.int/doclib/docs/2004/november/tradoc_120025.pdf.
14. Such as the 'Special 301' report, which is published every year by the US Trade Department. This report purports to detail the adequacy and effectiveness of intellectual property protection in countries throughout the world (and even in private companies, as recently proposed in the STOP initiative, presented by the US Administration at the end of 2004). The Special 301 report on intellectual property includes information on WTO disputes, 'out-of-cycle reviews' of policies in various countries, and putting countries on the 'Priority Watch List' or the regular 'Watch list.' Consequences for countries that are included in this report may vary from unilateral trade sanctions according to US law to dispute settlements in the framework of WTO or of bilateral agreements.
15. A source already exists which provides valuable information about the origin, the itinerary and the nature of counterfeit and pirated goods destined for, or in transit via the Community: the annual statistics on the goods originating from third countries seized by Customs at the Community border. The report is released by DG TAXUD. The figures for 2003 can be found at: http://europa.eu.int/comm/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm.
16. Council Regulation (EC) No. 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the WTO. Available at: http://europa.eu.int/comm/trade/issues/respectrules/tbr/legis/adgreg06a.htm.

PART II

IPRs, business and public–private partnerships

5. What is an idea worth?

Richard P. Rozek and George G. Korenko

I. INTRODUCTION

People assign values to ideas every day in the marketplace for intellectual property (IP). This marketplace is thriving. There were more than 625 transactions involving some form of IP rights in the pharmaceutical industry alone between July 2003 and June 2004.[1] IP does not have value unless it contributes to products or services that fill previously unmet needs, represent an improvement over existing products or services, or allow cost savings. For example, while a patent provides exclusive rights to an innovation, it does not ensure that consumers will purchase the product or service embodying the innovation. Emmett J. Murtha, former Director of Licensing at IBM, estimated that only about 5 per cent of the patents in a large portfolio have substantial value.[2] Many patents cover technologies that are not commercially viable or cannot be practiced without access to other technologies. Determining the value of IP requires an understanding of the characteristics of the research and development (R&D) process and the downstream markets for the associated products or services.

IP may be valued for internal business decisions, venture capital financing, financial reporting such as for Statement of Accounting Standards (SFAS) 141 and SFAS 142, licensing transactions, taxes, litigation or bankruptcy. Some of these forums have codified standards that an analyst must follow when valuing IP. There are three approaches frequently applied: the cost approach, the market approach, and the income approach. Not surprisingly, there is substantial agreement between these standards and one or more of the common IP valuation practices. The income approach is a primary valuation approach in all these forums. Analysts often rely on the discounted cash flow (DCF) and real option methods in applying the income approach. Corporate finance textbooks advocate the DCF method, which is widely used to value a variety of income-producing and cost-saving assets.[3] The real option method is particularly well suited to valuing early-stage technologies where management can alter the project after the initial investment in response to new information.

We discuss three approaches for valuing IP. We then describe different forums that require IP valuations, the acceptable approaches in each forum, and the importance of using consistent approaches for valuations across forums. Finally, we focus on the income approach – in particular the DCF and real option methods – since it is a primary approach in all forums and provide three examples to illustrate differences and similarities in the DCF and real option methods.

II. COMMON VALUATION APPROACHES

Three commonly applied approaches to value IP are the cost, market and the income approaches.[4] The choice of which specific approach to use depends on the facts and circumstances of the valuation problem at issue. We describe briefly each approach below.

A. Cost Approach

The foundation of the cost approach is that a company would pay no more for IP than the costs to replace it; that is, the replacement costs. The costs to replace the IP include the costs today of developing IP that provides similar benefits at similar costs adjusted for any obsolescence in the existing technology. That is, the cost approach attempts to quantify the amount required to replace the benefits of the IP at issue, net of obsolescence. This approach does not consider directly the future cash flows associated with the property, the period over which they may be available, or the risks associated with these cash flows. This approach provides an accurate measure of value for IP only by chance.

B. Market Approach

The market or comparable approach measures value by comparing the IP at issue to the value of similar IP traded under similar circumstances in third-party transactions. Ideally, it would be possible to observe the value of the IP obtained from a prior market transaction. However, it is exceedingly rare for such transactions to be available. More commonly, applying the market approach entails collecting data on the prices paid for reasonably comparable IP. This approach requires data from an active market in sufficiently similar property. Adjustments to the values obtained from the third-party transactions may be necessary for any material differences between the market transactions and the IP. The reliability of this approach depends directly on the availability of detailed

data regarding comparable third-party transactions and any necessary adjustments.[5]

C. Income Approach

The income approach is a widely accepted approach for valuing all types of assets including IP, business entities and capital assets, and liabilities such as bonds and mortgages. In general, the income approach considers the economic contribution of the IP in terms of the net cash flows realized, the profile of those cash flows, and the risks associated with realizing them. The income approach is consistent with economic principles. It captures the timing, market conditions and risks associated with the use of the IP. This approach requires data on the revenues, costs, risks, and economic life associated with the IP to be valued. In some cases, sufficiently reliable and accurate data are not available.

III. FORUMS WHERE IP IS VALUED

Assigning value to IP is important for companies in almost every industry including chemicals, computers, consumer products and services, electronics, media and entertainment, medical devices, pharmaceuticals, software and telecommunications. Companies in each industry may need to value their IP in numerous forums. The approach to valuing the associated IP often depends on the forum in which the valuation occurs. We describe briefly some of the more important forums and the acceptable valuation approaches in each forum.

A. Business Decisions

Valuing IP is frequently part of a company's internal business decision process. For some companies, their most important assets are intangible assets. Managers in such companies should understand the values of these assets, contemplate ways to enhance their values, and consider the effects of any decisions on their values. There is no required structure for providing input into internal business decisions. However, many companies actively involved in the marketplace for IP routinely use the income approach to determine the value of IP since it recognizes the future cash flows from the IP in the context of the added value to the company.

1. Acquisitions and divestitures

IP may also be an important part of a company's acquisition strategy. For example, a company may consider acquiring an R&D laboratory where the primary assets are the projects in development and the infrastructure to continue conducting R&D. The amount the company is willing to pay for the laboratory should reflect the expected net cash flows from the products that it expects to result from the R&D activities.[6] Similarly, companies must value businesses for divestitures or spin-offs. In such cases, considering the value of the IP transferred may be important for determining an appropriate selling price or issuing stock to shareholders, respectively.

2. Holding or licensing

IP may have strategic value. That is, the patent holder does not necessarily need to use the technology in a product or process for the patent to have value. A patent may provide value to the patent holder through its ability to exclude competitors. For example, companies may have patents for technologies that are substitutes for those they currently employ. They may choose to exploit these technologies or exclude others from using them by merely holding the patents in their IP portfolios.[7]

IP not currently used within the company may also represent a viable asset for the company to sell in the IP marketplace. Companies such as DuPont, IBM and Procter & Gamble have increased revenues by actively marketing their unused technologies.[8] The value of IP in a licensing transaction depends on the values of the licensed technology to the licensor and licensee as well as the bargaining power of the two parties. The minimum amount the licensor should accept is equal to its forgone profits from licensing the IP. The forgone profits depend of the incremental, risk-adjusted net cash flows the licensor would expect to realize from using or holding the IP. The maximum amount the licensee is willing to pay equals the lesser of the incremental, risk-adjusted profits from licensing and using the IP and the incremental cost to invent around the patent. The cost approach may be useful in determining the cost to invent around a patent, but does not recognize the future benefits to a licensor. Reliable comparable transactions may not exist until the technology is licensed. The income approach may be useful for estimating the incremental profits to the licensor and licensee since it considers the future net cash flows and adjusts for the risks associated with realizing those cash flows.

B. Venture Capital Financing

New venture capital investment in the US for 2005 totaled over $21.7 billion.[9] The biotechnology and software industries had the largest levels of

investment at $3.9 billion and $4.7 billion respectively.[10] Venture capitalists considering such investments in IP development projects must determine whether their investment is likely to provide a return commensurate with the risks they bear. To estimate the risks and returns, they frequently evaluate business plans that contain information that is helpful in evaluating the proposed investment: expected uses for the IP, profit potential, time to commercialization, and probability of success. These data focus on the future cash flows generated by using the IP and are the inputs required for a valuation using the income approach.

C. SFAS 141 and SFAS 142

Accounting standards in SFAS 141 and SFAS 142 require, among other things, that companies determine and report the fair values of acquired IP assets. The assets considered include marketing, customer, artistic, contractual and technology-related IP.[11] While using quoted market prices is the preferred valuation approach,[12] such prices are rarely available for IP.[13] As an alternative, SFAS 142 notes that a 'present value technique is often the best available technique with which to estimate the fair value of a group of net assets.'[14] Since the income approach applies present value techniques, it is likely to be a preferred approach given the data available for valuing IP under SFAS 141 and SFAS 142.

D. Taxes

IP valuations may be required to comply with tax regulations regarding prices charged for products or services exchanged between affiliates of a multinational company (that is, transfer pricing), cost sharing between affiliates, and patent donations. For transfer pricing, national and international tax authorities require that companies charge arm's length prices in inter-company transactions involving IP or other intangible assets. Under the US Internal Revenue Service (IRS) rules, the specified methods for determining transfer prices for IP include the comparable uncontrolled transaction (CUT) method, the comparable profits method (CPM), comparable profit split method (CPSM), and residual profit split method (RPSM).[15] The CUT and CPSM methods are the best methods to use under the US transfer pricing regulations if the taxpayer has reliable data on transactions for similar IP with third parties.[16] In applying the CUT method,

> The profit potential of an intangible is most reliably measured by directly calculating the net present value of the benefits to be realized (based on prospective

profits to be realized or costs to be saved) through the use or subsequent transfer of the intangible, considering the capital investment and start-up expenses required, the risks to be assumed, and other relevant considerations.[17]

Cost sharing agreements involve a company performing R&D at a facility located in one country using funds provided by affiliates in one or more other countries. Tax authorities in each country require that the affiliate in their country receive appropriate compensation and pay the appropriate taxes.[18] When a company enters into or exits a cost sharing agreement involving existing IP, the appropriate affiliate must make a buy-in or buy-out payment. To comply with the tax regulations, the amount of the buy-in or buy-out payment should be consistent with the present value of the transferred IP.[19] Since it considers the future net cash flows from developing and using the IP, the income approach is likely to be useful for determining the value of buy-in and buy-out payments.

IRS rules allow companies to reduce their taxable income based on the values of patents donated to universities and research centers.[20] The amount of the deduction depends on the fair value of the patent.[21] The IRS has argued successfully that patent validity, technological feasibility, and difficulty of enforcement must be included in the valuation of a patent.[22] While it would be difficult to account for these factors under the cost or market approaches, the income approach allows for these types of adjustments.

E. Litigation

Depending on the facts and circumstances in a specific litigation on patent damages, the patent holder may be entitled to lost profits, price erosion damages, reasonable royalties, or a combination of these three elements of damages. In any event, patent holders are entitled to no less than a reasonable royalty. The income approach may be used in determining the amount of each element of damages. For example, to determine a reasonable royalty, an economic expert can model the outcome of a hypothetical negotiation between the patent holder and the infringer at the time infringement began.[23] Expert testimony on damages often consists of applying the factors identified in the *Georgia-Pacific* case[24] to determine the minimum and maximum acceptable royalty rates for the licensor and licensee, respectively. The income approach to valuation is helpful in this context.

F. Bankruptcy

If a company is selling IP assets as part of a bankruptcy proceeding, interested parties must estimate the fair value of these assets. The context of the

bankruptcy may significantly affect the value of the IP if it is no longer part of the going concern. As a result, the market approach using ordinary transactions may not be applicable. The purchaser should be willing to pay no more than the amount of the incremental profits it expects to generate by using the IP. The income approach is helpful for measuring the incremental profits from using the IP.

G. Consistent Valuations across Forums

When preparing a valuation in a specific forum, it is important to anticipate that someone may review that valuation in another forum. For example, tax authorities can request valuations prepared for internal business decisions or SFAS 141 and SFAS 142 documentation to determine if these valuations are consistent with the company's transfer prices or tax deductions for donations. Similarly, attorneys may request in the discovery phase of patent infringement litigation transfer pricing valuations for use in a damage analysis. Consistent valuations capable of withstanding scrutiny across forums help to avoid any problems.

Companies can take steps to reduce the potential for inconsistencies. One important step is to establish a rigorous, documented, company-wide policy for internal valuations. This policy might specify the length of the period to use for forecasting cash flows, the appropriate inflation rate (if any), and the discount rate or rates to use in preparing valuations.[25] Most importantly, these valuations and the underlying principles should serve as a basis for analyses prepared for other forums.

To ensure a consistent position on the value of IP, staff from licensing, intellectual assets management, finance and tax should communicate, share internal results, and reach consensus on appropriate valuation approaches and assumptions. When valuations in two forums provide different values for the same IP, the company should be able to explain the reasons for the difference. For example, a valuation prepared in one year may differ substantially from a valuation prepared in the following year due to changes in the expected revenues and costs. If other fundamental data and assumptions are similar, these valuations may remain internally consistent. Other unexplained changes could result in unnecessary controversies.

IV. APPLYING THE INCOME APPROACH

Given the broad acceptance of the income approach across forums requiring valuations, we discuss alternative ways to apply this approach. Under the income approach, the fair value of any asset equals the present value of

the future stream of economic benefits from using the asset. Two frequently applied methods for applying the approach are the DCF method and the real option method.

A. DCF Method

The value of IP is the lump sum, present value (PV) of the anticipated future cash flows produced by using that IP. These cash flows are determined using data on expected revenues, costs and risks of the project. The only relevant cash flows are future cash flows; past cash flows or sunk costs are bygones and should not be included in a forward-looking valuation. Calculating the net present value (NPV) of an asset or liability requires:

- forecasting the positive and negative future cash flows based on the expected revenues and costs from using the IP over its remaining life;
- converting the future cash flows to present values; and
- summing the present values.

We convert future values to present values using a discount rate that measures the opportunity cost of capital for the level of risk associated with using the IP.[26] The appropriate discount rate allows us to consider both the time value of money and the risks associated with specific IP. The greater the risks associated with the future cash flows, the higher the discount rate. DCF analysis allows us to consider the timing, expected market conditions, and risks associated with each asset or liability. The DCF method's decision rule is to pursue only those investments with a positive NPV.

The first step in applying the DCF method is to forecast the incremental net cash flows[27] generated by using the IP over its economic life. Only the incremental cash flows are relevant; sunk costs and allocated fixed costs are not necessary. It is important to include all the relevant cash flows. For example, a company introducing a new product should consider whether the new product is likely to have a positive or negative effect on the cash flows for its existing products and include the associated amounts in the valuation. Since only incremental net cash flows are relevant, the forecast is likely to differ from accounting profits that include depreciation, amortization and allocated overhead costs.

The economic life of the IP may be less than the legal life. According to a study by Mansfield, Schwartz and Wagner, competitors had copied 60 per cent of the innovations in their study after only four years.[28] Alternatively, even after a patent expires, a company may continue to enjoy benefits that initially resulted from the patent, such as established consumer preferences for the patent holder's brand name product. In this case,

the company may have transferred some of the value of the patent to the brand's trademark.[29]

The second step in the DCF method is to determine the appropriate opportunity cost of capital. The cost of capital should reflect both the time value of money and the risks involved in using the IP. The time value of money compensates for the fact that a dollar today is worth more than a dollar tomorrow, since the company can invest the dollar and start earning interest immediately. The level of risk involved with specific IP depends on the volatility of the expected cash flows. For example, government bonds have a relatively low discount rate since they are virtually risk-free. Riskier investments including many early-stage technologies require a higher interest rate for discounting the future cash flows since such investments pose greater risks and must offer a higher return to attract investors.

The sum of the forecasted cash flows discounted to today is the NPV. The decision rule for the DCF method is to invest only in those projects with a positive NPV. Only these projects contribute to shareholder wealth.

We illustrate the application of the DCF method through a stylized example. Suppose Consumer Inc. is considering licensing the IP for the detergent product Cleanall. The product embodying the IP has already undergone substantial development. However, these costs are irrelevant to Consumer Inc.; the company is only concerned with the cash flows that marketing and selling the product are likely to generate once the IP is licensed. To determine whether to enter into a license agreement, Consumer Inc. staff prepared a forecast of the expected net sales revenue, costs of goods sold (COGS) including royalties to the licensor, and marketing expenses. The relevant tax rate for this investment is 35 per cent, and the appropriate real discount rate is 7 per cent. Incorporating these data into a DCF analysis, the NPV of licensing the IP embodied in the product Cleanall equals $68.1 million (see Table 5.1). Based on the positive NPV, Consumer Inc. should enter into the license agreement for Cleanall.

B. Real Option Method

The real option method captures the same type of information as the DCF method since the underlying asset is expressed as the NPV of the expected net cash flows. However, the real option method may be more appropriate for valuing certain early-stage technologies since it recognizes that risks can create opportunities as well as pitfalls. In addition, the real option method captures management responses to new information.

There are often many technical and market uncertainties associated with early-stage technologies, and the realized cash flows may differ substantially from the expected values.[30] As management collects new information

Table 5.1 Total NPV of net income earned by Consumer Inc. from worldwide sales of Cleanall based on the DCF method

Year	Net sales	COGS	Production margin	Marketing	Net income before taxes	Net income	Discount factor to 2004	NPV of net income
	($ Millions)							($ Millions)
	(1)	(2)	(1)–(2) (3)	(4)	(3)–(4) (5)	(5)×0.65 (6)	@7% (7)	(6)×(7) (8)
2004	–	–	–	–	–	–	1.0000	–
2005	–	–	–	7.0	(7.0)	(4.6)	0.9346	(4.3)
2006	28.6	14.3	14.3	24.0	(9.7)	(6.3)	0.8734	(5.5)
2007	51.3	25.7	25.6	15.4	10.2	6.6	0.8163	5.4
2008	79.3	39.7	39.6	23.8	15.8	10.3	0.7629	7.8
2009	107.9	54.0	53.9	32.4	21.5	14.0	0.7130	10.0
2010	137.8	68.9	68.9	41.3	27.6	17.9	0.6663	12.0
2011	180.1	90.1	90.0	54.0	36.0	23.4	0.6227	14.6
2012	186.9	93.5	93.4	56.1	37.3	24.2	0.5820	14.1
2013	198.0	99.0	99.0	59.4	39.6	25.7	0.5439	14.0
Total in $ 2004								$ 68.1

Notes:
( ) negative
– not applicable

about the IP that helps resolve technical and market uncertainties, it may be able to alter the initial plan for the project to capitalize on favorable opportunities or mitigate losses. Making decisions based on successive valuations using the real option method requires management discipline. For example, mitigating losses is not always easy. If new information regarding a technology results in a negative real option value, managers must take a dispassionate view and discontinue the project even if it is one they initially supported.[31]

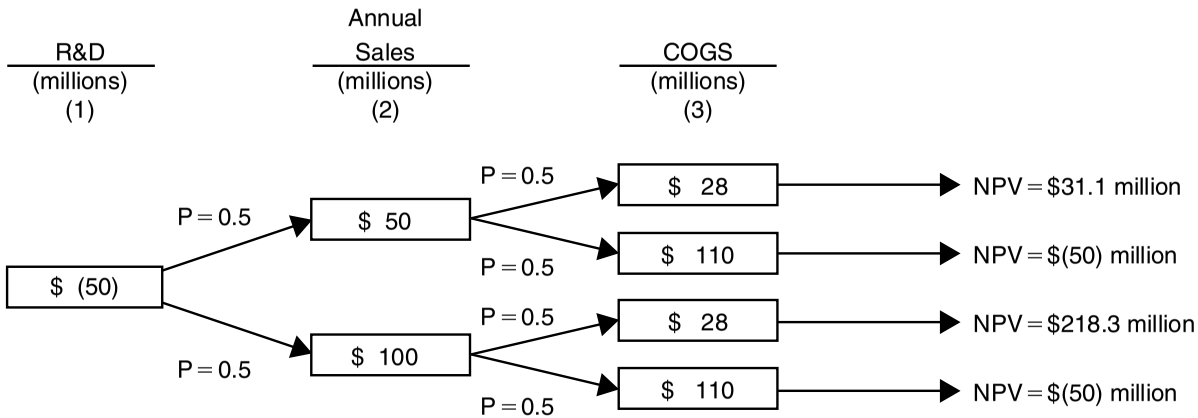
Using the real option method to value the IP in early-stage technologies provides a framework to model and quantify the value created by managing the project. This managerial flexibility is similar to the flexibility realized by participants in financial option markets. We discuss two ways to apply the real option method below.

1. Decision tree

One way to apply the real option method is to use a decision tree.[32] Decision trees are useful for analyzing the optimal decisions of a company considering an investment with multiple sources of uncertainty. Decision trees require information on the cash flows, probabilities and risks associated with each possible outcome of the project.

To illustrate how to apply a decision tree to the real option method, suppose ICU Corp. is considering a project to develop the IP for improving plasma television screen technology. The one-year R&D project will cost $50 million. The output of the project will be the IP and information on the incremental costs of production. The resulting technology, if used, will yield a stream of incremental revenues and costs over the nine-year expected life of the technology. The product refinement embodying the IP will have a positive but uncertain effect on future product revenues. Assume there are only two possible outcomes for incremental annual net sales with equal probabilities: a high result of $100 million and a low result of $50 million per year.[33] The expected annual net sales stream is $75 million.[34] The incremental COGS is uncertain but the company will know this cost at the end of the R&D phase. Assume the possible incremental COGS outcomes are high and low values of $110 million and $28 million per year, respectively, with equal probabilities. Finally, assume annual marketing costs after launch of the product will be $5 million, and the appropriate discount rate for applying the IP to this technology is 10 per cent.

Figure 5.1 contains the decision tree for ICU Corp.'s investment decision. If the R&D reveals that COGS will be $110 million, the company can abandon the project and incur only the $50 million in R&D costs. If the COGS will be $28 million, the project will be profitable and should be pursued. For this project, the real option method provides a value of $37.4



NPV of project = $0.25 \times \$31.1$ million
$+ \ 0.25 \times \$(50)$ million
$+ \ 0.25 \times \$218.3$ million
$+ \ 0.25 \times \$(50)$ million

Total = $37.4 million

Notes:
( ) negative
P probability
Detailed NPV calculations are available from the authors on request.

Figure 5.1 Total NPV of net income earned by ICU Corp. from plasma screen technology based on the real option method (decision tree)

million.[35] This positive value indicates that ICU Corp. should pursue the project. Active management of this project increases the value since the company can avoid adding to losses while retaining the potential for gains.

2. Black-Scholes

In the above example, we valued the real option using a decision tree. In some cases, other option valuation methods may be more suitable when the number of likely outcomes is large or if detailed data on the revenues, costs and probabilities associated with different outcomes are not available. Fisher Black and Myron Scholes developed a model for pricing options.[36] According to their model, the price of a financial call option on a stock depends on five factors:

- price of the underlying stock,
- exercise price of the option,
- standard deviation of the returns on the stock,
- current risk-free interest rate, and
- the option's expiry date.

These factors affect the likelihood and the potential magnitude by which the value of the stock will exceed the option's exercise price by a given date. The Black-Scholes model calculates a call option's value based on the likelihood that the underlying stock's value will exceed the exercise price before the option expires. Although the formula for calculating the value of the call option appears complex, we can easily input it into a spreadsheet.[37] We can apply this model to value IP assets using the real option method.

Valuing the IP embodied in an R&D project using the real option method does not involve stock prices. However, the analogs to the traditional inputs for the Black-Scholes model are as shown in Table 5.2.

To value IP using the Black-Scholes model, we must estimate the future cash flows expected from the project including the research costs required to bring the project to commercial launch, and evaluate the risk profile of the expected returns in terms of the appropriate cost of capital and the standard deviation.

For example, early-stage pharmaceutical R&D projects face both technical and market uncertainties. The technical uncertainty stems from concerns about the safety and effectiveness of a given compound. The market uncertainty arises from unknown future market conditions such as competitors' actions, insurance coverage for pharmaceuticals, regulation, and pricing flexibility. The real option method is appropriate in this case since it recognizes both kinds of uncertainty and the possibility of a flexible

Table 5.2 Inputs for valuing call and real options using Black-Scholes

Inputs for valuing a call option	Inputs for valuing IP as a real option
Price of the underlying stock	PV of the expected cash flows from the product embodying the IP after launch
Exercise price of the option	Costs required to commercialize the product, capitalized using an appropriate cost of capital
Standard deviation of the returns on the stock	Standard deviation of the project's expected returns
Current risk-free interest rate	Current risk-free interest rate
Option's expiry date	Expected time to product launch

management response. If an initial investment in pharmaceutical R&D yields successful results, the company may make additional investments in R&D. If the drug is safe in animal testing, the company may then make investments in safety and efficacy testing in humans. Thus, pharmaceutical R&D projects involve a sequence of options. Each option depends on the outcomes of prior R&D investments and on multiple sources of uncertainty.

To illustrate the application of the Black-Scholes option value model to real options, suppose the pharmaceutical company MegaPharm has a product covered by a patent in the early stages of development. It will cost MegaPharm $14 million to fund R&D in the next year. The company estimates that the product at its current profile for effectiveness will realize peak sales of $1 billion and 10 years remain before expected commercial launch of the product. In total, MegaPharm expects to spend $446 million on R&D.[38] The risk-free interest rate equals 5 per cent and MegaPharm uses a real discount rate of 10 per cent.[39] Finally, based on the volatility of the cash flows from its previous R&D efforts, MegaPharm estimates a standard deviation the cash flows for this product of 50 per cent.

To apply the Black-Scholes formula, we expressed the pre-launch cash flows in 2014 dollars and the after-launch cash flows in 2004 dollars (see Table 5.3) Based on our calculations, the inputs are:

- PV of the expected cash flows after launch = $127.7 million;
- capitalized costs required to commercialize the product = $353.0 million;
- standard deviation of the project's expected returns = 50 per cent;
- current risk-free interest rate = 5 per cent; and
- expected time to product launch = 10 years.

Table 5.3 Total NPV of net income earned by Megapharm from an early-stage pharmaceutical product based on the real option method (Black-Scholes)

	Risk free rate	Discount rate	Standard deviation	Years to launch					
	5.00%	10.00%	50.00%	10					
Line									
A. 2004 Cash flow	$(14.0)								
					Pre-launch costs ($ Millions)				
	2005	2006	2007	2008	2009	2010	2011	2012	2013
B. Cash flows	$(17.4)	$(24.1)	$(27.2)	$(28.8)	$(53.9)	$(45.6)	$(42.9)	$(45.6)	$(27.0)
C. Discount factor (10% rate)	2.3579	2.1436	1.9487	1.7716	1.6105	1.4641	1.3310	1.2100	1.1000
D. Cash flows in $2014 (B×C)	$(41.0)	$(51.7)	$(53.0)	$(51.0)	$(86.8)	$(66.8)	$(57.1)	$(55.2)	$(29.7)
E. Cost probabilities	100%	100%	100%	100%	100%	50%	35%	19%	19%
F. Value of probable costs (D×E)	$(41.0)	$(51.7)	$(53.0)	$(51.0)	$(86.8)	$(33.4)	$(20.0)	$(10.5)	$(5.6)
G. Expected costs (sum(F))	$(353.0)								

Table 5.3 (continued)

	Cash flows after launch ($ Millions)								
	2014	2015	2016	2017	2018	2019	2020	2021	2022
H. Cash flows	$(101.9)	$176.5	$324.0	$435.2	$481.8	$376.0	$345.8	$277.3	$220.5
I. Discount factor (10% rate)	0.3855	0.3505	0.3186	0.2897	0.2633	0.2394	0.2176	0.1978	0.1799
J. Cash flows in $2004 (H×I)	$(39.3)	$61.9	$103.2	$126.1	$126.8	$90.0	$75.2	$54.8	$39.7
K. Net cash flows (sum(J))	$638.5								
L. Asset value (K×20% probability of launch)	$127.7								
M. Black-Scholes option price	$58.4								

	2004 costs ($ Millions)	Imbedded option ($ Millions)	Total ($ Millions) (1)+(2)
	(1)	(2)	(3)
Research value (A and M)	$(14.0)	$58.4	$44.4

Note: ( ) negative

Using these data in the Black-Scholes model, the value of the option to invest in the project equals $58.4 million. Thus, for an investment of $14 million today, MegaPharm can realize a value of $58.4 million, for a net value of $44.4 million. Based on this valuation, MegaPharm should continue to invest in the pharmaceutical R&D project.

C. Comparing the DCF and Real Option Methods

The DCF method is useful for valuing IP such as late-stage technologies in the Cleanall example discussed above. It assumes that a project continues autonomously until completion and does not allow for management responses to new information. This assumption may not be appropriate in our examples for plasma television screen and early-stage pharmaceutical technologies. The DCF and real option methods use different frameworks for incorporating risks and management flexibility.

There are often many technical and market uncertainties associated with early-stage technologies, and the realized cash flows may differ substantially from the expected values. As management collects new information about use of the IP that helps resolve technical and market uncertainties, it may be able to alter the initial plan for the project to capitalize on favorable opportunities or to mitigate losses. Due to its treatment of risks and management flexibility for early-stage projects, the real option method often produces a different estimate of asset value than the DCF method.

To illustrate the difference between the DCF and real option methods, we calculated the value of the ICU Corp. R&D project for plasma television screen technology. The traditional DCF analysis would value the project at –$28.8 million (see Table 5.4). This negative value indicates that ICU Corp. should not pursue the R&D project. These results are contrary to our result from applying the real option method where, based on the real option value of $37.4 million, we concluded that ICU Corp. should pursue the R&D project. The difference between these two results is the fact that the ICU Corp. can choose whether to proceed to production after realizing the outcome from the R&D. This option has a value (measured by avoided losses) that the real option method captures but the DCF method ignores. The corresponding DCF calculation assumes that ICU Corp. will do the research and proceed to production regardless of the outcome of the R&D. This calculation ignores management's option to abandon the project if the research outcome is unfavorable. The real option method lets us value the IP while allowing that management may abandon the project if the outcome of the R&D is unfavorable.

Table 5.4 Total NPV of net income earned by ICU Corp. from plasma screen technology based on the DCF method

Year	Net sales	COGS	Production margin	Marketing	R&D	Net income before taxes	Net income	Discount factor to 2004	NPV of net income
	($ Millions)								($ Millions)
	(1)	(2)	(1)–(2) (3)	(4)	(5)	(3)–(4)–(5) (6)	(6)×0.65 (7)	@10% (8)	(7)×(8) (9)
2004	–	–	–	–	50.0	(50.0)	(32.5)	1.0000	(32.5)
2005	75.0	69.0	6.0	5.0	–	1.0	0.7	0.9091	0.6
2006	75.0	69.0	6.0	5.0	–	1.0	0.7	0.8264	0.5
2007	75.0	69.0	6.0	5.0	–	1.0	0.7	0.7513	0.5
2008	75.0	69.0	6.0	5.0	–	1.0	0.7	0.6830	0.4
2009	75.0	69.0	6.0	5.0	–	1.0	0.7	0.6209	0.4
2010	75.0	69.0	6.0	5.0	–	1.0	0.7	0.5645	0.4
2011	75.0	69.0	6.0	5.0	–	1.0	0.7	0.5132	0.3
2012	75.0	69.0	6.0	5.0	–	1.0	0.7	0.4665	0.3
2013	75.0	69.0	6.0	5.0	–	1.0	0.7	0.4241	0.3
Total in $2004									$(28.8)

Note:
( ) negative
– not applicable

V. CONCLUSION

Companies assign values to their ideas every day in multiple forums. Understanding the value of ideas is particularly important to those companies that depend on their IP to discover, develop and market new products. These companies must appropriately value their IP assets to make informed business decisions and comply with legal or regulatory requirements. Companies that fail to consider the value of their IP are more likely to pursue ideas that are not useful and fail to exploit valuable technologies. The underlying principle for valuing IP is that market forces determine the value. IP is only valuable if it contributes to a product or service that consumers prefer to those already available.

Choosing among the cost, market and income approaches to value a particular IP asset often depends on the forum in which the valuation is used. Among the commonly applied approaches for valuing IP, the income approach is accepted across forums. Under the income approach, both the DCF and real option methods are consistent with economic principles and are useful in determining the value of IP. The choice between these two income-based methods depends on the facts and circumstances surrounding the valuation of the IP at issue. The DCF method is often appropriate for valuing IP when the company expects management of the project to proceed as planned. The real option method is often more appropriate when using the IP may require management flexibility in responding to new information. Regardless of the forum or method chosen, companies should prepare valuations across forums that are internally consistent so that they can withstand scrutiny if reviewed within another forum.

NOTES

1. *Windhover's Pharmaceutical Strategic Alliances*, Vol. XV, July 2003–June 2004.
2. Interview with Emmett J. Murtha, from an article appearing in *Licensing Economics Review*, October 2001, http://www.frlicense.com/ARTICLE_10_02.html, extracted 1 November, 2004.
3. See, for example, Richard A. Brealey and Stewart C. Myers, *Principles of Corporate Finance*, Fifth Edition, New York: McGraw-Hill, Inc., 1996 (hereafter 'Brealey and Myers').
4. See, for example, Gordon V. Smith and Russell L. Parr, *Valuation of Intellectual Property and Intangible Assets*, Second Edition, New York: John Wiley & Sons, Inc., 1994, pp. 152–60. Other valuation methods such as the avoided royalty method combine elements of these three fundamental approaches. We do not discuss these other methods.
5. We must also identify any material differences between the transactions and make any necessary adjustments using an appropriate methodology.

6. Under current accounting standards, the company may also be required to report the value of certain acquired IP.
7. Pharmaceutical companies that discover, develop, make and sell brand name pharmaceutical products may file patent infringement lawsuits against rivals attempting to sell generic versions of their products before expiration of the patent on the brand name product. Such cases, and in some instances settlements of these cases, have received scrutiny from courts and antitrust authorities. See US Federal Trade Commission, 'Generic drug entry prior to patent expiration: an FTC study', July 2002; and David A. Balto and Michael Gallagher, 'Recent developments in patent settlement litigation', *Antitrust Report*, Fall 2003, pp. 39–72.
8. For example, between 1993 and 2002, IBM generated approximately $10 billion in royalties from its IP portfolio. See IBM press release, 'IBM Tops US Patent List for Tenth Consecutive Year', 13 January, 2003, http://www.ibm.com/news/us/2003/01/121.html, extracted 27 September, 2004.
9. Based on the PricewaterhouseCoopers/Thomson Venture Economics/National Venture Capital Association, MoneyTree™ Report, Investments by Industry 2004 to 2005, http://www.pwcmoneytree.com/moneytree/index.jsp, extracted 16 March, 2006.
10. MoneyTree™ Report, p. 2.
11. SFAS No. 141, 'Business combinations', Financial Accounting Standards Board of the Financial Accounting Foundation, June 2001, p. 28.
12. SFAS No. 142, 'Goodwill and other intangible assets', Financial Accounting Standards Board of the Financial Accounting Foundation, June 2001, p. 9.
13. SFAS No. 141 recognizes that even if market prices are available, they may not be representative of the fair value. See SFAS No. 141, 'Business combinations', Financial Accounting Standards Board of the Financial Accounting Foundation, June 2001, pp. 8–9.
14. SFAS No. 142, 'Goodwill and other intangible assets', Financial Accounting Standards Board of the Financial Accounting Foundation, June 2001, pp. 8–9.
15. *Internal Revenue Service Final Section 482 Regulations (TD 8552) for Intercompany Transfer Pricing*, issued 1 July, 1994 (Section 482 regulations), 1.482-4(a) and 1.482–6(c)(1).
16. See Richard P. Rozek, 'Applying the best method rule when reliable internal comparable intangibles exist', *Tax Notes International*, Vol. 12, No. 15, 8 April, 1996, pp. 1191–204; and Richard P. Rozek and George G. Korenko, 'Transfer prices for the intangible property embodied in products with extraordinary profit potentials', *Tax Notes International*, Vol. 19, No. 16, 18 October, 1999, pp. 1553–65. The CPM and RPSM are not as useful for valuing IP since they rely on the profitability of third-party companies. In comparison, the CUT and CPSM often rely on the specific terms of agreement with third parties and the profitability of specific IP.
17. Section 482 regulations, 1.482-4(c)(2)(iii)(B)(1).
18. See, for example, *Final §482 Regulations on Cost Sharing Agreements (TD 8632)*, issued 20 December, 1995.
19. US Internal Revenue Service, 'FSA on selecting a pricing method for cost sharing agreement buy-ins [FSA 200023014, released 6/9/00]', *Transfer Pricing Report*, Vol. 9, No. 4, 14 June, 2000, p. 111.
20. See the Internal Revenue Code, Section 170.
21. See the Internal Revenue Code, Section 170.
22. See *Smith v. Commissioner*, 41 T.C.M. 1427.
23. *Georgia-Pacific v. U.S. Plywood-Champion Papers Inc*., 446 F.2d.
24. *Georgia-Pacific v. U.S. Plywood-Champion Papers Inc*., 446 F.2d 295, 296–97. Factors to consider are: royalty rates from the patent itself, royalty rates from comparable IP, nature and scope of the license, licensing and marketing policies, commercial relationship between licensor and licensee, profitability of derivative or convoyed sales, duration of patent and term of license, commercial success and profitability, utility

and advantage over old technologies, nature of invention and benefits to users, value of use by infringer, customary profit split, share of profits attributable to the invention, opinion of experts, and outcome of hypothetical negotiation.

25. Testing the sensitivity of a valuation to changes in the underlying assumptions may also be useful.
26. Consider, for example, a riskless investment opportunity (for example, government bond) that would pay $100 in one year. If the investor earns 5 per cent, the investment option would be worth $95.24. The value of $100 payable in one year is worth $95.24 today or the investor would pay $95.24 now for this opportunity.
27. The net cash flows equal the difference between amounts received and amounts paid out.
28. Edwin Mansfield, Mark Schwartz and Samuel Wagner, 'Imitation costs and patents: an empirical study', *Economic Journal*, Vol. 91, No. 364, December 1981, pp. 907–18.
29. In our examples for this chapter, we assume the end of the patent's legal life marks the end of the economic life; that is, the patented technologies have no ongoing or terminal value.
30. Technical uncertainty refers to uncertainty surrounding the company's ability to produce a viable commercial product. Market uncertainty refers to the uncertainty about the success of the product in the market in light of consumer preferences, competitors' actions, and other demand and supply factors.
31. It may be difficult for managers to take a dispassionate view for some technologies. For example, Ronald Newbold, Senior Director-Strategic Research Initiations at Merck, recently compared drug candidates developed through licensing to initially discovered compounds. He said that '[w]e have so much emotionally invested and financially invested in those [internal] programs that we may tend to love the science too long.' See 'Merck sees slightly more success with external Rx than internal candidates', *The Pink Sheet*, 11 October, 2004, p. 12.
32. For a discussion of the decision tree approach, see Peter McNamee and John Celona, *Decision Analysis for the Professional*, Third Edition, Menlo Park, CA: SmartOrg, Inc., 2001.
33. That is, there is a 0.5 probability of the high outcome and 0.5 probability of the low outcome.
34. The expected revenue is calculated as follows: $(0.5)\times(\$100)+(0.5)\times(\$50)=\$75$.
35. Note than under the cost approach, the value of the IP after the R&D is completed equals $50 million regardless of the outcome. These $50 million in R&D expenses are now sunk costs. Recalculating the value of the project after the R&D is completed, the value of the IP in 2004 dollars equals either $0, $63.3 million, or $250.8 million depending on the realization of the incremental revenues and COGS.
36. Fischer Black and Myron S. Scholes, 'The pricing of options and corporate liabilities', *Journal of Political Economy*, Vol. 81, No. 3, May–June 1973, pp. 637–54.
37. The formula is Value $= [N(d_1)\times P]-[N(d_2)\times PV(EX)]$, where $d_1 = \frac{\log[P \div PV(EX)]}{\sigma\sqrt{t}} + \frac{\sigma\sqrt{t}}{2}$, $d_2 = d_1 - \sigma\sqrt{t}$, $N(d)$ represents the cumulative normal probability density function, EX represents the exercise price of the option, t is the number of periods to the exercise date, P is the current price of the stock, and σ is the standard deviation per period of the rate of return on the stock. See Brealey and Myers, pp. 577–8.
38. We distributed the total R&D spending over the product life cycle based on a proprietary NERA model of the profile for a typical pharmaceutical product. The cost estimate is derived from Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, 'The price of innovation: new estimates of drug development costs', *Journal of Health Economics*, Vol. 22, No. 2, March 2003, pp. 151–85. The $403 million estimate in the source converted to 2003 dollars equals $446 million.

39. This is consistent with studies of the real cost of capital in the pharmaceutical industry. See Stewart C. Myers and Lakshmi Shyam-Sunder, 'Cost of capital estimates for investment in pharmaceutical research and development', paper prepared for the Office of Technology Assessment, Congress of the United States, January 1991.

6. Intellectual property policies and scale neutrality: strategic management implications for SMEs

Grant E. Isaac

I. INTRODUCTION

As the title of this volume suggests, there are many debates associated with intellectual property policies which can be assessed from legal, economic and political economy perspectives. Often, the unit of analysis for these debates is the nation-state level where the questions posed deal with issues such as the welfare gains and losses resulting from intellectual property policies as well as the governance of intellectual property regimes. Yet, given the fact that intellectual property policies are – to a large part – designed to encourage innovation among private organizations, adopting an organization-level unit of analysis is crucial. Doing so deepens the assessment of intellectual property policies by explicitly linking the legal, economic and political economy perspectives with the strategic management perspective.

An important intellectual property policy debate at the level of the organization has to do with the *scale neutrality* of various intellectual property policy instruments such as patents. In a general sense, policy instruments that are scale neutral create symmetric strategic incentives for firms regardless of firm size (measured in terms of revenues and/or employees). Policy instruments that are not scale neutral create asymmetric strategic incentives for firms based on their size (Weidenbaum, 2004; Persson and Tabellini, 2000; Bernheim and Bagwell, 1988).

Consider first scale-neutral policy instruments such as constituent policy instruments that are designed to level the playing field for all actors regardless of scale. Firm-level environmental regulations are often cited as an example of constituent policy instruments where polluters – regardless of size – must reduce their ecological impact (Killinger, 2000).[1] From a strategic management perspective, scale-neutral environmental policy instruments that aim to internalize the costs of pollution for a product along its

entire life cycle create symmetric strategic incentives for firms to minimize costs by minimizing pollution (Field and Olewiler, 1995).

Consider next policy instruments that are not scale neutral. For example, some policies may target a redistributive policy goal such as progressive tax rates where those with more income and/or wealth pay a larger proportion of tax which is then redistributed to provide goods and services to those with less income and/or wealth (Palda, 2001; Laramie and Mair, 2000; Roberts, 1977; Romer, 1975; Buchanan, 1969). Another example would be industrial policies which provide public services to firms (ranging from information and advice to subsidies and grants) on a differential basis depending upon their size. From a strategic management perspective, the lack of scale neutrality creates asymmetric strategic incentives for firms. For example, firms with more income and/or wealth may reinvest their financial resources in order to limit their tax obligation in the short-term even if this reinvestment is not properly aligned with long-term strategic goals. Also, small firms reliant upon public services may ignore strategic growth opportunities if they would result in employment levels beyond the definition of a small organization. Therefore, from the strategic management perspective, the lack of scale neutrality in policy instruments differentiates firm incentives, which may have the effect of helping or hindering the achievement of the policy objective.

The neutrality of policy instruments is an important topic in the state–market interface where broad social goals are targeted and specific policy instruments are developed to direct the market outcomes toward the fulfilment of these goals. For example, consider the currently popular policy goal of encouraging knowledge-based growth (KBG) in all developed and many developing countries.[2] The broad social goal is to achieve and maintain economic growth by investing in those activities which have a relatively high economic return (advanced technology goods such as pharmaceuticals, information technologies and biotechnology) as opposed to those activities with a relatively low economic return (resource extraction and commodity trade). In economic terms, the former have been known as capital intensive industries because relatively high levels of capital investment are required to cover capital equipment needs. The use of the term knowledge-based firms (or industries) explicitly recognizes that such activities also require high levels of human capital in order to ensure a sustained flow of knowledge that adds to the stock of innovations that can be brought from the *(research) bench to the (executive) boardroom*. As a result, policies that encourage innovation are an important element of a national KBG strategy. Clearly, a careful analysis of the neutrality of various innovation policy instruments is crucial.

Innovation policy instruments include intellectual property rights – such as patents – which have been developed to encourage innovation in all firms

and, hence, produce KBG. An underlying assumption is that they are scale neutral. That is, there is not one type of patent for small firms and another type for large firms. Instead, patents are patents regardless of whether the innovator is a backyard hobbyist, a public research scientist or a research director in a large multinational corporation. Yet, is this assumption correct? *Are intellectual property rights scale neutral*? That is, does the size of the organization – in terms of financial resources – impact the efficacy of various property instruments in encouraging innovation? To answer this research question, a case study methodology is employed focusing on patents and their efficacy across small and large firms.

This chapter is organized as follows. In the next section, the economics of intellectual property will be explored in order to characterize patents as a policy instrument. In section III, patents will be assessed with respect to their scale neutrality and strategic management implications will be identified.

II. THE ECONOMICS OF INTELLECTUAL PROPERTY: POLICY IMPLICATIONS

The objectives of this section are, first, to identify the economic intuition behind the popular notion of Knowledge-Based Growth in order to explain the policy focus on intellectual assets, and second, to provide a comparative assessment of two intellectual property policies aimed at increasing the stock of intellectual assets – an innovation subsidy and patents.

The concept of Knowledge-Based Growth (KBG) has become a popular target of economic policy makers because it promises great economic reward while solving difficult policy issues. Economics has been described as the dismal science of allocating the scarce and finite factors of production (land, labour and capital) to supply infinite demands. At the national level, the endowment of these factors of production generates the production possibilities frontier which illustrates the range of goods and services that can be supplied at full production. While economic policy makers want to be at the frontier (meaning that the economy is operating at full employment), being at the frontier also means that decisions are made under a zero-sum policy game. That is, a policy goal of allocating more resources to one type of production would require fewer resources allocated to another type of production; someone must lose for another to gain. This is, of course, not a comfortable position for policy makers to be in.

Knowledge or ideas offer policy makers the promise of breaking free of the zero-sum policy game. As the infinite, inexhaustible fourth factor of production, knowledge can be used to gain greater efficiency in the

allocation of land, labour and capital. Allocating knowledge to one type of production no longer comes at the expense of another type of production (because it is infinite and inexhaustible). Investment in knowledge can lead to endogenous growth resulting in outward shifts of a nation's production possibilities frontier without utilizing more land, labour and capital, and for policy makers a positive-sum policy game is created (Aghion and Howitt, 1999; Barro and Sala-i-Martin, 1995, Grossman and Helpman, 1991; Romer, 1990). Hence, KBG has become a dominant objective for economic policy makers.

Investing in knowledge does, however, have its own challenges. Ideas often have a high fixed cost of production but a very low marginal cost of production (Jones, 2001). Consider the pharmaceutical industry. New drug discovery and development takes significant time and financial resources to achieve. Yet, once achieved, that development can be delivered to others in a virtually costless medium, a pill. Further, once created, ideas can be shared such that the recipient does not have to bear the costs borne by the original innovator. From the point of view of an economic policy maker, this is a very nice feature. Investments in knowledge only have to occur once and then can be diffused to benefit many at a very low marginal cost. As the knowledge is absorbed broadly, outward shifts of the production possibilities frontier become possible.

Yet for the innovator, the easy imitation of ideas creates an incentive problem. The high fixed cost of production and the low marginal cost of production actually create a disincentive to innovate. An innovator accepts the risks of innovation, produces an idea only to find that another – the imitator – who has not paid the fixed costs can adopt the idea. That is, while the innovator must price the idea high enough to cover the fixed costs of production, the imitator does not, and can actually drive the innovator out of the market that the innovator created in the first place. This is the so-called free-rider problem and if it exists, why would anyone innovate?

In economic terms, the problem is that ideas tend to be non-rivalrous with low excludability such that policy instruments must aim to deal with this (Jones, 2001). Rival goods/services can only be consumed by one person at one time while for non-rival goods/services, consumption by one person does not preclude consumption by another. Examples of the former include legal services or a computer terminal while examples of the latter include satellite signals and national defence. Knowledge is non-rival because more than one person can use the knowledge – say a managerial strategy such as just-in-time production – at the same time in different places. Excludability refers to the ability to make individuals pay for the use of the good/service. Goods/services with high excludability include legal services, toll roads, and stadium athletic events while those with low excludability include public

goods such as public roads and global common goods such as biodiversity. Knowledge has low excludability because once your idea is out there (for instance, released on the internet) then it is difficult or impossible to make others pay for the use of that idea. Clearly, policy instruments that encourage innovation must be capable of transforming intrinsically non-rival goods/services with low excludability into goods/services that are rival with high excludability. If not, why would anyone innovate?

Therefore, from a policy perspective, while KBG promises significant economic returns, there are challenges with respect to the incentives to innovate. The policy goal then is to strike a delicate balance: *to encourage innovators while simultaneously sharing the knowledge so that it diffuses widely*. Two broad policy instruments – an innovation subsidy and patents – can be comparatively assessed in order to illustrate the policy challenges.

An Innovation Subsidy Policy

To overcome the disincentive to innovate, policy makers could simple subsidize the costs of innovation. As a result, innovators would be on the same cost schedules as imitators. Two strengths of this policy may be identified. First, it directly targets the social goal of greater knowledge creation (although mandatory rules for knowledge sharing would have to be imposed). Second, with the fixed costs of production subsidized, consumers would face only marginal cost pricing in the marketplace rather than average cost/monopoly pricing. That is, for instance, new drugs would only be priced at the cost of the pill. There are, however, several weaknesses. First, if such a subsidy were offered then all firms would immediately become innovators to capture some of the public monies. Second, there is a non-linear relationship between basic research and development and successful goods/services. Either all research and development would be subsidized or policy makers could choose those projects that they believe are likely to succeed. The former creates a deadweight social loss equivalent to the amount of public money spent on those projects that failed (which could have been spent on other public goods) while the latter puts policy makers in the position of having to pick winners; an activity that does not have a terrific track record in most developed countries.

Patent Policy

Patents are state sponsored monopoly rights granted to innovators that aim to maximize incentives to innovate while also maximizing the dissemination of information. If an innovator can meet certain legal requirements – such as novelty and utility – then the patent is supposed to ensure that no

one else can simply duplicate their idea and benefit commercially. To acquire this protection the innovator must disseminate the knowledge by disclosing enough information about the idea for someone skilled in the relevant art to enable it (that is, to read the patent application and be able to reproduce the claimed results). Three strengths may be identified. First, innovators bear the financial risk of innovation. They must raise the capital and manage the research and development process. Second, success is determined by the marketplace. Monopoly profits through average cost pricing will only be achieved if there is sufficient demand in the marketplace. That is, policy makers have not had to pick winners. Third, the monopoly power expires over time such that competitive forces enter the market after a prescribed period of time. Weaknesses include the fact that the private sector increasingly controls the research agenda under this system and that consumers face monopoly prices during the tenure of the protection (although one might argue that with the subsidy they pay the monopoly prices through their taxes; at least with patents they pay for items they choose to purchase and not those picked by policy makers).

Discussion

It is not hard to imagine which policy is supported by developed countries pursuing a KBG agenda. While both policies add to the stock of knowledge, patents shift both the focus of research from basic to applied[3] and the financial risk of knowledge creation from the public sector to the private sector. And all the private sector asks for in return is monopoly rights that expire after a fixed amount of time. Thus, patents have become the dominant intellectual property policy instrument in knowledge-based industries. Moreover, they are assumed to be scale neutral such that organizations of any size can acquire them and, as a result, there is no need for an analysis of strategic options for firms. Yet, does this assumption hold? If patents are the dominant policy instrument for achieving a KBG agenda, then examining their neutrality is crucial. This is the objective of the next section.

III. STRATEGIC MANAGEMENT OF INTELLECTUAL PROPERTY

The following hypothesis is explored in this section:

> If patents are scale neutral, then a comparative assessment of the strategic options faced by large and small innovative organizations will reveal no differences.

Methodology

To aid in the comparative assessment that follows, consider the stylized product life-cycle curve for knowledge-based goods illustrated in Figure 6.1.[4] This diagram assumes that only a single innovation with a single use is being researched and developed.[5] For this innovation, there is a product development phase which intuitively is the phase in which the technical feasibility of the innovation is established. Of course, there is no guarantee that the rapid burn of cash will in fact ever turn the corner. An investment in this phase is essentially a bet that the scientific team can accomplish what they have said they could accomplish. Once the technical feasibility is established, then the innovation moves into the product marketing phase which intuitively is the phase where the commercial feasibility is established. While this diagram assumes a single project only, it nevertheless effectively captures the range of strategic options facing organizations involved in the research, development and commercialization of knowledge-based products. For example, it illustrates that significant financial investments must occur up front as the technical feasibility of a project is explored while the returns on the investment, if any, do not come immediately. Additionally, it also illustrates the prize of intellectual property rights; the magnitude of monopoly profits that can be earned in the commercialization stage.

From the hypothesis above, organizational size refers to the financial resources available to fund the research, development and commercialization of innovation along the Technology product life-cycle curve (Figure 6.1). It is assumed that large organizations have endogenous resources (Teece, 1986). That is, they have the internal financial resources to fully support their research and development portfolios. Small organizations require exogenous resources. That is, they do not have the internal financial resources and must rely upon external investors to fund their research, development and commercialization project(s). While simple, this assumption creates important differential implications for the strategic management of intellectual property by small organizations as opposed to large organizations as will be explored below.

Also referring to the research hypothesis, innovative firms can be defined in many ways. An illustrative, but non-exhaustive list includes definitions such as a required proportion of total expenses spent on basic and applied research, or revenues from the sales of new products, or as the contribution of skilled labour in the production of a good/service according to activity-based costing. Intuitively, all of these definitions share the notion that value comes from an investment in knowledge. Therefore, it is simply assumed that an innovative firm is one actively investing in ideas and seeking to

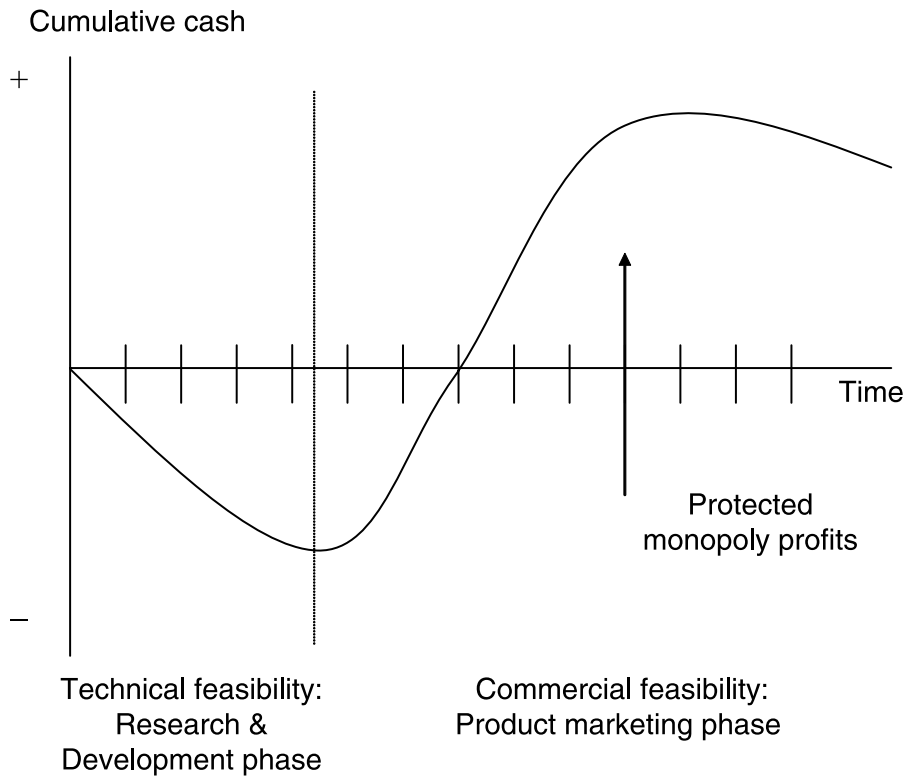


Figure 6.1 Stylized technology product life-cycle curve

protect the potential economic return from those ideas through intellectual property rights.

Analysis

The task now is to examine several strategic options facing large and small innovative firms when protecting their intellectual property in order to ascertain the neutrality of patents as an intellectual property policy instrument (Rothschild, 1987). There is limited literature on the strategic management of intellectual property (Smith and Hansen, 2002; Colson, 2001; Lang, 2001; Pickering and Matthews, 2000; Fahey and Prusak, 1998; Zahra et al., 1995; Berkowitz, 1993). This is unfortunate because beyond simply assessing whether or not an idea meets the requirements of novelty, utility, and so on, firms also have other strategic options; four of which are identified and assessed below.

a. Drivers for patenting intellectual assets

Investments in knowledge during the product development phase are essentially investments in intellectual assets. Yet, unlike tangible assets like buildings and equipment, intellectual assets are intangible, and accounting for their value is the source of considerable debate. In other words, what is the proper value of an idea, especially a truly novel idea where significant market development would have to occur before a commercial opportunity is realized? (Merges, 1998; Teece, 1998; Lerner, 1995; Bhagat et al., 1994). [6] Within this environment, patents have become a proxy for valuing ideas (Hall et al., 2000; Kortum and Lerner, 1999; Trajtenberg, 1990a; 1990b). The logic is that if the scientific community considers an idea to be novel enough to grant it protection, then this connotes that the scientific team has some intangible technical value (Rivette and Kline, 2000, Lanjouw and Schankerman, 1999) which can be considered as part of the organization's asset base.

Large innovative organizations are not as beholden to the value of their intangible intellectual assets as their small counterparts are. The former typically have a considerable tangible asset base and a current revenue stream from products in the marketing phase that is reinvested into a portfolio of research and development projects. Experience and expertise add to the likelihood of choosing projects with a higher probability not only of technical feasibility but also of commercial feasibility. Therefore, these internal resources – both financial and non-financial – mean that large innovative firms can use patents to focus on more long-term strategic resource alignment and to protect those sources of perceived long-term competitive advantage. The strategic implication is that large innovative

organizations are more free to invest internal resources in more novel and less incremental knowledge-based products.[7]

In contrast, for small innovative organizations intellectual assets may well be all that they have. These assets are used to attract equity investors whose capital is used to fund research and development projects. The strategic management implication of this dependence is that patents are often sought as a proxy for technical experience and expertise and for the potential future flow of innovative products. Without the internal resources – both financial and non-financial – small innovative firms typically use patents to secure short-term investment funds. In other words, financial resources are often dedicated to research and development in areas where patents are more quickly and easily obtained, and this may not be congruent with areas more aligned with a long-term competitive advantage. The strategic implication is a bias towards less novel and more incremental innovations that do not require as many financial resources to investigate.[8]

In comparison, patents are not scale neutral with respect to the drivers for patenting intellectual assets. For small innovative organizations, the exogenous resources mean that patents serve as a proxy for technical potential and thus securing them in the short-term creates a strategic incentive to focus on quicker incremental innovations. With respect to Figure 6.1, this implies that small organizations may choose innovation trajectories which, while turning the corner more quickly to limit the cash requirements in the product development phase, may not have the same commercial potential in the product marketing phase. For large innovative organizations, the endogenous financial resources mean that patents serve their more appropriate function of securing commercial rights for an idea creating an incentive to innovate focused on longer-term, novel innovations.

b. Protecting intellectual assets: application

Getting the patent application right is crucial, but not easy. On one hand, an organization has an incentive to maximize the protection it can obtain in the product space because this represents the potential monopoly profits that can be realized (Merges and Nelson, 1990). On the other hand, if the claim is granted such that the organization either infringes a previous application or the patent cannot actually be enabled for all claimed protection, then an expensive legal challenge can ensue. Finding this *optimal* patent space is not an inexpensive proposition in knowledge-based areas such as biotechnology. Prior patents must be searched, the filing must be vetted for enablement and a prognostication on future applications and uses must be undertaken.

For large innovative organizations there are often financial resources and experienced and expert patent analysts and agents to undertake this work

in a manner consistent with the long-term strategy for competitive advantage. In contrast, small innovative organizations with limited financial resources are strategically motivated to minimize the amount of cash spent on these activities. In addition, they tend to lack the experience and expertize to identify the *optimal* patent space to apply for in the application. Yet, the lack of resources to undertake proper application due diligence leaves the organization vulnerable to legal challenge based on either infringement or non-enablement.

Again, in comparison, patents as an intellectual property policy instrument are not scale neutral. With respect to patent applications, large innovative organizations are much better positioned to identify *optimal* patents as an intellectual property policy instrument than are small organizations.

c. Protecting intellectual assets: timing

When potentially patentable ideas are identified, organizations face an important strategic decision to make with respect to the timing of a patent filing. Consider again Figure 6.1. On one hand, filing right away ensures that the cash spent on ascertaining technical feasibility is protected if the innovation turns the corner. However, it also limits the time that monopoly profits can be realized in the marketing phase. Inversely, filing when an innovative product is ready for the marketing phase maximizes the time that monopoly profits can be realized, but also leaves the organization vulnerable to the possibility that another innovator will patent essentially the same idea. Consider, for example, a new drug based on a new molecular entity that is patented immediately but for which another 12 years of research and development must occur before regulatory approval and product marketing occurs. This would leave only eight years for monopoly profits to be realized. Remember, this time must be sufficient to cover not just the research and development cost of this product but also the cost of those innovative ideas that were invested in, but did not meet the technical feasibility or commercial feasibility requirements.

This strategic patenting decision is not scale neutral; organizational size does matter. Recall that small innovative organizations need to protect and then promote their ideas in order to obtain the investment capital necessary to achieve technical feasibility let alone to begin the market development process. Strategically, this means that for a small organization timing is not really an endogenous strategic variable; they cannot be patient and instead must patent early to attract investors at the expense of perhaps a greater period of time realizing monopoly profits. Yet, for a large organization, internal resources mean that timing is an endogenous strategic resource creating an opportunity for these organizations to move farther along the product development phase before disclosing their idea through a patent

application. Provided that such an organization can maintain their idea as a trade secret during this time, then the opportunity exists to realize monopoly profits longer.

d. Protecting intellectual assets: enforcement

In the case of a potential patent infringement it is up to the patent holder to make a strategic decision to enforce or not to enforce (Lanjouw and Lerner, 1998). Indeed, there is much at stake because failure to enforce an infringement essentially dissolves the intangible value of the patent as an intellectual asset. This is a strategic decision because defending a patent requires significant cash to cover the legal expenses and to sustain the organization while the litigation occurs (Somaya, 2003).[9] Moreover, this decision is going to be made subject to variables such as the financial resources available to enforce and the financial resources available to the infringer. In other words, one proactive strategy is for organizations to create a credible threat of being able to enforce their patent(s) through a war chest.

Clearly, patent enforcement strategy is not scale neutral. For small innovative organizations the financial resources available are targeted toward innovation efforts in order to develop an idea to the stage where it can be patented and to ensure that the patent application is as close to optimal as possible so that an equity investor can be attracted. Typically, there is nothing left to put in a reserve war chest in the event that a patent is infringed. That is, many small organizations are quite vulnerable to predatory infringement because they simply lack the resources to make the challenge. Fortunately, there is only limited evidence that larger organizations will risk the bad publicity associated with such predation (Lanjouw and Lerner, 2001; Lerner, 1995). Large innovative organizations, on the other hand, have the willingness and ability to enforce their patent protection. Therefore, as an intellectual property policy instrument, patents are not scale neutral as strategic patent decisions can again be differentiated based on organizational size.

Discussion

Recall the research hypothesis:

> If patents are scale neutral, then a comparative assessment of the strategic options faced by large and small innovative organizations will reveal no differences.

The comparative assessment above reveals that patents are not scale neutral with respect to their impact upon the strategic options of why an organization might patent, the patent application, the patent timing and

the patent enforcement. Patents are a policy instrument easily employed by large innovative firms with the to resources not only to align their patent efforts with long-term competitive advantage, but to ensure due diligence in the patent application, effective timing strategy and proper enforcement ability. The same cannot be said for small innovative organizations. For this group, the lack of endogenous resources means that patents are used to secure external funding. Relatively less strategic attention can be paid to the application of the patent while timing is not a strategic variable for this group. Finally, the lack of endogenous resources means that effective patent enforcement is difficult.

From a broader policy point of view, the lack of scale neutrality in the patent policy instrument can have two results. First, it can result in an inefficient allocation of resources targeted toward knowledge creation. Small innovative firms may sacrifice investments in capabilities leading to a long-term competitive advantage in order to protect some idea that can serve as a short-term asset in the attraction of external investors. Second, it can result in a concentration of novel innovations in the hands of large innovative organizations who have the resources to align long-term goals with current research and development projects. Furthermore, this concentration could spill over into areas of human and physical capital with the effect of undermining the *diffusion of knowledge* argument for patents in the first place as the commercial rights to more and more knowledge are held by fewer and fewer organizations.

NOTES

1. Although, in reality, many environmental policy instruments do address scale issues through, for example, differentiated implementation schedules and non-compliance fees for small firms relative to large firms.
2. The concept of Knowledge-Based Growth (KBG) will be examined in Section II: The Economics of Intellectual Property.
3. The Bayh-Dole Act 1980 allows US universities to patent innovations that were funded by public monies resulting in a shift of 'public science' from purely curiosity-driven research to research with a greater likelihood of commercial application and, therefore, the potential to earn revenue for the university (Guston and Sarewitz, 2002).
4. Other illustrations include the Cash Curve used by Andrew and Sirkin (2004).
5. If the innovation was horizontal in nature, that is, if it had multiple applications in multiple markets, then at the transition from the research and development phase to the product marketing phase there would be multiple curves plotted representing each application and the cumulative areas under these curves would illustrate the earnings. This is, of course, why horizontal or process-based innovations such as genetic transfer techniques are so popular.
6. When Thomas Edison invented the light bulb, he developed an innovative product for which there was absolutely no infrastructure to support it.
7. While this is true in principle, it is important to note that the risks of novel technical and commercial development do mean that even larger firms may adopt a 'me-too' innovation strategy.

8. Research and development at the frontiers of knowledge requires not only investment in the ideas, but also in the human and physical capital required to operationalize these ideas. For the former, this can include investment in graduate student training and basic interdisciplinary experimental research while for the latter, this can include investment in the design and manufacture of new machines and software which do not yet exist for the novel idea.
9. One recent study estimated that in the US, patent enforcement in the biotechnology sector cost an average of $US 5 million and took just over five years.

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7. Encouraging cooperation among the academic, government and private sectors in US biomedical R&D

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I. INTRODUCTION

Engaging in biomedical research and development (R&D) is risky since it requires substantial investments in both spending and time (over $800 million and 12 to 15 years to develop a pharmaceutical product) with no guarantee of a successful outcome. Many R&D projects fail to yield safe and effective products. Further, the social returns from the investments in biomedical R&D often exceed the private returns.[1] As a result, the market system alone cannot solve the problem of allocating the optimal amount of resources to biomedical R&D. To address the market failure, an R&D infrastructure has evolved that combines the academic, government and private sectors in the search for solutions to health care problems that affect people throughout the world. Each sector contributes to the biomedical R&D process. The government provides the legal framework for encouraging R&D. In the US, the federal government, primarily through the National Institutes of Health (NIH), also conducts basic and applied R&D and provides funds to academic institutions and private companies to carry out biomedical R&D projects. Scientists at academic institutions conduct R&D without regard to immediate commercial potential and train students to meet future manpower needs in the scientific community. Companies in the private sector pursue a broad range of R&D projects; identify commercially promising technologies; conduct large-scale clinical trials; assemble information that allows regulators to assess the safety and efficacy of potential products; and educate physicians, pharmacists, patients, and payers about the scientific benefits and costs of new treatments.

Potentially, academic and government laboratories are significant sources of new ideas for the private sector. However, patients do not benefit from these R&D efforts if safe and effective products remain in the laboratories. Improving processes for transferring technologies through licensing

between NIH and companies in the private sector, between academic institutions and companies, and between companies within the private sector will improve the flow of biomedical technologies to patients. License agreements are often complex transactions involving provisions governing forms of payment as well as term of the agreement, exclusivity, geographic territory, rights to sub-license, and allocating risks such as product liability. These transactions negotiated between willing participants allow the efficient transfer of intellectual property rights.

We focus on the complementary functions performed in the academic, government and private sectors and processes to encourage the flow of technology among the three sectors. We present specific examples of the three sectors participating jointly in the R&D process and thereby generating net benefits to society. Our overall conclusions are that the significant successes resulting from collaboration among the sectors rely on market principles for transferring technology among the sectors. Public policy toward biomedical R&D should seek to enhance the cooperation among the three sectors and facilitate the operation of market mechanisms for the transfer of technologies. Providing incentives to conduct R&D in the academic, government and private sectors provides society with an environment in which new, improved treatments for major health care problems such as AIDS, Alzheimer's disease, cancer, cystic fibrosis, muscular dystrophy, and Parkinson's disease are likely to emerge. Undermining intellectual property rights or imposing price regulation on the output of the R&D process will cause distortions that impede scientific progress. Such policies are detrimental to patients.

II. FRAMEWORK OF THE BIOMEDICAL R&D PROCESS

The academic, government and private sectors perform basic biomedical R&D; however, the government is the only institution that can create a legal environment for the R&D process and address the market failure created by the public good characteristics of biomedical R&D. Without the government providing the structure and R&D resources, scientists in the academic and private sectors would not have the legal framework or financial incentives to conduct innovative activities.

A. Government Conducts and Supports Biomedical R&D

Basic or discovery research is the foundation of development of new pharmaceutical products.[2] 'However, because the returns to basic research

accrue to society as a whole and often can not be captured by the firm performing the work, there tends to be underinvestment in these activities.'[3] 'Uncoordinated and isolated efforts within the private marketplace will not achieve the necessary outcomes as swiftly or as well if the public sector fails to provide financial support, and coordinate the efforts of private sector players.'[4]

To correct the market failure caused by the public goods characteristics of biomedical R&D activities, the government takes an active role in conducting and funding basic and certain applied biomedical R&D. 'The United States government is by far the single largest performer and funder of research and development in the world.'[5] The US federal government invests over $28 billion in biomedical research annually.[6] With respect to biomedical R&D, the federal and state governments support R&D at their own laboratories and through grants to outside researchers. One of the responsibilities of the NIH is to provide funding for academic laboratories to conduct basic R&D. Scientists in the academic sector have the freedom to investigate a wide variety of research approaches and ideas irrespective of their immediate commercial potential. These scientists can focus on investigating particular problems that a private company may not able to justify on a commercial basis.[7]

B. Government Creates a Framework to Encourage R&D

Academic and government institutions often do not have the expertise or resources to commercialize the results obtained from basic R&D. Even if an idea has significant medical potential, without the efforts to perform the clinical tests, obtain regulatory approvals, and inform the health care community about the results, the idea will not benefit patients or the general public who paid for the underlying R&D through taxes. Thus, the government has the unique responsibility to encourage biomedical R&D by establishing a mechanism to protect intellectual property rights and facilitate the transfer of technologies through enacting and enforcing antitrust, intellectual property, and consumer protection laws; setting standards; establishing regulations for safety and efficacy; and using tax policies to collect revenues and provide incentives (for example, R&D tax credits).

1. Intellectual property rights

The government enacts and enforces laws regarding patents, trademarks, copyrights and trade secrets to protect the intellectual property created in the biomedical R&D process. The US patent system has provided the 'institutional infrastructure necessary for the growth of a market for technology . . . [and] also enabled creative individuals to extract income from

their ideas by selling them off, making it possible for them to specialize in the inventive activities for which they had a comparative advantage.'[8] The exclusivity granted by a patent provides researchers with incentives to invest resources in R&D since it assures them that they will be able to reap the benefits of their investments. With regard to biomedical R&D, patents are extremely effective tools for protecting the output of R&D activities.[9] The government further encourages biomedical R&D by providing additional exclusivity to innovators for developing orphan drugs[10] or pediatric indications for existing products.[11] The government may need to create additional incentives to develop pharmaceutical products to treat third-world problems.[12]

Academic institutions are responding to the incentives created by the US patent system. From 1996–1998, US colleges and universities received 1492 patents for pharmaceutical technologies.[13] The growth in patenting by scientists at academic institutions has been so steady that patenting by academic institutions overtook that of government laboratories in the early 1990s. In health technologies, academic institutions have achieved their most significant presence with a 15 percent share of the combined patenting from the academic, government and private sectors.[14] Academic scientists often obtain patents at a relatively early stage of the R&D process, seven to ten years before a commercially viable product results. Companies in the private sector license the patented technologies and expand upon ideas generated in the academic and government sectors.

Merely obtaining a patent on an idea does not guarantee commercial success of an associated product. In general, '[l]ess than one percent of patent disclosures represent "crown jewels" with major commercial significance'.[15] Often, further development is required. The academic or government scientist obtaining a patent may not have the ability to conduct large-scale clinical trials, prepare regulatory filings, and educate physicians and patients about a new technology. Thus, these researchers often require help in the form of venture capital or a license to an established private-sector company with the requisite incentives and expertise to continue the development of a patented technology. Using funds raised through, for example, taxes or tuition as a source of venture capital is inefficient given the risk and speed with which the funding decisions must be made. The private sector is better able to bear the risks and react in a timely manner.

The exchange of intellectual property rights in free markets has brought forth new entrants (small businesses) into the health care industry and new products for treating major health problems. Licensing from academic institutions to private-sector companies has fostered new entry into the pharmaceutical industry.

2. Bayh-Dole Act

An early problem that inhibited the transfer of government-sponsored research results to other researchers was the lack of proper incentives to develop the associated technologies. Such incentives are the foundation of medical progress. The Bayh-Dole Act of 1980 (Bayh-Dole Act) encourages the transformation of government-funded patents into commercially viable products. Before the Bayh-Dole Act, the private sector was utilizing only 5 percent of federally owned patents, and no such patent was the foundation for a commercially viable product.[16] There was no incentive for private-sector companies to invest in developing these technologies if they could not exclude rivals.[17] The Bayh-Dole enables universities, non-profit institutions, and small businesses to hold the patent rights from government-sponsored R&D and collect any associated revenues. It provides incentives for these institutions to channel R&D into technologies that have commercial potential. As a result of the Bayh-Dole Act, 3159 academic institutions had technology transfer offices in 2003. The directors of these offices have the ability to negotiate licenses.[18]

3. Stevenson-Wydler Act

The Federal Technology Transfer Act of 1986 (Stevenson-Wydler Act) and the FY1990 Department of Defense Authorizations established Cooperative Research and Development Agreements (CRADAs) to facilitate the transfer of technology between government laboratories and the private sector. The Stevenson-Wydler Act encourages cooperation between the government and private sectors. Both sectors provide personnel, equipment, expertise and property to the research venture. The non-government party provides funding for the project and receives an option for an exclusive license to any findings. Subsequent negotiation between the parties determines the detail and scope of the license.[19]

4. Policies that avoid distortions

Some government policies create disincentives to devote resources to R&D. Interfering in the technology transfer process with a form of price regulation or tax on the terms of technology transfer will lead to undesirable results. For example, the NIH initially imposed a 'reasonable pricing' clause on companies developing products under CRADAs. NIH removed the policy in 1995 citing that the clause drove private-sector companies away from collaborating with the government on promising research projects. Further, 'if price controls had been implemented between 1980 and 2001, there would be between 330 and 365 fewer new medicines today'.[20] Market forces are already operating in the US.

> Powerful checks against the pricing power of pharmaceutical companies for drugs with feasible substitutes have emerged during the past three decades with changes in hospital purchasing practices and the growth of institutions such as health maintenance organizations (HMOs) and pharmacy benefit managers (PBMs). The most important development has been the increasing substitution of generic drugs for so-called 'branded' drugs.[21]

It is the continued flow of innovative products from the R&D process that provides the opportunities for the generic manufacturers in the future. There are benefits of therapeutic as well as generic competition. Multiple brand products to treat a particular problem provide choices to patients, physicians and payers. Competition among patented products helps to constrain health care costs.[22]

Imposing minimum royalty obligations on licensees of government technologies will create a disincentive to engage in transactions with government institutions. Requiring government or academic licensors to obtain a royalty rate to recover sunk costs of a government-supported research project will not produce the arm's length value of a technology. The economic value of a technology depends on the commercial potential (future sales) of products embodying the technology, not the costs of creating the technology. Potential private-sector licensees will seek R&D opportunities elsewhere. 'Reducing the patentees' right to exclude or its power to price is a partial repeal of the patent grant with mischievous social consequences.'[23]

C. Academic Institutions Facilitate the Flow of Biomedical Knowledge

Academic institutions provide training opportunities for employees of private-sector companies. Researchers in the private sector are able to expand their knowledge base by taking classes or engaging in dialogues with scientists at nearby universities. Undergraduate and graduate students at the academic institutions are the potential entrants into the labor force. Thus, there is a correlation between strong academic institutions and growth of the private sector.

Evidence of the complementary nature of the relationship between academic and private-sector organizations is the importance of local academic support in the decision of a company to locate a plant or R&D facility in a given state. Many biomedical research companies choose to locate facilities near an academic institution. In 2000, *Business Facilities* ranked the 'top 15 states for pharmaceutical and medical device manufacturing . . . [based on] . . . the growth in number of pharmaceutical and medical device manufacturing establishments, job growth in pharmaceutical and medical device manufacturing employment, and growth in exports figures for pharmaceuticals and medical devices products from the state'.[24] For every

state ranked, the selection of that state as a site depended in part on the proximity of academic institutions. Academic institutions are crucial components for growth of the pharmaceutical, biotechnology and medical devices industries.

D. The Private Sector Brings Products to Patients

Private-sector companies contribute to biomedical R&D at all levels, from conducting basic research in their own laboratories to licensing technologies to and from other entities. Important functions for the private sector in cooperating with academic and government scientists are to provide the resources needed to conduct large clinical trials, prepare data for regulatory filings, and inform and monitor medical professionals and patients using new therapies most efficiently. Companies in the private sector have the expertise and resources to perform these functions. The research-based pharmaceutical industry is one of the most research-intensive sectors and one of the largest employers of scientists in the US economy.[25] Pharmaceutical companies expected to invest $33.2 billion in R&D in 2003.[26] Past spending on R&D by pharmaceutical and biotechnology companies resulted in approval by the US Food and Drug Administration (FDA) for 21 new drugs and 14 new biologics in 2003.[27]

A primary role of the private sector is to bring biomedical products to commercial reality. The ultimate value of a biomedical technology is the benefit it provides to patients. The private sector is unmatched in its ability to conduct applied biomedical research, costly late-stage clinical trials required for regulatory approval, and product development. It costs more than $800 million and takes 10 to 15 years to bring a new pharmaceutical product to patients.[28] The level of risk faced by a company in the industry is high because most attempts to develop new pharmaceutical products do not succeed. 'Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.'[29]

The private sector in the US has the expertise to conduct expensive Phase III clinical trials, while the academic and government sectors do not have the resources. Phase III trials are expensive since they often require a large sample of people to test the product and the trials are for a span of time sufficient to gather data on long-term effects of a product. Clinical trial costs have increased in recent years. A reason for this increase is that

> the information required to support NDAs [New Drug Applications] has increased dramatically. Clinical trials for one of [a major pharmaceutical firm's] anti-infective NCEs [New Chemical Entities] approved in 1979 used 1,493 patients; the trials for a related anti-infective that the firm is currently developing will require testing on 10 ,000 patients.[30]

Other reasons for rising costs are 'the complexity and scope of the research required . . . the adoption of expensive new technologies . . . [and that] . . . firms are now focusing development more on treatments for chronic and degenerative diseases, which typically require longer and more expensive testing'.[31]

The private sector also provides an educational function crucial to the success of biomedical products. After the FDA approves a pharmaceutical product, companies must market and distribute the product. The FDA imposes restrictions on labeling and advertising that sellers of the product must follow so that patients, physicians, pharmacists and payers receive accurate information. Companies in the private sector are aware of these guidelines and have the resources to follow them. Activities such as conducting post-approval clinical trials, convening medical symposia, and personal contact with individual physicians to explain the therapeutic properties of a new pharmaceutical product are necessary for society to realize the benefits of R&D. Companies in the private sector perform these extensive educational activities most efficiently.

III. TECHNOLOGY TRANSFER

There are many patents granted to innovators in the private sector based on R&D in the academic and government sectors. For example, '[c]hemical technologies cite roughly six science references per patent, and a very high percentage of the citations are to papers by academic researchers receiving public funding.'[32] One study demonstrates the 'strong reliance of US industry patents on public sector science; overall, only 20.4 percent of the cited papers are from US industry . . . [and] . . . 73.3 percent are from public science'.[33]

Academic and government institutions regularly license the early-stage technologies to private-sector companies who are able to finance expensive late-stage clinical trials and provide expertise on bringing the product to market. According to one study, '73 percent of applicants for US patents said their discoveries were made wholly or partly through academic research.'[34] In return, the academic institutions receive revenues from licensing. The competitive discipline of the private sector, rather than academic freedom, is crucial to developing a commercially viable product. 'Pharmaceuticals are indeed an archetypical example of a "science-based" industry, wherein innovation – in the form of new therapeutical entities, and imitation/improvements of existing ones – is the fundamental source of competitiveness within the industry, largely shaping the dynamics of growth and decline of different firms.'[35] The willingness of a licensee to pay

for a technology depends on the expected future revenues from commercial products and the expected costs (not past or sunk costs) the licensee will have to incur to develop the technology further. Measuring the expected values must accurately reflect the risks associated with the future investments in R&D.

Many of the basic research projects conducted at NIH result in the publication of articles. Academic and private-sector innovators use these articles for information to develop their own ideas and, possibly, obtain patents. These patents may eventually lead to commercially available products. General research conducted by the federal government sometimes results in technologies for the development of some blockbuster drugs.[36] A NIH study of 47 FDA-approved blockbuster drugs that met the $500 million per year sales threshold revealed that NIH has use or ownership rights to patented technologies used in four of these 47 drugs.[37]

Given the public good characteristics of biomedical R&D, medical progress often involves the government in some way. Cockburn and Henderson reviewed the development history for 21 drugs with highest therapeutic impact introduced between 1965 and 1992. They found that '[o]nly 5 of these drugs, or 24 percent, were developed with essentially no input from the public sector.'[38] However, the government's share of R&D funded at academic institutions has been decreasing while the private sector's share has been increasing.[39]

In fact, many pharmaceutical products, even if they treat diseases affecting large patient populations, do not generate sufficient revenues to allow innovators to recoup the R&D costs. For example, only three out of every 10 marketed pharmaceutical products introduced from 1990 to 1994 had returns higher than average after-tax R&D costs.[40]

A. Cooperation: Academic and Industry Scientists

1. Academic sector interacts with the private sector

Academia and the private sector frequently cooperate in the biomedical R&D process. Academic institutions provide private-sector scientists with ideas, training opportunities for private-sector employees, and graduates to fill new jobs as companies expand. Academic institutions are not a substitute for private-sector companies. Rather, they engage in the transfer of technology with private-sector companies in several ways including:

- strategic alliances such as license agreements,
- formal partnerships,
- scientific collaboration,
- exchange of scientists,

- academic scientists as experts or advisors to industry,
- employment of high-level academic scientists in companies, and
- funding supplied by industry.[41]

Academic institutions rely on the private sector to continue developing biomedical technologies for commercial sale. State-supported universities, for example, have to fund a portion of their operations through taxes with the concern among taxpayers about the overall burden of taxes. Increasing taxes to create a source of venture capital is not a politically feasible alternative.

2. License agreements

Licensing is an important form of technology transfer between the academic and private sectors. It can facilitate the continued development of potentially useful technologies and generate revenues for academic institutions to continue R&D activities. To achieve the benefits from licensing, negotiations of the associated agreements should reflect competitive principles.

a. Provisions The parties involved in negotiating technology licenses must be free to determine the specific terms of the license as the market conditions for technology dictate. License agreements are often complex contracts with many different terms and conditions that reflect bargaining between buyers and sellers of technology. Provisions in license agreements specify factors such as:

- nature of the technology (for example, product patent, process patent, trademark);
- exclusive or non-exclusive;
- scope of territory covered under license;
- existence and amount of lump sum payments;
- existence and amount of milestone payments;
- existence, scope, amount, terms of royalty rate payments;
- term (for example, ten years, end of patent life) of license;
- restrictions (for example, field of use);
- conditions for termination or renegotiation;
- rights to sub-license;
- rights to improvements or updates; and
- assignment of liability risks.

b. Agreements: academic institutions and private companies To understand the licensing component of technology transfer, we examined information on licensing activities using two databases: *Alliances*[42] and

Windhover's Pharmaceutical Strategic Alliances. From the *Alliances* database, we identified 164 license agreements signed during the period, January 1998 through April 2001 in which one party was a North American academic institution and the other was a private-sector company. From *Windhover*, we examined agreements with the same type of licensor–licensee relationship for the period July 1998 to June 1999. We found 47 license agreements involving an academic institution and a private-sector company. Several characteristics are common to the agreements we identified from both databases.

- An academic institution is generally the licensor of technology.
- The technologies licensed span a broad class of diseases and medical problems.
- The associated technologies are often in the early stages of development (discovery or preclinical).
- The licensee is generally not a major research-based pharmaceutical company. The licensees are often start-up companies or new entrants into the pharmaceutical or biotechnology industries.[43]

There are several reasons for the licensing activity that exists between academic institutions and private-sector companies. Scientists in academic institutions have different incentives than scientists in government or industry laboratories. Academic institutions perceive the benefits of licensing technologies that have commercial potential rather than developing the technologies themselves. The preference for licensing is likely to be due to the need to obtain financing for further development through raising venture capital. Investors are unwilling to provide funds to academic institutions for further development. They want the discipline of the corporate structure to create the incentive to develop technologies efficiently. Bearing all the risk of investing in early stage research is not consistent with the role of academic institutions.

The complementary roles of academia and the private sector in conducting R&D facilitate sharing risks of further development. It is important for the licensor and the licensee to have close relationships, otherwise, commercialization would not occur and society could not benefit from the technology. One study found that 'the vast majority of inventions licensed are so embryonic that technology managers consider inventor cooperation in further development crucial for commercial success'.[44] Thus, the researchers suggest that commercial 'development would not occur unless the inventor's [licensor's] return is tied to the licensee's output when the invention is successful'.[45] A royalty payment based on future sales of any product embodying a given technology is one way to share risk between the licensor and

licensee. Such an arrangement maintains the licensor's interest in helping to develop the technology, and reduces the risk for the licensee.

Licensing in technology from government or academic laboratories allows industry to reduce the risk of investing in basic research that may never result in commercially viable products. Even when basic research ultimately results in a commercial product, the long period until commercial sale can constitute a risk for private-sector companies. For example, it took 41 years after the basic research for the FDA to approve imatinib mesylate. It is difficult for the private industry to justify to investors payoffs that will not occur for over 40 years. 'Private firms apply a relatively high discount rate to all investment projects, meaning that the benefits have to occur within a few years or they are frequently not valued high enough to result in an acceptable projected RoR [rate of return].'[46] High levels of risk create a market failure. '[W]hen market failures raise risks beyond levels acceptable to individual corporate investment criteria, the result is underinvestment in new technologies.'[47]

c. Royalty rates We conducted another search of the *Alliances* database and found 199 license agreements where data on royalty rates were available. An academic research center was the licensor in 109 of the agreements (54.8 percent), a private company was the licensor in 76 of these agreements (or 38.2 percent), and the remaining 14 agreements (7.0 percent) had the US federal government as the licensor. In all cases, the licensee was a company in the private sector. The average royalty rates for these agreements based on sector of the licensor were: 4.0 percent for the academic research centers, 8.7 percent for the private industry, and 5.0 percent for the government. The result that the royalty rate is higher for transactions where both licensor and licensee are in the private sector may be due to several factors. First, a private-sector licensor may have a greater bargaining advantage since it may be able to develop the technology further without a licensee. Second, the technology licenses between private-sector parties may be at a later stage of development compared to situations where government agencies or academic institutions are licensors. A majority of the research licensed by private companies is at a later stage in the development process than basic research licensed by academia or government. There is more knowledge associated with the advanced-stage research, and commercial sale of any products will begin earlier. Thus, it is likely to provide greater value to a company than basic research that requires additional investment in testing and a longer time to realize any benefits. Even though the government negotiated, on average, a higher royalty rate than the academic licensors, the highest rate obtained by the government was 8.0 percent, while the highest rate for an academic licensor was 10.0 percent.

d. Importance of licensed technologies Results obtained from a study indicated that the pharmaceutical industry was the source of 92 percent of the 196 NCEs approved by the FDA from 1981 through 1990.[48] That is, companies obtained about 8 percent of pharmaceutical products through licensing from academic and government research. However, this does not mean that 92 percent of NCEs were developed from internal research within the one company. Many license agreements exist between pharmaceutical companies. Such licenses between private companies are not included in the above estimate. An additional study looks at 691 NCEs that the FDA approved for sale in the US between 1963 and 1999. Over the period, licensed technologies represent 38.2 percent of the NCEs approved by the FDA.[49] This percentage reflects all licensing involving government, academic and private-sector licensors. Thus, pharmaceutical companies developed 61.8 percent of NCEs internally.[50] Further, a recent study found that '[p]roducts developed in an alliance tend to have a higher probability of success, at least for the more complex Phase II and Phase III trials, particularly if the licensee is a large firm.'[51]

B. Industry Supports Academic Research

The industry provides benefits to academic institutions through licensing income. The royalties paid by the private industry to universities as a result of licensing their technology can be used to further the research program at the universities. For example, '[g]ross license income received from licenses and options in fiscal year 2002, after elimination of double counting, was $1.267 billion reported by 218 institutions, up 18.3 percent from $1.071 billion in fiscal year 2001 reported by 198 institutions'.[52]

In general, licensing income provides revenues for academic institutions to continue R&D activities. US universities spent approximately $23.6 billion on research, received $641 million in adjusted gross licensing income, received 3079 patents and formed 275 start-up companies in FY 1999. The spending, income, patents and start-up companies appear to be concentrated among the major research universities.[53] Without licensing income from the private sector, these academic institutions would not have the means to advance their R&D programs.

The private sector, besides licensing, also sponsors research in academic institutions and other organizations. 'In 1998, corporations sponsored nearly $2 billion in research at universities, or about 9 percent of all research performed at US colleges and universities.'[54] However, there is some concern about scientific independence associated with industry funding research at academic institutions. There have been conflict of interest issues such as the source and conditions of research funding, which can

bias and otherwise discredit research.[55] Editors of certain scientific journals have established guidelines for authors requiring that they describe the role of any study sponsor and/or sign a statement stating that they take complete responsibility for integrity and accuracy of data.[56]

The flow of patented technologies is not always in the direction of academic institution to the private sector. 'The relationship between public and private sectors appears to involve much more than the simple, costless, transfer of basic knowledge from publicly funded institutions to profit-oriented firms.'[57] Companies can be a source of patented technologies to academic institutions as well. For example, DuPont conducted a type of 'reverse technology transfer, donating patents for technology it had discovered and developed to the University of Iowa, Virginia Polytechnic Institute and State University, and Pennsylvania State University'.[58]

IV. WORKING TOGETHER: EXAMPLES

The academic, government and private sectors work together in the biomedical R&D process to enhance social welfare. '[M]edical research has produced exceptionally high returns in the past and is likely to deliver exceptional returns in the future.'[59] In the future, '[m]edical research that reduced deaths from cancer by just one-fifth would be worth $10 trillion to Americans – double the national debt'.[60] Improvements in health have been responsible for increasing life expectancy and 'account for almost one-half of the actual gain in American living standards in the past 50 years'.[61] In addition, Toole found that, holding all else constant, 'a proportional increase in both public and private research inputs leads to a greater than proportionate increase in the number of approved [new molecular entities]'.[62]

There are numerous examples of pharmaceutical products developed through complementary R&D.[63] Among the leading medicines (annual sales over $500 million) currently available, the NIH has rights to patented technologies in erythropoietin (2 brands), filgrastim and paclitaxel. The product imatinib mesylate, a treatment for chronic myelogenous leukemia (CML), is an example of basic academic research resulting in an approved commercial product with significant potential to help affected patients. We discuss below three specific examples of the complementary roles of the academic, government and private sectors in improving health care.

A. Imatinib Mesylate

Imatinib mesylate is an example of basic academic research resulting in an eventual commercial product. In 1960, Peter Nowell of the University of

Pennsylvania discovered an abnormal chromosome in patients with CML. Over the next 30 years, researchers made several other discoveries that linked the abnormal chromosome with a cancer-causing protein. In 1993, Brian Druker, MD, of the Oregon Cancer Institute at Oregon Health & Science University and scientists from Ciba-Geigy (now Novartis Pharmaceuticals) began the first laboratory tests of the pharmaceutical product that would become imatinib mesylate. Novartis submitted the NDA for imatinib mesylate (brand name Gleevec®) in February 2001. The FDA approved imatinib mesylate in May 2001 due to the unprecedented effectiveness in early clinical trials (53 of 54 chronic-phase CML patients given a 300 mg dosage experienced a return of normal blood counts). 'A breakthrough cancer medicine, Gleevec® was quickly established among the world's top-selling prescription drugs. Gleevec® generated $1.13 billion in 2003 worldwide sales, an 83.4% increase compared with 2002.'[64] Through a CRADA, the National Cancer Institute (NCI) and Novartis Pharmaceuticals continued clinical trials of imatinib mesylate for other indications. In February 2002, the FDA approved imatinib mesylate to treat patients with Gastrointestinal Stromal Tumors.[65]

B. Paclitaxel

Another example of the benefits of the cooperative R&D process is paclitaxel. Paclitaxel currently treats breast, ovarian and lung cancers. Research by NCI in the 1960s demonstrated that paclitaxel is a highly effective treatment for cancerous tumors. During the next 25 years, scientists made little progress in developing a useful product.[66] NCI began clinical trials in 1984; and, in 1989, the NIH-supported researchers at the Johns Hopkins Oncology Center reported tumors shrank or disappeared in 30 percent of patients who received paclitaxel.[67] However, the NIH could not continue the research. It was unable to supply a sufficient amount of paclitaxel and needed to find a company to commercialize the product. NIH solicited a number of CRADA proposals from different companies and eventually transferred the technology to Bristol-Myers Squibb.[68] NIH provided preclinical and clinical data, research expertise in the area of anticancer agents, and a limited supply of paclitaxel.[69] In return, Bristol-Myers Squibb completed a large number of clinical trials and supplied the necessary amount of paclitaxel.[70] The FDA approved Bristol-Myers Squibb's NDA for its brand of paclitaxel (Taxol®) in December 1992. Worldwide sales of Taxol® were $934 million in 2003.[71]

C. Genomics

The future of R&D in the pharmaceutical industry is changing. In a recent survey of senior pharmaceutical industry executives, genomics received the largest number of responses to the question: 'Over the next three years, which area will play the most important role at your company in developing the pipeline for new drugs?'[72] Developing genomics involves government, academia and industry. The impetus to map the genome began at the US Department of Energy in 1984. Eventually other government agencies including NIH became involved. The Human Genome Project (HGP), which began in 1990 and was completed in 2003, was an internationally funded venture by both the academic and government sectors including Washington University of St Louis School of Medicine Genome Sequencing Center and National Center for Biotechnology Information of NIH. Researchers in the private sector have also made significant contributions to mapping the human genome. Celera Genomics (Celera) was founded in 1998 with the primary purpose of sequencing and assembling the human genome and completed its first draft of the human genome in 2000.[73] During the 13-year project, collaboration was possible due to the 'federal government's long-standing dedication to the transfer of technology to the private sector'.[74] Despite the completion of HGP, analyses of the data are likely to be a focus of R&D activities into the future.

V. CONCLUSION

Progress in biomedical R&D requires continuing efforts to encourage cooperation among the academic, government and private sectors in the US. Each sector is an important component of the R&D process. However, given that their roles are often complementary, mechanisms must exist to transfer technologies among the sectors. Licensing transactions conducted in free markets are the most efficient means of transferring the output of innovative activities among the three sectors.[75] Two important features of free markets are strong protection of intellectual property rights and the absence of price regulation. The government should provide strong intellectual property protection within its borders as well as encourage other nations to protect intellectual property rights. The transfer of technologies should occur in markets where the values of the technologies are determined by the interaction of willing buyers and sellers making decisions based on their estimates of the future values of the technologies. These future values for a technology should reflect prices determined by supply and demand, not administered price schemes.

Reduced incentives to devote resources to R&D result from attempts to undermine intellectual property rights or regulate prices of biomedical products created from the innovative efforts. Distortions in the form of shortages or delays in product introductions will result from poor intellectual property protection or price regulation schemes. Innovative activities to meet future health care problems will flourish when free market incentives are in place.

NOTES

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1. '[M]any economists view these conclusions [of independent studies] as evidence of an underinvestment in civilian technology.' Edwin Mansfield, 'Microeconomics of technological innovation', in *The Positive Sum Strategy: Harnessing Technology for Economic Growth*, edited by Robert Landau and Nathan Rosenberg, National Academy Press, 1986, p. 311.
2. During the basic research phase, laboratory and animal studies are conducted to assess safety, biological activity, and formulations for potential pharmaceutical products. John T. Kelly, 'The drug discovery, development, and approval process', *New Medicines in Development for Heart Disease and Stroke 2003*, p. 19.
3. Wendy H. Schacht, 'Federal R&D, drug discovery, and pricing: insights from the NIH–university–industry relationship', *CRS Report for Congress*, Congressional Research Service, June 19, 2000, p. 1.
4. Margaret M. Blair and Steven M.H. Wallman, *Unseen Wealth: Report of the Brookings Task Force on Understanding Intangible Sources of Value*, Brookings Institution, October 2000, p. 42.
5. Adam B. Jaffe and Josh Lerner, 'Reinventing public R&D: patent policy and the commercialization of national laboratory technologies', *RAND Journal of Economics*, Vol. 32, No. 1, Spring 2001, p. 167.
6. NIH, 'About NIH: Overview', http://www.nih.gov/about/NIHoverview.html, extracted 8 February, 2005.
7. Scientists in the academic sector receive funding for basic R&D from private companies as well.
8. Naomi R. Lamoreaux and Kenneth L. Sokoloff, 'Market trade in patents and the rise of a class of specialized inventors in the 19th century United States', *American Economic Review*, Vol. 91, No. 2, May 2001, p. 39.
9. Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson and Sidney G. Winter, 'Appropriating the returns from industrial research and development', *Brookings Papers on Economic Activity*, Vol. 3, 1987, pp. 783–820.
10. Diseases such as Huntington's disease and Tourette's syndrome affect a small number of people (under 200 000) in the US. Products to treat such problems are orphan drugs. Congress enacted the Orphan Drug Act (Pub.L. 97–414) to encourage development of orphan drugs.
11. The Food and Drug Administration Modernization Act of 1997 authorized six months of additional exclusivity for an innovator who successfully demonstrates the safety and efficacy of a product tested in children.

12. Biomedical R&D is often directed at the problems affecting large patient populations. Acemoglu and Linn found that 'a 1 per cent increase in the potential market size for a drug category leads to approximately a 4 per cent growth in the entry of new nongeneric drugs and new molecular entities.' Daron Acemoglu and Joshua Linn, 'Market size in innovation: theory and evidence from the pharmaceutical industry', *Quarterly Journal of Economics*, Vol. 119, August 2004, p. 1084.
13. US colleges and universities were awarded 878 and 614 patents in utility classes 514 and 424, respectively. These utility classes include patents related to 'Drug, bio-affecting, body treating compositions'. Appendix Table 6–68, National Science Board, Science & Engineering Indicators-2000, National Science Foundation (NSB-00-1), 2000.
14. See Diana Hicks, Tony Breitzman, Dominic Olivastro, and Kimberly Hamilton, 'The changing composition of innovative activity in the US – A Portrait Based on Patent Analysis', *Research Policy*, Vol. 30, April 2001, pp. 681–703.
15. Greg A. Stevens and James Burley, '3,000 Raw Ideas = 1 Commercial Success!' *Research-Technology Management*, Vol. 40, May–June 1997, p. 18.
16. Wendy H. Schacht, 'Federal R&D, drug discovery, and pricing: insights from the NIH–university–industry relationship', *CRS Report for Congress*, Congressional Research Service, June 19, 2000, p. 9.
17. In addition to the Bayh-Dole Act, numerous other factors have contributed to a change in the structure of the pharmaceutical industry, and thus changed how academia, government and private industry participate in the biomedical R&D process. See Iain M. Cockburn, 'The changing structure of the pharmaceutical industry', *Health Affairs*, Vol. 23, January/February 2004, pp. 10–22.
18. Carolyn Said, 'Once shunned, tech licensing now a cash cow for schools: route from lab to market often arduous', SFGate.com, 29 August, 2004. http://sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/08/29/BUGLI8FON61.DTL&type=business, extracted 8 February, 2005.
19. Wendy H. Schacht, 'Federal R&D, drug discovery, and pricing: insights from the NIH–university–industry relationship', *CRS Report for Congress*, Congressional Research Service, 19 June, 2000, p. 11.
20. PhRMA, *Pharmaceutical Industry Profile 2004*, http://www.phrma.org/publications/publications//2004-03-31.937.pdf, extracted 8 February, 2005.
21. F.M. Scherer, 'The pharmaceutical industry – prices and progress', *New England Journal of Medicine*, Vol. 351, 26 August, 2004, p. 930.
22. Competition among six brand statin products to lower cholesterol allows HMOs and PBMs to bargain for lower prices. Proposals by Angell to curtail R&D on therapeutically equivalent products ignore the economic benefits for patients from therapeutic competition. See Marcia Angell, 'The truth about the drug companies', *The New York Review of Books*, Vol. 51, July 15, 2004. http://www.nybooks.com/articles/17244, extracted 8 February, 2005.
23. Richard A. Epstein and Bruce N. Kuhlik, 'Is there a biomedical anticommons?', *Regulation*, Vol. 27, Summer 2004, p. 58.
24. The top 15 states were California, New York, Texas, Pennsylvania, Illinois, Florida, Massachusetts, Ohio, New Jersey, Indiana, North Carolina, Minnesota, Michigan, Tennessee and Washington. Donna Clapp, Mary Ellen McCandless, and Greg Eaddy, 'The healthiest states for pharmaceuticals: the right prescription for successful locations', *Business Facilities*, June 2000. All of these states have major academic research centers.
25. PhRMA, *Pharmaceutical Industry Profile 2004*, http://www.phrma.org/publications/publications//2004-03-31.937.pdf, extracted 8 February, 2005.
26. PhRMA, 'Table 1: Domestic R&D and R&D Abroad, PhRMA Member Companies, 1970–2003', *Pharmaceutical Industry Profile 2004*, http://www.phrma.org/publications/publications//2004-03-31.937.pdf, extracted 8 February, 2005. This amount represents the sum of Domestic R&D ($27.4 billion) and R&D Abroad ($5.8 billion) expected in 2003.
27. PhRMA, 'New Drug Approvals in 2003', http://www.phrma.org/newmedicines/resources/2004-01-22.123.pdf, extracted 8 February, 2005.

28. Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, 'The price of innovation: new estimates of drug development costs', *Journal of Health Economics*, Vol. 22, 2003, pp. 151–85.
29. PhRMA, 'New drug approvals in 2003', http://www.phrma.org/newmedicines/resources/2004-01-22.123.pdf, extracted 8 February, 2005.
30. Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski and Louis Lasagna, 'Cost of innovation in the pharmaceutical industry', *Journal of Health Economics*, Vol. 10, 1991, p. 132.
31. Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski and Louis Lasagna, 'Cost of innovation in the pharmaceutical industry', *Journal of Health Economics*, Vol. 10, 1991, p. 133.
32. Janice Long, 'Quantifying chemical R&D', *Chemical & Engineering News*, Vol. 79, 11 June, 2001, p. 5.
33. Francis Narin, Kimberly S. Hamilton and Dominic Olivastro, 'The increasing linkage between US technology and public science', *Research Policy*, Vol. 26, October 1997, p. 328.
34. Esther D'Amico, 'Specialty strategies: industry buys into university research', *Chemical Specialties*, April 1999.
35. Giulio Bottazzi, Giovanni Dosi, Marco Lippi, Fabio Pammolli and Massimo Riccaboni, 'Innovation and corporate growth in the evolution of the drug industry', *International Journal of Industrial Organization*, Vol. 19, 2001, p. 1162.
36. A blockbuster drug is often defined as a product with annual sales exceeding $1 billion.
37. NIH, 'A plan to ensure taxpayers' interests are protected', July 2001, http://www.nih.gov/news/070101wyden.htm, extracted 8 February, 2005. These drugs are erythropoietin (two brands), filgrastim, and paclitaxel.
38. Iain M. Cockburn and Rebecca M. Henderson, 'Publicly funded science and the productivity of the pharmaceutical industry', in *Innovation Policy and the Economy*, edited by Adam B. Jaffe, Josh Lerner and Scott Stern, National Bureau of Economic Research, Vol. 1, p. 21.
39. Albert N. Link, 'A suggested method for assessing the economic impacts of university R&D: including identifying roles for technology transfer officers', *The Journal of the Association of University Technology Managers*, Vol. 11, 1999.
40. PhRMA, *Pharmaceutical Industry Profile 2004*, http://www.phrma.org/publications/publications//2004-03-31.937.pdf, extracted 8 February, 2005.
41. Richard A. Levy and Kerstin B. Menander, 'Research in the pharmaceutical industry: major contributions to biomedical science and implications for public policy', *National Pharmaceutical Council*, 1992, p. 28.
42. Recombinant Capital, Inc. is a financial consulting firm for the pharmaceutical and biotechnology industries. Its *Alliances* database contains the information on license agreements.
43. Across all industries (including biomedical), 4320 start-up companies emerged from university licensing activity between 1980 and 2002. The Association of University Technology Managers, 'AUTM Licensing Survey: FY 2002 Survey Summary', p. 2.
44. Richard Jensen and Marie Thursby, 'Proofs and prototypes for sale: the licensing of university inventions', *American Economic Review*, Vol. 91, March 2001, p. 255.
45. Ibid.
46. Gregory C. Tassey, 'Technology and economic growth: implications for federal policy', 95–3 Planning Report, National Institute of Standards and Technology, October 1995, p. 43.
47. Ibid., p. v.
48. Kenneth I. Kaitin, Natalie R. Bryant, and Louis Lasagna, 'The role of the research-based pharmaceutical industry in medical progress in the United States', *Journal of Clinical Pharmacology*, Vol. 33, 1993, pp. 412–17.
49. Joseph A. DiMasi, 'New drug innovation and pharmaceutical industry structure: trends in the output of pharmaceutical firms', *Drug Information Journal*, 2000,Vol. 34, p. 1177.

50. Dr William T. Davis, Director of Licensing for Pfizer Inc., stated that '[i]t is impractical . . . to support the goal of 15 per cent annual growth with internal research alone.' Edward P. White, *Licensing – A Strategy for Profits*, Licensing Executives Society, 1997, p. 44.
51. Patricia M. Danzon, Sean Nicholson and Nuno Sousa Pereira, 'Productivity in pharmaceutical–biotechnology R&D: the role of experience and alliances,' NBER Working Paper Series, April 2003, p. 29.
52. The Association of University Technology Managers, 'AUTM Licensing Survey: FY 2002 Survey Summary', p. 2.
53. The top 15 universities (ranked by research expenditures) account for more than one-third of the total in any category. Business–Higher Education Forum, 'Working together, creating knowledge: the university-industry research collaboration initiative', 2001, Appendix B.
54. Business–Higher Education Forum, 'Working together, creating knowledge: the university–industry research collaboration initiative', 2001, p. 11.
55. Frank Davidoff, Catherine D. DeAngelis, Jeffrey M. Drazen, John Hoey, Liselotte Højgaard, Richard Horton, Sheldon Kotzin, M. Gary Nicholls, Magne Nylenna, A. John P. M. Overbeke, Harold C. Sox, Martin B. Van Der Weyden, and Michael S. Wilkes, 'Sponsorship, authorship, and accountability', *Journal of American Medical Association*, Vol. 286, 12 September, 2001, p. 1234.
56. 'Sponsorship, authorship, and accountability', *Journal of American Medical Association*, Vol. 286, 12 September, 2001, p. 1234.
57. Iain Cockburn and Rebecca Henderson, 'Public–private interaction in pharmaceutical research', *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 93, November 1996, p. 12729.
58. Esther D'Amico, 'Specialty strategies: industry buys into university research', *Chemical Specialties*, April 1999. The value of the patents DuPont gave to these institutions in 1999 was $64 million. Other companies donating patents include Caterpillar and Kellogg. These companies donated patents valued at $50 million and $49 million, respectively. The US Internal Revenue Service has recently started to review the methods for valuing such donations. Ashlea Ebeling, 'Business in the beltway: Washington blocks patent tax breaks', Forbes.com, 7 January, 2004, http://www.forbes.com/2004/01/07/cz_ae_0107beltway.html, extracted 8 February, 2005.
59. Funding First, 'Exceptional returns: the economic value of America's investment in medical research', May 2000, p. 2.
60. Ibid.
61. Ibid.
62. Andrew A. Toole, 'The impact of public basic research on industrial innovation: evidence from the pharmaceutical industry', *Stanford Institute for Economic Policy Research*, November 2000, p. 25.
63. Other examples of pharmaceutical products that developed through complementary R&D include: acyclovir, cisplatin, fluoxetine, latanoprost and tamoxifen.
64. 'Brand of the year: Gleevec', *Med Ad News*, May 2004, p. 1.
65. 'Gleevec® and GIST', http://www.gleevec.com/info/page/gist, extracted 8 February, 2005.
66. US General Accounting Office, Report to the Vice Chairman, Joint Economic Committee, US Congress, 'Technology transfers: benefits of cooperative R&D agreements', GAO/RCED-95-52, December 1994, p. 14.
67. Bristol-Myers Squibb Company, 'The Taxol (paclitaxel) Story', http://www.taxol.com/timeli.html, extracted 8 February, 2005.
68. The US Congress has raised some concern regarding the issue of whether US taxpayers received an appropriate return for their investment. Despite this concern, 'NIH and [Bristol-Myers Squibb] are both satisfied with the deals they have struck with each other relating to the development of Taxol®'. Susan Morrissey, 'Maximizing returns', *Chemical and Engineering News*, Vol. 81, 15 September, 2003, p. 18.
69. US General Accounting Office, Report to the Vice Chairman, Joint Economic Committee, US Congress, 'Technology transfers: benefits of cooperative R&D agreements', GAO/RCED-95-52, December 1994, p. 14.

70. In addition to its collaboration with NIH, Bristol-Myers Squibb entered into a license agreement with Florida State University to obtain rights to a technology for synthesizing paclitaxel. While most license agreements at universities 'struggle to earn $100,000 in their lifetime', Florida State earned royalties of $66 million in 2002 causing Royal Academy of Engineering's journal *Ingenia* to describe the collaboration as 'the most lucrative university technology license in the world', Helena Keers, 'City diary', *The Daily Telegraph*, 30 December, 2004.
71. 'Best-selling prescription drugs', *Med Ad News*, May 2004, p. 61.
72. John du Pre Gauntt, 'Targeted treatments and the prospects of pharmaceuticals', Economist Intelligence Unit White Paper, January 2005, p. 8.
73. Celera, 'Our history,' http://www.celera.com/celera/history, extracted 8 February, 2005.
74. Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml, extracted 8 February, 2005.
75. The research-based pharmaceutical industry in the US has flourished relative to the European industry since many European countries do not have free markets. See Alfonso Gambardella, Luigi Orsenigo, and Fabio Pammolli, *Global Competitiveness in Pharmaceuticals: A European Perspective*. Report prepared for the Enterprise Directorate-General of the European Commission, November 2000.

8. University technology transfer policy matters: is it time for a 'Bayh-Dole Modernization Act'?

Robin J.R. Blatt

INTRODUCTION

Public support and funding for scientific research and development (R&D) in the life sciences has increased exponentially during the recent decades in the United States (US). The US leads the world in government financing and support for non-military research R&D, especially support for work that directly relates to health and human development. A significant portion of federally funded research has led to a wide spectrum of novel basic and clinical research discoveries – all of which generally require commercial partners in order to develop them into products for hospital, physician or patient use.[1]

As a result, trends in federal science funding have fueled innovation, enabling academic scientists and universities to both progress and prosper. At the same time, a significant paradigm shift in science and technology policy also has occurred. For the past quarter of a century, since the passage of the Bayh-Dole Act of 1980[2] and the Stevenson-Wylder Technology Innovation Act 3,[3] US federal funding priorities have been geared toward promoting 'science with commercial twist'. These Acts have provided not-for-profit agencies (such as universities) and businesses with a series of incentives and rights, including ownership rights to technology and innovations developed through federally funded research and the ability to patent and license discoveries, in order to promote commercial applications for both public and economic benefit.

Today, most public and private universities in the US have established technology transfer offices for the purpose of actively mining internal scientific knowledge in order to increase institutional intellectual property (IP) assets and portfolios, establish academic–industry alliances, facilitate investment and promote commercialization of scientific discoveries to generate licensing fees, royalties and revenues for both the researcher and the institution.

The purpose of this chapter is to provide a brief overview of US technology transfer policies within the university setting and to explore the contemporary opportunities, challenges and conflicts that have emerged as a result of the goal toward privatization and commercialization of early stage government-funded R&D within the university setting. It is my premise that while promoting the transfer of taxpayer-funded research from the lab bench to the marketplace may serve as a stimulus for new companies, industries and products for public benefit, realization of these results is not automatic. We have reached an historic juncture where contemporary technology transfer policy issues require active re-examination and critical new questions need to be addressed. In essence, a number of normal evolutionary and ethical shifts have occurred since the passage of technology transfer legislation in the 1980s and it is my belief that the time has come for a new collaborative process that will result in new models and creation of a 'Bayh-Dole Modernization Act'.

US FEDERAL FUNDING OF 'SCIENCE WITH A COMMERCIAL TWIST'

Setting priorities and allocations for distribution of US government funds for science and technology is undertaken by the National Research Council (NRC) – an advisory group within the National Academy of Sciences (NAS). While a significant portion of US federal research funds are awarded to universities in the form of grants managed by government agencies, such as the National Institutes of Health (NIH), National Science Foundation (NSF), Centers for Disease Control (CDC), and the Department of Energy (DOE), in recent years there has also been an increase in funds allocated to Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs to promote commercial applications.

GOVERNMENT SECTOR TECHNOLOGY TRANSFER (INTRAMURAL RESEARCH PROGRAMS)

Biomedical research conducted *directly* by the NIH and Food and Drug Administration (FDA) intramural research programs are licensed through the NIH Office of Technology Transfer (OTT). This 'government-owned' research program 'pipeline' provides novel, fundamental research discoveries available for commercial applications and represents a 'supermarket' of research products or tools for its commercial partners and suppliers.[4] Most technology transfer activities at NIH date from the Federal Tech-

nology Transfer Act of 1986[5] which authorized formal research partnerships with industry and provided incentives to NIH to license technology by allowing NIH for the first time to keep its license royalties and share them between the individual inventors and their institutes. Overall product sales by NIH licensees have been estimated at more than $3 billion annually. According to a Department of Commerce report, NIH royalties contributed 70 per cent of the total invention royalties received by the Federal government.[6]

The NIH approach to negotiating biomedical licensing and technology transfer agreements differs from universities or corporations in a number of ways. First, given that NIH uses these agreements to further the overall agency health care mission, the public health consequences of such licenses are considered to be the first priority, not the financial terms that may be involved. Unlike those of the universities, NIH licenses are not linked to sponsored research or corporate funding requirements. Second, another difference between NIH technology transfer activities compared with academia or industry is that a mandate exists to try to make NIH-owned technology as broadly available as possible. This means that there is a strong preference for *non-exclusive licenses* with rights in all agreements limited to the scope needed to develop specific products. Potential exclusive licenses are limited to those technologies requiring substantial private risk and investment and are subject to a 60-day public notice and comment period in the Federal Register. In all of its agreements, the NIH retains the right to permit further research use of its technology whether to be conducted either in the intramural program, universities or companies. Because the commercial rights granted by NIH are considered *public assets*, its agreements have enforceable performance benchmarks to ensure that the public will eventually receive the benefit (through commercialized products) of the research it funded. Regulations governing the negotiation of NIH licenses and their mandated requirements are described in more detail at 37 Code of Federal Regulations (CFR), Part 404.[7]

ACADEMIC SECTOR TECHNOLOGY TRANSFER (EXTRAMURAL RESEARCH PROGRAMS)

As noted above, public and private universities in the US continue to receive substantial sums of federal dollars and have a longstanding mission to foster R&D and the dissemination of new knowledge. Since 1980, US legislation has also directed universities to promote commercial development of the discoveries made with federal funds. To support this mission, federal law encourages universities to patent their discoveries and to license them

to firms in the private sector. As a result, many universities have established technology transfer offices to mine and market the discoveries of scientists.

The transfer of new technology from academic institutions to the private sector has a long history. The Patent and Trademark Patent Policy Act of 1980,[8] commonly referred to as the Bayh-Dole Act, was passed to 'promote the economic development of federally funded research, thereby benefiting the public through commercialization of advances in research and technology' during a time when few patents were being issued on government-funded research. Prior to the passage of the Bayh-Dole Act, there were minimal models for academic–industry alliances, investment and commercialization; further, the science and technology emerging from the universities was often at such an early stage that it required ongoing inventor participation for the commercialization process to occur. Under Bayh-Dole, recipients of government funds are enabled to keep title to inventions so long as they promote utilization, commercialization, and access to the public. Since many universities are recipients of NIH grants and other federal funds for research, Bayh-Dole has provided for more local control of IP management and enabled the development of a university-based infrastructure that was lacking at the time.

In addition, the Bayh-Dole Act mandates that any revenues received must go back to the institution and that the inventor must share in the proceeds that result. According to university technology transfer annual surveys, it has been estimated that incentives stimulated by the Bayh-Dole Act have resulted in an estimated $35 billion in annual product sales.[9]

BAYH-DOLE ACT: CONTEMPORARY ISSUES AND CHALLENGES

After nearly 25 years since its passage, there has been increasing attention and analysis of the impact of the Bayh-Dole Act and its benefits and limitations on science and society. While it has been hailed as successful by leading experts in technology transfer, commercialization and entrepreneurship,[10] it has also 'contributed in a shift in scientific norms, a change in research culture, and the demise of academic use of information'. In a recent editorial published in *Science* citing the development of the Bayh-Dole Act from adolescence to adulthood, it was postulated that 'the ratio of its benefits to its costs depends on one's view of what's important'. According to the author, 'To those who had worried about technology transfer, it's a huge success. To others, who expressed concern about university/corporate relations or mourn the enclosure of the scientific 'knowledge commons', it looks more like a bad deal.'[11] Other critics have

gone as far as to state that 'The Pandora's Box Dole bequeathed to us is the Bayh-Dole Act, a law which has engorged the coffers of pharmaceutical corporations, at taxpayer expense'.[12]

In general, it is widely accepted that the purpose of IP protection is to support the intellectual process, to encourage innovation and to guarantee that some benefit will be retained by the inventor. It is also generally agreed that the 'knowledge commons' requires timely presentation and publication of results, open communication among researchers and full access to documentation of research methodology for the purposes of replication.

According to Rebecca Eisenberg:

> Concern about an anticommons, or proprietary rights 'thicket' is quite pressing in contemporary biomedical research . . . Exchanges of DNA sequences, laboratory animals, reagents and data that were once subject to a normative expectation of free access are today subject to license agreements, materials transfer agreements and database access agreements. These agreements need to be reviewed and renegotiated before research may proceed, imposing high transaction costs long before the research promises a likely revenue stream that would justify incurring these costs . . .'[13]

KEY POLICY ISSUES AND CONTROVERSIES

In recent years much attention has focused on patent policy questions and controversies stemming from federal legislation promoting technology transfer and commercialization. These issues range from 'double-dipping', whereby consumers must pay twice for discoveries developed with federal dollars, to concerns about intellectual property rights and the resulting decrease in the availability of information and results of research sponsored by the government. Other pressing issues are briefly highlighted below.

Global Health Inequities Associated with Bayh-Dole

Concerns exist regarding tax-funded research being handed over to companies that have been free to set prices which may not reflect priorities of the tax payers.[14]

Cloak of Secrecy Surrounding Agreements

Increasingly, given the threat to research as a result of secrecy restrictions imposed on scientists, some are calling for reform of the Bayh-Dole Act.

Corporate Profitability

The passage of Bayh-Dole has been referred to as 'the fruits of academic research [being] passed from taxpayer funded laboratories directly to the wallets of the pharmaceutical manufacturers'.[15]

Government Use License

The Government Use License provides agencies within the Federal government with the right to use any patented research tool arising in the course of federally-sponsored research without liability for patent infringement.[16]

Government 'March-In Rights'

The Bayh-Dole Act allows for federal government rights to products that were developed with federal funding; and, in recent years, a number of cases exist where the federal government has asserted 'march-in rights'.[17] For example, it has been asserted that if pharmaceuticals have been developed with federal research funding, the government maintains the right to 'march-in' on patented rights and to license them to other producers and manufacturers. In 2001 when concerns regarding use of anthrax for terrorism emerged, the Department of Health and Human Services sought to stockpile large quantities of the pharmaceutical ciprofloxacin (Cipro). The government asserted that quantities to treat 10 million people would be required, claiming that the need was greater than the supply and that the pharmaceutical company manufacturer (Bayer) did not have the infrastructure to produce the doses needed in the necessary time frame.[18] As a result, Senator Schumer requested Secretary Thompson to issue a compulsory license to generic manufacturers.[19]

DISSEMINATION OF FEDERAL RESEARCH TOOLS

As noted above, the Bayh-Dole Act provides a statutory basis for federal technology transfer activities related to patenting and licensing of federally funded inventions by recipient organizations. The Act permits recipients of federal grants and contracts to elect title to patentable 'subject inventions' that arise with the use of federal funds. If recipients elect title, the Act requires them to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions. The Act also retains for the funding agency

certain residual rights in subject inventions. Controversy exists over the use and definition of the term 'research tool' and the IP protection that research tools should be afforded. In the broadest sense 'research tools embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as "end products" '. The term may thus include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software. Although competitive pressures have always given scientists an incentive to withhold new research tools from their rivals, past practices allowed for relatively free exchange, typically without formal agreements and without explicit consideration of commercial rights or potential financial benefits.[20]

Issues in Access to Generic Drugs

Given that federal law allows the US to purchase generic versions of pharmaceuticals directly from manufacturers, there are claims that use of this right could help to significantly reduce consumer prices and increase supplies.[21] In an effort to close loopholes in the Drug Price Competition and Patent Restoration Act of 1984 (Hatch-Waxman Act) that have allowed brand name drug companies to keep generic drugs off the market, Charles Schumer, along with Senator John McCain (R-AZ), of the Greater Access to Affordable Pharmaceuticals Act (GAAP), proposed bipartisan legislation to improve access to generic drugs.[22] The legislation would remove a number of obstacles currently blocking entry of many low-cost generic drugs to the market, including eliminating potential abuses of the 180-day exclusivity period granted to the first generic applicant, which has enabled Bayer to keep lower cost versions of ciprofloxacin off the market. The bill makes the exclusivity period available to the next-filed applicant if the first applicant has reached a financial settlement with the brand-name to stay out of the market until the patents have expired, fails to go to market within 90 days once their application is effective, does not get FDA approval within 30 months, fails to challenge a new patent within 60 days, withdraws their application, or is determined by the HHS Secretary to have engaged in anti-competitive activities.

BASIC QUESTIONS FOR CONSIDERATION

As discussion proceeds on the relevance of Bayh-Dole as it exists today, a number of basic questions requiring further consideration and quantification include:

- What are the costs and benefits associated with Bayh-Dole and how should they be characterized?
- How can the costs of intellectual property and technology transfer be monitored, measured and projected on a global basis?
- How would free dissemination of early stage scientific discoveries by universities enhance follow-on research?
- Would scientific discoveries languish in government and university archives absent patents on government-sponsored research results?
- What type of control of basic research discoveries, including research tools, should academic institutions exercise?
- Is market thinking impeding access to dialogue and free exchange of ideas that are necessary for scientific progress?
- What risks to innovation and commercialization might ensue on a going forward basis if the university technology transfer policy is not revised to reflect 21st century needs?
- Will modernizing the Bayh-Dole Act enhance global health care and delivery and better serve public health and societal needs?

SUMMARY

Increasing access to US government funded science and technology is critically important in a globalized economy. While some health policy experts have argued that proposing changes to the patent laws or the Bayh-Dole Act would be divisive and would be likely to be unsuccessful, I believe that at this important juncture, discussion and analysis about the Bayh-Dole Act requires a step back and a look at both sides of the scale and the inherent conflict contained therein. On the one side of the scale, fostering an open community for research in which free discussion and maximum collaboration can occur is needed for scientific progress. On the other side of the scale, patent protection and financial incentives are critical to foster private sector investment and the commercialization process.

The Bayh-Dole Act of 1980 attempted to establish a balance between these two inherent conflicts and to bridge a gap. And, like all partial solutions, in doing so it has created other issues and challenges that must be addressed.

Development of a 'Bayh-Dole Modernization Act' that fosters equal access to new knowledge, science and technologies emerging from the federally funded R&D and commercialization process, while at the same time enabling IP protection and providing proper incentives, must remain a priority among scientists, industry and policy-makers worldwide.

NOTES

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2. Bayh-Dole Act of 1980, Public Law: 96–517, 12 December, 1980.
3. Stevenson-Wylder Technology Innovation Act of 1980. Public Law: 96–480, 21 October, 1980.
4. Steven M. Ferguson (2002) op. cit.
5. Federal Technology Transfer Act of 1986, Public Law: 99–502, 20 October, 1986.
6. Steven M. Ferguson (2002) op. cit.
7. Steven M. Ferguson (2002) op. cit.
8. Patent and Trademark Act Amendments of 1980, Pub. Law. No. 96–517, 94 Stat. 3015 (codified as amended in 35 U.S.C. §§ 200–212). For background, see 'The Bayh-Dole Act: A Guide to the Law and Implementing Regulations', Council on Governmental Relations (1999) available at http://www.ucop.edu/ott/bayh.html.
9. For example, see the Association of University Technology Managers (AUTM) 'AUTM Licensing Survey' available at www.autm.net/surveys. For additional information, see also, R.R. Nelson (2001), 'Observations on the post-Bayh-Dole rise of patenting at American universities', *Journal of Technology Transfer*, Chicago, Illinois: Technology Transfer Society (January); David C. Mowery, Richard R. Nelson, Bhaven N. Sampat and Ziedonis Arvids A. (2004), *Ivory Tower and Industrial Innovation*: *University–Industry Technology Transfer Before and After the Bayh-Dole Act in the United States*, Stanford, CA: Stanford Business Books.
10. Donald Kennedy (2005), 'Bayh-Dole: Almost 25', Guest Editorial, *Science*, available at www.sciencemag.org/cgi/content/summary/307/5714/1375).
11. See note 10.
12. Judith Gorman (2000), 'Paper cuts: the golden fleece', AlterNet, 13 June.
13. See generally, R. Eisenberg, (1996), 'Public policy and private development: patents and technology transfer in government-sponsored research', *Virginia Law Review*, **82**; Michael A. Heller and Rebecca S. Eisenberg (1998), 'Can patents deter innovation? The anticommons in biomedical research', *Science*, 1 May; and Michael A. Heller (1998), 'The tragedy of the anti-commons', *Harvard Law Review*, **111**; Arti Rai and Rebecca Eisenberg (2003), 'Bayh-Dole reform and the progress of biomedicine', *American Scientist* **91** (1).
14. 'Innovation's golden goose', *The Economist* 365 (2002); For a recently proposed model of university licensing that could help alleviate access to medicine issues in developing nations, see Amy Kapczynski, Samantha Chaifetz, Zachary Katz and Yochai Benkler (2005), Addressing global health inequities: an open licensing approach for university innovations', 20 *Berkeley Technology Law Journal* 1031.
15. See generally, Ralph Nader, James Love, Robert Weissman, letter to Dr Harold Varmus, Director of NIH, asking for NIH to give the World Health Organization, WHO, access to US government funded medical inventions, 3 September, 1999; Letter from NIH Director, Dr Harold Varmus to Ralph Nader, James Love and Robert Weissman responding to their request calling on the NIH to provide the World Health Organization, WHO, access to US government funded medical inventions, 19 October 1999.
16. See generally, 35 U.S.C. 202(c)(4).

17. March-in rights, including procedures, are described at 37 CFR Part 401.6. For background information, see B.M. McGarey and A.C. Levey, 'Patents, products and public health: an analysis of the CellPro march-in petition' 14 *Berkeley Technology Law Journal* passim; Mary Eberle, (1999) 'March-in rights under the Bayh-Dole Act: public access to federally funded research, 3 *Marquette Intellectual Property Law Review*. 155; Tamsen Valoir, (2000) 'Government funded inventions: the Bayh-Dole Act and the Hopkins v. CellPro march-in rights controversy', 8 *Texas Intellectual Property Law Journal*. 211.
18. See generally, Consumer Project on Technology, www.cptech.org/ip/health.
19. Charles E. Schumer (2001), 'New Cipro source could dramatically increase supply', press release, 16 October.
20. Report of the National Institutes of Health (NIH); Working Group on Research Tools, 4 June, 1998.
21. 'Greater Access to Affordable Pharmaceuticals Act (GAAP) will save consumers billions by making less-costly generics available', *Public Citizen*, 8 May, 2000; *Public Citizen*, 'Legislation closing loopholes in Drug Patent Law (S. 812/H.R. 5311, H.R. 5272) will help assure consumers access to lower-priced generic drugs' 21 August, 2002; available at www.citizen.org.
22. See generally, Greater Access to Affordable Pharmaceuticals (GAAP) Act, S. 812/H.R. 1862.

APPENDIX 8.1

SELECTED TECHNOLOGY TRANSFER LEGISLATIVE MILESTONES

(Source: http://www.dtic.mil/techtransit/refroom/laws)

Stevenson-Wylder Technology Innovation Act of 1980 (PL 96-480)[15 USC 3701-3714]

- Focused on dissemination of information.
- Required Federal Laboratories to take an active role in technical cooperation.
- Established Offices of Research and Technology Application at major federal laboratories.
- Established the Center for the Utilization of Federal Technology (in the National Technical Information Service).

Bayh-Dole Act of 1980 (PL 96-517)

- Permitted universities, not-for-profits, and small businesses to obtain title to inventions developed with governmental support.
- Provided early on intellectual property rights protection of invention descriptions from public dissemination and FOIA.
- Allowed government-owned, government-operated (GOCO) laboratories to grant exclusive licenses to patents.

Small Business Innovation Development Act of 1982 (PL 97-219)

- Required agencies to provide special funds for small business R&D connected to the agencies' missions.
- Established the Small Business Innovation Research Program (SBIR)

Cooperative Research Act of 1984 (PL 98-462)

- Eliminated treble damage aspect of antitrust concerns of companies wishing to pool research resources and engage in joint precompetitive R&D.

- Resulted in Consortia: Semiconductor Research Corporation (SRC) and Microelectronics and Computer Technology Corporation (MCC), among others.

Trademark Clarification Act of 1984 (PL 98-620)

- Permitted decisions to be made at the laboratory level in government-owned, contractor-operated (GOCO) laboratories as to the awarding of licenses for patents.
- Permitted contractors to receive patent royalties for use in R&D, awards, or for education.
- Permitted private companies, regardless of size, to obtain exclusive licenses.
- Permitted laboratories run by universities and non-profit institutions to retain title to inventions within limitations.

Federal Technology Transfer Act of 1986 (PL 99-502)

- Made technology transfer a responsibility of all federal laboratory scientists and engineers.
- Mandated that technology transfer responsibility be considered in employee performance evaluations.
- Established principle of royalty sharing for federal inventors (15% minimum) and set up a reward system for other innovators.
- Legislated a charter for Federal Laboratory Consortium for Technology Transfer and provided a funding mechanism for that organization to carry out its work.
- Provided specific requirements, incentives and authorities for the Federal Laboratories.
- Empowered each agency to give the director of GOCO laboratories authority to enter into cooperative R&D agreements and negotiate licensing agreements with streamlined headquarters review.
- Allowed laboratories to make advance agreements with large and small companies on title and license to inventions resulting from Cooperative R&D Agreements (CRDAs) with government laboratories.
- Allowed directors of GOGO laboratories to negotiate licensing agreements for inventions made at their laboratories.

- Provided for exchanging GOGO laboratory personnel, services and equipment with their research partners.
- Made it possible to grant and waive rights to GOGO laboratory inventions and intellectual property.
- Allowed current and former federal employees to participate in commercial development, to the extent there is no conflict of interest.

Executive Orders 12591 and 12618 (1987): Facilitating Access to Science and Technology

- Promoted the commercialization of science and technology.

Omnibus Trade and Competitiveness Act of 1988 (PL 100-418)

- Placed emphasis on the need for public/private cooperation on assuring full use of results and resources.
- Established centers for transferring manufacturing technology.
- Established Industrial Extension Services within states and an information clearinghouse on successful state and local technology programs.
- Changed the name of the National Bureau of Standards to the National Institute of Standards and Technology and broadened its technology transfer role.
- Extended royalty payment requirements to non-government employees of federal laboratories.
- Authorized Training Technology Transfer centers administered by the Department of Education.

National Institute of Standards and Technology Authorization Act for FY 1989 (PL 100-519)

- Established a Technology Administration within the Department of Commerce.
- Permitted contractual consideration for rights to intellectual property other than patents in cooperative research and development agreements.
- Included software development contributors eligible for awards.

- Clarified the rights of guest worker inventors regarding royalties.

National Competitiveness Technology Transfer Act of 1989 (PL 101-189)

- Granted selected federal laboratories opportunities to enter into CRDAs [Cooperative Research and Development Agreements] and other activities with universities and private industry, under essentially the same ways as highlighted under the Federal Technology Transfer Act of 1986.
- Allowed information and innovations, brought into, and created through cooperative agreements to be protected from disclosure.
- Provided a technology transfer mission for the nuclear weapons laboratories.

APPENDIX 8.2

DEFINITIONS RELATED TO TECHNOLOGY TRANSFER AND RESEARCH TOOLS

(Source: Report of the National Institutes of Health (NIH), Working Group on Research Tools, Presented to the Advisory Committee to the Director (4 June, 1998); Available at http://www.nih.gov/news/researchtools/appendb.htm)

The **Bayh-Dole Act**, 35 U.S.C. §§ 200–211, provides the statutory basis and framework for federal technology transfer activities, including the patenting and licensing of federally funded inventions by recipient organizations. The Act permits recipients of federal grants and contracts to elect title to patentable 'subject inventions' that arise with the use of federal funds. If recipients elect title, the Act requires them to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions. The Act also retains for the funding agency certain residual rights in subject inventions.

The **Federal Technology Transfer Act of 1986***,* 15 U.S.C. 1301 *et seq.*, supplements the Bayh-Dole Act with regard to the technology transfer activities of federal laboratories, authorizing, among other things, cooperative research and development agreements (CRADAs), retention of royalties, and royalty-sharing with employee-inventors.

Subject Inventions are defined by the Bayh-Dole Act regulations (37 C.F.R. 401.2(d)) as any invention of a party to a government funding agreement conceived or first actually reduced to practice in the performance of work under the funding agreement.

A **patent** is a document issued by the Department of Commerce Patent and Trademark Office (PTO) under authority of the United States Constitution and other laws and implementing regulations. A patent contains a narrative description of the subject matter covered by the patent called the *specification*. It also contains one or more *claims* that describe the subject matter covered by the patent in highly technical and specific terms, much as the metes and bounds of a survey might exactly describe and identify the land conveyed by a deed. A patent represents the right to exclude others from making, using or selling the subject matter described

by the claims of the patent. Virtually every country in the world provides its government with the right to issue patents in order to allow patent owners to exclude others from using the patented subject matter within its borders. In the United States, only the person or people who invent the subject matter have the right to obtain a patent. However, it is commonplace for employers to require employee-inventors to assign to the employer the right to seek the patent, and therefore the ownership of the patent.

A **license** is a contract between the owner(s) of the subject matter of the license and one or more parties that seeks the right to make, use, sell or import the subject matter of the license. Commonly, a license conveys rights to patented subject matter, but it may also convey rights to tangible subject matter that is not unpatented. Licenses are negotiated agreements that become binding contracts when signed by the parties. In the United States, only one owner need sign a license if the subject matter is patented. Thus, a patented technology co-owned by three parties can be licensed by one of the parties without the other owners' knowledge or consent. This is not so in most European countries, which require that all owners join in any licenses. Although licenses generally address a standard set of legal issues, there is no standard license or license term. The terms negotiated into licenses by the parties are as varied as the circumstances driving the agreement.

Standard issues addressed by negotiated **license terms** include:

- the general use that may be made of the subject matter (research use, commercialization);
- whether only one party is obtaining rights (exclusive), more than one but still only a few (co-exclusive), or potentially many (non-exclusive);
- the specific type of applications which may be pursued by the party (field of use to develop vaccines, diagnostic products, therapeutic products, human uses, veterinarian uses):
- royalty rates, or how much the user will pay the owner for the rights conveyed by the license (fee upon signing, annual fee, % of net sales, reimbursement of patent costs, costs of enforcing and defending the patent).

A **material transfer agreement** (MTA) is a negotiated contract between the owner of a tangible material and a party seeking the

material and the right to use the material for research purposes. The material may be either patented or unpatented. Material transfer agreements tend to be shorter than license agreements, and they are generally considered to be more informal than licenses agreements, although both are enforceable contracts. The purpose of an MTA is to document the transfer and outline the terms of use, including identification of the research project, terms of confidentiality, publication and liability. As with licenses, there are no standard MTAs, although the academic community and NIH developed an under-used model MTA for biological materials called the Uniform Biological Material Transfer Agreement (UBMTA). MTAs do not usually require financial payments at the time of the transfer, but many MTAs allow the provider to either own, or license exclusively, or obtain payments upon the sale of, developments that the recipient makes with the provider's materials. These are loosely called 'reach-through' provisions, and are considered by many providers to be desirable because they allow the provider to obtain rights in subject matter that the provider would not otherwise have rights to through its ownership or patent coverage of the material alone. Reach-through provisions are considered undesirable by many recipients because they burden all the developments created after the use of the material, and because they are seen as providing an unfairly high level of compensation to the provider for use of the material.

A **sponsored research agreement** is a negotiated contract between two or more parties, typically an academic research institution and a private corporation, under which the private corporation provides financial support to the research laboratory in return for an option to license any patentable subject matter that arises out of the research. As with licenses and MTAs, sponsored research agreements contain widely variable provisions because they are negotiated on a case by case basis. Terms may include: delay of or editorial power over, academic publications related to the research; future license terms; ownership of any intellectual property arising out of the research, confidentiality provisions, and so on. The research carried out under the sponsored research agreement may be either collaborative, carried out with the corporate partner, or solely conducted by the university.

An **NIH grant** is government financial support of an academic biomedical research project. Numerous federal laws, regulations and policies apply to NIH grants and follow the funding into the research project. Among those are laws allowing the grantee to

elect title to and own the intellectual property arising out of the grant, and encouraging the grantee to patent and license such intellectual property. NIH grant funds and funds provided by corporations under sponsored research agreements may be comingled into the same biomedical research project, as long as the grantee is able to reconcile the requirements of both the sponsored research agreement and the NIH grant requirements. Because certain provisions, including those related to publication and license options requested by corporate sponsors, are considered to be incompatible with NIH grant requirements, the NIH issued a guidebook for grantees called *Developing Sponsored Research Agreements: Considerations for Recipients of NIH Grants and Contracts* to assist grantees in ensuring that all sources of project funding are compatible.

Unique Research Resources are defined by NIH grants policy as resources developed during the conduct of NIH-funded research which are necessary for further studies. Categories of these resources include: synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data.

PART III

IPRs, pharmaceuticals and biotechnology

9. Pharmaceutical innovation and intellectual property rights: a global public good?

David Goren

INTRODUCTION

In the course of this chapter I will address the question of how a new balance must be achieved between rewarding innovative pharmaceutical research, while meeting the needs of a growing public demand for innovative health care solutions at lower prices. The pharmaceutical industry is in a transition phase.

An unusual social contract has prevailed over the past decades between innovative pharmaceutical research companies and the societies they serve. This balance permitted high risk to be highly rewarded. However, this covenant is breaking down – as equilibrium moves to instability.

It is with this environmental shift in mind that I propose a fresh examination of the needs of the parties (that is, those doing research, and those benefiting from it) in order to achieve a new balance between what research companies do and what is expected of them.

In order to understand possible alternatives to the current IP structure, it is necessary to define the components of IP, and identify those that are failing, or at least leading to failure. Once the problem areas are defined, I will shift to describing (or explaining) the rewards and difficulties we find in society, which at least in part, derive from the problem areas defined. This will be followed by an analysis and discussion of solutions and their global implications.

BENEFITS AND PROBLEMS ARISING IN PHARMACEUTICAL INTELLECTUAL PROPERTY RIGHTS

The most significant dilemma facing the world today in health care is a mismatch between society's ability to pay and its demand for innovative health care solutions, at least at current prices.

Many have blamed 'patents' (intellectual property rights) for this price gap, or more simply, Patent = Monopoly = BAD.

I propose that patents and other forms of IP specific to pharmaceuticals are the most important success factors for pharmaceutical research, and not, as commonly claimed, responsible for the problem. What is needed, instead, is a revised balance between expectations and ability to deliver, and at what cost.

But first, let us list the various forms of intellectual property mechanisms, including those that are pharmaceuticals-specific (*):

1. Patent (plus patent term restoration*)
2. Trademark
3. Copyright
4. Data exclusivity*
5. Orphan drug*
6. Pricing

These forms of IP are commonly granted in Western countries. In fact, in the United States, it is codified in the Constitution: '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.'

A patent is a tradeoff between public and private benefit. It provides the innovator with an incentive to release information and knowledge (the invention) into the public domain, in exchange for providing an *artificial* (legal) form of protection. Were the property physical, it could benefit from various forms of *physical* protection, against unfair use. A fence could be built, for example. Due to its *intellectual* nature, it requires *special* protection, or a legally constructed *fence*.

Trademarks and copyrights, other forms of IP, have the added benefit for consumers, as they assure the consumer that his/her purchase is genuine. Trademarks protect the owner from 'cheap' copies, a reward for building market demand, and they also protect the consumer from mistakenly purchasing these 'cheap' copies. Trademarks also provide the consumer with valuable information on the origins and, subsequently, on the quality of the product. The consumer knows that when buying a 'Gucci' bag, it is the 'real' thing; that the product is of a certain quality. This information also fulfils the social status function. The reward will go to the innovator. A cheap copy allowed to flourish rewards the wrong person and 'fools' the consumer.

Copyrights perform a similar function for writers of various types. When you 'invent' a book, a copyright assures that only you (and your publisher)

will reap the rewards of that creation. Likewise, the reader can be assured that the reputation you have built as a writer will be reflected in the novel, to the extent that the writer lives up to the standard s/he has set. Creating art is an agonizing process; duplication is much simpler. In short, consumers know they got the 'real thing'.

The last category, pricing, may surprise you. Why is pricing an intellectual property right? I believe that pricing is an important, if not the most important, component of intellectual property rights. What could be more critical, than an innovator's right and/or ability to exploit his/her invention to the maximum ability to make a profit? In actuality, that is the essence of the incentive – the inventor's ability and right to set the price, according to what the market will bear.

All of these forms of 'artificial' protection provide an incentive where otherwise one would not exist naturally (that is, barriers to entry). In addition to these general provisions, there are protections which have been developed and granted specifically to pharmaceutical invention.

PHARMACEUTICAL-SPECIFIC INTELLECTUAL PROPERTY RIGHTS

There are several aspects of IP which are specific to pharmaceuticals. The first, patent term extension, is a 're-instatement of patent life "lost" during registration'. This recognizes the unusual delay in pharmaceuticals due to the registration process and other government requirements unique to medicine approval.

A second unique IP provided to drug research, is data protection or secrecy of the registration file, which contains trade secrets. In exchange for sharing these research data, above and beyond what is required for patent registration, but required by health authorities for approval, governments promise not to share or rely upon these new and confidential data for a fixed period of time.

Finally, the Orphan Drug Act provides additional incentives to pharmaceutical companies to bring medicines to patients where the financial incentives would not naturally be there.

The current system has brought many innovations which otherwise would probably have remained unavailable, resting in a lab. The American orphan drug law is responsible for introducing many new medicines, for a relatively small number of patients, but ones who otherwise would be suffering greatly.

In a Forbes article reviewing commercializing orphan drugs (Act 1983), it was concluded that 'What's *not* lacking are drugs to test' (emphasis added).[1] In fact, the problem is in providing funding. The article goes on to

describe a non-profit organization created to bring such medicines to the target populations, noting that the key problem is funding research. In fact, 11 medicines received FDA approval for orphan designation in 2003, and six in 2002.[2]

The FDA created a category for medications used to treat 'rare diseases'[3] meaning any disease or condition which (A) affects fewer than 200 000 persons in the United States, or (B) affects more than 200 000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. (Orphan Drug Act, as amended, SEC. 526 [360bb]. (a)(2).)

Orphan drug status gives the manufacturer specific financial incentives to provide the drug. Orphan drugs are controlled by the FDA's Office of Orphan Products Development (OOPD), including separate data protection[4] and supplemental research funding. Clinical trials are awarded grants from $100 000 to $200 000 per year in direct costs for up to 3 years.[5]

Why are unique forms of protection provided to pharmaceuticals in most western countries? There is obviously a benefit to society served by such *special* protections. The need is based on the distinctive 'social contract' between innovative pharmaceutical companies and the people they serve. On the one hand, society wants to provide adequate reward/incentive to the innovator to continue to innovate and bring the results to patients; while on the other hand, we ensure society's maximal access to such innovations.

Then along comes the social factor – is health care a *right* or a *privilege*? Whose responsibility is it to provide health care? Who should finance it? These are mostly questions that are beyond the scope of this chapter, though they must be answered by each society, as defined by ability to pay, and need to provide, matched to that society's expectations from its *provider/payor system*.

Health care consumers are becoming more educated and consequently more demanding. Pharmaceutical IPR is at the crossroads of two systems whose conflict has led to the current crisis – the social system provided by governments to their constituents, and the free-market, for-profit operations of pharmaceutical corporations. The government is charged with improving society's lot, while the corporation is responsible for maximizing shareholder wealth. Yet, somehow, together, they must provide the next generation of health care invention – which you and I will need to enjoy our goal of healthier, happier and more prosperous lives.

A substantial trigger for rethinking this balance is the ageing societies of the western world, resulting in greater demand for health care services while simultaneously reducing tax revenue needed to finance health care. For

Table 9.1 The ageing of American society

	% Americans 65+	% Americans 85+
2000	12.7	1.6
2010	13.2	1.9
2020	16.5	2.1
2030	20.0	2.5
2040	20.5	3.8
2050	20.3	4.8

example, it is estimated that in 2050, the percentage of Americans aged 65 and over will almost double (see Table 9.1).[6]

In addition, certain disease prevalence is increasing alarmingly. According to the International Diabetes Federation, 'In 1985 an estimated 30 million people worldwide had diabetes, and in 2000, little over a decade later, the figure had risen to over 150 million. This figure is expected to rise to almost 333 million by the year 2025.'[7]

A second and no less important factor is the great need but inability of third world countries to pay their own way and provide better access to all aspects of health care to their constituents. The current economic stagnation in some parts of the world has also accelerated the phenomenon. Not a day goes by without some significant article in a major journal which describes the 'new health care crisis'.

Though this system worked well into the 20th century, there is clearly a need to make adjustments and prepare for new health care innovations which will demand different incentives, as well as ensure the more even distribution of innovation across the globe. Large rewards were paid to those who innovated; creating some of America's largest and wealthiest corporations – by all measures a great American success! A new era of targeted therapies could either 'break the bank' or possibly save the system from bankruptcy, but our ability as an industry to commercialize our knowledge and profit from it will determine the outcome.

Though it is beyond the scope of this chapter to address the incentives to patients and providers, there is a critical need to rethink these structures as well. Exploration of how we encourage patients to seek treatment, and practitioners to deliver care will be a critical piece of the puzzle. These incentives are related only tangentially to intellectual property concerns, though they have direct impact on the ability of both society and the inventor to benefit from inventions.

This shortage of services *vis-à-vis* willingness to pay is the shift in balance which created disequilibrium. In many countries, it has also caused a shift

of the pharmaceutical financial burden to patients, which is different from most other elements of the health care care equation.

In many countries, in the year 2000, already more than 50 per cent of the financial burden was borne by the private sector (including patient co-pays), according to the WHO. These countries include Mexico, Korea, Brazil, China and India, where patients pay most of the bill out-of-pocket. In the US and South Africa the private sector burden is largely funded through private insurance.

In the UK, Japan, France, Germany, Australia, Canada and Spain, the private and co-pay burden is growing, though is currently less than 50 per cent.

CREATING A NEW BALANCE: PROPOSED SOLUTIONS

When designing a solution to the current global IP predicament, one must consider the following principles:

1. Innovation must be rewarded *adequately* to account for relative risk (otherwise investment will go to other areas of innovation).
2. Rewards must find their way to the most efficient innovators (or participants in the innovation chain).
3. Intellectual property rights are more critical to pharmaceutical innovation since they are one of the only and therefore, most important institutions ensuring proper reward.
4. Health care intellectual property rights must be adequately defensible to reward innovation, yet must not become an impediment to technology transfer, especially to those who are less able to pay.
5. One must include pricing in any form of discussion of pharmaceutical intellectual property rights since it represents the ultimate form of an innovator's ability to exploit his/her invention for profit/reward.
6. A solution must be global to avoid the free-rider phenomenon existing today.

Health care financing is undergoing a period of disruption as health care financiers (mostly governments) are faced with declining resources to meet increasing needs. The answer will certainly not be to attack the source of the solution – pharmaceutical IPRs. The removal of the so-called 'monopoly' of a patent will not solve the world's health care problems. In fact, it will kill the innovative engine which is our best hope for delivering solutions to today's health problems.

It is true that our industry is profitable; while it is also true that a higher percentage of that profit has been ploughed back into R&D than in most other industries – that R&D which has delivered significant improvements in health status around the world. Research by pharmaceutical companies had tripled since 1990, to approximately $32 billion in 2002.[8]

According to a 2003 PhRMA paper,[9]

> on average, a pharmaceutical company's R&D to sales ratio is higher each year than those of companies such as Microsoft, Boeing, and IBM. Data collected from the National Science Foundation show that although the pharmaceutical research industry recorded only 2.5 percent of the domestic sales of companies that conducted R&D in 1998, it accounted for 8.7 percent of all company-funded R&D, 18.7 percent of all company-funded basic research, and 4.8 percent of all research scientists and engineers.

The challenge to improving global health has been access – ensuring that the world's population has maximum access to the finest medical technology, rather than limiting it. The United States has led the way in terms of creating appropriate incentives for pharmaceutical research and has moved into first place in terms of delivering such innovation.

Even in the poorer countries, the health care problem has been more due to access than patents. An LA Times writer, Joel Hay,[10] notes in response to the California Legislature initiative to purchase medicines on the internet from Canada, that 'if brand-name manufacturers set global prices for drugs, billions of people in Africa, Asia and Latin America would simply be locked out of the new drug market.' He goes on to point out the economic benefit which the State of California derives from pharmaceutical innovation. Haye goes on to describe the decline of vaccine research in the US as a result of the price controls and the consequential removal of free market financial incentives.

In some cases, our success as the pharmaceutical industry is our current threat. Take, for example, oncology. The losses to society from cancer are huge ($189 billion),[11] yet the progress in successful treatment is monumental. 'New drugs have enabled doctors to almost double median length of survival for advanced colon cancer in the last five years' according to Catherine Arnst, in a June 2004 *Business Week* article. While it is easy to see the value of 'curing' cancers, the huge increase in cost of treatment has caught the attention of the public and politicians. For example, 'the wholesale cost to treat a single colon cancer patient has shot up from $500 in 1999, to $250 000 today'.[12] Arnst goes on to note that 'insurers have been willing to pay so far because drugs are still cheaper than surgery'. Note that insurers (or payors) are setting our standard of health care rather than consumers, physicians, policy-makers, and so on. She goes on to explore the

cynical equation of these financiers, as 'patients haven't lived long enough to become a huge cost burden'.

Who benefits from that longer life? Society gets extra output, the patient gets extra family time – what is the value of an extra day? Week? Year? As survival rates increase, we can expect the additional 'burden' to become even more central in the debate, as insurers struggle with their own profitability. In fact, the cost of disease is significant. A recent Duke University study, concluded that the top six diseases cost each American family almost $20 000 per year in lost national income. The largest estimated cost of $359 billion is attributable to cardiovascular disease.[13]

One could view increasing health care costs as a zero sum game. In other words, there is a fixed pie for health care and everyone must fight for what they can get. Or, we can search for the win–win which leaves *adequate* profits for all. We (society) will need to decide whether we want to allocate more of our resources to transactions (insurance payment processes and limitations on health practice) or to innovation (new medicines, devices and procedures).

Targeted treatment, to the patients with the highest likelihood of success, through R&D or diagnostics, would lead to more cost-efficient health care. This can be achieved by providing the appropriate incentives in IP to focus innovation in these areas. Rather than focusing on how to lower 'cost', it would benefit everyone if we saw health care and associated IP as an investment which must be made wisely, for the best outcomes, as defined by society. Though present budget problems can be overwhelming, we must not lose track of future generations and our obligation to provide for their needs.

What is the value of an extra year of life? The personal value and the value to society? The *Business Week* article describes an example of a patient who should have 'given up', but had access to new lung cancer medicines (one still experimental in the research phase), and is alive as a result of the treatment. Society should be willing to pay for the 'benefit' derived from the pharmaceutical company investment.

There is a direct conflict between our desire to have the most innovative health care system (including and maybe most importantly pharmaceuticals), and our ability and/or willingness to pay for such innovation. No other model of innovation has worked as well as the IP-reward system, which has generated the greatest technological (pharmaceutical, device, procedure, and so on) advances in health care ever. What has not advanced at a similar pace, is the 'system'. The same *Business Week* article reports that the recent oncology conference (ASCO the 'premier cancer meeting') generated much excitement around new treatments, while devoting no time to costs or how to finance providing these new treatments to patients. We

demand the best health care, almost treating it as a basic right, while we have not yet worked out the best financing system to get us through the impending age shift.

Therefore, I propose a global agreement on pharmaceutical intellectual property protection and exploitation. Such agreement would require that:

1. All member countries provide the minimum protections including patent, trademark, copyright, data protection, orphan drug, free market pricing;
2. Pharmaceutical companies register their products in all markets within a specified period of time, such as five years, in order to benefit from this package;
3. Free-market pricing prevail, while consideration be given to ability to pay, as classified by a world-recognized body;
4. Such a system would likely increase pharmaceutical prices in wealthier countries like France and Germany, while greatly improving access in poorer countries to the full range of medicines at significantly lower prices.

CONCLUSION

I believe that any solution to the current health care IP crisis requires that society maintain the appropriate profit motive in rewarding innovation and allow the free market to operate properly, while balancing public interest. However, this requires that all join hands and play fairly. As the world becomes ever more global, the rules will also need to be more global. And as the rules become more global, there will need to be a system that allows companies to effectively implement free-market variable pricing.

The way out of the current 'crisis' is to move toward compromise. Compromise, by definition, means that not everyone will get exactly what they want. To reach a compromise let us first identify the three major 'players' – the ones who pay for, the ones who provide (including pharmaceutical companies) and the ones who receive the care. One could simplify further and argue that payor and receiver are one and the same.

A middle ground will need to be found between the demands of the receivers and the abilities of the providers and financiers. It will be incumbent upon governments to act responsibly and globally. Some of the wealthier countries, free-riding off others, have been purchasing medicines at prices below what companies want to charge, taking unfair advantage of their massive buying power. These countries are not allowing the market to operate freely.

I believe we must remain true to the free market ideal for pharmaceutical R&D, and the future of health care innovation. There remains a critical need for strong IP and access to new technologies in order to continue to encourage good health, a key factor also for economic growth. Effective IP should provide the incentive to invest, otherwise why would an investor trust their dollars in our hands – if they can make more money putting it in someone else's?

It is worthwhile to note that the current pipeline 'crisis' of large pharmacentical companies is actually stimulated by IP. The expiration of patents and other forms of protection have set in motion a process by which research-based companies are extremely anxious to acquire new technologies and research (and ultimately medicines). It is how they will provide value to stakeholders, including shareholders. It will result in an even greater search for new, profitable chemical entities to solve the world's health problems.

Effective IP protection is not meant to provide the research-based pharmaceutical companies with a 'recoup cost' incentive, rather a 'big bang' incentive, in order to fund the next generation of innovation. It does that both by the immediate return, but even more, by the message it sends to all innovators, that the right innovation in health care can make 'big bucks'. A high-risk industry needs that. In order to achieve a new balance in health care, new thinking is needed. The current zero-sum attitude will need to be abandoned, and a global approach will be needed, with cooperation between industry, governments and the general public.

> To reward inventions 'by privileges leading to monopoly positions cannot . . . be regarded as beneficial to the welfare of a country'
>
> *Johann Heinrich von Justi, 1758*

> 'that he, the inventor, ought to be both compensated and rewarded . . . will not be denied . . . it would be a gross immorality of the law to set everybody free to see a person's work without his consent, and without giving him an equivalent'
>
> *John Stuart Mill, 1848*

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10. The realities of TRIPS, patents and access to medicines in developing countries

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The question of patents and access to medicines in developing countries has been a controversial and often emotional debate for years, particularly since the WTO Ministerial Meeting in Seattle, USA in 1999. Often, the relationship between patents and access to medicines in developing countries is presented as a simple equation: the stronger the patents, the less access to medicines. In the media, the perceived conflict between patents and access to medicines is presented even more starkly: a child suffering from late-stage AIDS is presented on-screen and the viewer is informed that, if only the AIDS drugs were affordable, the child would live, but the price of the patented drugs are far beyond what the child's family can afford. The program then cuts to an interview with a pharmaceutical industry executive, who speaks about the importance of intellectual property rights for future innovation, which is why patents should be upheld, even in developing countries. The viewer is thus left with the following impression: the child will die because the companies holding the patents on the drugs which he or she needs want to protect their profits.

Given this presentation of the situation, it is only human to conclude that, if patents on drugs are resulting in the deaths of so many people around the world, they should be weakened or even dropped when they prevent people from getting the medicines they need. Indeed, health and consumer activists are advocating weakening of patents on pharmaceutical products, arguing that such actions will make drugs more affordable and more available to people in need. This critique by some activist groups can be summarized by a press alert released by Oxfam and the Treatment Access Campaign (TAC) of South Africa, asserting that a particular company, 'by aggressively enforcing its patents in poor countries, is pricing life-saving drugs beyond the reach of millions of poor people'.[1]

It is true that access to essential medicines is a major problem in many developing countries and can be one even among impoverished populations

in industrialized countries. Indeed, the WHO estimates that about one-third of the world's population lacks access to essential medicines.[2] Given the vital role that quality medicines play in saving lives and improving health worldwide, ameliorating this lack of access should be a global priority. Thus, in examining policies to ameliorate this problem of access, policy-makers and the public at large often pose questions and concerns regarding the role of patents in the access to medicines debate.

This chapter will, therefore, examine the bases upon which the critique of patents as a possible barrier to access is based. In particular, the following assumptions will be examined:

1. Essential drugs are patented drugs;
2. Generics are always cheaper, as patents on medicines make them more expensive to the consumer due to monopoly pricing power given to the patent holder;
3. The WTO/WIPO Treaty Regarding Intellectual Property Rights (TRIPS), which mandates an international minimum standard for intellectual property protection for all WTO members, including developing countries, perpetuates an unfair system detrimental to the interests of developing countries.

Based on these assumptions, some countries and health activists propose that unauthorized copies of patented drugs (either bioequivalent generics or chemically equivalent *similars*) should not be barred from entering markets where patents are in place but people do not have sufficient access to them. Advocates of this point of view argue that access to medicines will be expanded and improved if governments follow the following policies:

1. Governments should nullify the patents on medicines essential for addressing the health needs of their countries and permit local copy producers to manufacture these drugs without the authorization of the patent holder. This action is termed issuing a *compulsory license*;
2. Where the patented products are available on the world market at a lower price than available domestically, the government should allow the free import of these drugs into their country, even though such importation is normally a violation of the rights of the patent holder. Such importation without the authorization of the patent-holder is called *parallel importation.*

THE PATENTING OF ESSENTIAL DRUGS

The World Health Organization (WHO) has compiled a list of over 300 medicines which it deems as being essential for every country in the world to have available to treat their citizens. The 'Model Essential Medicines List' or 'EML' (formerly known as the 'Model Essential Drugs List' or 'EDL') is based upon the recommendations of an expert committee selected by WHO and has been in existence for almost 30 years.[3] It is used by many developing countries as a guide to which drugs should be included in their national essential drug lists and medicines programs. As such, it is a good model for determining which drugs are internationally recognized as being needed for addressing the health care needs of developing countries and if access to these drugs is indeed blocked by patents.

Professor Amir Attaran examined exactly this question in a recent article.[4] He looked at the patent status of the 319 drugs on the WHO EML and researched if there were active patents on them in sub-Saharan African countries and in least-developed countries outside Africa, as well as selected mid-income developing countries. The total population covered was more than 4 billion people, roughly two-thirds of the world's population and the majority of people living in developing countries. He found that only 17 essential drugs were patentable, although not actually patented, so that the overall patent incidence is low (1.4 per cent) and concentrated in larger markets.[5] The conclusion that he drew is that, 'Patents cannot cause essential drugs to be inaccessible in "many" developing countries because they do not exist 98.6 per cent of the time'.[6]

Why are patents so rare on essential drugs in developing countries, especially poor countries? Much of the WHO list includes substances that were never patented (such as oxygen) or drugs whose patents have expired. Furthermore, companies do not patent every product everywhere in the world. Patents are granted on a national basis and are enforced nationally;[7] thus, getting a patent granted involves paying legal costs, official translation costs and application fees, in each individual country. Furthermore, countries require that the patent-holder pay a maintenance fee so that his or her patent does not elapse; this fee in many cases increases towards the end of the patent life. Finally, the patent holder must assume that he or she will need to pay legal fees to defend his or her patent against infringement. All of these costs mount up dramatically.[8] Given the costs associated with maintaining patents, applicants choose to patent their products only in those countries in which having and enforcing a patent make commercial sense. Given the low commercial market potential in least-developed and low-income developing countries, it is not surprising that companies generally choose not to incur the expenses involved in patenting their products in those countries.

One can argue, however, that access to the few patented drugs on the EML is nevertheless limited due to the impact of patents on these drugs. The majority of these patented EML drugs are anti-retroviral AIDS drugs, as well as some products used to treat AIDS-related diseases and malaria.[9] It is true that large populations in desperate need of these particular medicines are not receiving them – for example, although WHO has set a target of having 3 million people receive sustainable ARV treatment by 2005, as of December 2004 only about 700 000 AIDS patients in developing countries were receiving such treatment.[10] Some spokespersons representing generic AIDS drugs manufacturers argue that generic copiers could supply these markets, but the patents on these drugs block them from doing so.[11] Thus, according to these spokespersons, the solution for promoting access to patented medicines on the EML is to weaken or eliminate patents on them so that alternative suppliers could enter the market. Such a perspective has also been put forward by governmental officials – EU Trade Commissioner Pascal Lamy suggested such an idea at the Seattle WTO Ministerial Conference in 1999.[12]

But would weakening patents on these drugs actually be the solution for increasing access to them? A closer examination of the patenting of anti-retrovirals in low-income developing countries, as well as specifically in sub-Saharan Africa, shows that these products are generally not patented in most of these countries (South Africa is an exception due to its unique market structure in Africa). In a 2001 survey of patents on 15 antiretroviral drugs in 53 African countries, Prof Amir Attaran and Ms Lee Gillespie-White found that 'these antiretroviral drugs are patented in few African countries (. . .) and that in countries where antiretroviral drug patents exist, generally only a small subset of antiretroviral drugs are patented.[13] Furthermore, some companies (such as Roche and Bristol-Myers-Squibb) have publicly announced that they will not enforce patents on their anti-retroviral products in sub-Saharan Africa and/or least developed countries. Thus, for many countries with high prevalence of HIV in their population, patents on many (if not all) antiretrovirals do not exist or are not enforced. Generic copiers could thus introduce their products into these markets if they wished to do so. However, given the low purchasing power of people in these markets, generic companies generally do not enter these markets, or the products are offered at prices similar to those being offered by the multinational innovator companies.

Indeed, contrary to a widely-held assumption that copy drugs are cheaper than patented, originator medicines, price comparisons based on data accumulated by Medicins Sans Frontières and analysed by the Hudson Institute show that, in many cases, the prices of antiretrovirals in low-income countries from the originator are comparable or even below the

prices offered by generic companies.[14] This is valid for a variety of countries and also applies to the few antiretroviral drugs which are patented in several developing countries, including low-income developing countries. These low prices for patented antiretrovirals come about through individual company decisions, of course, but the overall access to these medicines by developing countries is facilitated through the Accelerating Access to AIDS drugs Initiative (AAI), a partnership of five international organizations and seven multinational drug companies to help expand access to antiretrovirals in Africa and other regions dealing with the AIDS pandemic.[15] Thanks to AAI, well over 150 000 people living with AIDS in Africa are being supplied on a sustainable basis with triple ARV therapy using quality antiretrovirals. Comparing these figures with WHO's estimates for the total number of people being treated with triple-ARV regimens in Africa, it is clear that AAI is providing a substantial portion of this treatment in Africa,[16] certainly far more than are supplied with copy drugs. For example, MSF, treating patients in a variety of African countries with copy and patented antiretrovirals, reaches about 20 000 people in Africa, of which only one-third are treated with copy drugs from India.[17] MSF and other aid agencies use drugs produced by the multinationals as well. Thus, more patients in Africa than ever before are receiving quality antiretroviral therapy thanks to public/private sector partnerships that do *not* weaken patents on these important medicines.

It has also been argued that price reductions seen in antiretrovirals in developing countries came about as a result of generics coming in at lower prices than the originators' products.[18] According to this view, such price competition from copy products has led to lower prices of both original and copy antiretroviral products in developing countries. This explanation for the dramatic reductions in the prices of antiretrovirals in low-income developing countries is not supported by the facts, however. The individual company announcements of the first round of dramatic price reductions by AAI companies started in May 2000 and ended in December 2000, with shipments of drugs at reduced prices starting shortly after the respective companies announced their price cuts. The first announcement by a copy company for offering antiretrovirals at a reduced price came months later (early 2001) and ad hoc shipments at that price came months after that.[19] The AAI companies continued making price reductions on an individual basis as became possible due to improvements in manufacturing techniques and increases in volumes shipped; generics reduced their prices afterwards in response. This situation is illustrated by the evolution of ARV prices in Uganda. According to WHO statistics released at a technical briefing for delegates to the World Health Assembly in May 2002 regarding the prices of first-line ARV treatment in Uganda, the multinational AIDS

drugs manufacturers dropped their prices dramatically by the end of 2000, as noted above.[20] According to WHO, these price reductions were made significantly before the announcements of price reductions on ARVs by generic manufacturers. When the multinational companies reduced prices further during the course of 2001, generics followed the multinationals in reducing prices a few months later. As of 2005, the prices of ARVs offered by major multinationals in developing countries through access and partnership programs are comparable, or lower than, the prices of ARVs from copy producers, as shown in a major study by the Hudson Institute.[21]

Thus, experience shows that access to essential medicines can be expanded for populations in low-income countries *without* weakening patents. Indeed, partnerships with patent-holders, rather than arguments about patents, have helped governments supply medicines to their populations without weakening or eliminating patent rights on these products. Such partnerships, which can also include investments in health infrastructure or which can encourage contributions by international donors to such infrastructure initiatives so that drugs can be effectively used, are especially important for the poorest countries. Indeed, given that public health spending in many of the poorest countries in Africa which are most affected by AIDS and other epidemics is under US$2 per person per year, virtually any medicines, whether an original product or a generic copy, are unaffordable for these poor populations. Only external financial assistance can help such populations afford the drugs they need.

'MONOPOLY PRICING POWER' AND PATENTS

It is often alleged that patents grant 'monopolies', since patents give patent-holders exclusive rights to a specific invention during a limited period of time. However, the effect of patents is actually significantly less powerful than what a 'monopoly' means in the common usage. Usually, when one speaks of 'monopolies', one thinks of the classic monopolies of the 19th century in the USA: the Sugar Trust, Standard Oil and others. These monopolies or cartels controlled all sources of supply of a certain product and did not allow alternative suppliers to enter the market (or co-opted them into the cartel). Thus, purchasers were compelled to buy from the monopoly, which could set its price at the profit-maximizing maximum familiar to all economics students. High prices and limited supply resulted.

Superficially, one might say the same about patents. After all, if there is a patent on Product X, then the patent holder can prevent anyone else from manufacturing, selling, offering for sale, or importing Product X into a national market for as long as the patent is valid in that national market.[22]

However, in the pharmaceutical industry, these rights do not grant monopoly pricing power due to the influence of therapeutic competition. Such competition arises as innovators try to find medicines for treating a disease or condition which are different from the patented drug. Indeed, nearly all patented drugs in use today face competition from two to ten close substitute molecules to treat the same condition.[23, 24] The case of AIDS drugs is illustrative of this process. The first AIDS drug, AZT, was marketed in 1987 and for a while was the only drug effective in treating AIDS. However, soon thereafter, other drugs which attacked the AIDS virus in a manner similar to AZT, but using different compounds, came onto the market. Furthermore, drugs using novel ways of attacking HIV at various stages of its life cycle have since come onto the market. As a result of this creative process stimulated by patents, there are now over 20 AIDS drugs on the market in four distinct therapeutic classes enabling patients to be treated effectively in a variety of ways. Given the variety of combinations in which these drugs can be combined as alternatives for treatment, none of them can be said to be 'monopolies' for AIDS treatments.

The speed at which alternative treatments come onto the market to create therapeutic competition has increased over the past years as well. Major products launched in the late 1980s enjoyed market exclusivity of four to six years, while products launched a decade later could only benefit from 0.5 to two years of exclusivity.[25] The speed to market of alternative therapies is a function of the R&D process in the pharmaceutical industry today, in which several companies pursue similar research leads in hopes of developing an effective and commercially attractive product. Thus, they are simultaneously developing competing drugs in the same therapeutic category. While the first company to successfully complete the development of a drug in that category and gets a patent is seen as the innovator, and products patented in the same category thereafter are sometimes called 'me-too' products,[26] in reality all of these drugs were produced through innovative research and each presents a significant difference compared to the first-patented drug – otherwise they would not be patented.

Such a portfolio of therapeutic alternatives is beneficial for public health, as the research by Professor Albert Wertheimer shows.[27] Patients may not respond to the first patented product, or may develop resistance to it, thus alternative products are needed. Furthermore, as innovators refine their products, perhaps by making formulations which are more tolerable or which have added effectiveness, the resulting improved products bring significant benefits to patients compared to the original medicines.

Such 'incremental innovation' is important in improving public health. For example, reformulated drugs provide improved safety and efficacy, and extend the range of indications in the original therapeutic area.

Furthermore, multiple medicines in one therapeutic class offer various advantages to patients. For example, for diseases of the central nervous system, where overall response rates to medicine are 50 per cent or less, patients who fail to respond to one drug, often respond to another agent of that class. Furthermore, advanced delivery systems such as transdermal delivery, delayed-onset extended-release oral formulation, liposomes, or polymers provide sustained therapeutic drug levels for longer periods of time. They also enable smaller or fewer doses, a less invasive mode of administration, and prolonged circulation of short-lived compounds. Of strong interest to payers, incremental innovation leads to cost savings. For example, the introduction of controlled-release dosage forms for cardiovascular therapies, significantly improves treatment compliance and implies lower aggregate health care costs linked to reduced physician, hospital and laboratory interventions.[28]

Furthermore, it must be recognized that patents are not eternal, nor even particularly long-lived compared to other intellectual property rights. Patents have a nominal life of 20 years, as opposed to copyrights (given for the life of the author plus a certain number of years depending on national legislation) and trademarks (which are valid as long as they are enforced). However, patents are applied for very early in the pharmaceutical R&D process and a large part of this nominal patent life is taken up with long development times (up to 12 years). Thus, a pharmaceutical product may have its patent expire only eight years after it is marketed! After that time, generic competitors can enter the market and engage in price competition with the originator, which usually results in lower prices for the now off-patent product in cases where multiple generic competitors produce competing versions of the drug (which is often not the case in developing countries, where perhaps only one or two generic manufacturers may be present, thus the price competition pressure will be lower).[29]

For these reasons, patents on pharmaceuticals do not create monopoly pricing power, but only give the patent-holder certain exclusive rights for a limited period of time. The pricing power of the patent-holder is limited, however, due to the impact of therapeutic competition during the life of the patent and by generic competition after the patent expires.

The possible impact of patents on prices in mid- to higher-income developing countries can be examined where such countries institute stronger intellectual property protection. Richard Rozek and Ruth Berkowitz of National Economics Research Associates (NERA) reviewed the prices of eight drugs in six different therapeutic classes across nine different countries, including countries with patent protection and those without such protection.[30] Rozek and Berkowitz reviewed the experience of five countries which implemented stronger IP protection in the period studied

(1985–1996) and four countries which had weak IP regimes during the same period. In their study, the authors concluded that 'price movements of branded pharmaceutical products are generally not affected by changes in patent laws'.[31] Furthermore, Rozek and Berkowitz found that their research shows that

> improving IPP [intellectual property protection] does not have a measurable impact on real or nominal prices of existing drugs (those marketed before the implementation of IPP). Moreover, in our set of countries with price regulation, IPP had little, if any, impact on price changes of all drugs, including those introduced after the change in patent protection.[32]

TRIPS AND ACCESS TO MEDICINES

The TRIPS Agreement provides the international minimum standard for intellectual property protection for WTO members. With regard to patents, TRIPS determines the length of nominal patent life, defines the exclusive rights given to patent holders, states the conditions for patentability for inventions, and other standards for patent protection. As such, the TRIPS Agreement has been particularly under attack by those who feel that patent protection blocks access to medicines. Such critics claim that, by establishing an international standard, TRIPS imposes a stronger patent regime on developing countries than these countries can reasonably support in terms of the alleged adverse impact of patents on access to medicines and public health.[33] Therefore, according to this line of reasoning, developing countries should be allowed to have weaker patent protection than mandated under their TRIPS obligations, particularly regarding pharmaceutical products. Thus critics argue that, while patents can remain strong in industrialized countries (where R&D into pharmaceuticals takes place), developing countries (which are primarily consumers, not developers of medicines) should be allowed to copy them or to allow imports of copy products from abroad, as these copies are assumed to be cheaper than the original products.[34] Also, copying products helps to develop drug production technology in developing countries and thus economic advancement – supporters of this theory point to the growth of pharmaceutical industries in Switzerland, Japan and (more recently) India as proof that copying is a vital step towards creating national capacity in the pharmaceutical sector.

Leaving aside the question of whether patents as such block access to essential medicines (which has been discussed above), it is worthwhile considering if TRIPS obligations on developing countries are indeed detrimental to the public health interests of these countries. This question was strongly debated among WTO Member States and in the media in 2001

leading up to the WTO Ministerial Conference held in Doha, Qatar, in November 2001. The resulting Doha Declaration on TRIPS and Public Health addressed many of the concerns that developing countries had expressed regarding the impact of TRIPS on public health.

One aspect of this question involves least developed countries, who are least able to afford medicines (either innovator or copy medicines). Given that these countries are generally resource-constrained and thus unable to invest into setting up and maintaining patent systems, it was decided at the 2001 WTO Ministerial Conference in Doha to give a waiver until 2016 for least-developed countries to fully implement the TRIPS Agreement with regard to pharmaceutical products.[35] (It should be noted, however, that several least-developed countries in western Africa had already strengthened their patent protection in 2000 to fulfill their TRIPS obligations via ARIPO and maintained this level of protection after the Doha Declaration, despite arguments by international activists that they should reduce their patent protection.)

With regard to other countries, the WTO Ministers made it clear in the Doha Declaration that the TRIPS Agreement 'does not and should not prevent Members from taking measures to protect public health'.[36] Furthermore, the Member States reaffirmed their commitment *to* the TRIPS Agreement and also their commitments *in* the TRIPS Agreement – there was no weakening of TRIPS obligations in the Doha Declaration.[37] Thus, with regard to the impact of the TRIPS Agreement on public health, the Ministers agreed by consensus that Member States can meet their public health needs within the existing TRIPS framework, with one exception.[38]

The one exception involved the case where countries wished to issue a compulsory license, but had insufficient or no capacity in the pharmaceutical sector domestically. While they could issue such a license for a foreign producer to import copies into their markets, what would happen if the product they needed was patented in all possible supplier countries? Although India and a few other countries currently do not have product patent protection for pharmaceuticals and thus companies in these countries could be alternative suppliers, these countries are obligated to institute such protection by 2005 under the TRIPS Agreement. Several developing countries thus were concerned that, post-2005, these countries (especially India, which has a significant copy drug industry) would be prevented from supplying copies of medicines patented after that date and thus there would be no alternative to the patent-holders for obtaining these new drugs.[39] The WTO Ministers therefore asked the WTO Council on TRIPS in Paragraph 6 of the Doha Declaration to consider how this perceived problem could be solved.

A complicating factor in this issue was that Article 31(f) of the TRIPS Agreement said that products produced under a compulsory license could only be used to 'predominantly supply' the domestic market and thus substantial exports of drugs would not be permitted. Thus, even if a country could theoretically serve as an alternative supplier of copy drugs using a compulsory license on a drug, this license could not be used only for producing copies for export. After much negotiation among WTO Member States during 2002 and 2003, a solution was found in August 2003. WTO Members decided that a waiver of TRIPS Articles 31(f) and also 31(h) (which governed royalty payments to the patent-holder in cases of compulsory licenses) would be granted to exporting countries in cases where countries which had insufficient or no capacity in the pharmaceutical sector issued a compulsory license for producing drugs for addressing public health problems, such as AIDS, tuberculosis, malaria and similar epidemics. The waiver would be granted to a country in which potential producers for export existed and would be subject to conditions of the products not being diverted to third markets and that this waiver would not be used for commercial purposes.[40] With this solution (which was scheduled to be codified into an official amendment of TRIPS during the course of 2005), the WTO Members have addressed a particular aspect of TRIPS which Members felt could have a negative impact on public health and which could not be addressed by the existing provisions of TRIPS. National governments are now in the process of implementing this WTO Decision and the Chairman's Statement into their national legislation, with Canada being the first country with a significant generics industry to complete such implementation.[41] The European Union is also putting forward a proposed Regulation as well, a process which was still ongoing as of February 2005.

A little-known aspect of TRIPS, which has a direct impact on public health but which is not related to the Doha Declaration on TRIPS and Public Health, concerns TRIPS' provisions regarding anti-counterfeiting. Counterfeit drugs pose an important and growing threat to public health, as is recognized by WHO, NGOs, national governments and the pharmaceutical industry (including the R&D-based, generic, and self-medication pharmaceutical industries).[42] In mandating that Member States establish strong criminal penalties to deter counterfeiting in Art. 61, TRIPS helps in fighting counterfeit medicines.

FLEXIBILITIES IN THE TRIPS AGREEMENT

The key achievement in the Doha Ministerial conference debate in 2001 regarding TRIPS and public health was the Doha Declaration on TRIPS

and Public Health, which made important clarifications of particular provisions of the TRIPS Agreement. These clarifications focused on use of the patent without the authorization of the patent holder (otherwise known as 'compulsory licensing') and the importation of the patented product without the authorization of the patent holder (also known as 'parallel importation'). In particular, the Doha Declaration stated that Member States can decide themselves upon the grounds upon which compulsory licenses can be granted,[43] as well as what situations can be considered as 'national emergencies'[44] (which allows the obligation on Member States to consult with the patent holder before issuing a compulsory license to be waived.[45]) Likewise, the Doha Declaration clarified that Member States can decide autonomously whether they will allow a regime of international or national exhaustion of patents to be applicable in their territories[46] (that is, if they will allow parallel imports of medicines into their markets).

International activists have cited these clarifications as being important for governments to be able to promote public health despite the existence of patents on medicines. Advocates of these policies claim that compulsory licensing would promote access to medicines by bringing in generic competition (both domestic and foreign), while parallel trade would allow countries to purchase drugs at the lowest world price. Both of these policies should reduce health care costs substantially, according to this perspective, and indeed activist groups work together with UN agencies to compile databases of comparative drug prices to show that parallel trade would result in cost savings.[47]

However, experience shows that these policies would not be the boon to public health which their advocates promise. With regard to parallel trade, it must be recognized that such trade always moves products from lower-priced markets to higher-priced markets. This means that consumers in the lower-priced markets will see their supplies of drugs disrupted as products are diverted away from them towards the richer markets. However, consumers in the richer markets will not benefit, given that the parallel traders pocket the majority of the price differential.[48]

A further pernicious effect of parallel trade on public health involves counterfeit and substandard drugs. Since parallel-traded products go through unauthorized channels, the quality of these products is difficult to control, and unscrupulous traders may use the opportunity to mix in counterfeit with real products. Attempting to monitor the quality of parallel-imported drugs is a significant strain on the resources of national regulatory authorities, which is why the Registrar of Medicines in Kenya warned her counterpart in South Africa to avoid implementing a parallel trade policy, based on Kenya's own poor experience with such a policy.[49]

Finally, lower priced medicines are offered by the patent-holders to poor countries as part of a company's global 'differential pricing' policy. If such drugs offered at low prices to poor countries are diverted to rich country markets, however, then the consumers in the poor countries are deprived of vitally-needed medicines and the company offering the differential-priced drugs suffers from lost revenue in the industrialized country markets. Cases involving such diversion of AIDS drugs have already captured world headlines in recent years.[50] Thus, parallel trade cuts away at the basis of differential pricing systems and would lead to the weakening or even possible termination of such programs which benefit poor countries. In sum, parallel trade is a policy which may benefit some businesses in the rich countries, but would be a terrible policy for developing countries.

Compulsory licensing is also not a panacea for solving health care problems. First of all, experience has shown time and time again that partnership between patent-holders and governments has created broader and more effective access to medicines.[51] Compulsory licensing is a dramatic, exceptional act which would seriously damage relationships between governments and producers of innovative drugs necessary to address public health needs. Furthermore, there is the practical consideration of who will produce the drugs under a compulsory license. Will they be able to produce the medicines at the same quality as the originator? Will the price actually be lower? After all, building up a manufacturing facility is costly, and the scale of production for a single national market alone may not be sufficiently high to achieve economy of scale per unit cost savings, which are particularly important in the pharmaceutical industry. Furthermore, issuing a compulsory license would also give strong disincentives for companies to introduce their products onto the market, thus limiting consumers' access to innovative medicines which would benefit their health.

Given these practical considerations, it is probably no surprise that compulsory licenses on pharmaceuticals have very rarely been issued by WTO Members after these countries have implemented TRIPS. There are only three publicly-announced cases: Zimbabwe (2003), Mozambique (2004) and Zambia (2004), and these compulsory licenses did not result in any actual production. Furthermore, given the lack of patents on the drugs subject to the compulsory license in Mozambique and Zambia (aside from a fixed-dose triple antiretroviral product called Triomune, produced by the Indian generic copy company Cipla), the practical purpose behind these licenses remains unclear. In contrast, countries which had extensive compulsory licensing regimes on pharmaceutical products, such as Canada and New Zealand, eliminated those regimes in the early 1990s because they did not serve their national health aims.

CONCLUSIONS

In reviewing the facts about TRIPS, patents and access to medicines in developing countries, it is clear that the assumptions about this topic noted in the beginning of this chapter are not supported by the facts.

1. Essential drugs are, to an overwhelming extent, not patented (or the patents on them are not defended) in low-income countries. Furthermore, when these drugs are patented, they are offered at dramatically lower prices (or even for free) by the patent holder. In fact, patented essential drugs are offered via partnership programs by the patent holder at prices comparable to or lower than those offered by international copy drug producers. Furthermore, in the antiretroviral field, the patent-holders led the way with price reductions on their products, with copy producers following with price cuts of their own;
2. The alleged 'monopoly pricing power' from patents actually does not exist, due to therapeutic competition during the patent life;
3. WTO Member States agreed in the Doha Declaration on TRIPS and Public Health that Member States can achieve their public health goals within the terms of the TRIPS Agreement. The one exception, regarding compulsory licenses for export to countries with insufficient or no manufacturing capacity in the pharmaceutical sector, was resolved by consensus of WTO Member States in August 2003 through a WTO Decision and Chairman's Statement.

Policy makers in many countries have gone beyond the empty rhetoric of 'patents vs. patients' or blaming TRIPS for insufficient access to medicines. It is to be hoped that the way is now free for decision-makers, responsible NGOs, and the media to go beyond this debate and focus on the real barriers to access to quality health care: lack of funds, insufficient infrastructure, and social factors which limit access to drugs. By focusing on these real barriers to access, effective policies will be created which will truly save lives and improve quality of life for millions around the world.

NOTES

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1. OXFAM, Treatment Access Campaign (TAC), press alert, 17 July 2001.

2. Gro Harlem Brundtland, Director-General of WHO, opening address to World Health Assembly, May 2001.
3. More information regarding the EML and the list of medicines on the list can be accessed via the Internet: http://www.who.int.
4. Amir Attaran, 'How do patents and economic policies affect access to essential medicines in developing countries?', *Health Affairs*, Vol. 23, no. 3, pp. 155–66.
5. Ibid. p. 155.
6. Ibid. p. 159.
7. There are two regional patent regimes in Africa: ARIPO (for anglophone countries of southern Africa) and the *Organisation Africaine de la Propriété Intellectuelle* (OAPI) (for 16 francophone states of western Africa). However, enforcement remains a national competence. WIPO Patent Coordination Treaty (PCT) applications can apply to several countries but the patent applicant must state in which countries he or she would like to patent.
8. Douglas Hawkins, 'Studies on the cost of patenting', *University of Baltimore Intellectual Property Law Journal*, 1997.
9. The drugs patented in the countries surveyed in Prof. Attaran's study are available at: http://content.healthaffairs.org/cgi/content/full/23/3/155/DC1.
10. ' "3 by 5" Progress report, December 2004', 26 January, 2005, Available at: http://www.who.int/3by5/progressreport05/en/ Accessed 29 March, 2005.
11. Statement by William Haddad, 'WHO 3×5 partners meeting', May 2004.
12. It should be noted that the WHO Essential Medicines List is a basic list of necessary medicines on which developing countries can base national formularies. However, improved and new drugs are needed to address many of the conditions which the EML products are designed to treat, prevent or cure, and such further innovation depends upon intellectual property protection as well as other factors (such as sufficient financing to purchase drugs, and so on).
13. Amir Attaran and Lee Gillespie-White, 'Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa?', *Journal of the American Medical Association*, Vol. 286, No. 15, 17 October, 2001, p. 1886.
14. Carol C. Adelman, Jeremiah Norris, S. Jean Weicher, 'Myths and realities on prices of AIDS drugs', Hudson Institute, 2004.
15. Eric Noehrenberg, 'Accelerating access to AIDS medicines initiative: a public/private sector partnership to save lives', *Sustainable Development International*, Edition 9, September 2004.
16. '700 000 people living with AIDS in developing countries now receiving treatement', Joint Media Release WHO/UNAIDS/Global Fund/US Government, Accessible at http://www.who.int/3by5/en/pr_en.pdf. Accessed 29 March 2005. AAI is providing treatment to about 157 000 people living with AIDS in sub-Saharan Africa as of the end of 2004, 'Industry lauds Accelerating Access Initiative (AAI) progress in expanding access to AIDS drugs'. IFPMA media release, 26 January 2005, accessible at: http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=2330, Accessed 29 March 2005.
17. 'Will India allow them to live?', interview with Ellen t'Hoen, MSF, *BusinessWorld*, 20 December, 2004.
18. 'India's choice', Editorial, *The New York Times*, 18 January, 2005.
19. It is indeed true that the prices of locally-produced antiretrovirals in Brazil were significantly below the prices of these drugs in industrialized-country markets already in 1999. (Presentation by Ellen t'Hoen, MSF, at the TACD Conference on the Future of WIPO, 13 September, 2004.) However, locally-produced antiretrovirals in Brazil are not bioequivalent to the originator products, but are chemically-equivalent 'similars'. Also, the production of antiretrovirals in Brazil is heavily subsidized by the Brazilian government, who is also the major purchaser of these drugs for the national AIDS program. Thus, the real price of antiretrovirals should also include the level of subsidies (roughly US$50 million per year for about 200 000 AIDS patients) which would make the price significantly higher. Also, the current prices of Brazilian-manufactured antiretrovirals is much higher than the prices offered by the patent-holders to sub-Saharan African countries.

20. WHO, Technical Briefing for the World Health Assembly, May 2002.
21. Adelman, Carol C.; Jeremiah Norris and Jean S. Weicher, 'Access to medicine: the full cost of HIV/AIDS treatment', Hudson Institute White Paper, 2nd edition, May 2005.
22. These rights are listed in TRIPS Art. 28.1(a) and are consistent among all WTO Member States.
23. K. Cool and I. Dierickx, 'Rivalry, strategic groups and firm profitability – an analysis of the US pharmaceutical industry', *Strategic Management Journal*, **14**, 1993.
24. A. Afuah, 'Technical progress and product market success in pharmaceuticals: the case of cholesterol ethical drugs', POPI Working Paper 3:92, Massachusetts Institute of Technology, Cambridge, MA USA, 1992.
25. Richard B. Sykes, 'New medicines: the practice of medicines and public policy', The Nuffield Trust, The Stationery Office, London, 2000.
26. National Institute for Health Care Management (NIHCM) Foundation, 'Changing patterns of pharmaceutical innovation', 2002.
27. Albert Wertheimer, R. Levy and T. O'Connor, 'Too many drugs? The clinical and economic value of incremental innovations', *Investing in Health: The Social and Economic Benefits of Health Care Innovation*, Vol. 14, 2001, pp. 77–118.
28. E. Snell, 'Post marketing development of medicines', *Pharmacy International*, Vol. 7, February 1986; A. Wertheimer et al, 'Too many drugs? The clinical and economic value of incremental innovations', 2001; M.P. Cramer and S.R. Saks, 'Translating safety, efficacy and compliance into economic value for controlled release dosage forms', *Pharmacoeconomics*, **5**(6), 1994.
29. The experience of Canada is illustrative, in that the generics market is dominated by two companies. The lack of competition among generic firms leads to Canadian generic drug prices being higher than in the US or in major European countries. (Please see 'Generic drugopoly: why non-patented prescription drugs cost more in Canada than in the United States and Europe', Brett J. Skinner, *Public Policy Sources*, No. 82, The Fraser Institute, August 2004.)
30. Richard Rozek and Ruth Berkowitz, 'The effects of patent protection of the prices of pharmaceutical products: is intellectual property protection raising the drug bill in developing countries?', National Economic Research Associates, January 1998.
31. Ibid., p. 1.
32. Ibid., p. 26.
33. A variety of papers on these topics can be accessed via: http://www.cptech.org/.
34. Ibid.
35. WTO Declaration on the TRIPS Agreement and Public Health, 14 November, 2001, Paragraph 7.
36. Ibid. Paragraph 4.
37. Ibid. Paragraphs 4 and 5.
38. Paragraph 7 of the Doha Declaration on TRIPS and Public Health granted an additional transition period until 2016 for least developed countries to fully implement the TRIPS Agreement with regard to pharmaceutical products. This extension is a recognition of the limited resources which countries have available to invest in setting up and maintaining patent systems, thus requiring more time before setting up such systems. This extension does not mean that TRIPS prevents least developed countries from achieving their public health goals within the context of the agreement.
39. Drugs already on the market in countries which implement product patent protection in 2005 will remain off-patent because patents are not retroactive. 'Mailbox' protection may apply to some products in these markets, however (TRIPS Art.70.8).
40. WTO Decision of 31 August, 2003 and the General Council Chairman's Statement on 31 August, 2003.
41. An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa).
42. WHO IFPMA etc Working Group on Counterfeit Medicines.
43. Doha Declaration, Paragraph 5.b.
44. Doha Declaration, Paragraph 5.c.

45. TRIPS Art. 31(b).
46. Doha Declaration, Paragraph 5.d.
47. UNAIDS/WHO/UNICEF/MSF. Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS, June 2004.
48. Parallel Trade: A recipe for reducing patients' access to innovative and good-quality medicines', IFPMA, 2000.
49. Letter from the Director, National Quality Control Laboratory of Kenya to Director, Medicines Control Council of South Africa, October 1997.
50. J.P. Garnier, 'Global community girds for battle against scourge of Aids', Times On Line, 1 December, 2003. Accessed 12 October, 2004 via http://www.timesonline.co.uk/article/0,,9911–916103,00.html.
51. 'Building healthier societies through partnership', IFPMA, May 2004.

11. Patenting genes

Trevor Cook

INTRODUCTION

Genes, and the proteins for which they code, have much in common. They are both types of chemical, and they are both found in the body, and yet they elicit very different attitudes when it comes to their patenting. Although it is through proteins by which the body operates, it has been genes, and not proteins, which have caused the greatest controversy in the patent world. Yet genes by themselves do little, their importance lying in the fact that they are stretches of DNA that contain the code which specifies the sequence of amino acids making up each of the tens of thousands of different proteins, and which do the work by which the body functions. Why then should genes have apparently caused so many problems for the patent community? Moreover why should the issue be of such current interest, when there have for many years been patents with claims to gene sequences, some of which indeed are so old that they have now expired?[1] This chapter explores these issues from the perspectives of European and United States patent laws.[2]

Genes and proteins are both products of nature, and, having exemplified some of the patent claims found in so-called 'gene patents', this chapter continues with a discussion of the issues raised by seeking to patent them as products of nature, and how the European and United States patent systems, in broadly similar ways, address these. It then discusses some of the differences that have arisen between Europe and the United States as to gene sequence patents. The law in the United States has to a large extent been shaped by the need to respond to the consequences of two Court decisions in the early 1990s that had the effect of creating a per se rule of non-obviousness for gene sequence patents. In contrast, Europe saw, in its first wave of 'public policy' challenges to gene patents, controversies of a primarily ethical nature directed to the morality of 'patenting life'. This was also reflected in the controversy during the 1990s over the Biotechnology Directive,[3] which eventually became law in 1998, even though as yet it has not been nationally implemented in all Member States of the European Union (EU).[4] Such controversies have their basis in a particular provision of the European Patent Convention (EPC), which excludes from patentability,

'inventions the commercial exploitation of which would be contrary to *ordre public* or morality'.[5]

The chapter then discusses how, notwithstanding these two differing legal backgrounds, both jurisdictions have more recently been able to shape similar responses to some of the more recent challenges of biotechnology patenting, such as the controversy over patenting fragments of DNA of speculative utility. The chapter concludes with a discussion of some of the more recent criticisms of gene patents encountered in Europe (which might be termed the second wave of 'public policy' challenges to gene patents, as they differ from the more fundamental objections found in the first wave of challenges) and considers whether these are likely to affect the law in this area.

WHAT ARE 'GENE PATENTS'?

The claims which define the scope of the monopolies respectively secured by various 'gene patents', as the term seems to be used by various commentators, can take many different forms; this very fact of itself must render unsound any general conclusions as to such patents. Numerous different examples of such claims exist, and it is important in analysing such claims to distinguish between those claims that are sought in published patent applications, and those that are allowed, after examination, by Patent Offices in granted patents, as patents can only be enforced after they have been granted. Thus in the European Patent Office (EPO) the ratio of patent applications claiming human DNA sequences to granted patents increased rapidly over the period 1978 to 2001 to a ratio of about 10 to 1, whereas granted patents have throughout the same period run at only a couple of hundred a year.[6] Two examples of DNA claims that have been the subject of extensive scrutiny in the context of litigation are Kirin-Amgen's EP 0 148 605 B2 and Myriad Genetics' EP 0 699 754 B1.

Traditionally claims to genes have taken the form of those to gene sequences as found in the first generation of patents resulting from the sequencing of the DNA which codes for a protein known to exist in the human body and having a known therapeutic utility. Such claims are exemplified by the sequence claims of Kirin-Amgen's EP 0 148 605 B2, the UK designation of which was the patent at issue in *Kirin-Amgen Inc and others v Transkaryotic Therapies Inc and others*.[7] The only independent claim to a gene sequence[8] is Claim 1, which is to:

1. A DNA sequence for use in securing expression in a procaryotic or eucaryotic host cell of a polypeptide product having at least part of the primary

> structural conformation of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and to increase haemoglobin synthesis or iron uptake, said DNA sequence selected from the group consisting of:
> a. the DNA sequences set out in Tables V and VI or their complementary strands
> b. DNA sequences which hybridise under stringent conditions to the protein coding regions of the DNA sequences defined in (a) or fragments thereof; and
> c. DNA sequences which, but for the degeneracy of the genetic code would hybridise to the DNA sequences defined in (a) and (b)

Tables V and VI referred to in these claims set out certain DNA sequences as discovered by the patentee and the corresponding polypeptides, or proteins,[9] for which these DNA sequences, or genes, code. The gene sequence claims are not limited only to these two sequences, but also to other (albeit in (b) and (c) undisclosed) sequences which could be expected to code for the same or similar proteins having similar desired activity. In addition to such claims to DNA sequences, the validity of which was not directly in issue in the litigation, the patent had claims to proteins, and to processes for expressing such proteins, as well as pharmaceutical compositions containing such proteins. The only claims directly at issue in the litigation, those to proteins, were found invalid, and as to which Lord Hoffmann stated in the House of Lords:

> Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new.

A more recent example of the claims of a patent identified by some commentators as a 'gene patent' is provided by the four independent claims (1, 2, 25 and 26) of Myriad Genetics' EP 0 699 754 B1, one of the 'BRCA patents', the exploitation of which in the diagnosis of a predisposition to certain breast cancers has been on terms that have attracted considerable criticism:[10]

> 1. A method for diagnosing a predisposition for breast and ovarian cancer in human subject which comprises determining in a tissue sample of said subject whether there is a germline alteration in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in SEQ. ID. NO:2 or a sequence with at least 95% identity to that sequence, said alteration being indicative of a predisposition to said cancer.

2. A method for diagnosing a lesion of a human subject for neoplasia associated with the BRCA1 gene locus which comprises determining in a sample from said lesion whether there is an alteration in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in SEQ. ID. NO:2 or a sequence with at least 95% identity to that sequence, said alteration being indicative of neoplasia.
25. A method for diagnosing a predisposition for breast or ovarian cancer in a human subject which comprises determining in a tissue sample of said subject the level of an expression product of the BRCA1 gene, said gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in SEQ. ID. NO:2 or a sequence with at least 95% identity to that sequence.
26. A method for diagnosing a lesion of a human subject for neoplasia associated with the BRCA1 gene locus which comprises determining in a sample from said lesion the level of an expression product of the BRCA1 gene, said gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in SEQ. ID. NO:2 or a sequence with at least 95% identity to that sequence.

These claims are neither to the BRCA1 gene sequence as such, whether *in situ* or isolated, nor to the polypeptide for which it codes, identified as SEQ ID NO:2 (and set out in full in the patent). Instead the claims are limited to methods of diagnosis that are based on identifying certain properties of such gene sequence in the tissue in question. An EPO Opposition Division revoked these claims in May 2004, essentially on the ground that their basis was not properly disclosed in the original application as filed and thus they impermissibly extended the content of the application as originally filed, as stated by the Opposition Division in the grounds for its decision:[11]

> the expression 'a sequence with at least 95% identity to that sequence' can only result from the selection and mosaicing of features and definitions from a number of lists in the original description and claims. This particular sequence is thus not directly and unambiguously derivable from the application documents as filed.

Thus the objection that met favour with the EPO Opposition Division was not to such claims in principle, but rather to the fact that, as worded, they could not, directly and unambiguously, be derived from the information set out in the patent application as originally filed.[12] It is, however, worth observing in this context that claims so expressed, even were they to be held valid, could only ever purport to monopolize the method of diagnosis as claimed – they do not purport to monopolize any other research into the sequence to which the claim relates, or any therapy based on such knowledge of the sequence.[13]

PATENTING GENES AS PRODUCTS OF NATURE IN EUROPE

The basic principles governing the patentability of genes in Europe are now summarized in Article 3 of the Biotechnology Directive (and its corresponding Recitals 20 and 21):

> 3.1 For the purposes of this Directive, inventions which are new, which involve an inventive step, and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
> 3.2 Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

These principles, which reflect, in the context of genes and other 'biological material',[14] principles of general application to all inventions, are largely declaratory of case law in the EPO and national courts. Thus, in response to an attack on validity based on lack of novelty, an EPO Opposition Division in *Howard Florey Institute/Relaxin*[15] upheld claims to isolated DNA fragments which code for a certain form of a human hormone, the protein relaxin, noting:

> It is common ground amongst the parties that until a cDNA encoding human H2-relaxin and its precursors was isolated by the proprietor, the existence of this form of relaxin was unknown. It is established patent practice to recognize the novelty for a natural substance which has been isolated for the first time and which had no previously recognized existence.[16]

The issues of inventive step and of industrial applicability (or its United States equivalent, utility) identified in addition to novelty in Article 3.1 are discussed further below, as although they raise some issues specific to gene patents they do not do so as a direct consequence of genes being products of nature. However, Article 3 of the Biotechnology Directive fails expressly to identify another general requirement for patentability in Europe, which is, in consequence of the presence of genes in nature, also of potential significance in its application to claims to gene sequences. This requirement, established by Article 52(2)(a) EPC, is that a patent claim be not for a 'discovery . . . as such', and is alluded to, but only in relation to genes and other 'biological material' when found in the human body, by Article 5 of the Directive (and the corresponding Recitals 22 to 25):

> 5.1 The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including

the sequence or partial sequence of a gene, cannot constitute patentable inventions

5.2 An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element

The requirement might be thought to be of narrow scope in Europe in view of the observation by an EPO Opposition Division in *ICOS Corporation:*[17]

11 (i) . . . Although [DNA] encoding the V28 protein exists as a segment of the human genome and thus is part of nature, the purified and isolated [DNA] having that sequence does not exist in nature and thus cannot be discovered. The purified and isolated polynucleotide encoding V28 protein is de facto, not a discovery.

However, the requirement that patent claims be not for a 'discovery . . . as such' (or in the words of Article 5.1 of the Directive, for a 'simple discovery') does in fact impose certain important practical restrictions on how claims to genes (whether or not human) can be formulated. It also affects how they are to be interpreted when it comes to attempts to enforce them, as explained, in relation to a table of gene sequence information in a patent specification ('Table VI' in the following quotation), by the House of Lords in the English case *Kirin-Amgen Inc and others v Transkaryotic Therapies Inc and others:*[18]

76. . . . the Court of Appeal was right in saying that Table VI could not have been the invention. Standing alone, it was a "discovery . . . as such" within the meaning of section 1(2) of the Act: see *Genentech Inc's Patent* [1989] RPC 147, per Purchas LJ at p 204 and per Dillon LJ at p 237. On the other hand, as Whitford J said in the *Genentech* case ([1987] RPC 553, 566):

'It is trite law that you cannot patent a discovery, but if on the basis of that discovery you can tell people how it can be usefully employed, then a patentable invention may result. This in my view would be the case, even though once you have made the discovery, the way in which it can be usefully employed is obvious enough.'

77. In such a case, while it may be true to say, as the Court of Appeal did ([2003] RPC 31, 62) that Table VI lay 'at the heart of the invention', it was not the invention. An invention is a practical product or process, not information about the natural world. That seems to me to accord with the social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which

> does not infringe the claims. The specifications of valid and subsisting patents are an important source of information for further research, as is abundantly shown by a reading of the sources cited in the specification for the patent in suit. Of course a patentee may in some cases be able to frame his claim to a product or process so broadly that in practice it will be impossible to use the information he has disclosed, even to develop important improvements, in a way which does not infringe. But it cannot be right to give him a monopoly of the use of the information as such.

Thus the requirement that the claim be not for a 'discovery . . . as such' should serve in practice to preclude the first person to identify a gene sequence securing a monopoly to all uses of such sequence information, even though such person may possibly be able to secure a monopoly on all uses of that sequence as a chemical, or at least to such uses of the sequence in its isolated form.

PATENTING GENES AS PRODUCTS OF NATURE IN THE UNITED STATES

The law in the United States, unlike that in Europe, does not expressly exclude 'mere discoveries' from patentability,[19] although in practice it adopts a somewhat similar approach to that in Europe to patenting genes as products of nature. This is explained by the United States Patent and Trademark Office (USPTO) when responding to certain comments on its revised Interim Utility Examination Guidelines:[20] '[A]n inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.'

The United States approach so articulated has, however, been criticized on the ground that:[21]

> only human-made inventions meet the standards imposed by the condition of alternativeness of inventions; thus only these human-made inventions can, or should be, statutorily patentable subject matter. It is very important to emphasize that only directly human-made inventions are (or should be) patentable. Where the discoverer isolates or purifies a natural substance without modifying it, the condition of alternativeness is not met because the composition of the purified substance remains the same. An isolated and purified gene remains the same as in nature and performs only its natural function. Therefore, patentable inventions must meet not only the three substantive conditions of patentability [namely, novelty, non-obviousness and utility] but also a fourth – alternativeness.

Something of a response to this condition of 'alternativeness' is provided in European law by the exclusion from patentability for 'discoveries . . . as

such', at least as this exclusion has been explained by Lord Hoffman in the passage from *Kirin-Amgen v Transkaryotic Therapies* quoted above. However, the public policy basis for 'alternativeness' as a ground of objection to patents is limited, as if patents are justified on the grounds of providing an incentive to undertake and to publish research by awarding a limited monopoly in the fruits of that research for a limited time, then such incentive effect can hardly be affected by the 'alternativeness' of the results.

Similar criticisms have also been voiced by certain important players within the US biotechnology industry:[22]

> The legal theory supporting gene patents is rooted in the notion that they aren't patents on the naturally occurring gene *per se*, but on an isolated and purified form of the gene. This theory traces back to a 1911 case, *Parke-Davis v HK Mulford*, decided by the US Court of Appeals for the Second Circuit. In the modern world of genomics, that logic is a distinction without a difference. If you accept that argument, then would it not follow that you could patent a human heart once you removed and preserved it? A human gene is created first in nature, the same way other parts of human bodies are, and the fact that it may be isolated, cloned and purified doesn't change that root of origin.

Even though one can criticise this author's particular analogy (it is the value of the information about the structure and function of a naturally occurring chemical that warrants a patent on it in its isolated form, and such an approach can hardly be applied to an isolated organ) this author's more fundamental practical objection to gene patents emerges in the next paragraph of her paper, where she opines that 'with the sequencing of the human genome, finding a new gene is now a process that involves little invention'. If that be the case, as indeed in many cases it is, then one would have thought that there should be little scope for simple 'gene patents'. Indeed that is the situation that is increasingly met in Europe, although not, as we shall see, in the United States.

INVENTIVE STEP IN EUROPE AS TO GENE PATENTS

Assuming product claims such as those discussed above to be novel, and not regarded as discoveries as such, they may still be at risk of challenge for lack of inventive step on the basis that if one knows that something which is naturally occurring is potentially useful, it may then be obvious to try to produce the same material artificially. The attack of obviousness, or lack of inventive step, is thus an important one in biotechnology in Europe, and the position of the EPO in this field is conveniently summarized in the

following quotation from the 'Case Law of the Boards of Appeal of the EPO':[23]

> In T 386/94 (OJ 1996, 658) again citing T 816/90, the board ruled that in gene technology inventive step could not be acknowledged if, at the priority date, a skilled person could expect to perform the cloning and expression of a gene in a fairly straightforward manner, and the cloning, although requiring much work, did not pose such problems as to prove that the expectation of success was ill-founded.

A similar view has been taken by the English courts, in which the attack of obviousness has also featured in much biotechnology litigation. The English courts have adjudicated on more challenges to the validity of biotechnology patents than others in Europe, in part because they have usually been prepared to adjudicate on applications for patent revocation of the UK designation of a European Patent, notwithstanding the existence of an ongoing EPO Opposition proceeding in relation to such European Patent.

Inventive step was not in issue at the UK trial in *Kirin-Amgen*,[24] although this action concerned a protein that was at the priority date already known, isolated and characterized, as in the earlier case *Genentech's Patent*.[25] Here, a claim to an already known, isolated and characterized protein, t-PA, when produced by means of recombinant DNA technology, was held by the Court of Appeal to lack inventive step as being no more than a statement of what was an obvious research goal. Being the first to achieve that goal through the use of conventional techniques did not therefore merit a patent. Genentech were the first of several teams working in this area successfully to discover, by the use of laborious, costly and time consuming, but essentially known, techniques, the cDNA sequence which coded for t-PA. This could then, by known techniques of recombinant DNA technology be used to produce the t-PA in pure form and in relatively large quantities. Genentech's achievements in so doing were characterized by one member of the Court of Appeal as follows:

> What was it that Genentech achieved? The answer seems to me as follows.
>
> First, they won the race. The goal was known, and others were trying to reach it. Genentech got there first.
>
> Second, the goal was to find a means of making, and having found it actually to make, the desired protein – a substance identical to that which already existed in nature.
>
> Third, they reached the goal by a route the general nature of which was already practised.
>
> Fourth, the success was due to the fact that they were the first to create by recombinant means a full-length insert.

> Fifth, on the way to the goal they constructed a number of organisms, of which the two expression vectors referred to in claim 9 were examples, which had never existed before. Some of them contained the full length insert. These constructs were of no value except as a means to an end.
>
> Sixth, on the way to the goal they discovered the nucleotide and amino acid sequences of 'natural t-PA'. This discovery was not in itself a goal, and it is a fair inference that Genentech would not have set out to achieve it simply as a matter of pure research.
>
> Seventh, the publication of Genentech's work was of value to subsequent workers in two respects. It demonstrated that the desired protein could be made by recombinant methods within the existing technologies; and (by communicating the sequences and the restriction map) enabled the subsequent workers to reach the goal by a more direct route, at less expense and in a shorter time, and with a lesser risk of failure.
>
> Eighth, the publication of Genentech's work also enabled other workers to know what route Genentech had taken. But nobody would ever wish to take the first part of the route again, or to traverse any of the later parts in precisely the way described.

The majority in the Court of Appeal found all the claims of the patent to be invalid as lacking inventive step. The patentees' aim was known, as was sufficient of the theory and practice for them to know how, eventually, and with enough hard work, to achieve such aim. It was obvious to them (and also to several rival teams working on the same problem and aiming for the same goal, itself a strong indication of obviousness) that it was desirable to produce human t-PA by recombinant DNA technology. The fact that the patentees achieved this aim before anybody else, ought not of itself allow them to patent it as patents were only granted for getting there first if the goal was not an obvious one. All the steps taken by the patentee to identify the gene that coded for t-PA and their use of that knowledge to produce t-PA were therefore, despite the effort involved, no more than an obvious application of known technology.

However, a Technical Board of Appeal of the EPO, considering somewhat different claims of the equivalent patent prosecuted via the EPO, held the patent valid on amended claims and rejected an attack based on lack of inventive step, noting that in 1982, when the patent was applied for, the synthesis and cloning of cDNA was not yet routinely established because genetic engineering had not made all the technical and theoretical advances which have since then become available to a competent laboratory. The Board also listed a number of factors that would have influenced the degree of confidence of the skilled person in the successful conclusion of cloning and expressing human t-PA.

By contrast, in *Genentech Inc's (Human Growth Hormone) Patent*[26] certain claims to cloning vectors comprising the cDNA of human growth

hormone were held by an English court not to lack inventive step, as the work of a competing team showed that the patentee had taken non-obvious cloning steps. Another English case in which a 'gene patent' with a much later priority date was also held to lack inventive step is *DSM's Patent.*[27] The claim in issue was for the gene that coded for a particular enzyme, the protein phytase. The Patents Court held that, once a pure sample of a protein or protein fragment had become available, 'working out the identity and order of the amino acids in the chain was a well known exercise'. Various purification techniques were also well known to the skilled man, who would also know that 'in order to isolate a gene of interest, it would be necessary first to construct a DNA library, which would have to be screened with an appropriate oligonucleotide probe', the success of which would depend upon the quality of the available probes and there would have to be 'a degree of trial and error in varying the stringency conditions in which the hybridization and post-hybridization washing was carried out'. The patentee argued that it had only been able to make the invention because it had used a particular apparatus in the purification step, as other similar techniques had failed. However, use of this particular apparatus was well-known and simple and it was commercially available, it was not time-consuming and, while it might not have been the first choice, would have been an obvious technique to adopt for separating proteins for further use. Therefore, its use did not confer inventive step.

In *Chiron Corporation v Organon Teknika*[28] a lack of inventive step attack failed against a patent that reflected the first identification, isolation and characterization, after many years of failed attempts, of the virus responsible for most cases of non-A non-B Hepatitis – namely Hepatitis C(HCV). The critical difference between this and *Genentech's Patent* was that in the latter the naturally occurring material being sequenced had already been isolated and characterized, and its significance, and thus its potential utility, already established. In *Chiron* the patentee was also the first to isolate and characterize Hepatitis C, as a consequence of the molecular biology that it undertook. The value of that discovery lay in the use of the relevant sequence in diagnostic kits testing for HCV infection – claims to use of the sequence information in developing vaccines against HCV were held invalid on the ground of insufficiency, as there was no teaching as to how this might be done.

Thus in Europe, the application of traditional standards of inventive step to patent applications for 'gene patents' has often resulted in such applications being found not to meet the requisite standard.

INVENTIVE STEP IN UNITED STATES AS TO GENE PATENTS

In contrast to Europe, the United States has seen the development of an entire body of case law that is in practice specific to gene sequence patents, and which starts from the surprising premise that obviousness of identifying and sequencing the gene can never be relevant to patentability, and thus claims to such sequences can never be obvious. The problem is not a general one met in the United States with biotechnology patenting, but is specific to gene sequence patents.

The problem in the United States started with the decision of the Court of Appeal for the Federal Circuit (CAFC),[29] *In Re Bell*.[30] In so far as this treated a gene sequence as nothing more than a mere newly identified chemical having utility it is unobjectionable. However it failed in the context of obviousness also to recognize that although the gene sequence could not be precisely predicted from knowledge of the structure of the already known protein for which it coded, the gene sequence could, in general, be derived (albeit indirectly), from such knowledge, but by the use of known biochemical techniques.[31] As observed in 'A Patent System for the 21st Century':[32]

> In *Bell* and then *In re Deuel*, the court held that a gene is just another type of chemical compound and the issue for non-obviousness is the structure (that is the sequence) of the gene. Unless the sequence is predictable from the prior art, the gene is non-obvious. The court created a per se rule that the obviousness of obtaining the gene could *never* be relevant to patentability. This per se rule is highly unusual and flies in the face of significant Federal Circuit precedent rejecting the creation of any per se rules relating to non-obviousness.

The authors go on to contrast this with the position in the EPO and other industrialized countries, and which subsequently they urge be adopted by the USPTO and the CAFC:

> All other industrialized countries approach the non-obviousness of novel genes by focusing on the technical hurdle the inventors faced – cloning the gene. For example, the European Patent Office (EPO) in the counterpart application for the *Bell* invention, found that the gene in question was obvious (lacked inventive step) because it was believed there were obvious methods available to clone it.[33] The EPO has also taken a strict stance on the obviousness of recent genomics invention. They recognize that generally there is nothing inventive per se in obtaining such sequence. The current view of the EPO is that a genomics invention will only have an inventive step if the applicant can demonstrate either that obtaining the sequence was in fact a technical achievement or that they have discovered a new or unexpected property associated with the gene.

Genomics-based inventions are, therefore, not patented as frequently in foreign patent systems.

The per se rule in the United States as to the unobviousness of gene sequences can be seen to have had several consequences for the law in the United States, apart from the immediate and obvious one of making it easier to secure granted patents for gene sequences. It has resulted in effect in what can now be seen in retrospect to have been a reactive 'backlash' in which other grounds of attack on patentability have been stretched beyond their previously accepted limits to compensate for the absence of an obviousness assessment.

One example of this reaction was the controversy that erupted late in the 1990s over patent applications for gene fragments of uncertain utility called 'expressed sequence tags' (ESTs). It was generally recognized that the lack of utility could itself be a ground of objection in such cases, although in Europe, the objection would probably be less the corresponding one of lack of industrial applicability, but rather one of lack of inventive step, as such sequences would not solve a technical problem. The consequence in the United States was the USPTO's Interim Utility Examination Guidelines, first published in draft in 1999,[34] and requiring the disclosure of a 'specific, substantial, and credible utility', a requirement which, as discussed below, has been fed back into European practice in this area.

Another consequence of this reaction in the United States has been a series of decisions of the CAFC which have elevated, especially in the field of gene patents, the requirement of sufficiency, and in particular that of 'written description',[35] as most recently demonstrated in *In re Wallach.*[36]

THE FIRST WAVE OF PUBLIC POLICY CONCERNS IN EUROPE AS TO GENE PATENTS

Europe avoided the trap of per se non-obviousness for gene sequence patents into which the United States has fallen. However, it fell into a different trap in the field of biotechnology patenting, albeit of wider application than to only 'gene patents', and largely reflected in objections formulated under the exception to patentability in European law for inventions 'the commercial exploitation of which would be contrary to *ordre public* or morality'.[37]

Such objections were amongst those raised in *Howard Florey Institute/ Relaxin*[38] where claims to DNA fragments encoding for a certain form of the human hormone Relaxin were upheld. This ground of objection was a generalized one as to 'the alleged intrinsic immorality of patenting human

genes', based, in so far as it can be understood, on the misconception that patents on human genes could in some sense confer a right of ownership over people. As the Opposition Division observed:

> It cannot be overemphasised that patents covering DNA encoding human H2 relaxin, or any other human gene, do not confer on their proprietors any rights whatever to individual human beings . . . No woman is affected in any way by the present patent – she is free to live her life as she wishes and has exactly the same rights to self determination as she had before the patent was granted.

In part the scope for such objections in relation to certain aspects of genetic engineering in Europe may be a matter of culture, and reflect the greater public scepticism in Europe towards genetic engineering in general. However, its engagement with the patent system is certainly a consequence of opportunity, as in Europe the centralized post-grant EPO opposition system has provided activists with a comparatively cheap, high profile, public platform to attack patents in this area under the express statutory exclusions from patentability on grounds of '*ordre public* and morality' and for 'plant and animal varieties'.[39] This has made it easier to openly raise issues of policy in genetic engineering in that official and public forum, than in any other, notwithstanding that patent examiners are hardly trained to be arbiters of morality and policy generally as to genetic engineering.

The Biotechnology Directive has, by Articles 6 and 4 respectively, clarified the scope of both these exceptions, but not in such ways as impact directly on the question of 'gene patents'.

UTILITY OBJECTIONS IN THE UNITED STATES AND INDUSTRIAL APPLICABILITY OBJECTIONS IN EUROPE TO GENE PATENTS

There was no real scope for any concern over utility or industrial applicability with the first generation of gene patents, as the genes in issue related to proteins of known potential therapeutic utility. However, the increasing ease of sequencing throughout the 1990s made it easier to identify novel DNA sequences in the human genome with little or no knowledge of the proteins, if any,[40] for which the DNA sequences so identified coded. The result was an increasing number of objections to claims to such DNA sequences on the ground of lack of utility, in the United States, and on a range of grounds, including the corresponding one of lack of industrial applicability, in Europe.

The industrial applicability issue has been less the subject of case law in Europe in the context of biotechnology, although its counterpart in the United States, utility, has been much more fully developed, no doubt primarily because of the deficiencies of United States law in addressing the obviousness of DNA sequences, but also as a result of the broader approach in Europe to the question of inventive step, where there can in effect be no invention in devising, or identifying, new things that lack a technical effect.[41] However, the basic principles of utility and industrial applicability are well established and understood in both jurisdictions. Thus, for example, in neither can a new chemical be patented unless it has some use – say as a drug, as a lubricant or an intermediate in the production of something useful, even though such use does not form a limitation to the claim, which, not being use bound, can then serve to monopolize any use of such chemical during the patent term.

The application of this principle in biotechnology can be most clearly seen in relation to the attempts made to patent gene sequences of unknown, or at least highly speculative, utility, namely gene fragments or 'expressed sequence tags' (ESTs), or variations in differing gene sequences between, namely 'single nucleotide polymorphisms' (SNPs[42] and 'haplotypes'[43]). These can be contrasted for example with the situation in *Relaxin*, or in any of the cases discussed above in the context of inventive step in Europe, where the utility of the gene sequence, as coding for a specific protein, which had known utility, was clear.

The USPTO, rather than addressing the root of the problem, namely the sterile United States approach to obviousness when applied to gene sequences, instead focused on utility, and established the need for an application to 'disclose a specific, substantial, and credible utility' when responding to certain comments on its revised Interim Utility Examination Guidelines:[44]

> If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the 'utility' requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

In Europe the issue was also, to a limited extent, addressed in Article 5 of the Biotechnology Directive:

> 5.3 The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application

Recital 23 explains this further:

> 23 Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention

An EPO Opposition Division in *ICOS Corporation*[45] interpreted this requirement for an 'indication of function':

> 11 (ii) . . . to be a requirement for indications that are more than speculative. In other words, DNA sequences with indications of function which are not substantial, specific and credible shall not be patentable inventions according to Article 52(1) EPC because they lack technical character.

The United States language of 'substantial, specific and credible' has thus been adopted in Europe, even though the issues that it addresses can often in Europe be addressed on grounds other than that of industrial applicability. Thus the decision in *ICOS Corporation*[46] provides an example of the manner in which other, more traditional, objections, may apply no less than that of the lack of industrial applicability objection as so formulated. Here various patent claims, including those to a purified and isolated polynucleotide (DNA sequence) encoding a certain amino acid sequence (polypeptide), which had a predicted structure consistent with a certain known type of receptor, were held invalid. They were also held to lack industrial applicability, but also on the grounds that they lacked inventive step, were insufficient and, as summarized in the headnote to the report:

> The disclosure of a predicted function of a protein in combination with a method of verification of this function is not necessarily adequate to sufficiently disclose the function of the protein. In the absence of a disclosed compound (a ligand for a predicted receptor protein) methods utilising this compound (modulating the binding of the ligand) are not considered sufficiently disclosed. A list, in the description, of speculative functions of a protein is not in itself a reliable basis for acknowledging industrial application of this protein. A DNA sequence encoding a protein without a credible function is not a patentable invention.

The harmonization of the views of the European and the United States Patent Offices (as well as that of Japan) on such issues is also reflected in the following set of conclusions reached at the Tripartite meetings between officials of such Patent Offices:[47]

1. A mere DNA fragment without indication of a function or specific asserted utility is not a patentable invention.
2. A DNA fragment, of which specific utility, e.g. use as a probe to diagnose a specific disease, is disclosed, is a patentable invention as long as there is no other reason for rejection.

3. A DNA fragment showing no unexpected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention (EPO, JPO). The above-mentioned DNA fragment is unpatentable if the specification fails to indicate an asserted utility (USPTO).
4. The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention.

A further set of conclusions, added after another meeting in 2000 was:

1. All nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, without indication of function or specific, substantial and credible utility, do not satisfy industrial applicability, enablement or written description requirements.
2. Isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed, which satisfy industrial applicability, enablement, definiteness and written description requirements would be patentable as long as there is no prior art (novelty and inventive step) or other reasons for rejection (such as, where appropriate, best mode [US] or ethical grounds [EPC/JP]).

As can be seen from their conclusions as to claims to DNA fragments, supplemented by those as to 'all nucleic acid related inventions', despite the various different problems that they have encountered along the way, Europe (as well as Japan) and the United States are starting to reach remarkably similar results on the questions of gene patenting, even if their reasoning for coming to such conclusions may sometimes differ.

CURRENT CRITICISMS OF GENE PATENTS

It was not until the 1990s, as exemplified by the controversy over the Biotechnology Directive that 'gene patents' became the subject of public discussion, at least in Europe. However, many of the criticisms then directed towards 'gene patents', as can be seen from the decision in *Relaxin*, were to them as a matter of principle. Such controversy has now to a large extent been resolved, even if not to the satisfaction of its more vociferous participants, by the Biotechnology Directive. The more recent discussion differs in that it has criticized 'gene patents' in the context of the control that they are perceived potentially to give to patentees over the application of information about gene sequences. Such a concern is expressed in

'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice':[48]

> Patents for genetic sequences might unduly prevent access to genetic information, restricting knowledge and technology transfer, and diminishing the potential benefits of biotechnology for the public at large.
>
> Patents for genetic sequences might adversely affect the commercial exploitation of biotechnology, unnecessarily hindering the efforts of the bioscience sector and deterring companies from investing in research and development in this area.

Such criticisms have, however, largely been fuelled by anecdotal concerns driven by the control that 'gene patents' are seen to allow patentees to exercise over exploitation of diagnostic tests, and in particular in the context of the licensing practices associated with testing for mutations of BRCA genes associated with certain breast cancers.[49]

As explained above, the patent claims in issue as to the BRCA1 gene were so expressed as to purport to monopolize only the method of diagnosis as claimed, and not any other research into the sequence to which the claim relates, or any therapy based on such knowledge of the sequence. Moreover, at least in Europe the statutory defence for 'use for experimental purposes relating to the subject matter of the invention'[50] would render research into better methods of diagnosis of mutation in the BRCA1 gene non-infringing, even were the current decision of an EPO Opposition Division finding the patent to be invalid to be overturned and the patent held valid. It does not appear that the heat has been taken out of the BRCA controversy in Europe by the decision of an Opposition Division of the EPO to revoke one of the BRCA patents as can be seen from the following article published after such revocation:[51]

> One reason why the market system does not always operate properly in the cases of patents on genes is because genes and genetic sequences are different from classical chemical compounds. Genes and genetic sequences have informational content. One cannot 'invent around' the sequence if it patented, because each gene and each gene sequence is unique in its kind. Hence through patenting, a 'double' monopoly arises.
>
> . . . I believe that a claim to exclude gene based diagnostics from patenting is legitimate from the standpoint that the patenting system should not interfere with the availability of a genetic test for the patient. The basis for such an exemption has been laid years ago. Article 52(4) of the European Patent Convention of 1973 excludes 'diagnostic methods, practised on the human body' from patenting. This definition dates back to the days when people did not want surgical methods and other medical practices to be patented. This could be updated to include genetic testing.

The identification of the problem in the first of these two paragraphs reflects the argument as to 'alternativeness' under United States law

discussed above. Although its effect may be moderated in Europe by the exclusion from patentability for mere discoveries, it remains a valid observation that one's scope to 'invent around' a sequence if it is patented is limited, because each gene and each gene sequence is unique in its kind. However, as observed above in relation to 'alternativeness', merely because each gene and each gene sequence is unique is not of itself a reason not to grant patents in respect of inventions based on such discoveries, as absent any other incentive than patents to undertake and to publish research on genes by providing a limited monopoly in the fruits of that research for a limited time, then such incentive effect can hardly be affected by the 'unique nature' of the results.

The second of the two paragraphs proposes extending the exception from patentability in Article 52(4) EPC for methods of treatment of the human or animal body by surgery, therapy or diagnosis, to include genetic testing. It is not apparent why diagnosis should not cover genetic testing, but in any case the aim of this exception is to prevent patent claims being drafted that medical practitioners would infringe by their activities. The exception does not prevent claims being written, albeit sometimes in a roundabout way, which can be asserted against those commercial enterprises that offer such services, or the means to undertake such services. If the intent of the proposal is to go further than this, then what is the justification for singling out genetic testing for special treatment under patent law, different from that of other medical treatments?[52]

However, gene patents are not relevant only to diagnostics. They play a role in the development by pharmaceutical companies of new therapies, so the perspective of such companies, who in fact themselves do relatively little gene patenting, (this activity being in the main undertaken by smaller biotechnology companies that seek to license to pharmaceutical companies the products of their research or the use of the 'research tools' that their patented discoveries purport to protect) is relevant. Moreover, it is a perspective which is unlikely to be skewed in favour of such patents, as pharmaceutical companies may have to seek licences under such patents for their research activities. Despite this, the view from the pharmaceutical industry is rather different, and authors from that industry who have studied this issue consider there to be no evidence that the patenting of human gene sequences stifles research or has an adverse impact on medical research.[53]

CONCLUSIONS

What then is the difference, in terms of patents, between genes and proteins, and should special provision be made for gene patents? The difference

between genes and proteins cannot simply lie in the information content of genes, as proteins are a reflection of such information. Instead it may lie in the fact that genes are, at least at present, little more than naked information that, unlike proteins, have little immediate use that goes beyond their information content.[54] That difference brings into sharp relief the expressed concerns as to 'patenting information', as opposed to the applications of that information, which in the absence of an analysis such as that undertaken by Lord Hoffman in *Kirin-Amgen v Transkaryotic Therapies Inc* can be all too easily thought of as undermining one of the core justifications of the patent system in terms of its role in disseminating information.

However, at least in Europe, such concerns as to gene patents have little foundation, once one moves from the general (which is where much of the discussion and comment has to date resided) to the specific, and starts to look at real life situations, at granted patent claims upheld in opposition and in litigation, and at the scope of such granted patent claims in terms of against what activities they can, and cannot be, successfully asserted.

Not only should we be wary of legislating on the basis of anecdotal concerns that have been inadequately analysed, but we should beware of doing so on the basis of historical considerations that have little relevance for the future. Thus the 'low-hanging fruit', the subject of the first generation of gene patents, in terms of proteins of known therapeutic utility and the gene sequences that code for them, or gene sequences of clear diagnostic utility, has been picked, and the patents that resulted from that activity are now expiring, at least in Europe. New gene patents face not only a stricter legal climate than ever before, but must face the ever expanding potential prior art that is constituted by every published patent application anywhere in the world, and the ever expanding gene sequence databases.

Moreover, specific measures fashioned in an attempt to address concerns that arose from earlier generations of gene patent are likely to be of doubtful relevance for the new generation of gene patents, which will focus for example less on identifying sequences than on identifying SNPs and other sequence differences between different populations. In the same way as the United States has fallen into error with its per se rules as to obviousness of gene patents, no per se rule can be structured which will distinguish between the inventions of the past and those of the future, or for that matter between those inventions that are felt to merit patents, and those that do not. The most reliable rules, even in an area such as gene patents, are those that are based on long-standing and traditional tenets of patent law, rigorously applied – utility (or industrial applicability), not being a mere discovery, novelty and inventive step. Technology-specific per se rules have the capacity to undermine such traditional tenets, which are ultimately the only reliable guide to patenting in new areas of technology.

NOTES

1. See for example EP 148 605 B, which expired in December 2004, and had been filed 20 years earlier in December 1984. This was the subject in the UK of the litigation that culminated in the judgment of the House of Lords on 21 October 2004 in *Kirin-Amgen Inc and others v Transkaryotic Therapies Limited and others* – for reports of the earlier stages of such litigation see below at note 7. This patent had claims to the sequence of the gene that codes for the protein erythropoietin, and such claims were in issue in the litigation to the extent that their interpretation affected the interpretation placed on certain claims in the patent to the protein. However, some of the corresponding United States patents to those in issue in the UK proceedings, because they are based on an application filed before the United States changed its rules on patent term, still have some time to last.
2. Other jurisdictions, such as Australia and Canada, have also considered the issues raised by gene patenting under their own laws. As to Australia, see the Reports of the Australian Law Reform Commission – ALRC Report 99 of June 2004, 'Genes and ingenuity: gene patenting and human health', ALRC Issue Paper 27 'Gene patenting and human health' and ALRC Discussion Paper 68 'Gene patenting and human health' of March 2004. As to Canada, see the Report of the Canadian Biotechnology Advisory Committee of June 2002 to the Canadian Government entitled 'Patenting of higher life forms and related issues'.
3. Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJ L 213, 30.7.98, p 13). For a discussion of its history, and of certain 'unsolved questions' that it has left, see E.R. Gold and A. Gallochat, 'The European biotech directive: past as prologue' *European Law Journal*, Vol. 7, No. 3, September 2001, pp 331–366.
4. National implementation throughout the EU should have taken place by 30 July 2000, and most but not all, EU Member States, including the UK, have now implemented the Directive. Implementation proved especially problematic in France and Germany, which in so doing introduced 'purpose-bound' limitations to claims for inventions concerning material isolated from the human body (France) and human/primate gene sequences (Germany) – see Commission Report (COM) 2005 312 final of 14.7.2005).
5. Article 53(a) EPC as amended by Article 16, EPC Revision Act of 2000 (not yet in force).
6. M. Stott and J. Valentine. 'Gene patenting and medical research: a view from a pharmaceutical company', *Nature Reviews Drug Discovery*, **3**, 364–8 (2004). The authors, however, distinguish the situation in Europe from that in the United States, where they estimate that in 2001 alone, about 1500 patents were granted claiming human genetic material, although the authors believe the rate of granting of such patents subsequently to have dropped following implementation of the United States Patent and Trademark Office Utility Guidelines (discussed below).
7. *Kirin-Amgen v Roche Diagnostics* [2002] R.P.C 1, *Kirin-Amgen Inc v Transkaryotic Therapies Inc* [2002] R.P.C. 2; *Kirin-Amgen Inc v Transkaryotic Therapies Inc (No. 2)* [2002] R.P.C. 3, *Kirin-Amgen Inc's Patent* ([2002] R.P.C. 43, *Kirin-Amgen Inc v Transkaryotic Therapies Inc* [2003] R.P.C. 3; [2005] 1All E.R. 667, [2005] R.P.C 9.
8. A gene is a DNA sequence that codes for a protein. In multi-celled organisms only a small proportion of DNA codes for proteins, as between genes, and also within most genes, there are DNA sequences, some of which can be extremely long, called introns, that do not code for proteins and the function of which is at present unknown. DNA as it occurs in nature, containing introns, is referred to as genomic DNA, whereas DNA which codes for a protein but which lacks its natural introns is referred to as cDNA.
9. A protein is a type of polypeptide, and in practice the two terms are often used interchangeably.
10. For a discussion of the background to this controversy and an outline of the various criticisms levelled against the patentee's licensing practices see M. Rimmer, 'Myriad genetics: patent law and genetic testing', (2003) *European Intellectual Property Review* pp 20–33. See also below in the section entitled 'Current criticisms of gene patents'.

11. This was an 'added matter' objection.
12. Auxiliary requests seeking a variety of alternative claims were also rejected on a variety of grounds, including those as to lack of inventive step over certain teaching as to BRCA1 gene mutations that had already been made available to the public at the priority date of such claims.
13. This is irrespective of the existence or otherwise of an experimental use defence. Such a defence, as to 'use for experimental purposes relating to the subject matter of the invention' exists in the patent laws of most European countries as a consequence of its inclusion in the Community Patent Convention, and applies whether or not the research has a commercial aim. It would in the present case allow commercial research to be done into diagnostic applications of the BRCA1 gene sequence if they were directed towards improving on the subject matter of the patented invention. However, no such defence exists in the United States and neither, despite suggestions in earlier case law to the contrary, does the common law imply one – see *Madey v Duke University* 307 F. 3d 1351; 64 USPQ 2d 1737 (Fed Cir 2002), cert denied 539 US 958 (2003) and *Integra Lifesciences 1, Ltd v Merck KGaA* 331 F.3d 860; 66 U.S.P.Q.2D 1865, (Fed Cir 2003) 1255. Ct. 2372 (Supreme Court 2005).
14. These principles are stated to apply to genes and to cell lines, by virtue of Article 2.1(a), which provides that 'biological material' 'means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'. Thus the Article has no direct application for example to claims to proteins as, unlike DNA, these do not contain genetic information and are not capable of reproducing themselves or being reproduced in a biological system.
15. *Official Journal of the European Patent Office* 1995, p. 388.
16. *Official Journal of the European Patent Office* 1995, 388, at paragraph 4.3.1. Here, however, the claimed fragments were not genomic DNA, containing introns, but instead cDNA, which similarly codes for a protein but which lacks the introns naturally found in genomic DNA. As cDNA does not occur in the human body, such sequences were novel for that reason alone, irrespective of the fact of their isolation. However, it would appear that isolated genomic DNA sequences, containing introns, had they been disclosed in the patent application, could properly have been claimed as such.
17. *Official Journal of the European Patent Office* 2002, p. 293.
18. Paragraphs 76 and 77 of the speech of Lord Hoffmann in *Kirin-Amgen Inc and others v Transkaryotic Therapies Inc and others*, 21 October 2004, House of Lords.
19. Indeed it could hardly be otherwise, given that the United States Constitution confers power to grant patents in respect of 'discoveries'.
20. United States Patent and Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 10092, 1093 (2001).
21. Nuno Pires de Carvalho, 'The problem of gene patents', *Washington University Global Studies Law Review*, Vol. 3, No. 3, 2004, pp. 701–53 at p. 733.
22. Barbara A. Caulfield, 'Why we hate gene patents', *American Lawyer*, January 2003 pp. 51–52. When this was written Ms Caulfield was Executive Vice President and General Counsel at Affymetrix, a leading US biotechnology company.
23. 4th Edition, 2001, at p. 119.
24. In earlier opposition to the patent at the EPO, inventive step had been in issue, and such attack had failed: see T 412/93 *Kirin-Amgen/Erythropoietin* [1995/8] EPOR 629.
25. [1987] RPC 553; [1989] RPC 147 (CA). In addition to claims to the protein of interest, and to processes for its production using recombinant DNA technology, there were also claims to recombinant cloning vectors, comprising the DNA sequence that codes for the protein of interest, and which represent yet another type of 'gene patent' claim.
26. [1989] RPC p. 613.
27. [2001] RPC p. 675. The patent was also held to be insufficient.
28. [1994] FSR 202 (Pat Ct); [1996] RPC 535 (CA); [1994] – see also the EPO Technical Board of Appeal Decision in T 188/97 *Chiron/NANBV* (unreported) where the claims of the equivalent European Patent (the patent in issue in the UK proceedings had been prosecuted nationally, to achieve a relatively rapid grant) were to a large extent successfully challenged on grounds other than inventive step, mainly on grounds of insufficiency.

29. The CAFC is the common appellate Court for all appeals in patent matters in the United States, whether from Federal Courts or from the USPTO.
30. 26 USPQ 2d 1529 (Fed Cir 1993). See also *In re Deuel*, 34 USPQ 2 1210 (Fed Cir 1995).
31. The task of working back from a protein to the gene that codes for it is complicated by the 'redundancy of the genetic code', an expression which describes the situation whereby more than one sequence of three bases in the gene codes for an individual amino acid in the protein. Thus one cannot simply write down a gene sequence knowing the sequence of amino acids in the protein for which it codes even though one can (assuming the sequence in question to be a coding sequence) so undertake the reverse process and write down the sequence of amino acids which make up a protein which is coded for by a given cDNA sequence. However, since the early 1980s the problem caused by the 'redundancy of the genetic code' can be overcome, in most cases, by techniques that have become increasingly standard and which do not necessarily involve any inventive activity.
32. National Academies Press, Washington, 2004, pp. 75–8 at p. 75.
33. [FN 121 in Original] EPO Technical Board of Appeals Decision No. T 0475/93-3.3.4 (1997).
34. See note 20 above, and the USPTO's 'Revised utility guidelines training materials' at http://www.uspto.gov/web/menu/utility.pdf.
35. The requirement for 'written description' would appear, in the current state of United States law, to be different to, but related to, that for enablement, although the precise nature of the relationship is (at least to this author) unclear. There is no specific corresponding requirement under European patent laws, although the requirement under Article 138(1)(b) EPC for a patent to 'disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art' has a degree of flexibility inherent in it which could perhaps be argued to correspond in certain cases not only to the United States requirement for enablement but also that for written description, even though it would appear never to have been expressly so construed in Europe. As to this, it should be noted that paragraphs 119 to 120 of the speech of Lord Hoffmann in *Kirin-Amgen Inc and others v Transkaryotic Therapies Inc and others* discuss an insufficiency attack on a claim to unknown analogues of erythropoietin, based on the same factual assertion as succeeded against such a claim, on the basis of lack of written description, in *Amgen Inc. v Chugai Pharmaceutical Co. Ltd* 18 USPQ 2nd 1016 (Fed. Cir. 1991), and as to which Lord Hoffmann, though coming to no concluded view, saw the force of the reasoning.
36. 378 F. 3d 1330 (Fed. Cir. 2004).
37. Article 53 (a) EPC as amended by Article 16, EPC Revision Act of 2000 (not yet in force).
38. *Official Journal of the EPO* 1995, p. 388.
39. In fact most such controversy originally concerned genetically modified animals, rather than patents for gene sequences, and much of it has involved consideration of the other exception from patentability to that for inventions contrary to '*ordre public* and morality' and found in European patent law, that under Article 53(b) EPC, for 'plant and animal varieties or essentially biological processes for the production of plants or animals . . .'.
40. Much DNA does not code for proteins, has no known function and so is not in fact a 'gene' – see note 8 above.
41. See T 939/92 *Agrevo / Triazoles* [1996] OJEPO 309, [1996] EPOR 171 for an application of this broader principle of inventive step. In the context of gene sequences, industrial applicability merely described as 'use as a probe' is unlikely to confer inventive step on a gene sequence whose significance is unknown, as such utility is itself obvious. Similarly a gene sequence whose likely utility, as to the protein for which it is thought that they might code, is assigned by known computer programs comparing its degree of similarity, or homology, with sequences of known function, is also, at least from a European perspective, likely to lack inventive step. However, see also *Chiron v Murex* [1996] FSR 153; [1996] RPC 535 (CA) in which part of a claim was held invalid by the English Court of Appeal as lacking utility as it included within its scope a vast number of compounds which were useless for any known purpose.

42. 'SNPs are single base pair positions in genomic DNA at which different sequence alternatives (alleles) exist in normal individuals in some population(s)': 'SNPs: what they are and what they might tell us', Anthony Brookes Research Group, available at http://www.cgr.ki.se/cgb/groups/brookes/snps.htm, quoted in Trilateral Project WM4, 'Report on comparative study on examination practice relating to single nucleotide polymorphisms (SNPs) and haplotypes', 10–12 June, 2003: see below.
43. 'The term "haplotypes" refers to a combination of SNPs on a chromosome, usually within the context of a particular gene', 'Haplotype identification' at http://www.variagenics.com/articles/haplotypeid.html, quoted in Trilateral Project WM4, 'Report on comparative study on examination practice relating to single nucleotide polymorphisms (SNPs) and Haplotypes', 10–12 June, 2003 – see below.
44. See notes 20 and 34 above.
45. *Official Journal of the EPO* 2002, p. 293.
46. *Official Journal of the EPO* 2002, p. 293.
47. Trilateral Project 24.1, 'Biotechnology – comparative study on biotechnology patent practices – Comparative Study Report', 1998 and Trilateral Project B3B (ex–24.1), 'Comparative study on biotechnology patent practices – theme patentability of DNA fragments', Updated to 23 June 2000. These two reports, and other trilateral reports, may be found on the websites of each of the three Patent Offices involved, namely www.uspto.gov, www.jpo.go.jp, and www.epo.co.at or www.european-patent-office.org. See for example the index to these studies at http://www.epo.co.at/tws/sr-3.htm. Other reports, concerned with more specific aspects of gene patents are 'Trilateral Project b3B: Mutual understanding in search and examination: Comparative study on biotechnology patent practices: Theme – Nucleic acid molecule related inventions whose functions are inferred based on homology search' (2000) and 'Trilateral Project WM4: Report on comparative study on examination practice relating to single nucleotide polymorphisms (SNPs) and haplotypes' 10–12 June, 2003. Other reports concerning biotechnology patenting, but that are not directly relevant to gene patenting, have also been published.
48. A study by the Intellectual Property Institute (IPI) on behalf of the DTI, May 2004.
49. See note 10 above.
50. Found in the national patent laws of most European countries, and based on the wording found in Article 31 of the Community Patent Convention of 1975, Article 27 of the Community Patent Convention of 1989 (OJEC L 401, p. 1) and now as repeated in Article 9 of the Proposal for a Council Regulation on the Community Patent (OJEC C 337 28.11.2000, p. E/278).
51. G. Matthijs 'Patenting genes' *British Medical Journal* 2004; **329**: 1358–60.
52. Similar pressures exist in the United States, which lacks any equivalent to Article 52(4) EPC and where methods of medical treatment can be patented, but medical practitioners have a defence from patent infringement suits when they use a patented medical or surgical procedure. Thus the proposed Genomic Research and Diagnostic Accessibility Act of 2002 would have provided a defence from patent infringement for those individuals who used patented genetic sequence information for non-commercial research purposes (an activity which in Europe would probably fall within the statutory defence for use for experimental purposes relating to the subject matter of the invention or that for use of private and non-commercial purposes) and for those medical practitioners utilizing genetic diagnostic tests.
53. M. Stott and J. Valentine 'Gene patenting and medical research: a view from a pharmaceutical company', *Nature Reviews Drug Discovery* **3**, 364–8 (2004).
54. The situation might be different were gene therapy to become a viable treatment option.

PART IV

IPRs, competition, access and antitrust in the age of the information society

12. Balancing intellectual property rights and competition law in a dynamic, knowledge-based European economy

Duncan Curley

INTRODUCTION

The creation of a favourable climate for technological innovation is a critical component of the drive to make the European Union the world's leading knowledge-based economy by 2010.[1] A strong, harmonized and affordable system of intellectual property rights (IPRs) is intended to underpin this policy objective, in recognition of the need to incentivize industry to undertake the necessary investment in research and development.[2]

Although IPRs vary, they are fundamentally monopoly or quasi-monopoly rights. They confer a statutory period during which the proprietor has a legal right to prevent others from carrying out certain acts (such as making, selling and importing products) that fall within the ambit of the granted monopoly. Patents and copyright are two examples of IPRs that will be specifically referred to later in this chapter; others include design rights, trademarks, database rights and plant variety rights.

The effect of IPRs may be of concern to those responsible for safeguarding European consumers from the improper use of monopoly power. It is the European Commission which bears the principal responsibility for regulating the conduct of undertakings on European markets, by enforcing EC competition law, as laid down in particular in Articles 81 and 82 of the EC Treaty, and by formulating competition policy. It is of course important for undertakings operating on European markets to understand how (if at all) EC competition law may circumscribe their rights, since this may affect not only decisions on whether the cost of seeking IPR protection is justified, but also companies' future decisions on whether to invest and attempt to innovate in particular areas of technology.

In order to balance the relative importance of IPRs and competition law, the European courts have developed a distinction between the *existence*

and the *exercise* of IPRs, so as to allow competition law to be brought to bear in circumstances where there has been activity which transcends the legitimate use of these monopoly rights, such as to perturb the efficient functioning of markets. The origins of the existence/exercise distinction can be traced back to the European Court of Justice's 1966 decision in *Consten and Grundig v Commission*.[3] Consten and Grundig had arranged for a French trademark registration to be used as a device to prevent parallel imports of dictating machines into France. The Court could not criticise the trademark registration itself: the existence of this national right was protected under the terms of the Treaty.[4] However, the implementation of the agreement infringed Article 81(1) because it frustrated one of the fundamental objectives of competition policy, namely, the abolition of barriers to trade between Member States and the formation of a single European market in goods and services.

One sees from the landmark decision in *Consten and Grundig* that EC competition policy is not formed in isolation, solely as an extension of economic policy. Other priorities and objectives contained in the EC Treaty (such as the single market imperative) are also in play and must be considered. Amongst these objectives are the protection of consumers, the encouragement of the growth of small and medium-sized undertakings and the promotion of technological development, by 'ensuring that there is a climate of free enterprise among firms that is conducive to innovative behaviour, and [. . .] by establishing conditions that favour the dissemination of technology'.[5]

This raises the question of the relative emphasis to be placed by the European Commission (when formulating competition policy) on seeking to foster innovation whilst also ensuring that there is effective price competition on European markets. Are these two objectives in conflict, when competition law impacts upon the exercise of IPRs? In endeavouring to answer this question, we will examine first the impact of Article 81 on the exploitation of IPRs, particularly in the context of the European Commission's approach to IPR and technology licensing (as embodied in its modernised Technology Transfer Block Exemption Regulation). We will then analyse the impact of Article 82 on the exercise by dominant firms of their IPRs and consider whether its application is consistent with that of Article 81. In the concluding section, we will consider whether there is any inconsistency in the application of EC competition policy and the objective of encouraging innovation and the dissemination of technology in a dynamic, knowledge-based European economy.

I. THE IMPACT OF ARTICLE 81

Article 81 regulates joint conduct between companies, by prohibiting agreements 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. Article 81(1)(b) expressly prohibits such agreements which limit or control 'production, markets, technical development or investment'.

The preservation of incentives to innovate has long been a feature in the application by the European Commission of Article 81(1). For example, the prohibition of clauses in patent and know-how licence agreements which have the ability to frustrate or disincentivize one of the parties to invest in innovative technology was a well-established feature of the Commission's old decisional practice.[6] In addition, licensing arrangements used to extend or leverage market power to products not covered by IPRs have also been condemned under Article 81(1).[7]

Nevertheless, the European Commission has for many years recognized that licensing of IPRs usually assists in the exploitation of innovative technology or creative works, thereby enabling more and better products to be brought to market and allowing greater consumer choice. In recognition of these pro-competitive benefits of licensing, the European Commission has used its power to issue block exemption regulations, which allow licence agreements to benefit from an automatic exemption under Article 81(3) from the prohibition in Article 81(1). The first combined block exemption for patent and know-how licence agreements was issued in 1996,[8] although it was criticized for not taking into account commercial realities and for being too rigid.[9] In 2003, the Commission decided substantively to modernize its policy towards IPR licence agreements and its technology licensing block exemption, publishing a revised technology licensing block exemption and a set of draft guidelines.

The Technology Transfer Block Exemption Regulation

After a six-month period of consultation and debate, a modernized Technology Transfer Block Exemption Regulation (the TTBER) for intellectual property licences and technology transfer agreements was brought into force on 1 May 2004.[10] The TTBER provides a wide, umbrella-type exemption from Article 81(1) for licensing deals between two parties. The Commission also issued detailed guidance on the application of Article 81 to IPR licence agreements in the form of a Commission Notice.[11]

In order for an agreement to come within the TTBER's exempt 'safe harbour', the parties' market shares must be below certain thresholds.

Assessment of the parties' market shares involves defining the relevant market and analysing economic data. For the analysis under the TTBER, two economic markets must be examined: the market for the products which are to be made pursuant to the IPR licence agreement and the market for the granting of IPR licences for technology. Undertakings with more than a 30 per cent individual share of a relevant product market or a relevant technology market are unable to take advantage of the TTBER's safe harbour. If two undertakings are competitors on either a relevant product market or a relevant technology market, their combined market share must be less than 20 per cent in order to come within the TTBER.

The introduction of economic effects-based assessment (and in particular the market share thresholds in the TTBER) was controversial. Critics referred to the difficulty of obtaining sufficient data to calculate market shares in certain licensing situations.[12] Furthermore, it has been said that in fast-moving sectors of the economy undergoing rapid technological change, a market share analysis may give a static and misleading impression of a firm's market power.[13] We will return to this issue later.

The reform of the TTBER and the publication of the Notice have rendered the Commission's approach to technology licensing more transparent. There is, for example, a pertinent section in the Notice, which directly addresses the role of investment in technology and the creation of IPRs in maintaining incentives to innovate, as part of the Commission's policy of fostering dynamic competition:[14]

> In the assessment of licence agreements under Article 81 it must be kept in mind that the creation of intellectual property rights often entails substantial investment and that it is often a risky endeavour. In order not to reduce dynamic competition and to maintain the incentive to innovate, the innovator must not be unduly restricted in the exploitation of intellectual property rights that turn out to be valuable.

There is no doubt that the Commission intended its new policy towards IPR licensing to have positive effects by encouraging technological innovation and effective dynamic competition. However, the European Commission has not yet won the debate over whether the TTBER will actually serve to promote licensing and the dissemination of technology, or whether it will cause companies to shy away from these activities because of the regulatory compliance burden involved.

Having looked briefly at the use of competition policy as a tool to assist in providing a framework for innovation in the EU, and having seen how this has recently influenced the application of Article 81 to agreements for the exploitation of IPRs, culminating in the TTBER, we now turn to

examine whether this policy is applied consistently in the interrelationship between the exercise of IPRs and Article 82.

II. THE IMPACT OF ARTICLE 82

Article 82 of the EC Treaty prohibits undertakings with a dominant position on a particular market from conducting themselves in a way which constitutes an abuse of their market power. An undertaking with a dominant position has sufficient market power to enable it to behave to a significant extent independently of competition from other undertakings. Where there is only one dominant undertaking on a market with several smaller, fragmented players, the dominant company may behave akin to a monopolist, for example, by means of its pricing strategies or by the imposition of trading conditions on its smaller competitors. A high market share may be indicative of a dominant market position. However, 'neither the creation nor the strengthening of a dominant position is in itself contrary to Article [82] of the Treaty'.[15] It is only when, for example, unilateral activities by a dominant undertaking work to the disadvantage of consumers that such activities may constitute an abuse of a dominant position within the meaning of Article 82.

The prohibition under Article 82 places a special responsibility on dominant firms not to act in a way that may be an abuse of their powerful market position. It imposes strict parameters on the way in which dominant firms may conduct themselves, with the aim of maintaining what little competition already exists on a market dominated by one main player.

Ownership of IPRs and Market Power

Ownership of IPRs does not automatically confer either market power or a dominant position on a particular market, but it may do so, if there are no non-infringing substitute products or alternative technologies available. This proposition has been explained by economists,[16] as follows:

> A patent confers the right to exclude others from making or using the product or process that is the subject of the patent. A copyright protects a particular expression of ideas. Does either instrument 'define' a relevant market? The answer is, not necessarily.
>
> Relevant markets are determined by reference to substitution, in demand as well as supply. This substitution is intrinsically an economic notion: when prices rise on what you currently buy, to what (and whom) can you turn as an alternative?
>
> . . . Relevant markets are shaped by economic substitutability. The fact that a patent can let you exclude technological substitutes need not say very much

about the availability of economic substitutes. Thus, a patent (or copyright) may well serve as the starting point of a relevant market inquiry in an antitrust case involving IP. However, the inquiry cannot end there; rather, just as we would in any other antitrust case, we must explore the alternatives that buyers would regard as economic substitutes.

Refusal to License: an Abuse of a Dominant Position?

The tension between IPRs and competition law is perhaps most stark in the cases where a dominant undertaking has refused to grant a licence of its IPR, and the remedy sought under Article 82 has been a compulsory licence. The inviolability of a firm's IPRs – whatever position they may hold on a particular market – is sacrosanct to companies dependent on IPR royalty streams for their survival.

The notion that a firm may be forced to grant a licence of valuable IPRs to a competing entity by virtue of EC competition law appears to strike at the heart of a company's basic right to exercise its property as it sees fit. We have already seen (in the discussion of Article 81, above) that the exercise of IPRs (as distinguished from their existence) may engage competition law. This includes Article 82, with the result that a dominant undertaking may be forced to deal with its competitors, by licensing its IPRs. The circumstances in which this may occur are self-evidently of interest to any IPR-based company wishing to secure its market position and to build market share.

The problem is that there is little relevant caselaw under Article 82 from which to divine clear guidance. Whilst the European Commission can issue and replace block exemptions and so update and revise its policies under Article 81, only the European Court of Justice can clarify or alter the law under Article 82 (although the Commission can select which cases it wishes to pursue, according to its prevailing policy dispositions).[17] There is – at the time of writing – no written document that expresses clearly the policy objectives underlying Article 82.[18]

The background to the few instances in which competition law has been used to condemn a refusal to license IPRs as an abuse of a dominant position is the jurisprudence on refusals to deal generally, in an Article 82 context. A refusal to deal with weaker competitors has long been an established 'head' of abuse under Article 82, since the European Court of Justice's judgment in 1974 in the *Commercial Solvents* case.[19] Commercial Solvents Corporation decided unilaterally that it would no longer supply the European market with the necessary raw materials for the production of a chemical, ethambutol. It continued, however, to supply its own European subsidiary exclusively with these raw materials, in order to make its own sales

of ethambutol in Europe. The European Court of Justice held that Commercial Solvents had a dominant position on the European market for the production and sale of the raw materials necessary for the manufacture of ethambutol. Because of its dominant position, Commercial Solvents could not refuse to supply the raw materials for the manufacture of ethambutol to those companies that asked for them, because this would be acting in such a way as to eliminate competition from the secondary market.

The abuse of refusal to deal was examined in 1988 specifically in an IPR context in the case of *Volvo v Veng*.[20] Volvo, the Swedish manufacturer of cars, brought a legal action in the UK against Erik Veng (UK) Limited, which sold car body panels. Volvo alleged that the importation and sale in the UK by Veng of Volvo front wing components infringed Volvo's UK registered design. The UK court referred questions to the European Court of Justice to give a preliminary ruling on the meaning of Article 82 of the Treaty. This included the question of whether it was an abuse of a dominant position to refuse to license IPRs to third parties in order to allow them to supply body panels, notwithstanding an offer to pay a reasonable royalty for all components sold under the licence.

The European Court of Justice held that the right of a proprietor of a registered design to prevent third parties from manufacturing, selling or importing products which incorporated the design constituted the very subject-matter of the exclusive right conferred by the IPR. Any obligation imposed on the proprietor of an IPR to grant a licence would take away the substance of the exclusive right. Thus, a refusal to grant a licence could not in itself constitute an abuse of a dominant position. However, the court was careful to note that the *exercise* of an exclusive right by the proprietor of an IPR could be prohibited by Article 82, if the dominant undertaking had carried out other acts, in addition to the refusal to license (including, for example, an arbitrary refusal to supply spare parts to independent repairers, or the fixing of prices for spare parts at an unfair level).

The conclusion that was drawn from *Volvo v Veng* was that if a dominant company owns IPRs which enable it to prevent competitors from producing directly competing products, it was not an abuse per se for it to refuse to grant licences. Dominant undertakings would only commit an abuse of a dominant position within the meaning of Article 82 by refusing to license their IPRs, if they did *something more* than merely exercise those rights to prevent the monopoly given to them from being infringed.

Magill, 'exceptional circumstances' and *IMS Health*

The background to the European Court of Justice's 1995 decision in the *Magill* case[21] was the planned launch by Magill of a comprehensive weekly

television guide that would list the programming schedules for each of the Irish television channels for the coming week. However, the Irish broadcasting channels RTE and ITP refused to provide basic information on the television schedules to Magill and asserted the subsistence of copyright in the compilation of the programme schedules. They refused to license this copyright to Magill. RTE and ITP each produced their own television guides, but there was no comprehensive guide on the market which provided a ready reference to all of the programmes being shown on all channels over the subsequent week.

The European Court of Justice, citing its own decision in *Volvo v Veng*, held that the exercise of an exclusive right (such as copyright) by the proprietor may *in exceptional circumstances* be abusive conduct under Article 82. This was such a case. RTE and ITP were – by force of circumstance – the only sources of the basic programme scheduling information. By refusing to provide this information and by their reliance on their copyright, RTE and ITP had prevented the appearance of a brand new product, a comprehensive weekly guide to programmes, for which there was proven consumer demand. In doing so, the court held that they had sought to reserve to themselves the secondary market of television guides, by excluding all competition on that market.

It is possible to distinguish the test propounded in *Magill* from the earlier test cited in *Volvo v Veng*. In the latter case, the European Court of Justice had been careful to make clear that a refusal to license was not a per se violation of Article 82. In order to amount to an abuse of a dominant position, there had to be evidence of other aspects of unilateral conduct which, coupled with the refusal to license, could amount to abuse. By requiring simply that 'exceptional circumstances' be demonstrated in the context of a refusal to license, the court in *Magill* appeared to have watered down the test stated in *Volvo*.

In consequence of the ruling in *Magill* and the particular facts of that case, there was much subsequent debate in the literature about whether 'exceptional circumstances' might apply to force compulsory licensing of IPRs in circumstances where 'weak' IPRs were thought to be undeserving of legal protection, without the requirement to demonstrate other unilateral conduct as well. This debate was fuelled by the views of officials in the Court of Justice and the Commission's legal service to the effect that the decision in *Magill* should be limited to unmeritorious IPRs and it did not apply to patented technology which was based on extensive investment in research and development.[22] This sentiment was endorsed by one of the UK patent judges, Mr Justice Laddie, in his decision in *Philips v Ingman*, [23] in which he doubted whether the 'exceptional circumstances' principle in *Magill* applied to patents.

The Court of First Instance (the CFI) muddied the waters further in its decision in 1997 in *Tiercé Ladbroke v Commission*.[24] It was held that a refusal to supply could not fall within the prohibition under Article 82 unless it concerned a product or service which was either essential for the exercise of the activity in question, in that there was no real or potential substitute, or was a new product whose introduction might be prevented, despite specific, constant and regular consumer demand on the part of consumers. It seems implicit from the CFI's ruling that a refusal to license can be an abuse of a dominant position not only in circumstances where its effect is to stifle the emergence of a *new* product on a secondary market (per *Magill*), but also in circumstances where the refusal extends to products (or services) which are essential (to the requesting undertaking) to enable it to carry out the very activity performed by the dominant undertaking itself (that is 'essential for the exercise of the activity in question').

Today, many years after the first decision in *Magill*, it is still uncertain when precisely 'exceptional circumstances' may exist so as to remove the ability of an owner of IPRs with a dominant market position freely to exercise its choice of licensing partners. It is disappointing to many that the European Court of Justice did not take the opportunity in April 2004 to clarify the law in its decision in *IMS Health v NDC Health*.[25]

IMS Health arose as a result of a referral to the European Court of Justice from a court in Germany. The issue was whether, in the circumstances of the case, an abuse had been committed when a dominant undertaking had refused a licence to its weaker competitor to use a database in which copyright subsisted, despite an offer to pay valuable consideration for the licence. The information contained in the database consisted of regional sales data on pharmaceuticals, organized in a database according to what was called 'brick' structure. NDC had previously attempted to enter the market in Germany for the sale of similar data and services, with a database structure that was derived from IMS' brick structure. IMS had sued NDC for copyright infringement and had sought an interim injunction. NDC asked IMS to grant it a copyright licence to use IMS' brick structure, in exchange for payment, but IMS refused. NDC therefore lodged a complaint under Article 82 with the European Commission.

The European Commission adopted an interim measures decision,[26] which required IMS to grant an immediate licence to all undertakings on the market for German regional sales data services, on request and on a non-discriminatory basis, for the use of the brick structure. IMS applied to the Court of First Instance for annulment of the Commission's interim measures decision and the President of the Court of First Instance granted the application for suspension. The national case then continued, but the German court decided to refer the question of whether IMS had the right

to final injunctive relief under German copyright law, if the refusal by IMS to enter into a licence with NDC on reasonable terms was abusive conduct within the meaning of Article 82.

In giving his opinion, Advocate General Tizzano thought that in order for an unjustified refusal to license to be abusive under Article 82, it was not sufficient simply to rely on the fact that the IPR was essential for operating on the market in question. The Advocate General said:

> in weighing the balance between the interest in protection of the intellectual property right in the economic freedom of its owner, on the one hand, and in the interest in protection of free competition, on the other, the balance may in my view come down in favour of the latter interest only if the refusal to grant the licence prevents the development of the secondary market to the detriment of consumers. More specifically, I consider that the refusal to grant a licence may be deemed abusive only if the requesting undertaking does not wish to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right but intends to produce goods or services of a different nature which, although in competition with those of the owner of the right, answers specific consumer requirements not satisfied by existing goods or services.

Although Advocate General Tizzano sought to amplify the court's earlier ruling in *Magill*, when the European Court of Justice gave its decision in *IMS Health*, the opportunity to confirm the Advocate General's opinion was not taken. The European Court of Justice instead tied its conclusions closely to the facts of the case, without making any clear statement of principle, stating that the central issue was a matter for the national court to determine in the dispute in the main proceedings. The court did, however, state that in order for the refusal of a copyright owner to give access to a product or service that was indispensable for carrying on a particular business to be abusive under Article 82, it was sufficient that three cumulative conditions were satisfied:[27]

- the refusal was preventing the emergence of a new product for which there was a potential consumer demand;
- the refusal to license by the copyright owner was not justified by objective considerations;
- the refusal was such as to exclude any competition on a secondary market.

It is not clear whether this is a different, general test from *Magill* 'exceptional circumstances' or whether it is simply a reiteration of the court's previous findings in *Magill*, with no additional statement of principle intended.

It is unfortunate that the court's decision in *IMS Health* offers little real assistance in discerning whether Article 82 and *Magill* compulsory licensing would apply when a competitor seeks to bring to market not just a new product (as in *Magill*), but merely a different product (or perhaps a 'me too' product)[28] which infringes the rights of a dominant undertaking. It appears (at least from its interim measures decision in *IMS Health*) that the European Commission is presently of the view that Article 82 has the more expansive application hinted at by the CFI in *Tiercé Ladbroke*, so that the remedy of compulsory licensing would not be restricted only to circumstances in which the market for a *new* product is being surpressed, by reason of a refusal to license. If confirmed by the European Court of Justice, this view would represent a further erosion of the exclusivity granted to the owners of IPRs. This view may soon be tested, if an appeal from the Commission's important decision in the *Microsoft* case[29] reaches the European Court of Justice.

Microsoft

On 24 March 2004, the European Commission concluded its five-year investigation into the activities of Microsoft Corporation (Microsoft), the US software company. The Commission complained of two alleged abuses of dominant position by Microsoft. First, it was said that Microsoft had refused to supply important interoperability information to its competitors, so as to allow them to offer their own work group server operating system software products. This software provides (for example) 'file and print' services to a group of personal computers (PCs), facilitating common access by a network of PC users to shared services. The second part of the case concerned the tying by Microsoft of its Windows media player to its Windows operating system. For present purposes, we will focus only on the former (work group server operating systems) aspect of the decision.

The Commission based its finding of dominance on Microsoft's very large market share of new PC operating system licences, which it said had been over 90 per cent since 2000. This was (according to the Commission) approaching a position of complete monopoly. Given the prevalence of the Microsoft Windows operating system on the PCs of many work group networks, Microsoft had an in-built advantage over its competitors in the market for work group server operating systems software, in that it was in the best position to engineer the most efficient software to interact with the ubiquitous Windows operating system installed on most PCs.

The Commission said that Microsoft had used its position of near dominance on the market for PC operating systems to leverage its position in the market for work group server operating systems, where its market share was conservatively estimated to be at least 60 per cent. The main rival to

Microsoft's operating system software, NetWare (sold by Novell), was in a weak market position, and other operating systems, such as Linux and UNIX, had only a limited presence on the market.

The Commission's investigation had been instigated by a complaint by Sun Microsystems Inc. (Sun) on 10 December 1998. Sun had previously written to Microsoft requesting that it be provided with specifications that would enable it to produce a competing work group server operating system software product to that offered by Microsoft. Microsoft refused Sun's request. Microsoft alleged that the interoperability information constituted valuable intellectual property, which was protected by copyright, trade secret laws and patents.[30]

The Commission characterized Microsoft's refusal to supply this information as akin to the refusal to supply a raw material, as in the old *Commercial Solvents* case (see above). The Commission noted in its decision that the specifications might constitute innovations that were prima facie protectable by Microsoft as trade secrets. The Commission also acknowledged that if it ordered Microsoft to disclose these specifications to its competitors (such as Sun) for the purpose of allowing them to produce rival work group server operating systems software, this might constitute compulsory licensing of Microsoft's IPRs. Nevertheless, Microsoft was ordered to disclose complete and accurate specifications of the protocols necessary for its competitors' work server operating system products to be able to talk to Windows-operated PCs on an equal footing with Microsoft's own work group server operating system.[31]

Microsoft had contended that none of the conditions identified in *Magill* were present in this case. The Commission stated that the 'exceptional circumstances' test was not limited only to one particular set of circumstances, per *Magill*. What was necessary was to analyse the *entirety* of the circumstances surrounding a specific instance of a refusal to supply. There were several features specific to this case that meant that Microsoft's refusal to supply interoperability information to Sun was an abuse of a dominant position. These included Microsoft's '*overwhelmingly*' dominant position on the market for PC operating systems and the fact that Microsoft had in the past disclosed interoperability information to other companies, in a period when it was trying to grow its share of the work group server operating system software market.

III. CONCLUSIONS

Although the revised TTBER is not without its critics, the attitude of the Commission to intellectual property licence agreements under Article 81

has undoubtedly been made more transparent by virtue of the public dialogue on the form of the block exemption and the extensive guidance issued by the Commission in its Notice. What is also clear is that the Commission's assessment of the potential anti-competitive effects of IPR licence agreements is now firmly grounded in economics and, in consequence, is more relaxed than it once was.

Furthermore, with the advent of a modernized system of competition law enforcement in the EU from 1 May 2004, it is now possible to justify restrictive clauses in an IPR licence agreement without recourse to the TTBER, if (for example) the parties have made substantial investments and undertaken significant risks in developing a technology, even though they may have high market shares or significant market power, such as to take their agreement outside the safe harbour of the TTBER. The Technology Transfer Guidelines state:[32]

> the innovator should normally be free to seek compensation for successful projects that is sufficient to maintain investment incentives, taking failed projects into account. Technology licensing may . . . require the licensee to make significant sunk investments in the licensed technology and production assets necessary to exploit it. Article 81 cannot be applied without considering such ex ante investments made by the parties and the risks relating thereto. The risk facing the parties and the sunk investment that must be committed may thus lead to the agreement falling outside Article 81(1) or fulfilling the conditions of Article 81(3), as the case may be, for the period of time required to recoup the investment.

A further embodiment of the Commission's liberalized policy towards the assessment of IPR licensing agreements under Article 81 is its Notice containing guidance on the application of Article 81(3).[33] This Notice is intended to assist undertakings in 'self-assessing' their contractual arrangements against the Commission's criteria for exemption under Article 81(3). Although the focus in the Notice is on demonstrating quantitative economic efficiencies, qualitative efficiencies may also be taken into account. Thus, if the parties can demonstrate that an agreement will produce a technological innovation that will generate significant economic benefits, such as new or improved products, this may be taken into consideration in the overall assessment under Article 81 (although it is not yet clear how far a putative technological advance may be weighed in the balance against potentially 'hardcore' contractual restrictions in an agreement, or indeed whether it would ameliorate the Commission's generally diffident attitude to a contractual arrangement between direct competitors).

To conclude the discussion on Article 81, whilst the focal point of policy remains price competition, the Commission's desire to encourage innovation and the dissemination of technology runs as a consistent theme

throughout the modernized rules, specifically the TTBER, the accompanying guidelines and the Article 81(3) Notice. In addition, the rules now contain sufficient flexibility to permit dynamic efficiencies to be accommodated in an Article 81 analysis of an IPR licensing arrangement. Are these themes echoed in the complementary application of Article 82?

A frequent criticism of Article 82 is that its protective function often appears to work so as to insulate smaller companies from the effects of competition, rather than to safeguard the efficient functioning of markets. If this is a true function of Article 82, there is a danger that competition law may have the effect of unfairly constraining successful undertakings that have achieved high market shares by bringing to market innovative, successful products that are popular with the majority of consumers.

It is suggested that undue focus on high market shares may be particularly unwarranted in certain new economy industries, where companies are more likely to base their business model on IPRs, rather than on tangible assets. Attacking monopoly with the blunt tool of a competition policy focused on reducing high market shares may serve to exacerbate the tension between competition law and the exercise of IPRs by successful (dominant) firms.[34] There appears to be at least the beginning of a trend in this direction in the recent decisions of the European Commission under Article 82.

The old-fashioned view of *Magill* was that compulsory licensing of IPRs would only be entertained if unlicensed undertakings could not enter a secondary market for products not made by the dominant rights-holder, because the products in question could not be made without infringing the rights-holder's IPRs. The interim measures decision in *IMS Health* and the outcome of the *Microsoft* investigation suggest that the Commission does not believe that Article 82 should be so limited. In *Microsoft* in particular, there were already other work group server operating system products on the market. It could not be said that access to Microsoft's interoperability information was *essential*, in order for competition to take place (although the Commission alleged that the effect of Microsoft's refusal to supply the requisite information would be to force the market to migrate towards an industry standard for work group server operating systems based on Windows, thereby discouraging other companies from coming up with innovative solutions of their own and limiting technical development to the prejudice of consumers).[35]

Whereas one may have some sympathy for the argument that in *Magill* the copyright in simple lists of TV programmes generated without particular skill or creative thought was being used to stifle a new product for which there was pent up consumer demand, in *Microsoft* the means of effecting interoperability was (according to Microsoft) the subject of patent

protection. The notion that this protection should be abrogated by a compulsory licensing order under Article 82 is of serious concern.

In this context, it is hard to ignore some of the negative sentiment about IPRs that has permeated recent statements by officials from the European Commission.[36] Patents have been said, for example, to be overly broad and/or too long in duration, such that they may have the effect of retarding innovation, in some instances. If true, the traditional rationale for IPRs is turned on its head. It is suggested that one should guard carefully against giving credence to generalized statements about the (lack of) benefits of IPR protection. After all, a legal system of patent monopolies has been in place in the UK for 400 years. The modern system is tried, tested and is generally effective. There is a legal mechanism for removing patents which are undeserving of a 20-year monopoly, without resorting to compulsory licensing under competition law.

If eventually adopted by the European Court of Justice, the broad 'entirety of the circumstances' test employed by the Commission in its *Microsoft* decision could mean that a dominant firm may be forced to license its IPRs to competing entities which intend to offer a product which will *directly* take market share away from the dominant company. This raises an interesting innovation/investment conundrum: why should a company invest in new technology in order to compete more effectively on the merits and to boost revenues, if there is a danger that one day the IPRs and other advantages conferred by such investment will be removed by competition law?

In conclusion, there is a danger that over-application of Article 82 along the lines suggested in the *Microsoft* decision could further erode the penumbra of exclusivity granted to the owners of intellectual property. As such, it may upset the delicate balance between competition law and the need to preserve incentives to innovate offered via IPRs. This would run contrary both to current policy under Article 81 and to the important objectives for the European economy, as expressed at the Council meeting in Lisbon in 2000.

NOTES

1. This objective of European Community (EC) industrial policy was proposed by the European Council at Lisbon in March 2000.
2. Deputy Director General Stoll, D.G. Internal Market (European Commission), at *The Pan-European IP Summit*, Brussels, 2 December 2004.
3. [1996] ECR 299.
4. Article 295.
5. D. Hildebrand in *The Role of Economics Analysis in the EC Competition Rules*, 2nd edn (2002), Kluwer Law International, p. 18.

6. *Rich Products*/*Jus-Rol* [1988] 4 CMLR 527; *Delta Chemie*/*DDD* [1989] 4 CMLR 535.
7. For example, in the European Court of Justice's decision in *Windsurfing International v Commission* [1986] 3 CMLR 489, a patent to a rig, a component of a sailboard used in the sport of windsurfing, was the subject of a patent licence agreement. The patentee imposed an obligation on its licensees to sell only complete sailboards, which included non-patented components. The Court held that this obligation restricted competition in the market for the sale of separate, non-patented components.
8. Regulation 240/96 [1996] O.J. L31/2.
9. See the Commission's Evaluation Report on Regulation 240/96, COM (2001) 786 final of 20.12.01.
10. Regulation 772/2004 on the application of Article 81(3) to categories of technology transfer agreements. For a detailed analysis of the TTBER see D. Curley (2004) *Intellectual Property Licences and Technology Transfer: A Practical Guide to the New European Licensing Regime*, Chandos Publishing (Oxford) Limited.
11. Commission Notice C101/02 (2004).
12. P. Treacy and T. Heide (2004), 'The New EC Technology Transfer Block Exemption Regulation', *European Intellectual Property Review* **26**(9), p. 420.
13. This criticism of the TTBER was rejected by the (then) European Commissioner for Competition, Mario Monti, in a speech which he made in January 2004: see Commission Press Release SPEECH/04/19 of 16 January 2004.
14. See the Notice, paragraph 8.
15. *Gøttrup-Klim* [1996] 4 CMLR 191.
16. S. Addanki and K. Anderson (1995), 'The Relevant Market in Intellectual Property Antitrust: An Economist's Overview,' Practising Law Institute/Patents, Copyrights, Trademarks and Literary Property, 414–577.
17. 'Rethinking Article 82 EC: The challenges ahead', lecture by Professor Richard Whish to The Law Society's European Group, London, 27 April 2004.
18. Although (as at October 2004) the European Commission is conducting a review that is examining whether its present policies under Article 82 are economically sound and transparent and in December 2005 it published a discussion paper on the application of Article 82 to exclusionary abuses.
19. *ICI and CSC v Commission* [1974] 1 CMLR 309.
20. [1989] 4 CMLR 122.
21. *RTE and ITP v Commission* [1995] ECR I-743.
22. V. Korah (1996), *Technology Transfer Agreements and the EC Competition Rules*, Oxford, Clarendon Press, p. 54.
23. [1998] 2 CMLR 839.
24. [1997] ECR II-923.
25. Case C-481/01.
26. Decision 2002/165/EC: O.J. 2002 L 59.
27. Paragraph 38 of the judgment.
28. T. Cook (2004), 'Has copyright hit the wall?', *Copyright World*, 142, p. 20.
29. C(2004) 900 final (24.03.2004).
30. Although it appears from the decision that Microsoft did not clearly demonstrate to the Commission how the sanction of compulsory disclosure would cut down its IPR protection: see 'Court tells Microsoft to prove IP threat', *Financial Times*, 12 August 2004, p. 26.
31. Microsoft subsequently applied to the President of the Court of First Instance to suspend this part of the Commission's decision, pending Microsoft's appeal on the merits. However, on 22 December 2004, Microsoft's request for suspension was refused: see Commission Press Release MEMO/04/305 dated 22 December 2004.
32. At paragraph 8.
33. Commission Notice C101/97 (2004): Guidelines on the application of Article 81(3) of the Treaty.
34. *Intellectual Property and Antitrust: Steps Toward Striking a Balance*, Langenfeld, J. 52 [2001] Case W. Res. 91.

35. Expressly prohibited pursuant to Article 82(b) of the Treaty.
36. See for example L. Peeperkorn (2003), 'IP licences and competition rules', *World Competition*, **26**(4) 527–39; 'Singing in tune with competition and innovation: the new EU competition policy towards licensing', paper presented by Mr Philip Lowe, Director General, D.G. Competition (European Commission) at the Fordham Corporate Law Institute Annual Conference, New York (2004).

13. Technology, time and market forces: the stakeholders in the Kazaa era[1]

Uma Suthersanen

> history has shown that time and market forces often provide equilibrium in balancing interests, whether the new technology be a player piano, a copier, a tape recorder, a video recorder, a personal computer, a karaoke machine or an MP3 player. Thus, it is prudent for courts to exercise caution.
>
> Judge Thomas, *MGM Studios et al. v. Grokster Ltd.*[2]

INTRODUCTION

Every technological revolution has invariably been greeted by howls of hysteria from copyright owners. Historically speaking, technology has always changed the relationship between three key stakeholders in the world of commercial copyright goods: the author, the industry in charge of the copyright good, and the consumer. The piracy threat posed by reprographic technology was resolved by lucrative blanket licensing deals between copyright collecting societies and a host of disparate mass users of copyright works including churches, universities, businesses and libraries; the piracy threat posed by video technology led to lucrative video (and now DVD) rental income for the copyright owner; the piracy threat posed by downloading of music will soon turn into a booming business model for buying singles through iTunes, Napster (*ex post*) and MyCoke.com. History shows us, however, that the stakeholder triumvirate, that is author–industry–consumer remains consistent. One major reason for this is that the structure and performance of this relationship, and the market for the copyright good, has relied on, and continues to rely on, technological improvements to compensate for any shifts in control and power.

The US Supreme Court was of this view in *Sony v Universal City Studios*. Nevertheless, subsequent case law indicates that courts have, perhaps, wielded the sword of copyright law too vigorously in relation to more recent

technological innovations such as peer-to-peer sharing software. We discuss this briefly in *A&M Records Inc. v Napster*. The tide was seemingly turned with the US 9th Circuit's decision in *MGM et al. v Grokster*. So important is this balance between property rights and the future innovation policies that the US Supreme Court reviewed the *Grokster* holding, and reversed that decision. Whilst doing so, the majority opinion declined to revisit the *Sony* decision; nevertheless, this did not stop Justice Breyer in reaffirming that *Sony* was good law in his concurring opinion.

The technology cases reveal a dilemma as technology poses as both a threat and an opportunity to the copyright owner simultaneously. Technology facilitates the reproduction of works, and hence the constant calls for increased protection. However, technology also facilitates the dissemination of works, a circumstance requiring an innovation-friendly copyright policy. How do we deal with the dilemma of technologies that simultaneously expands and encroaches a copyright holder's space? The technology cases are not the only outcome of this dilemma – international, US and EU copyright laws and policies all tend towards widening the scope of copyright protection, without the necessary corresponding safeguards for technological innovation. Technological protection measures and digital rights management are now core concepts within the copyright laws of major developed countries.

The technology cases also reveal which stakeholders are involved in policy making. One means of determining whether changes in policy are required is to utilize the stakeholder methodology in order to gauge whether theoretical models concerning the economic and social behaviour of rights holders and authors correlate to the current working practices and behaviour of the major players in the sectors concerned. Thus, a stakeholder analysis enables us to identify the core interests of the key individuals, corporations and societies who play a part in the production and consumption of copyright goods in the entertainment and information technology sectors. This analysis may not give us solutions, but it will help in discerning whether there should be a re-evaluation of the current copyright theory, law and policy so that it may better reflect the interests of key participants. A fundamental concern in considering what constitutes market harm to *which* stakeholder, should be whether any anti-competitive behaviour is evident from the perspectives of consumers and other stakeholders. It is submitted that in considering market harm, our analysis should consider the main players in the relevant product field: music copyright owners (authors and sound recording companies), consumers of music (browsers, samplers, listeners, potential purchasers, information Samaritans, and unabashed free riders) media players, software and communications manufacturers and suppliers, current retailers and potential online retailers.

I. APPRAISAL OF THE TECHNOLOGY CASES

1.1 Seeking the Initial Stakeholders: Author and Societal Needs

At issue in *Sony Corp. v Universal Studios, Inc.*[3] was the fact that Sony's Betamax home videotape recorders were in widespread usage amongst television viewers who were employing them to record programmes for later viewing, known as time-shifting. The plaintiffs claimed that the use of the Sony recorders by private individuals in their homes for their own private use constituted copyright infringement of the works thus taped. They further claimed that defendant Sony, as the manufacturer and seller of the recorders and Betamax tapes, was liable as a contributory infringer. The Supreme Court concluded that Sony was not liable for contributory infringement. In relation to a technology that is used by consumers, an important factor in the *Sony-Betamax* decision was the potential of the technology to be employed for non-infringing uses. Sony supplied equipment that was generally capable of copying copyright works, or non-copyright works, or copyright works which could be copied without objection from the copyright holder.[4] Indeed, the product need merely be capable of substantial non-infringing uses.[5] Moreover, the Supreme Court had refused to hold the manufacturers and retailers of video tape recorders liable for contributory infringement despite evidence that such machines could be and were used to infringe plaintiffs' copyright-protected television shows.[6] Although Sony may have had general knowledge that its VCR would be used for the unauthorized copying of protected works, and although it had advertised the VCR for just such a purpose, this was insufficient. The Supreme Court was of the express opinion that such generalized knowledge was insufficient to impose liability for vicarious or contributory infringement.[7]

The Supreme Court also identified two stakeholders within the constitutional basis of copyright law, Article 1.8, US Constitution demanded that a balance be achieved between the interests of authors in the control and exploitation of their writings on the one hand, and society's competing interest in the free flow of ideas, information and commerce on the other hand.[8] The court went further and emphasized the two different justifications for copyright protection: reward for the authorial labour and creativity; and stimulation of general creative activity and access to products of such activity. The Supreme Court then held that the reward aspect of copyright law was a secondary consideration. Instead, the ultimate aim of copyright law is the achievement of a *public purpose*: to stimulate creative activity for the general public good and to ensure public access to the products of such activity.[9]

A similar phenomenon in more recent technological terms is 'space shifting'. In *Recording Indus. Association of America, Inc. v. Diamond Multimedia Systems Inc.*[10] the defendant was the manufacturer of a portable, hand-held playing device (the Rio player), which was capable of receiving, storing and re-playing MP3 files: these files were transferred to the Rio player from the hard drive of a personal computer. In *obiter* the 9th Circuit held that the Rio player merely makes copies in order to render portable, or 'space-shift,' those files that already reside on a user's hard drive. Placing reliance on the *Sony* decision, the court opined that such copying of files is paradigmatic non-commercial personal use which is entirely consistent with the purposes of the copyright law.[11] Thus, the impact of the *Sony* decision is far-reaching in that it clearly puts technological progress before copyright interests. Indeed, without it, lawful purchasers of copyright works such as broadcasts, cable services, music or films would not now be able to shift, for the sake of convenience and portability, their lawful purchases from one place–time-medium dimension (such as scheduled TV programming, CDs or DVDs) to another place–time–medium dimension (such as an MP3 player, an iPod or a TiVo).

1.2 The File Sharers and Multi-use Technology

The above findings in the *Sony-Betamax* decision were applied in a desultory manner in the subsequent big technology case – the *Napster* decision – where the primary focus was on the unfair dealings of the defendant and the consequent effect on competition. The *Napster* and subsequent cases since then all deal with file sharing or peer-to-peer (P2P) technology. P2P systems usually lack dedicated, centralized infrastructures, but depend on the voluntary participation of peers to contribute resources (that is music, text, image or film files) out of which the infrastructure is constructed. In a peer-to-peer distribution network, the information available for access does not reside on a central server or one computer; rather each computer makes information available to every other computer in the dynamic peer-to-peer network. At any given moment, the network consists of other users of similar or the same software online at that time. Because the information is decentralized in a peer-to-peer network, the software provides a method of cataloguing and indexing all the available information and files so that users may access and download them.[12] There are three different methods of indexing:

i. a centralized indexing system, maintaining a list of available files on one or more centralized servers;
ii. a decentralized indexing system, in which each computer maintains a list of files available on that computer only; and

iii. a 'supernode' system, in which a select number of computers act as indexing servers, and which was developed by KaZaa BV, a Dutch company.[13]

Important factors in considering the technology are that the servers do not create, copy, store or make available any of the sound, text or image files on its servers (whether transient or otherwise). Neither are the contents of the files routed or transmitted through the P2P network or servers. The contents of all files are held at all times on the users' computers, and what P2P basically does is to hold a database of file names and, if requested, the IP address information of each user.

Napster was sued in 1999 by several major recording companies who claimed that Napster's P2P file-sharing technology made it contributorily and vicariously liable for its users' alleged copyright infringement. The courts, both at first and appellate instances, were not overly enthusiastic with the assortment of defences raised by Napster to explain its conduct, and Napster's use of the *Sony-Betamax* defence was unsuccessful.[14] On the facts, the district court and the copyright owners clearly accepted that the program was capable of non-infringing uses:[15] authorized music and non-copyright music were being traded on the system; and new and established artists were being promoted utilizing the software technology. Thus, file sharers employed Napster for a variety of reasons and uses:

i. appropriation that is to consume the work without authorization and payment;
ii. browsing that is to test market a work before deciding whether to purchase it;
iii. publicity and promotion that is to act as an information/entertainment Samaritan by 'helping' to disseminate works of lesser known groups or people.

Nonetheless, the *Napster* courts ignored this avenue of reasoning, and instead, held that the Napster program had unacceptably harmed the sound recording industry's market, especially in relation to sales within college markets. The primary issue, from the courts' perspectives, was whether file-sharing causes market harm to the property owner. In doing so, the courts rejected Napster's report alleging that P2P file-sharing stimulates more CD sales than it displaces, hence benefiting the music industry. One main reason for the courts' hostility to Napster was that the Napster network had created barriers to the sound recording industry entering into the market for the digital downloading of music.[16] As the appellate court emphasized, the

> lack of harm to an established market cannot deprive the copyright holder of the right to develop alternative markets for the works . . . Having digital downloads available for free on the Napster system necessarily harms the copyright holders' attempts to charge for the same downloads.[17]

A further important factor in the *Napster* decision was whether, in respect of contributory infringement, Napster had the requisite amount of knowledge. Could the company really be said to have encouraged and assisted in the infringement of the plaintiffs' copyright? Did it not have a disclaimer on its site and a specific injunction to its users against the download and distribution of copyright music? Once again both courts were in agreement: Napster had both actual and constructive knowledge that its users exchanged copyright music. Relying on the district court's findings, the appellate 9th Circuit held that without the support services that Napster provides, its users could not find and download the music they wanted with the ease of which the defendant boasts, and that Napster provides 'the site and facilities' for direct infringement. The appellate court continued to hold that, regardless of Napster's non-infringing uses, the evidentiary record was that Napster knew or had reason to know of its users' infringement of plaintiffs' copyrights, and had the means to block access to the system by suppliers of the infringing material. It is difficult to discern, from a reading of the *Sony* decision whether this approach adopted by the 9th Circuit was correct, because both courts utilized the element of 'non-infringing' use in diametrically opposite ways. As far as the Supreme Court in the *Sony-Betamax* case was concerned, the fact of potential non-infringing uses led directly back to the activities of the users which, in turn, led to the Court's declaration that 'time-shifting' activities constitute fair use. The 9th Circuit proceeded from a reverse direction: having held all activities of users as being non-fair uses of a copyright work, the fact of the capability of the system for potential non-infringing uses did not sit well in its rationale for contributory infringement.

This is a similar stance to that adopted by the United Kingdom House of Lords in *C.B.S. Songs Ltd. & Ors v Amstrad Consumer Electronics Plc. & Anor*.[18] On the issue of whether the manufacture and sale of analogue tape recorders constituted authorization of infringement of copyright works, the court held that the defendant may have conferred on the purchaser the power to copy 'but did not grant or purport to grant the right to copy'.[19] One view of the British court is that there are a variety of places and manufacturers which offer 'materials which by their nature are almost inevitably to be used for the purpose of an infringement', such as home taping devices, borrowed records from friends and public libraries, radio performances, trial records, record clubs offering introductory trials.

However, in all these instances, the lenders and sellers do not authorize infringing use.[20]

Indeed, using this analogy, it is difficult to see how any type of technology could be held liable under United Kingdom law in that the very nature of computers, modem and the Internet (and Internet cafés) are all 'materials' which almost inevitably lead to copying and distribution, and the Napster, Aimster, and Kazaa technologies are just additional facets in this digital environment. More to the point, these arguments in relation to control and knowledge do not extend easily to the next generation of cases involving decentralized P2P systems as offered by the Gnutella and Kazaa software.

1.3 Decentralized Systems: the Kazaa and Gnutella Phenomenon

The *Napster* judgment acts almost as a disincentive to new types of technologies or business models. It is true that the individual users of the system were indulging in infringing activities by making available, downloading and generally trafficking in digital versions of music. And no criticism is made here of the recording industry's policy of actively pursuing such individuals except to note that these suits, including one to sue a dead woman,[21] do generate extremely poor public relations.[22] However, should the producers of the technology which enables such activity be punished? Indeed, the *Napster* decision appears to ignore the teachings of the Supreme Court in *Sony-Betamax* which was that the ultimate aim of copyright law is the achievement of a *public purpose* rather than reward or a fair return for labour invested in the work. 'Conversely, it is obvious that once a user lists a copy of music he already owns on the Napster system in order to access the music from another location, the song becomes "available to millions of other individuals", not just the original CD owner.'[23]

The Napster model was effectively destroyed by industry, only to be replaced by newer and faster file-sharing technology such as Kazaa.[24] In the most recent *Grokster* decision, the plaintiffs comprised a majority of the film and sound recordings industry in the United States, thus having a dominant position in the market comprising 'copyrighted motion pictures and sound recordings in the United States'.[25] The defendants manufacture and distribute freely two P2P software applications, Grokster and Morpheus. The Court of Appeal held for the software manufacturers, relying on the *Sony* doctrine. The lower courts agreed that the defendants' software was capable of substantial non-infringing uses and, therefore, that the *Sony-Betamax* doctrine applied.[26] The court further reiterated the *Sony-Betamax* standard: 'a product need only be *capable* of substantial noninfringing uses' and such uses have commercial viability.[27] Moreover, the courts were

convinced that both programs were technologically advanced enough to have numerous other uses, significantly reducing the distribution costs of public domain and permissively shared art and speech, as well as reducing the centralized control of that distribution. All these were held to distinguish the situation in *Grokster* from *Napster*.

Moreover, once substantial non-infringing use was established, the remaining issue was whether the defendants had reasonable knowledge of infringing activities and failed to act on that knowledge to prevent infringement.[28] The district court and the court of appeal held that no control was possible under the decentralized, Gnutella-type network or the quasi-decentralized, supernode, Kazaa-type network since no central index is maintained; even if the defendants 'closed their doors and deactivated all computers within their control, users of their products could continue sharing files with little or no interruption.'[29]

Furthermore, the lower courts accepted the evidence that the activities of Grokster and StreamCast did not materially contribute to copyright infringement, including the following arguments:

- their sites do not provide the site and facilities for infringement in the first place;
- the defendants' software communicates across networks that are entirely outside the defendants' control;
- in the case of Grokster, the network is the proprietary FastTrack network, which is not controlled by Grokster, whereas in the case of StreamCast, the network is Gnutella, the open-source nature of which apparently places it outside the control of any single entity;
- all infringing conduct occurs after the product has passed to end-users.

The Supreme Court's decision

On appeal to the Supreme Court, the majority opinion was that *Sony* was misapplied by the Court of Appeal, and that both Grokster and Streamcast were liable for secondary infringements. The reason for this was that both had taken active steps to encourage or 'induce' infringement. The Supreme Court then went further and transplanted the common law rule of inducement of infringement (stating as their justification the *Sony* decision to take the staple-article doctrine from patent law) which is as follows:.

> [O]ne who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties. We are, of course, mindful of the need to keep from trenching on regular commerce or discouraging the development of technologies with lawful and unlawful potential. Accordingly, just as *Sony* did not find intentional inducement despite

> the knowledge of the VCR manufacturer that its device could be used to infringe, mere knowledge of infringing potential or of actual infringing uses would not be enough here to subject a distributor to liability. Nor would ordinary acts incident to product distribution, such as offering customers technical support or product updates, support liability in themselves. The inducement rule, instead, premises liability on purposeful, culpable expression and conduct, and thus does nothing to compromise legitimate commerce or discourage innovation having a lawful promise. [citations omitted]

What accounts for this *volte face*? First, the majority opinion was persuaded as to acts of inducing infringement such as advertising and internal emails exhorting both their own employees and others to switch to their services when the Napster service was shut down.[30] Second, the court opined that there was no evidence that either company made an effort to filter copyrighted material from users' downloads or otherwise impede the sharing of copyrighted files – on this point, the Supreme Court again was convinced that both networks could have blocked 'anyone from continuing to use its software to share copyrighted files'.[31] Third, the Supreme Court held that the Court of Appeal had misapplied the *Sony* decision. According to the Supreme Court, the *Sony* staple article rule is applicable only if there is no evidence of intent and actions directed to promoting or inducing infringement.[32] Here, the Supreme Court held that there were three features which pointed to inducement:

- both companies showed themselves to be aiming to satisfy a known source of demand for copyright infringement, that is the market comprising former Napster users;
- this evidence of unlawful objective is given added significance by MGM's showing that neither company attempted to develop filtering tools or other mechanisms to diminish the infringing activity using their software. While the Ninth Circuit treated the defendants' failure to develop such tools as irrelevant because they lacked an independent duty to monitor their users' activity, the Supreme Court thought otherwise and stated that this evidence *underscored* Grokster's and StreamCast's intentional facilitation of their users' infringement;
- finally, both software manufacturers made money by selling advertising space, by directing ads to the screens of computers employing their software; thus, the extent of the software's use determined the gain to the distributors, and the commercial sense of the companies' enterprises turned on high-volume use, which the record showed was infringing.

So can we characterize this decision as having affirmed its technology-friendly stance, as it did in the *Sony-Betamax* decision? For the answer to

that question, we must turn to Justice Breyer's intriguing concurring opinion whereby he appears to have painstakingly proven that, had it not been for the inducement issue, the facts relating to Grokster/StreamCast were indeed very similar to the Sony facts. For instance, Justice Breyer pointed out that of all the VCR taping actually done by Sony's customers, only around 9 per cent was of the sort the *Sony* Court referred to as authorized, but this alone had constituted a sufficient basis for rejecting the imposition of secondary liability. Breyer then went on to show that when measured against this, the evidence showed that the Grokster software was also capable of substantial or commercially significant non-infringing uses since the petitioners' (that is MGM et al.) own expert declared that nearly 10 per cent of the downloads were non-infringing. Second, Breyer emphasized strongly the significant future market for non-infringing uses of Grokster-type peer-to-peer software, predicting that :

> Such software permits the exchange of *any* sort of digital file – whether that file does, or does not, contain copyrighted material. As more and more uncopyrighted information is stored in swappable form, it seems a likely inference that lawful peer to-peer sharing will become increasingly prevalent. . . . There may be other now-unforeseen noninfringing uses that develop for peer-to-peer software, just as the home-video rental industry (unmentioned in *Sony*) developed for the VCR. But the foreseeable development of such uses, when taken together with an estimated 10 per cent noninfringing material, is sufficient to meet *Sony*'s standard.[33]

In other words, had it not been for the evidence of inducement, the technology manufacturers would not have found themselves liable for secondary infringement. Moreover, Breyer specifically rejects Justice Ginsburg's strict interpretation of the *Sony* rule which she sets out in the third concurring opinion in this judgment. Instead Breyer bizarrely opts for the Court of Appeal's adoption of the *Sony* rule as providing the balance required for entrepreneurs who need assurance that 'they will be shielded from copyright liability as they bring valuable new technologies to market'. Indeed, he agrees that *Sony*'s rule is strongly technology protecting and the rule deliberately makes it difficult for courts to find secondary liability where new technology is at issue. He states of *Sony*:

> It establishes that the law will not impose copyright liability upon the distributors of dual-use technologies (who do not themselves engage in unauthorized copying) unless the product in question will be used *almost exclusively* to infringe copyrights (or unless they actively induce infringements as we today describe). *Sony* thereby recognizes that the copyright laws are not intended to discourage or to control the emergence of new technologies, including (perhaps especially) those that help disseminate information and ideas more broadly or more efficiently.

> Thus *Sony*'s rule shelters VCRs, typewriters, tape recorders, photocopiers, computers, cassette players, compact disc burners, digital video recorders, MP3 players, Internet search engines, and peer-to-peer software. But *Sony*'s rule does not shelter descramblers, even if one could *theoretically* use a descrambler in a noninfringing way. [34]

In many ways, Breyer's *dictum* on the *Sony* decision is a thinly veiled criticism of the majority's opinion. For instance, he states that the *Sony* rule is mindful of the limitations facing judges where matters of technology are concerned. The majority opinion referred to the fact that Grokster and StreamCast did not use filtering technology to limit instances of infringement. Breyer's stance on this is:

> Judges have no specialized technical ability to answer questions about present or future technological feasibility or commercial viability where technology professionals, engineers, and venture capitalists themselves may radically disagree and where answers may differ depending upon whether one focuses upon the time of product development or the time of distribution. Consider, for example, the question whether devices can be added to Grokster's software that will filter out infringing files. MGM tells us this is easy enough to do, as do several *amici* that produce and sell the filtering technology. Grokster says it is not at all easy to do, and not an efficient solution in any event, and several apparently disinterested computer science professors agree. Which account should a judge credit? *Sony* says that the judge will not necessarily have to decide.

Breyer points out that the importance of the *Sony* rule for technology creators is the impotence of the later vis-à-vis copyright owners and their legal might.[35]

II. LEGAL RESPONSES BY THE COPYRIGHT OWNERS

2.1 Building Empires on Justificatory Rhetoric

The legal and economic rationales for copyright law have been in formation for the last 350 years. Early writers, such as Locke, Kant, Mill and Hegel offered a bifurcated perspective of copyright rationales: property rights should be granted either on the principle of rewarding or incentivizing labour or on the more deontological and humanist principle of a person's right to personality and dignity. In later years, the arguments were couched in more Romantic rhetoric, with authors pursuing a more egotistical agenda and advocating authorial rights as being the natural and just result of either the author's persona or the author's labour. Nevertheless, nineteenth

century debates on copyright law began to adopt a more societal approach as lobbyists argued that author's rights benefited the common weal such as the promotion and preservation of indigenous literature and arts. Mankind's fundamental freedoms included a right to be recognized and rewarded for moral and material interests resulting from any scientific, literary or artistic production.[36] In the mid-twentieth century, societal concerns soon encompassed economic goals as valued and pursued within a market-based economy. Copyright was now justified in economic terms – either in terms of welfare economics (Arrow) or neo-Schumpeterian economics.[37] The result of this continuous stream of justifications has been to strengthen the proprietary component within copyright law over the public interest component. This strengthening, in turn, produces a steady proliferation of legal instruments which allow the author of a work (or the owner, in reality) to control exploitation of and access to the work.

Justificatory rhetoric defending copyright employs exciting if somewhat unilluminating terms such as 'natural rights', 'reward', 'unfair competition', 'incentives', 'human rights', 'public goods', 'theft' and 'allocation of resources'. The various justifications are not discrete but rather form one continuous and overlapping line of defence against the non-believers. Thus one can say that copyright is a means for authors to claim their 'natural right' to a 'reward' for their creative efforts, whilst simultaneously acting as a deterrent against 'theft' of the author's 'fundamental right' to enjoyment of his 'property'. We can, nevertheless, categorize the copyright justifications into three broad balancing equations:

- the balance between property as capital reward and the public domain;
- the balance between property and ethics (for example public education and public computing projects);
- the balance between property, market and fair competition (against societal, scientific and technological development).

The first category is reflected in Locke's theory which simply stated that all resources given by God were part of the 'commons' other than one's own body. However, God had endowed every individual with a right to use (or expend labour on) such common resources. Where one has worked on such resources and 'mixed his labour', the resulting product of that labour will become our personal or private property.[38] The attraction of Lockean property lies in the central tenet that anyone could become the stakeholder since 'everyone has an inalienable right to his labour'. This basis can then be extrapolated into all sorts of rights and consequential reasoning – the author has a right, but so does a performer or a sound recording engineer and even a 'legal person' such as a media conglomerate.[39]

Lockean theory has been criticized as being implausible seventeenth century rhetoric being applied to modern intangible rights.[40] While the appropriation of physical matter from the commons does in some way diminish the opportunities for others to gain from the commons, it is argued that a creator, in the absence of prescriptive laws, does not diminish anything by using incorporeal elements from the commons. Another view is that the Lockean doctrine is applicable only to subject matter of finite capacity, as in water or land, but not in instances of infinite resources such as intellectual property. As David Hume stated, 'property has no purpose where there is abundance' as property rights only arise out of the scarcity of objects.[41] There is no scarcity, surely, in intellectual property which can be consumed without the supply being exhausted. The discussion below, however, indicates that today's laws allow the building and protection of digital barriers, for instance, called 'technological protection measures'. In other words, intellectual property law artificially creates scarcity. From this perspective, technology is a strange creature which enables both scarcity and abundance.[42]

Lockean property, nevertheless, is not absolute. Conversely, these modern developments do suggest that although the Lockean concept of property may be dated, it is arguable that the Lockean proviso may be of more importance today due to the continuous encroachment of technology over intangible matter. His proviso is that the initial common resources or their equivalent should be either used or returned to the commons for others to exploit.[43] At least, the proviso offers two simple balancing factors: balancing the reward to the labourer-creator and the maintenance of the commons. Moreover, it is arguable that the Lockean proviso is so vague as to why subject matter should be excluded from protection that we can postulate several policy rationales. Thus, one can argue that intellectual property subject matter must be made free for others for a variety of reasons:

- the raw materials and basic building blocks of creation must be left for future generations of creators; this would include discoveries, traditional or ancient knowledge, and creative works for which the relevant intellectual property rights have expired;
- intellectual property matter which has become a *de facto* standard to which other creators or competitors require access to;
- where intellectual property rights threaten the very existence and workings of the 'commons' that is the competitive market system.

This categorization reveals why and how we identify the different stakeholders with these standard justifications. The categorization also explains why, when considering the copyright–technology tension, one must look

beyond the interests of the immediate copyright industry to other sectoral interests. For instance, by employing Locke's concept of property as the justification for intellectual property, almost anyone or anything can constitute an 'author' or an 'owner', as long as labour is expended. The Lockean stakeholder is only held back by another Lockean stakeholder – a healthy public domain. Thus, it may be that older justifications for property rights such as Locke's theory are too basic and outdated; nevertheless, it is clear that since the beginning, there have been two key stakeholders: the labourer (or author or legal owner or entrepreneur) and the 'commons' (which can be other labourers or competitors or the market or society. Locke is useful in making us question the notion of and the need for the existence and maintenance of the 'public domain' (as opposed to the private domain) or 'intellectual commons' (as opposed to intellectual property).

The second main classification for justifications for copyright law does not really go further than Locke but rather emphasizes one aspect of Locke – ensuring fair and equal shares for all based on ethical grounds. Civil law copyright systems are an example of this type of justification. The German copyright system, for example, not only derives from the Hegelian romantic notion that the author's rights are for the protection of the authorial personality but also from the classic civil and political human rights regime. This ethos of the fundamental freedom to personal development and human dignity is enshrined within the German copyright law in relation to its criterion of originality (that is a work must constitute the personal intellectual creation of the author) and moral rights (which allow an author to control the way their work is perceived by the public).[44]

The absence of law and rhetoric on the 'public domain', 'intellectual commons' and limitations in European civil law copyright law, for example, is understandable – these are noticeably less important than legalistic and administrative mechanisms such as a strong jurisprudential and political stance on collective management and copying levies.[45] The prime concern of this type of justification is to espouse a system which allows all stakeholders to use works, and all stakeholders to pay or receive remuneration for such usage. 'Free' lunches are theoretically possible, but practically do not occur. Instead, detailed mechanistic legal rules on collective management, levies and contractual arrangements[46] allow all stakeholders from the author to a private user and his family to corporate producers (and even the state) to benefit from any exploitation of their works, whilst maintaining a strong deontological, if impractical rhetoric based on natural rights and personal dignity which is so characteristic of Continental European thinking.[47] Take the current EU copyright law for instance. It is strongly premised on the notion that all types of private non-commercial copying must be

compensated for (despite fair dealing and 'free use' provisions within UK and German law, for example)[48] and 'the rightholders receive fair compensation'.[49] This in effect demands that some sort of compulsory licensing system, such as the private copying levy schemes in Europe, be in place.[50] Belatedly, the Americans have shown interest in these schemes today.[51]

The rest of this chapter primarily concentrates on the third strand of justification – the balance between market and fair competition, and discusses the concepts of market harm and competition against the notion of societal, scientific and technological development. Most of the rationales for copyright protection posit that property rights for the author must be balanced by a contrary set of rules and regulations for the benefit of the public. Users of copyright works must be allowed to reproduce, or communicate copyright works for certain purposes, for example, educational, research or reporting purposes. The third strand of justification is not so much concerned with whether these current societal 'rights' are being eroded, but with whether future societal development and competition are being impeded.

2.2 International Law and New Technologies

Technology has always made relationships between the different stakeholders dynamic. Indeed, the modern music industry owes its current structure, as do so many other copyright industries, to one of the biggest technological breakthroughs in early history – Gutenberg's movable type and the ability of businesses to mass-produce sheet music. The establishment of the merchant cities throughout Europe and the concomitant expansion of a new middle class saw the secularization of the arts, including literature and music. This, in turn, ushered in the public consumer and the then equivalent of the recording company – the entrepreneurial music publisher.[52] Early copyright laws confirmed his economic interests, and not unlike the entertainment industry of today, the key element lay in the control of distribution of copyright goods. Publishers dominated the music world where the custom was for composers to dispose of their copyrights in both the publication and performance rights to their publishers, who made money from the sale of sheet music. There was even concern in the beginning as to the increase of sales of domestic pianos. Mass possession of these products (much like mass possession today of personal computers) had led to a growing pirate music publishing industry and the sale by street hawkers of pirated printed songs. Another technological revolution was the Aeolian machine, or the pianola which led to some consternation as to whether copyright embraced the concept of 'mechanically produced music'.[53] Once again, within the United Kingdom, corporate interests demonstrated their

ability to re-define and amalgamate themselves with the formation of the Mechanical Copyright Protection Society Ltd (MCPS) in the United Kingdom. Even to this day, the corporate structure of the MCPS is reminiscent of its early beginnings: the MCPS is wholly owned by the Music Publisher's Association.[54]

The next technological breakthrough in the music industry was the invention of the phonogram, and the establishment of sound recording companies, which ascended to power as recorded music achieved dominance. The third real breakthrough is Internet distributed music. So profitable is the phenomenon that excessive rent seeking does occur – not only dedicated sound recording companies, but all sorts of transnational entertainment corporations promote music which is viewed as an ever-expanding series of 'revenue streams' – record sales, advertising revenue, movie tie-ins, streaming audio on the Internet which is no longer tied to a particular sound carrier.[55]

A similar scene is played out internationally, where copyright law appears ready, albeit often in a belated fashion, to embrace the new avenues of exploitation that new technologies offer. For example, the Berne Convention of 1886 has been amended several times to keep apace: Berlin (1908) incorporated photography, film, and sound recording; Rome (1928) added broadcasting; Brussels (1948), television. The two new international copyright instruments merely confirm that, inevitably, copyright law does extend its umbrella of protection to secure the rights of authors and producers against new technology-enabled exploitations. As the Boyle-Lessig et al. faction argue, the 'intellectual commons' is being steadily depleted due to the 'second enclosure movement'[56] which is taking place in various forms:

1. the constant expansion of the duration of copyright protection from the maximum term of 28 years under the 1710 Statute of Anne to the author's life[57] to the life of the author plus several years[58] to the now international standard of life of the author plus 50 years pma – thus, we see a constant delay of works entering the commons;[59]
2. the expansion of protectable subject matter over the last 200 years from literary and artistic works in the eighteenth century, to photographs in the nineteenth century, to cinematographic works at the turn of the century, thence to sound recordings and broadcasts and to computer programs in the mid-twentieth century, and finally to quasi-copyright/*sui generis* database protection in the latter end of the century;[60]
3. the broadening of the scope of protection so that copyright in a single work can be employed to control the production and distribution of all other derivative forms of this work (such as adaptations, parodies, translations, arrangements) to such an extent that the penumbra of protection extends even to the 'idea' behind a work, rather than its

'expression';[61] this 'reach through' effect does take a toll on authors of future works;

4. the gradual but unceasing bloating of an owner's rights so that permission is now required for reproducing, communicating, distributing, renting and lending a work; [62] the 1996 WIPO Treaties further widened the communication right to include a making available right, incorporated into the copyright laws of many countries including Iraq;[63]
5. laws protecting technological measures[64] and the digital rights management systems[65] embedded in most digital versions of creative works today which allow owners to keep track of the distribution and usage of copyright works.

Art.11, WIPO Copyright Treaty and Art.18, WIPO Performances and Phonograms Treaty both envisage copyright owners locking up digital versions of works by employing technological protection measures. The provisions dictate that contracting parties provide adequate legal protection and remedies against the circumvention of these technological measures by unauthorized third parties. The problem with the circumvention measures, however, is that they may be employed to overprotect works. These technological measures do not merely prevent copying or downloading of music, but they can do the following:

- prevent access to works which are not subject to copyright protection at all, for example where the work comprises wholly or substantially pure data or ideas, or comprises materials which are not subject to copyright protection under certain jurisdictions (such as laws, government reports and court judgments), or where the work comprises public domain materials which have fallen out of copyright protection;
- prevent copying altogether even where the user wishes either to copy insubstantial parts of the work (which is a non-infringing act under copyright law) or where the user has a valid defence for copying parts of the work (for example, archival usage or fair use);
- where the technological measure allows a lawful purchaser of the copyright work to access (and maybe to copy) the product but limits the number of times this may be done.

Thus, these last changes in domestic copyright laws go much further in allowing the copyright owner to deny access to works;[66] moreover, as critics of the Lockean theory should note, unlike their analogue equivalent, digital works *can* be locked up.

The industry is currently attempting to bring in specific legislation to P2P services. The Bill called Inducing Infringement of Copyrights Act [SB2560]

was introduced into Congress in June 2004, but was opposed by the technologies, consumer electronics and internet industries. All these key players were of the opinion that using copyright law could stifle innovation across various sectors by criminalizing the creation of products that could 'induce' copyright violations.[67] One consequence of the collapse of the Induce Act has been provision by Sony BMG, Universal Music Group and Warner Music Group of a P2P service called Peer Impact. The service was scheduled for launch in the first quarter of 2005, and offers licensed downloads of movies and games in addition to music. Unlike Kazaa and other P2P services, Peer Impact distributes only licensed and public-domain content – those who pay for the track will download it from those who have already paid for the file.[68]

The proliferation of all these rights means that any person who wants to upload a work on the web needs to ensure that such works are not protected. This is an increasingly impossible task for an individual to do in light of the truly global nature of websites. Access to works in a country other than the country of upload has created problems as some jurisdictions uphold the law of the country of download as the governing law for the contents of a web page.[69]

Thus, copyright can be conferred on different types of subject matter in different parts of the world – for example, US citizens will be amazed that UK law protects judgments and statutes whilst French law allows authors the moral right of retraction of published works from circulation. Different works attract different rights which may belong to different owners or be managed by different collecting societies – for example, one may need to enquire as to the ownership and terms of usage in relation to the reproduction right, the distribution right and the communication to the public (including the making available) right. If there are underlying works that are incorporated within the work, a licence for them may be required. And different licences may be required in different jurisdictions – a major difficulty is that global licences are, as yet, still not available. Indeed, the law is so uncertain and tenuous currently that operators of public domain sites such as the Project Gutenberg feel obliged to place this notice on the page of Shakespeare's Henry V: 'Copyright laws are changing all over the world, be sure to check the copyright laws for your country before posting these files!!'[70]

III. THE STAKEHOLDER MAP

Traditionally, the initial step in policy analysis has been to evaluate the nature of the 'problem' which a policy seeks to address.[71] This process includes the identification of the key stakeholders within the policy area – that is to say,

the different institutions and interests which have a stake in the operation of the policy. Stakeholders can be natural persons, groups or legal entities. Stakeholder analysis also involves the analysis of the policy preferences of each stakeholder and evaluation of the extent of their leverage in influencing policy content. The role of the policy maker is then to formulate proposals which deliver the desired outcomes whilst retaining the support (or at least the acquiescence) of the key stakeholders. It can also be linked to both institutional appraisal and social analysis (see conclusions below). Consequently, stakeholder analysis can be usefully applied to the issue of the production and usage of copyright goods (mainly literary works) within the higher education sector. It is argued that current copyright policies do not necessarily take into account all the problems encountered by copyright users, or more importantly, by the copyright producers for whom the system was supposedly devised. Given this, the application of stakeholder analysis to aspects of current copyright policy can clarify the needs and concerns of different legitimate stakeholders within the policy. Stakeholder analysis makes a distinction between two categories of interests. Applying this typology to the field of copyright policy, we identify the following distribution of interests:

- primary stakeholders: these are the groups of persons who are directly affected by the policy either positively (for example all beneficiaries of the current copyright regime) or negatively (for example all those technology suppliers who are not automatically exempt from the infringing activities of users of their technologies).
- secondary stakeholders: this group of persons has an indirect interest in the policy, and includes intermediaries who are involved in the production of copyright goods (for example software companies who deal with encryption and search technologies, or ISPs and telecommunication carriers involved in transmitting digital goods and who may be affected eventually by any digital rights management (DRM) projects).

3.1 The Single Creator Stakeholder

Copying is usually unfair to someone. The author or copyright owner may not have intended their work to be emulated by another without payment; even where no rights accrue, copying can be unfair. It is true that intellectual property rights are not based on whether it is fair or unfair to copy – nevertheless, copyright justifications based on competition and market failure do, in some respects, emulate unfair competition laws in aiming to balance the protection of creativity against the encouragement of a competitive market.

It is assumed that most cultural innovation gives rise to stakeholders. However, key stakeholders do not necessarily take an active part in the formation of intellectual property laws until they perceive harm to themselves. This rather depends on how creativity is managed and exploited within any society. For instance, in the pre-industrial Western societies, creativity was under a patronage system. Authors and painters did not seek to enforce property rights, or even to push for property rights in their works. Indeed, many artists had no wish to engage in 'trade', but preferred to be hired on a stipend basis by a great household or noble patron. For artists such as Michelangelo, belonging to a great Court or house meant a shift in social status from that of a tradesman to that of a gentleman in service.[72]

Copyright itself was perceived as being important not from the perspective of the author but from that of industry – the single-creator stakeholder, the writer, was paid for his or her work and that was all that mattered. It was sufficient that there were mercantile customs in place to remunerate the author in terms of money, reputation and identity. Moreover, authors had other sources of income – journalism and periodical literature.

A second reason for lack of action by the stakeholders is that individual creators regarded themselves as benefiting from dissemination of their works, and benefiting even more from access to each other's works. Thus, for instance, the academic scholar is notorious for not being interested in enforcing his rights, and even actively advocating the denial of copyright since this is perceived to be beneficial to him in carrying out his scholarly and teaching duties or his promotion activities. What the academic does not perceive, however, is the exploitation of his work by others who do seek compensation or remuneration, for example publishers, universities, collecting societies, and so on. Many understand but do not consciously remember that publication of their article in a journal produces income somewhere for someone and it may be in their interest to join the chain of creation and remuneration.[73] Authors only become active stakeholders and form their own associations when they perceive unfair exploitation.

3.2 Corporate Stakeholders and Cultural Diversity

Industry, on the other hand, is a rent-seeker. As we saw, most of the plaintiffs in the technology cases are not the creative community comprised of authors but rather the creative industries comprised primarily of the five major sound recording companies ('the Majors').[74] These corporations are the principal investors in artists, and hundreds of millions of pounds are spent by the industry, not only in recording the creative effort of individual artists but also

marketing those efforts. The argument is – if there were no copyright system to guarantee returns for investment, the recording industry would stop investing in new artists, which would, in turn, be bad for societal needs.

Yet, because the cultural market cannot easily be targeted, the rent-seeking opportunities are limited if the rent-seeker stakeholder is confined to a few fields. Despite the efforts placed by the sound recording and film companies in creating and controlling consumer demands (for example teenage bands, the 'summer hit' or 'the Christmas number 1'), it is truly difficult to predict the consumer needs and trends. The entertainment industry must cast its net wide enough to capture all possible hits. This 'hit and miss' strategy basically suggests that the copyright-creative industry field hosts lots of active rent-seekers who cannot target their rent with any efficiency or clarity. They have to enter the market just in case other competitors occupy and subsequently dominate that market – this is pre-emptive squatting. Or else they have to enter a market that a rival(s) has entered just in case it becomes a lucrative market. This was exactly the case in the 1920s when the sound recording companies camped for a couple of days in cities in the southern US states, and recorded everyone who turned up in hope of finding 'the' blues singer.[75]

This is to be contrasted with the practices by the pharmaceutical industry where the range of diseases that can be targeted for rent is more distinct and clear. Chronic, incurable diseases such as HIV, Crohn's disease and Alzheimer's disease offer a continuous rate of income. Moreover, income collection in relation to many drugs is organized and, again, continuous in developed countries with good health infrastructure and services. Compare this with the music, film or publishing industries where the tastes of consumers are difficult to discern over a five-year period, and it is difficult to reap the rewards due to technological improvements in copying and distributing some copyright goods. Recent phenomena such as *Kazaa*, *Morpheus* and *Grokster* indicate that the Internet has shifted from 'web traffic' to a 'P2P file-sharing traffic', with considerable implications for the extent of control that copyright rent-seekers have on the distribution network.

Multilevel-creator stakeholders do not necessarily care about the unfair exploitation as much as the rent-seeking opportunities created by property rights – hence the constant push for wider copyright. These players invest widely in a plethora of cultural goods – the few works which do produce the winning 'lottery ticket'[76] are then made to subsidize the rest of the products. Note, however, that the casting of the net wide in order to maximize profits works in two ways:

(a) maximizing rent by pushing the boundaries of the law to encapture more and more intellectual property goods (tactics include reducing

the threshold of originality or introducing non-traditional rights to capture hitherto allowed activities);[77]

(b) maximizing rent by supporting the creation, manufacture and distribution of a wide variety of goods (for example expanding music categories to include Indie and World music; expanding film repertoire to include foreign films category).[78]

These corporations do add, as well, to the cultural diversity that we have today. Hence, one can and does sympathize with the entertainment industries' attempts to forestall continued drops in their profits.

3.3 Consumer Substitutes and Business Models

From a practical perspective, if copyright owners are to prevent digitally perfect copies of their works from being copied and disseminated via the Internet, the onus is then on them to employ copy protection devices, such as 'password codes' or encryption or scrambling programs. Although technologies have been available for some time that would prevent MP3 files from being copied and recopied, the sound recording industry has only recently begun to implement such technologies under the 'Secure Digital Music Initiative', which will prevent SDMI-compliant devices from playing unauthorized copies. However, the Majors have been reluctant to embark on these initiatives, and nowhere is this more clear than in their battle to prevent online distribution of music.

The first issue is that of substitutable goods. Arguably, the *Napster* courts were wrong in that sharing activities do not act as substitutes for market mechanisms but instead exist alongside them.[79] Moreover, the courts were also incorrect to view P2P activities as a barrier to entry to the online retail market for music. Normal economic assumptions are that competitors ought to be encouraged to introduce new business models, especially where the de facto or de jure monopolist in that particular market has not satisfied market demand. If one views Napster as a new business model, it is debatable whether the file sharing it facilitated can be regarded solely as a market substitutive activity in light of these facts: when the Napster program was launched in 1999, it was the first program which allowed P2P music file sharing; in contrast, there were no legal Internet services offering music from any of the five Majors' catalogues until 2002. In its heyday, the Napster programme facilitated the download of over 1400 songs per minute and attracted over 20 million users.[80] It is not difficult to conclude that there was an unsatisfied market demand here for a different distribution network of copyright goods, in different media. Simply put, the market wanted to download single music tracks and could not. But did the market

also want to pay? Or is file sharing satisfying several types of market demands: browsing, borrowing (or sampling) to create new types of music, free riders (that is with no intention to pay); music enthusiasts and fans (who will pay)? And more importantly, should the property rights of the sound recording industry outweigh the market consequences of the industry's lethargy?

Just as the film industry failed abysmally to tap the new business model represented by video technology, the sound recording industry has been slow in embracing the Internet technology towards a more consumer-orientated business matrix. The Majors have refused to offer substitutes either in terms of products, price or distribution channels. Online piracy has, according to them, been driving down sales of CDs. Instead of competing with such services, the Majors have tried to shut down P2P services in the courts. The main strategy has been to protect the current distribution network and prevent the entrance of new services (business models offering new forms of distributions) and products (singles now sold in downloadable, digital format). Reluctantly, they did engage in legitimate online ventures but instead of offering licences of their music to third-party online services, the industry's stubbornness led to doomed subscription services.[81] For subscription online music services to work, they must be inexpensive, comprehensive, and offer greater ease, variety and reliability.

It was not until April 2003, when Apple's iTunes combined a comprehensive catalogue with freedom from subscription fees, that a significant consumer base emerged for licensed online music. Nevertheless, even the iTune phenomenon could be bettered if the Majors would bring the retail price of downloads down from the current £0.79 or US$0.99 – this is still equivalent to the same as or even slightly higher than the cost of a full CD.[82] Hence it still serves as a poor substitute for album sales to both record stores and to illicit P2P services. Moreover, the pricing of certain singles is proving beyond the means of Majors – single tracks which exceed 10 minutes appear to be non-downloadable. This is often the case with opera arias – yet this is paradigmatic of the Major's myopia as the classical opera market is comprised usually of well-heeled patrons who are willing consumers of an umpteenth version of the whole of *Xerxes* as well as of single bestsellers such as *Ombra mai fu* if sung by their favourite baritones or contraltos.

The *ex post* Napster situation indicates that a significant percentage of consumers are more than willing to pay for their music but only if the music is downloadable in the desired format. For example, rather than buy a whole album, many consumers prefer buying a single 3-minute track for £0.79. The statistics of the British Phonographic Industry indicate that the expenditure of users who download music from the Internet has dropped

by 32 per cent in relation to spending on albums, and by 59 per cent in relation to spending on singles. The statistics on downloading indicate two types of market harm:

(a) from the perspective of authors and legal owners of copyright music, this downturn in purchasing may indicate that, in terms of the musical composition and performance, unauthorized perfect substitutes are available in the marketplace due to the sharing phenomenon;
(b) from the perspective of the consumer, this downturn may indicate that the P2P technology offers new goods in terms of alternate pricing and format of musical goods that is cheaper digital singles.[83]

Another recent study by two European economists shows that P2P technologies may actually improve consumer demand. The study accepts that it may be difficult to wean consumers off free copies of the works; however, the authors assert that consumer demand may be driven high enough to offset the negative effects of P2P technology, that is free riding by some consumers. Moreover, the browsing activity of the consumer may replace costly marketing and promotion activities by the sound recording industry so that the industry would actually increase its profits in spite of lower revenues.[84]

3.4 Effect of Shared Monopolies on Competition

Another concern is the narrow sense in which courts construe 'market harm' in relation to new technologies. In the *Napster* and *Aimster* cases, for instance, P2P sharing is viewed as harming the market for CD sales. A wider perspective of market and harm reveals the opposite concerns. In relation to the P2P services, an analogous query is whether the copyright in recorded music, which is primarily owned by the five Majors, is effectively being used to stamp out competitive distribution means of music and to control Internet licensing practices, thus harming the wider culture and Internet retail market. In the *Grokster* decision, for example, the copyright owners alleged that over 90 per cent of the files exchanged through use of the P2P file sharing software involved copyrighted material of which 70 per cent is owned by the plaintiff copyright owners. Another source states that the collective catalogues of the Majors comprise about 85 per cent of the distribution rights in the recorded music industry.[85] Copyright laws today are far more pervasive than a decade ago – new communication rights over the Internet, new access rights and laws on digital rights management are all part of the copyright owner's armour now. Copyright laws allow the industries to wield influence over the entry of new Internet

services since online companies must secure licences from the Majors to operate legally. If the Majors can use licensing practices to create prohibitive barriers to entry or to bind contractually online companies to uncompetitive pricing policies, then they stand a chance of maintaining profits from the shared monopoly.

The potential abuse of market power by intellectual property owners is especially great in the online music industry as the essential inputs are individually controlled by a small number of intellectual property owners. And in relation to sound recordings, the ownership of property rights (as opposed to authorship of works) is fragmented between the five Majors. Hence there is a real danger that anti-competitive practices of shared monopolies escape the competition authorities, although there are no substitutes on the marketplace.[86] Majors can use their dominant position to extend on-line services to consumers. It is hard not to conclude that their market power was extended into downstream distribution channels to stop new products and services from emerging. The European Court of Justice recognizes this 'shared monopoly doctrine' and has emphasized two key elements for a healthy competitive market environment in recent decisions including *Magill* and *IMS:*[87]

(a) maintaining a market structure which allows the emergence of new products for which there is potential consumer demand;
(b) allowing secondary or downstream markets to develop.[88]

The decisions in *Magill* and *IMS* were limited to consideration of licensing opportunities for third parties in relation to products or services governed by intellectual property rights. Nevertheless, an important consideration in the cases is how market opportunities cannot be stifled by intellectual property rights. Thus, in all three decisions, the Court of Justice was of the view that where a market (including a potential market or even hypothetical market) is identified and there is a likelihood that refusal of a licence by the copyright holder will exclude all competition on a secondary market, then the conduct of the intellectual property holder will be considered to be anti-competitive, especially where the products or services are indispensable in order to carry on a particular business.

Indeed, Kazaa has asserted antitrust claims alleging that the five Majors engaged in a concerted refusal to license their music to anyone other than two selected Internet distributors which are, in reality, owned by the Majors themselves.[89] Whatever doubts there may be in respect of the antitrust case, there is no doubt that the Majors have delayed the creation of an online market, and have also ensured that prices in this emerging market of online sales are high enough so as not to dramatically undercut the profits gained

from the CD market. As the *Grokster* court remarked, the introduction of new technology is always disruptive to old markets, and particularly to those copyright owners whose works are sold through well established distribution mechanisms.

3.5 Is Sharing Good?

Sharing activities are important in achieving public policy aims. Benkler's study of large-scale sharing activities leads him to conclude that sharing enables market models through which excess capacity of private goods could be cleared.[90] He points out, for example, that many users take part in file sharing for social reasons as well as for personal gains such as the SETI@home[91] (where 5.3 million users from 226 countries allow their idle computers to be used for analysis of radio astronomy signals as part of the search for extraterrestrial intelligence) and or Genome@home[92] projects (a project dedicated to modelling new artificial genes that can create artificial proteins). The reason that peer-to-peer architecture is scientifically important is that this type of architecture makes efficient use of growing distributed processing and storage capacity of networked computers. Altruistic P2P sharing activities enable special-purpose virtual supercomputers to exist, which is vital in public resource computing projects that would otherwise not be possible.

Moreover, sharing activities have proven to be of more benefit to the economy and societal development than private capital mechanisms. The US Government, for example, had concluded in its NII Report in 1995 that the scope of intellectual property rights in the digital environment had to be expanded so as to encourage private sector investment in the infrastructure underlying a national digital network.[93] Moreover, the national information system would only grow in a commercial sense if the infrastructure worked as a television or cable network, that is if the public could be persuaded to subscribe to digital network services so as to enjoy movies, music and other content on demand. Hence the perceived importance of expanded copyright protection to ensure higher returns for the contents industries.[94] In enacting the WIPO treaties, the US[95] and the European Union[96] have both acknowledged the widening of copyright policy towards assisting copyright industries in controlling not only the reproduction and dissemination of works on the Internet, but in controlling the access to the works in the first lace.

However, in reality, the industries did not invest in the infrastructure with new business models or new products or new services. The Internet has expanded due to the Samaritan nature of most of its users. As Litman states,

> Anecdotal evidence indicates that at least for some material, untamed digital sharing turns out to be a more efficient method of distribution than either paid subscription or the sale of conventional copies. If untamed anarchic digital sharing is a superior distribution mechanism, or even a useful adjunct to conventional distribution, we ought to encourage it rather than make it more difficult.[97]

Perhaps we should. In Litman's view, the Internet has evolved primarily into a 'gift economy' in that consumer-to-consumer interaction, such as web blogs has led to

> more information, better information, and more accessible information; more complete and deeper archives; wider ranges of divergent sources. . . . Because of the disparate contributions of a host of volunteers, one can find information that would not appear in conventional reference sources.[98]

P2P sharing technologies and activities should not automatically be considered as being a potentially infringing, illegal or nefarious activity. Perhaps they are just the next stage in societal development.

3.6 More Stakeholders: Downstream Technology Usage, Production and Standards

The war between copyright and technology is also one between two giant industrial sectors competing for market space and power. A healthy competitive market requires a plethora of technology to challenge existing modes and to create new modes of creation, circulation and consumption. This does not occur where the scope of copyright protection is extended so as to prevent new streams of goods and services. The concern is that the legislator and some courts are heeding the industry's chant that large-scale file sharing compromises private property rights. However, such sharing, as we indicated above, may also enable new downstream or secondary products and services, thus generating another revenue stream for the economy as a whole.

Moreover, today's technologies are being developed so as to be network-enabled, with built-in communication functions to connect to other software, computers and servers in order to facilitate both collaboration between creators of works and the dissemination of that information to audiences worldwide. Such technology wares provide the basic infrastructure for local networks and the Internet.

And indeed, this is the argument in the brief of the Business Software Alliance, submitted for the Supreme Court's review of the *Grokster* decision in March 2005. The brief emphasizes the view that technologies which enable users to exchange information, especially peer-to-peer technology,

are a critical component of future product innovation.[99] Shifting liability to Grokster has an impact on technology producers. Imagine corporations such as Adobe, Apple, Autodesk, Borland, Dell, Hewlett Packard, IBM, Intel, Microsoft and others who, as creators of software products are subject to significant piracy but who also have significant interest in the parameters of secondary infringement liability rules. As their brief indicates in the Grokster trial, manufacturers of software and hardware technologies need to ensure that copyright protection and secondary liability rules do not impede or hamper technological innovation and product development.

The particular concern of technology developers and manufacturers relates to the general purpose and multi-use technologies and products.[100] In a sense, the potentially infringing technologies of earlier periods were easier to control – photocopier machines had specific uses, as did video cassette recorders. The computer or the file sharing software or the latest mobile phone, on the other hand, is capable of many uses, including uploading, downloading and copying. As the *Sony-Betamax* case noted, even single-use technologies and products are capable of both infringing and non-infringing activities. Courts cannot second guess what a new product is capable of – who could have envisaged the shape of mobile telephony today with downloadable tunes and photo-messaging? Technologies of today become obsolete due to shifts in cost and performance of technology components like processors, software, memory chips, and transmission protocols. Digital copying itself did not become a problem when the first computers or the Internet were invented – rather it became an 'issue' when technology cost and performance enabled mass consumption of personal computers, with a linked up telephone line and a high-speed modem, together with viable compression software.

Time and technology, as we have witnessed in the past 30 years, wreak havoc with established patterns of production, distribution and consumption; yet, they also prompt innovative responses.

3.7 From Controlling Distribution to Controlling Standards

A further reason why we have to exercise caution in allowing intellectual property rights to control the downstream market is that this extension can be used to develop a de facto standard, that is the war between copyright and technologies does become a battle of standards.

The recent *Microsoft*[101] decision illustrates this dilemma. The European Commission held Microsoft's refusal to supply to its competitors 'interoperability information' as constituting anti-competitive behaviour. Interoperable information is the software code information required by

competing software applications firms in order to interface with another program or operating system. Competitors would not be allowed to use the information, at least under European software law, to manufacture competing operating systems such as a substitute to Microsoft's XP software, but they are allowed to develop secondary application products such as media players or word processors. However, this would also allow the competing firms to develop products in competition with Microsoft's own application products.

This refusal to license IPRs was part of Microsoft's larger strategy – its practice of bundling its personal computers with its own proprietary digital media player (Windows Media Player – WMP). WMP is on over 90 per cent of all Windows machines, with the result that media streams are now encoded in the Windows Media format. Nevertheless, WMP standards do not merely reflect music platforms but also Digital Rights Management control and the nature of operating systems on the downstream markets, that is mobile phones or television. Thus, by using its IPRs and refusing licences on its protocols, Microsoft is betting that when digital media are delivered to other platforms beyond the PC, there won't be effective competition in the player market since all content will be in Microsoft's propriety WMP format. Why? Because content created on PC platforms would be tied to the WMP format, the de facto standard.

Ayres and Nalebuff suggest a further reason why firms employ every possible tactic to dominate and control the complementary downstream market. In their view, Microsoft bundles products and then uses IPRs to deny licences of access to such products so as to prevent secondary markets becoming 'entry point(s)' into Microsoft's operating system software. Media players can, the authors assert, morph into operating systems for mobile phones, TV set-top boxes, and handheld devices.[102]

Caution should certainly be adopted before one allows copyright owners to stifle the advancement of the sciences and technology, especially where a future secondary market for goods or services is threatened.

CONCLUSION: TECHNOLOGY AS THE DRIVING FORCE OF COPYRIGHT

Technological change has long driven copyright, and each technological revolution has been invariably greeted by hysteria from copyright authors and owners. Thus, much concern was expressed at the increase of sales of domestic pianos in the nineteenth century as this had escalated the pirate music industry. Time and reason, however, restores the equation. The increase in music piracy in Britain, for instance, led to corporate action in

the formation of the Music Publishers Association in 1881, whose mission was 'to protect the interests of the music publishing trade, especially in the proposed new Copyright Act, and in the matter of performing rights.'[103] Another technological revolution was the pianola, which led to some consternation as to whether copyright embraced the concept of 'mechanically produced music'.[104]

A similar scene has been played out internationally in the twentieth century where copyright law responds rather promptly to embrace new technologies. For example, since the Berne Convention in 1886, the convention has been amended several times to keep pace with technological changes which have produced new types of works (such as photographs and films) and new means of exploitation (such as sound recording, broadcasting and television).[105] The two latest international copyright instruments merely confirm that, inevitably, copyright law does extend its umbrella of protection to secure the rights of authors and producers against new technology-enabled exploitations.

Yet do we shift the blame onto the manufacturers of technologies that allow copying and distribution of infringing material? Admittedly, this is an accepted tenet in copyright law, and under most laws, a party can be held liable for contributory or secondary infringement if he has knowledge of the infringing conduct of another, and has authorized, caused, facilitated or materially contributed to the infringing conduct.[106] Merely supplying the 'means' to accomplish an infringing activity has rarely led to the imposition of liability under the British and American case law, though some cases now cast doubt on this accepted doctrine.[107] The Supreme Court in *Sony-Betamax* refused, as we saw above, to hold manufacturers and retailers of video tape recorders liable for contributory infringement despite evidence that such machines could be and were used to infringe plaintiffs' copyright-protected works.[108] Will the Supreme Court maintain its stance in its review of the *Grokster* decision?

The basic policy argument in favour of imposing contributory or secondary infringement on the providers of certain types of technologies is logical. Technologies that enable mass copying and communication of copyright works is damaging to the interests of copyright authors and owners in both philosophical and economic terms. Such mass piracy cuts into the natural rights basis of copyright protection; and it also damages the economic incentives for the production and rewards of new works. This may lead to a less than optimal creation and production of copyright works.

However, in considering file sharing technology, we can discern more stakeholders besides the copyright owners and the consumers of the work: the manufacturers of the software required to enable such sharing; the manufacturers of network and communications ware; the different types of

users who engage in file sharing activities; and finally, the beneficiaries of public resource computing projects (which rely primarily on sharing activities). Practically speaking, there are two outcomes – either technology manufacturers and distributors will stop copyright infringement, or such providers will pass the cost of damages to their customers, thereby raising compensation for the victims of copyright infringement.

One option is to have courts and the law declare all providers of all types of digital and Internet technology liable. Moreover, only industry-approved devices and technologies will be 'allowed' to survive in the marketplace. This, however, leads to more serious repercussions namely in the information technology sector and the Internet itself – especially where the essential inputs of data such as published literary and musical works are individually controlled by a small number of intellectual property owners. Economic efficiency demands that intellectual property rights within the musical works market do not erect barriers (as any licensing structure of copyright would) to software, communications or network development. Copyright law will enable copyright holders to assert plausible claims against a wide variety of as yet unknown providers of Internet technology. Consider how the advent of product liability in tort law has forced all manufacturers to reckon with the ways customers might misuse new products, even if manufacturers sincerely do not believe that their behaviour is responsible for the injuries caused by misuse. Something similar could happen with copyright law. Technology that makes the Internet easier to use will invariably make copyright infringement easier to commit because the Internet operates by making copies. Why not make those technology providers reckon with the infringement their technology facilitates?

The second option is to force those who provide such technologies to pay. This logic underpins the private copying levy system that operates in many European countries. However, this approach is based on the premise that manufacturers of technologies that facilitate reproduction and communication of protected works *should* be made to pay a levy.

So, we return to the primary query: is the manufacturer to be held liable? Should courts jeopardize technologies that are not fully developed or understood? Or should they make rules which threaten the future innovation of other industrial sectors? One person who believes that we can rest safe as long as the *Sony* liability rule is administered in a flexible manner is Justice Breyer in the recent Supreme Court *Grokster* decision; his fellow brethren, however, think otherwise. Another school of thought is to eschew the legal and social considerations to which Breyer and Ginsburg in the *Grokster* decision allude, and to look at it purely from the financial perspective. For an example of this genus of argument, note the following

argument in the brief submitted by the Business Software Alliance in the *Grokster* decision:

> Estimates of losses from infringement of US movie and music copyrights on a global basis stand, conservatively, at $7.2 billion annually. The software industry estimates global losses of another $32 billion annually from piracy. By comparison, the US Department of Commerce estimates that domestic spending on information technology equipment and software exceeds $500 billion annually, while estimated annual sales by US information technology companies and their overseas affiliates exceed $1 trillion annually. Beyond these figures, by enhancing output across the economy, the information technology sector is estimated to have generated 28 per cent of GDP growth in the US economy as a whole. [citations omitted][109]

In other words, never mind the piracy – the pirate technologies generate more growth.

NOTES

1. The author wishes to thank Brian Tutt and Graham Dutfield for their comments on the chapter. Note that all URL citations are up to date as of 15 February, 2005.
2. *Metro-Goldwyn-Mayer Studios, Inc. v Grokster Ltd*., 380 F.3d 1154, 1158–60 (9th Cir. 2004).
3. 464 US 417 (S. Ct. 1984).
4. Ibid., at 436–7.
5. Ibid., at 442.
6. *Sony*, 464 US 417 (S. Ct. 1984), at 439.
7. *Sony*, 464 US 417, at 434–42. This is a similar stance adopted by the United Kingdom House of Lords in *C.B.S. Songs Ltd. & Ors v Amstrad Consumer Electronics Plc. & Anor*, [1988] AC 1013 (H.L.) – discussed above.
8. 464 US 417 (S. Ct. 1984) at 429–32.
9. Ibid.
10. 29 F.Supp.2d 624 (C.D.Cal.1998), 180 F.3d 1072 (9th Cir. 1999).
11. Ibid. at 1079.
12. See *A&M Records Inc. v Napster Inc*., 114 F.Supp.2d 896 (N.D. Cal. 2000) (*Napster I*), at 905–8; on appeal, 239 F.3d 1004 (9th Cir.2001) at 1011–13. See also Napster, Inc.'s Opening Brief, op.cit., at 9–10, and Brief for the United States as *Amicus Curiae*, at 9; both documents filed in *A&M Records Inc v Napster, Inc*. and *Jerry Leiber v Napster, Inc*. (Appeal Nos. 00–16401 and 00–16403) (on file with author).
13. See *A&M Records, Inc. v Napster, Inc*., 293 F.3d 1004, 1011–13 (9th Cir. 2001); *In Re Aimster Copyright Litigation, Appeal of John Deep*, 334 F.3d 642, 646–47 (7th Cir. 2003); *Metro-Goldwyn-Mayer Studios, Inc. v Grokster Ltd*., 380 F.3d 1154, 1158–60 (9th Cir. 2004).
14. The other defences were the AHRA non-commercial user exceptions and the 'safe-harbour' defence provided under the DMCA. Both the first instance and appellate courts found that most of the activities indulged in by its users infringed copyright by accepting the industry's claim that more than 80 per cent of the files available on the Napster network may have been copyright protected and owned or administered by plaintiffs. *Napster*, 114 F.Supp.2d 896 (N.D. Cal. 2000), at 911; 239 F.3d 1004 (9th Cir. 2001), at 1015.

15. *Napster I*, 114 F.Supp.2d 896 (N.D. Cal. 2000), at 904.
16. *Napster I*, 114 F.Supp.2d 896 (N.D. Cal. 2000), at 913.
17. *Napster*, 239 F.3d 1004 (9th Cir. 2001), at 1017.
18. [1988] AC 1013 (H.L.).
19. Ibid. at 1054; the court substantiated this reasoning by approving a passage from the earlier decision of *C.B.S. Inc. v Ames Records & Tapes Ltd*. [1982] Ch. 91 where the court had held that 'an authorisation can only come from somebody having or purporting to have authority and that an act is not authorised by somebody who merely enables or possibly assists or even encourages another to do that act, but does not purport to have any authority which he can grant to justify the doing of the act.', at 106.
20. *CBS v Amstrad*, op. cit., at 1055.
21. http://www.boston.com:80/news/odd/articles/2005/02/04/music_industry_sues_83_year_old_dead_woman
22. Indeed, the recent decision of the Norwegian Supreme Court to uphold just such a ruling against an individual does signify that the law is willing to lend support to stem such blatant acts of misappropriation. A Norwegian student was held to be in breach of copyright law for running a website which linked to downloadable MP3 files. He was ordered to pay £8000 compensation to Norway's performing rights society, Sony Music and Universal Music, 28 January 2005, at http://news.bbc.co.uk/1/hi/technology/4216551. stm. See also 'UK record industry warns illegal filesharers – stop or risk court action', British Phonographic Industry Press Release, 24 March, 2005.
23. *Napster*, 239 F.3d 1004 (9th Cir. 2001), at 1019.
24. Other P2P networks include Gnutella, eDonkey, WinMX and BitTorrent.
25 *Metro-Goldwyn-Mayer Studios, Inc. and others v Grokster, Ltd*., *Streamcast Networks Inc. and others* 259 F. Supp. 2d 1029 (C.D. Cal. 2003), at 1041; 380 F.3d 1154 (C.A. 9 (Cal.),2004); 125 S.Ct. 2764 (S.Ct, 2005).
26. The evidence was overwhelming that numerous copyright owners and creators (including thousands of musical groups) authorized free distribution of their work through the Internet, whilst others used the software to share public domain works made available through Project Gutenberg as well as historic public domain films released by the Prelinger Archive.
27. *Napster I*, 239 F.3d.
28. *Napster I*, 239 F.3d at 1027.
29. *Metro-Goldwyn-Mayer Studios, Inc*. 259 F. Supp. 2d 1029 (C.D. Cal. 2003), at 1041.
30. *Metro-Goldwyn-Mayer Studios, Inc. and others* 125 S.Ct. 2764 (S.Ct, 2005), at 2772–4. Note that similar advertising in the *Sony* decision was acceptable. Justice Souter, in the *Grokster* decision stated that 'There was no evidence that Sony had expressed an object of bringing about taping in violation of copyright or had taken active steps to increase its profits from unlawful taping. Although Sony's advertisements urged consumers to buy the VCR to 'record favourite shows' or 'build a library' of recorded programs, neither of these uses was necessarily infringing, at 2777.
31. 125 S.Ct. 2764 (S.Ct, 2005), at 2774.
32. Ibid. at 2778–9.
33. *Metro-Goldwyn-Mayer Studios, Inc. and others* 125 S.Ct. 2764 (S.Ct, 2005), at 2789–90, citing Robert Merges' work in 'A New dynamism in the public domain', 71 *University of Chicago Law Review* 183 (2004).
34. At 2791.
35. Finally, Breyer is unabashedly on the side of caution – even pointing out that it is not at all accepted that unauthorized copying diminishes revenues of copyright owners. He asks us to compare the evidence of S. Liebowitz, 'Will MP3 downloads annihilate the record industry? The evidence so far', p. 2 (June 2003), http:// www.utdallas.edu/liebowit/intprop/records.pdf, with F. Oberholzer and K. Strumpf, 'The effect of file sharing on record sales: an empirical analysis', p. 24 (March 2004), www.unc.edu /cigar/papers/FileSharing_ March2004.pdf.
36. This culminated, during the post-WWII and Cold War eras, in copyright being

embraced internationally by human rights rhetoric in the Universal Declaration of Human Rights and the 1966 International Covenants. For a discussion on human rights within international copyright law, see Uma Suthersanen (2005), 'Towards an international public interest rule? Human rights and international copyright law', in *Copyright and Free Speech* (eds. J. Griffiths and U. Suthersanen), Oxford University Press, chapter 5.

37. For a discussion on innovation, economics and intellectual property rights, see Graham Dutfield and Uma Suthersanen (2004), 'The innovation dilemma: intellectual property and the historical legacy of cumulative creativity', 4 *Intellectual Property Quarterly* 379, at 381–3.
38. J. Locke (1993), 'The second treatise of government', in *Two Treatises of Government*, J. M. Dent: London, chapter 5, paragraph 27.
39. The recording industry would agree with this, and also with the exaggerated version of the Lockean tenet proposed by J.B.M. Jobard who advocated for perpetual protection which arose from the permanent and inalienable natural right to man's work: J.B.M. Jobard (1844), *Nouvelle économie sociale ou monoautopole industriel, artistique, commercial et littéraire*, Paris, at 5, 130, 239, cited by F. Machlup and E. Penrose (1950), 'The patent controversy in the nineteenth century', 10 *Journal of Economic History* 1, at 9; another firm advocate of such a system was Lysander Spooner – see G. Dutfield (2003), *Intellectual Property Rights and the Life Sciences Industries: A Twentieth Century History*, Ashgate: Aldershot, at 53.
40. For denunciations of the Lockean concept as applied to intellectual property, see J. Waldron (1993), 'From authors to copies: individual rights and social values in intellectual property', 68 Chi-Kent L. R. 842 at 871, 879–80; and W. Kingston (1990), *Innovation, Creativity and Law*, Studies in Industrial Organisation, Kluwer Academic Publishers: Deventer, at 83.
41. Cited in Arnold Plant (1934), 'Economic theory concerning patents for inventions' 1 *Economica* 30.
42. Tom Bethell (1998), *The Noblest Triumph: Property and Prosperity Through the Ages*, St Martin's Press: New York, at 263 *et seq*.
43. J. Locke, op.cit., paragraphs 27, 31, 39.
44. George Hegel (1952), *Philosophy of Right*, T.M. Knox, tr., at 68; Article 2(2), German Law on Copyright and Related Rights 1968 stating the creativity principle, and *Re Neo-Fascist Slant In Copyright Works*, Case 11 U 63/94, Oberlandesgericht (Regional Court of Appeal), (Frankfurt Am Main), 6 December 1994, [1996] E.C.C. 375, holding that copyright is part of the general inherent rights of a person and has a constitutional basis in Articles 1 and 2 of the German Constitution, which guarantee the basic human rights of human dignity and free development of personality.
45. For a discussion on collective management, and the types of levies collected, see Uma Suthersanen (2000), 'Collectivism of copyright: the future of rights management in the European Union', in E. Barendt and A. Firth (eds), 5 *Yearbook of Copyright and Media Law*, Oxford University Press, at 15–42.
46. G. Schricker (2004), 'Efforts for a better law on copyright contracts in Germany – a never ending story', *International Review of Industrial Property and Copyright Law*, **35**(7) 850.
47. *Re Neo-Fascist Slant In Copyright Works*, [1996] E.C.C. 375 (Regional Court of Appeal – Frankfurt Am Main) (confirming that copyright has its basis in Articles 1 and 2, German Basic Law); C. Colombet (1997), *Propriété littéraire et artistique et droits voisins*, Dalloz, at 12–14 (discussing the natural rights basis of French copyright law).
48. For fair dealing, see ss. 29 *et seq*., Copyright, Designs and Patents Act 1988; for free use or *freie benutzung*, see Article 24, of Copyright and Related Rights Law of 9 September 1965.
49. Art. 5(2), European Parliament and Council Directive 2001/29 of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society, L167/10.
50. J.A.L. Sterling (2003), *World Copyright Law*, Sweet & Maxwell, para. 10.04.

51. William W. Fisher III (2004), *Promises To Keep: Technology, Law and the Future of Entertainment*, Stanford University Press, 199–258; Neil W. Netanel (2003), 'Impose a noncommercial use levy to allow free peer-to-peer file sharing,' 17 *Harvard Journal of Law & Technology* 1; Raymond Shih Ray Ku (2002), 'The creative destruction of copyright: *Napster* and the new economics of digital technology', 69 *University of Chicago Law Review* 263; Lawrence Lessig (2004), *Free Culture*, Penguin Press, at 300–3 04; Jessica Litman, 'Sharing and stealing', 23 November, 2003. http://ssrn.com/abstract=472141.
52. The Father of Music Publishing was born during this era when, under an exclusive contract with the city of Venice, Ottaviano dei Petrucci prepared his first publication, a collection of 96 popular songs (mostly French chansons), which qualified him for this title. Russell Sanjek (1988), *American Popular Music and Its Business: The First Four Hundred Years*, Oxford University Press: New York, Volume 1 at 37–38.
53. V. Bonham-Carter (1978, 1984), *Authors by Profession*, 2 vols, The Society of Authors/ Bodley Head: London, Vol. 1 at 214–15.
54. U. Suthersanen, 'Collectivism of copyright . . .', op.cit., at 15.
55. Reebee Garofalo (1999), *From Music Publishing to MP3: Music and Industry in the Twentieth Century*, American Music, Fall.
56. Lawrence Lessig (2001), *The Future of Ideas: The Fate of the Commons in a Connected World*, Random House; James Boyle (2003), 'The second enclosure movement and the construction of the public domain' 1–4, in *The Public Domain* (ed. James Boyle), Vol. 66, Nos. 1&2, Law & Contemporary Problems, also available at http://www.law.duke.edu/ pd/; Elizabeth L. Eisenstein (1983), *The Printing Revolution in Early Modern Europe*, Cambridge University Press, at 83–84 (1983) who describes the enclosure of the literary 'commons' following the emergence of printing privileges for publishers, booksellers and stationers.
57. UK Copyright Act 1814.
58. The first post mortem formula was under the British 1842 Copyright Act (the Talfoud Act) where copyright lasted until 7 years *post mortem auctoris*.
59. The international standard of life and 50 *post mortem auctoris* is steadily being pushed up to life plus 70 years pma. The trend began its life as a result of EU copyright harmonization, but it has now gathered momentum through the United States FTA drive. As a result of this, the copyright laws of Singapore, Australia, Chile and Morocco all adopt the longer life plus 70 years term. For a discussion on the general jurisprudential legality of this trend, see the US Supreme Court's judgment in *Eldred v Ashcroft*, 123 S. Ct. 769 (2003).
60. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases, 1996 O.J. (L77) 20.
61. For a discussion of the 'idea-expression' principle in international copyright law, see J.A.L. Sterling (2001), *World Copyright Law*, Sweet & Maxwell.
62. See for example Art. 8, WIPO Copyright Treaty 1996 (WCT); Arts. 10 & 14, WIPO Performances and Phonograms Treaty 1996 (WPPT).
63. This implausible provision has been inserted by the Iraqi Coalition Provisional Authority in 1 May 2004; see CPA Order Number 83, available at http://www.iraqcoalition.org/regulations/#Regulations.
64. Art. 11, WCT; Art. 18 WPPT.
65. Art. 12, WCT; Art. 19, WPPT. 'Rights management information' refers to any information which a copyright owner deems appropriate to annex to the copyright work, the most likely means of inserting such information being by digital means such as watermarks or other digital identifiers. The information can relate to the identity of the work, the author or the rights owner, or terms and conditions as to use of the work, or bar coding. The rights management information can also, if stretched, refer to other identifying information placed on a copy of a work by the reproduction device: for example, if a person records a film being screened in a theatre with his video camcorder, the latter will mark the film with several identifiers: the date on which the recording took place or the serial number of the camcorder. This apparently non-erasable information can be

used by the industry to trace the origin of an illegally copied film. See generally chap. 5, *The Digital Dilemma: Intellectual Property in the Information Age*, Committee on Intellectual Property Rights in the Emerging Information Infrastructure, National Research Council, (National Academy of Sciences, 2000). Two examples of such systems are the Secure Digital Music Initiative (SDMI) and the DVD Copy Control Association (DVD-CCA); see http://www.sdmi.org/FAQ.htm and http://www.dvdcca.org/faq.html.

66. For the EU, see Arts. 3, 5(2)(b), Directive 2001/29/EC of the European Parliament and of the Council on the harmonization of certain aspects of copyright and related rights in the information society, adopted on 9 April, 2001.
67. The Bill calls for section 501 of the US Copyright Act to be amended so as to make liable anyone who intentionally induces copyright violations, that is anyone who 'intentionally aids, abets, induces, or procures' a violation. Interestingly, the notion of 'intent' can be shown from a variety of acts, including whether the activity relies on infringement for its commercial viability.
68. Like iTunes and Napster, songs will cost a dollar each. See http://www.peerimpact.com/ and www.wired.com/news/digiwood/0,1412,65836,00.html?tw=wn_story_related.
69. This dilemma has recently arisen in relation to French libel law and the sale of Nazi memorabilia on Yahoo's French site. The French court ordered Yahoo!, a California-based company to block French Internet users' access to Nazi material presented or sold not only on Yahoo.fr but also on their US website, Yahoo.com. The US District Court ruled that enforcement of this French judgment on US territory would be in contravention of the First Amendment on Free Speech. On appeal, the US 9th Circuit reversed the District Court's decision but held that it did not have personal jurisdiction over the French defendants. See *L'Union des Etudiants Juifs de France* v *Yahoo! Inc*., T.G.I. Paris, Nov. 20, 2000, J.C.P. 2000, Actu., 2219, obs. J. Gomez, available at http://www.juriscom.net/txt/jurisfr/cti/tgiparis 20001120.pdf. (Engligh translation available at http://www.cdt.org//speech/international/001120yahoofrance.pdf.); *Yahoo!, Inc. v La Ligue Contre Le Racisme et L'Antisemetisme*, 169 F. Supp. 2d 1181 (N.D. Cal. 2001); *Yahoo!, Inc. v La Ligue Contre Le Racisme et L'Antisemetisme*, 379 F.3d 1120, 1120, 1127 (9th Cir. 2004). For a discussion on the issues, see Ayelet Ben-Ezer and Ariel L. Bendor, *Conceptualizing Yahoo! V. L.C.R.A.: Private Law, Constitutional Review, And International Conflict Of Laws*, [2004] 25 Cardozo Law Review 2089.
70. See http://www.gutenberg.org/dirs/etext00/0ws 2310.txt.
71. This ensuing discussion draws upon the *Professional Policy Making for the Twenty First Century*, Report by Strategic Policy Making Team, Cabinet Office, 1999, available at http://www.cabinet-office.gov.uk/moderngov/policy/index.htm; *Guidance Note on How to Do Stakeholder Analysis of Aid Projects and Programmes*, 1995, Department for International Development (DFID) available at http://www.dfid.gov.uk/.
72. L. Jardine (1996), *Wordly Goods – A New History of the Renaissance*, (Macmillan:London, at 244–5.
73. U. Suthersanen (2003), 'Copyright and educational policies – a stakeholder analysis', 4 *Oxford Journal of Legal Studies* 586.
74. The five major recording labels ('Majors') are Sony Music Entertainment, Vivendi's Universal Music Group, BMG Entertainment (sometimes referred to as Bertelsmann), Warner Music Group, and EMI Recorded Music.
75. Bruce Bastin (1986), *Red River Blues: The Blues Tradition in the Southeast*, London, Macmillan, at 36–37.
76. F.M. Scherer (2001), 'The innovation lottery' in R. Dreyfuss, D.L. Zimmerman and H. First, eds, *Expanding the Boundaries of Intellectual Property*, Oxford University Press.
77. Dutfield and Suthersanen, 'The Innovation Dilemma', op. cit. at 391.
78. Kristin Thompson (1985), *Exporting Entertainment: America in the World Film Market, 1907–1934* London, BFI Publications.
79. Yochai Benkler (2002), 'Coase's Penguin, or, Linux and the Nature of The Firm', 112 *Yale Law Journal* 369, at 398.

80. The Napster program allowed music aficionados to do the following: make MP3 music files, stored on individual computer hard drives, available for copying by other Napster users; search for MP3 music files stored on other users' computers; and transfer exact copies of the contents of other users' MP3 files from one computer to another via the Internet. Important factors in considering the technology are that Napster servers did not create, copy, store or make available any of the MP3 files on its servers; the contents of all MP3 files were held at all times on the users' computers; the contents of the MP3 files were not routed or transmitted through Napster's servers as the latter merely held a database of MP3 file names and, if requested, the IP address information of each user.
81. Matthew Fagin et al. (2002), 'Beyond Napster: using antitrust law to advance and enhance online music distribution', 8 *Boston University Journal of Science & Technology Law*, 451, at 464–5.
82. Saul Hansell, 'E-Music Sites Settle on Prices. It's a Start', *N.Y. Times*, 3 March, 2003, at C1.
83. See the 'Statistics' link in the British Phonographic Industry website at http://www.bpi.co.uk/. There are contrary views as to whether P2P file sharing of music recordings decreases or increases sales – compare Felix Oberholzer and Koleman Strumpf, 'The effect of file sharing on record sales: an empirical analysis', (March 2004), available at http://www.unc.edu/~cigar/papers/FileSharing_March2004.pdf (stating that file sharing does not reduce CD sales, and may even increase sales), with Stan Liebowitz, 'Will MP3 Downloads Annihilate the Record Industry? 'The Evidence So Far' (June 2003), available at http://www.utdallas.edu/~liebowit/intprop/records.pdf (stating that P2P file sharing led to a decline in CD sales).
84. Martin Peitz and Patrick Waelbroeck (2004), 'File-sharing, sampling, and music distribution', December, International University in Germany Working Paper 26/2004, http://ssrn.com/abstract=652743.
85. Matthew Fagin et al., 'Beyond Napster . . .', op. cit., at 535; A. Maul (2003–2004), 'Are the major labels sandbagging online music? An antitrust analysis of strategic licensing practices', *NYU Journal of Legislation and Public Policy* 365 at 369.
86. A. Maul, op. cit.
87. *Radio Telefis Eireann and Independent Television Publications Ltd v Commission* (C-241-242/91 P) (Magill), [1995] E.C.R. I-743; IMS *Health GmbH & Co OHG v NDC Health GmbH & Co KG* (Case C-418/01), [2004] 4 C.M.L.R. 28. The *Bronner* decision is also relevant although it does not involved IPRs – nevertheless, it is discussed extensively in relation to these two decisions in European jurisprudence – *Bronner GmbH and Co. KG v Mediaprint Zeitungs-Und Zeitschriftenverlag GmbH and Co. KG* (C-7/97), [1999] 4 C.M.L.R. 112.
88. Brian A. Facey and Dany H. Assaf (2002), *Monopolization and Abuse of Dominance in Canada, the United States, and the European Union: A Survey*, 70 *Antitrust Law Journal* 513, 539–42 (discussing concept of 'joint dominance' or 'shared monopoly' and its application in Canada, US, and European Union).
89. The two companies were MusicNet and Pressplay. A. Maul, op. cit., at 367. Napster had also counterclaimed antitrust allegations, but due to the demise of the company in 2001, no action was taken. In respect of Kazaa's claim, it was dismissed for lack of standing – *MGM Studios Inc. v Grokster, Ltd*., 269 F. Supp. 2d 1213 (C.D. Cal. 2003).
90. Yochai Benkler (2004), 'Sharing nicely: on shareable goods and the emergence of sharing as a modality of economic production', *Yale Law Journal* 273 at 281. Note also his discussion of the much vaunted open source phenomenon as exemplified by the GNU-Linux open operating systems, or the intriguingly altruistic 'Distributed Proofreaders' service which proofreads voluntarily e-texts which are posted on Project Gutenberg – Yochai Benkler (2002), 'Coase's Penguin, or, Linux and the Nature of The Firm', 112 *Yale Law Journal* 369, at 398.
91. http://setiathome.ssl.berkeley.edu/.
92. http://www.stanford.edu/group/pandegroup/genome/.
93. Information Infrastructure Task Force, 'Intellectual Property and the National

Information Infrastructure: The Report of the Working Group on Intellectual Property Rights' 7–17, 218–38 (1995).

94. Jessica Litman (2001), *Digital Copyright*, Prometheus Books, at 90–100.
95. Digital Millennium Copyright Act.
96. Directive 2001/29/EC on copyright and related rights in the information society.
97. Jessica Litman (2004), 'Sharing and Stealing', *Hastings Communications and Entertainment Law Journal*, **27**, p. 9.
98. Jessica Litman, 'Sharing and Stealing', 23 November, 2003, http://ssrn.com/abstract=472141, at 8.
99. *Metro-Goldwyn-Mayer Studios Inc*., et al. *v Grokster, Ltd*., et al., No. 04-480, 24, January, 2005, On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit, Brief of the Business Software Alliance As Amicus Curiae Supporting Petitioners, available at Westlaw, 2005 WL 166590.
100. Ibid.
101. Art. 6, EC Directive on Legal Protection of Computer Programs 91/250 OJ 1991 L122/42; *Microsoft*, Case COMP/C-3/37.792. Another very interesting facet to the case was the issue of Microsoft bundling its Media Player to the Windows operating system. See Ian Ayres and Barry Nalebuff (2005), 'Going soft on Microsoft? The EU's antitrust case and remedy', Vol. 2 Issue 2, Article 4, *The Economists' Voice*, at http://www.bepress.com/ev.
102. Ian Ayres and Barry Nalebuff, op. cit.
103. (1881) *Musical Opinion & Music Trade Review*, July, 358, as reprinted in J. Coover (1985), *Music Publishing, Copyright and Piracy in Victorian England*, Mansell Publishing: London & New York, at 9.
104. V. Bonham-Carter (1978, 1984), *Authors by Profession*, 2 vols., The Society of Authors/Bodley Head: London, at Volume 1, 214–15; U. Suthersanen (2000), 'Collectivism of copyright: the future of rights management in the European Union', in *Oxford Yearbook of Copyright and Media Law*, (eds. Barendt/Firth), Oxford University Press, at 15.
105. The Berlin revision (1908) incorporated photography, film, and sound recording; the Rome revision (1928) added broadcasting; the Brussels revision (1948) added television.
106. CITE US/UK laws.
107. *In re: Aimster Copyright Litigation*, 334 F.3d 643 (7th Cir. 2003).
108. *Sony v Universal Studios*, 464 US 417 (S. Ct. 1984), at 434–442; see also *Napster*, 239 F.3d 1004 (9th Cir. 2001), at 1021.
109. 'Briefs in support of petitioners' by Business Software Alliance, in *Metro-Goldwyn-Mayer Studios, Inc. v Grokster Ltd*., 380 F.3d 1154, 1158–60 (9th Cir. 2004). For this and other briefs filed by amici curiae, see the US Copyright Office website at http://www.copyright.gov/docs/mgm/.

14. Author's rights and internet regulation: the end of the public domain or constitutional re-conceptualization?

Guido Westkamp

Copyright has changed dramatically. The 1996 WIPO Treaties,[1] the Digital Millennium Copyright Act and the European Directive Copyright and Related Rights in the Information Society,[2] in an attempt to rejuvenate traditional copyright to make it viable for the information society, have additionally altered the traditional structure copyright law. Today's prominent catchphrases indicate that the former 'bundle of exclusive rights' enjoyed by an author now encompasses the use of a work and also entails the author's exclusive right to authorize or prohibit access to it. Whereas the notion of a use right may be inferred from changes and amendments implemented in relation to existing economic rights, the idea of an access right is closely connected with the legal protection afforded to technological measures employed by the right holder. These measures may restrict access to certain parts of a work or make access to the work subject to the right-holder's consent. It is now prohibited to circumvent such means in order to gain unauthorized access. These safeguards are flanked by amendments in the ambit of economic rights. Global and European instruments have introduced not only a novel right of public communication, which includes (but is apparently not restricted to) making the work available to the public by providing access at a time and place chosen by the user, but in addition have implemented, at least at European level, a new notion of the reproduction right covering even purely technically caused copies during an electronic transmission. Both exclusive rights are intended to deal with digital uses, in particular on the internet, though the statutory provisions do not expressly refer to such restricted application.

This raises a number of complex issues. The principal problem is that, when perceived more comprehensively, the rights granted allow the inference of a general right to control access or use. The potential effect is a restriction of judicial freedom of movement because the notion of use and access might

operate as a new discursive scheme within the confines of a given national copyright architecture. The most interesting and critical aspect is not only the fact that the rights granted will lead to a reduction in the public domain, but that the concept of the public domain – that is the public interest in receiving and imparting with information and ideas – is being subjected to a legal discourse which may motivate judges to completely ignore or devalue it. Thereby, the inherent tensions in copyright law, between freedom of information and communication and a level of protection which is sufficient to safeguard the interest of authors and exploiters, is subject to a novel evaluation, which places more emphasis on control over information than requiring a substantive analysis of copyright infringement.

What will be demonstrated here is that the highly critical methodology in copyright might have to be re-conceptualized. The amendments to specific economic rights and the additional layer of safeguarding technological control through legal means have the potential to transform the undercurrent that has always subtly accompanied copyright law: the application of basic principles which allow for a more sophisticated and balanced test, a test which structurally enables courts to perceive the public interest as a meta norm in copyright. Otherwise, copyright will not only verge on industrial property protection standards such as the commercial use right in patent or trademark law. Beyond that, a use and access right permits control over items which, on the basis of the distinction between expression and information/ideas, is not within copyright control. The most critical issue then is that such new position in copyright is not restricted to commercial uses but impacts upon private communication.

The chapter will, after a brief overview of the public domain topos in copyright and general law, describe the structure of these two pillars and assess their potential impact upon the legal methodology used in copyright.

I. THE PUBLIC DOMAIN AND ITS PLACE IN THE TRADITIONAL COPYRIGHT DISCOURSE

The term 'public domain', in traditional copyright doctrine, is often deemed as a negative exclusion, the other extreme of a predominant rule in favour of protection. The terminology is blurred by the fact that there is no apparent methodological recourse to such overriding principle. Courts normally apply a methodology which is prescribed by the present copyright structure. The usual three step-structure, under which courts have to find subsistence, infringement and the absence of limitations or exceptions, makes it indeed difficult to see the location of an overriding paradigm within the methodological approach, and therefore courts will have to juxtapose the notion of

a work with given limitations: once the presence of a work is established, copyright subsists, yet the scope of protection necessary may vary. This, in turn, depends upon aspects such as the quality of a work, the purpose for which it is used, and other factors. These are underpinned, again, by specific constitutional aims and purposes. Hence, the US Constitution maintains a more functional approach[3] than authors' right systems based upon the protection of the author's personality,[4] and the constitutional undercurrent will influence the interpretation of any norm which allows courts to incorporate freedom of information and communication aspects into a specific copyright infringement test.

In traditional copyright law, the public domain notion may, conversely, also be taken so as to denote all types of information which can be used freely, and it that sense the public domain topos must be perceived in a doctrinal sense, that is, as a general principle which, albeit subtly, underpins the entire printed and doctrinal structure of copyright, and thus represents the existence of constitutional norms in copyright. This notion goes well beyond a perception as a simple exception in particular cases. The necessity to employ overreaching notions only emerges once any conflict cannot be satisfactorily resolved by the direct application of statutory law.

The public domain emerges at various levels of the traditional copyright infringement test, albeit more as a discursive and metaphorical blueprint. It is important, however, to ascertain the methods by which the public domain impacts upon copyright protection, and therefore the structure of copyright law should briefly be investigated. Methodologically, the public domain may appear at the level of individual provisions, in particular express limitations in the respective copyright statute which safeguards certain uses, and the salient distinction between expression and ideas underlying the entire global understanding of copyright law. This is the route followed by American copyright law which, under § 107 of the Copyright Act 1976, condenses the conflict resolution into a discreet fair use provision; it provides courts with a very flexible tool to canalize copyright protection where necessary, whilst additionally requiring a level of originality which is in line with the constitutional aim of copyright to promote useful arts and sciences.[5] The same approach can be recognized in authors' right systems where the constitutional conflict can be resolved by applying a higher level of originality. The judicature of the German Federal Court of Justice in relation to structural works – that is, works which have no inherent quality but may be protected under a 'thin' copyright for the selection and arrangement of information – is a good example for the ways in which freedom of information may be revered at a different level by allowing a very similar conflict resolution in relation to the quality of the work; hence, works of a routine or technical character are given less, or indeed no protection for lack

of a personal intellectual creation, and such endeavours must reach a level of creativity which bears a striking distance from routine and everyday creations.[6] Even in jurisdictions which do not employ any express fair use limitation or a high originality threshold – in particular, in the common law world – courts are often prepared to deny protection by creating unwritten requirements, such as a commercial use or some jeopardy to the authors' market.[7]

These underlying doctrines, with their insistence upon a function of copyright that enables courts to strike a balance, are albeit nebulously embedded in constitutional norms. These are primary examples of how the seemingly narrow and linear copyright test – that is, a test involving the presence of protectable subject matter, an infringing act and the absence of statutorily defined limitations – can be disentangled so as to allow the infliction of overriding considerations.

II. AMENDING ECONOMIC RIGHTS: TRANSIENT COPIES AND PRIVATE COMMUNICATION

The notion of a use right, as understood here, follows from the convergence and amendments in the area of economic rights. In conventional copyright doctrine, rights referring to the physical use of protected works permit the owner to reproduce the work and distribute a physical copy to the public. Rights relating to non-physical uses protect against acts which make the work *publicly* receivable only. Although both sets of rights are not mutually exclusive, they cover quite distinct aspects of use. Communication rights require the presence of a 'public', whereas the reproduction right is concerned with the making of a permanent copy. This interaction leads to an important finding in that, apparently, a dichotomy exists under which, by way of negative exclusion, (traditional) copyright does not provide for a use right. In traditional copyright doctrine, the status of a permanent copy is to function as a prerequisite for a subsequent communication. Reception of the information contained in a work is directed towards a different copy. It may follow that a reproduction is a representation of the work which replaces the original. The act of communication between work and user, then, is not within the ambit of copyright control since the reproduction right, as such, cannot apply to subsequent communication acts. Subsequent acts will only infringe once a communication reaches the *public*, and it follows that a private communication cannot be impeded by copyright.[8] In addition, the exhaustion principle[9] maintains at least a certain level of communication freedom in that copies stored on a physical carrier can be freely disseminated.

On a more subtle level, the distinction drawn between reproduction and communication also provides for a further dichotomy which highlights the relationship between industrial property rights and copyright. Patents and trademarks grant use rights restricted to commercial situations. Copyright applies irrespective as to whether the work is used privately or commercially, but the ambit of the right was restricted by subtle dichotomies which maintain a certain level of private communication and dissemination of information.

The key problem today is that the reproduction right, extended so as to cover every electronic representation of the work,[10] can occur simultaneously during an electronic transmission, an act which is to be classified as a communication – at least, this is the position taken under both the 1996 WIPO Copyright Treaties and the EU Information Society Directive.[11] Such *raison d'être* shifts the judicial freedom to maintain fundamental rights in receiving information. The communicative act can be controlled via a right to 'copy', a prerogative which used to have an entirely different function in traditional copyright doctrine. This not only leads to an interesting debate as to whether an act of public communication absorbs the reproduction right, but also to an absurd problem in relation to defining what the 'public' is. Historically, communication rights have been extended to cover a gradually increasing *extent* of recipients, from a theatre audience to acts of television broadcasting.[12] [KC1]These types of communication could, in terms of whether a particular communication would infringe, be more easily assessed because the public reached was describable in terms of its typical size, and also because of the fact that the communication was intended to reach a large number of recipients simultaneously. In turn, this denotes that the term 'public', in the accepted sense, operated as a metaphor for typical commercial uses, a function not only crucial to assessing the concrete damages for copyright infringement but also to the scope of licences granted in copyright contract law. A communication right which simply couples an act of a non-simultaneous communication with a notion of the 'public' which cannot be defined by taking recourse to the act in question will come dangerously close to an overall notion of a use right which enables the control even of private one-to-one communications.[13] Judicial interpretation thus will turn from assessing the commercial impact of the act in question to a strictly ontological investigation of what the 'public' is – how many people can constitute the public, or whether a non-private relationship between sender and receiver is present. With respect to the public domain principle, such broad interpretation of statutory copyright law seals off the escape route provided for under traditional copyright doctrines and its inbuilt dichotomies. Methodologically, this causes frictions because courts will have to employ overriding principles of communication freedom

which can no longer be found within the existing framework. And if the public interest still has its place in copyright, this will mean a shift towards constitutional scrutiny. Under constitutional law, as will be discussed later,[14] this will generate a number of problems since such all-embracing transformation of copyright will have to be reconciled with general national constitutional doctrine and methodology. More critically, courts may assert a general use right on the level of ordinary copyright law, a position which may additionally well be influenced by the presence of rights in technological measures.

The following analyses the scope of both the reproduction right and the public communication right.

1 Reproduction

Electronic transmissions always require the making of certain transient copies and temporary copies. This has been quickly adopted by the industries concerned. Today, the EU Information Society Directive takes an extremely broad stance as to what constitutes a reproduction – every representation, regardless of whether direct or indirect, permanent or durable.[15]

The history of extensions made to the reproduction right can be traced back to the early discourses surrounding the specific problem of software protection, a development which, as a consequence of a perplexing notion of software as literary works, required legislators to accommodate typical computer uses into the copyright system as well.[16] This was accomplished by giving control over the use of a computer program via a wide notion of what constitutes a reproduction, which then covered temporary reproductions in computer RAM.[17] The European Software Directive provided, however, for certain legislative freedom in that a temporary reproduction would only infringe if the use of the program requires the making of copies.[18] This provision has never been fully tested in court but generated a widespread legal discourse.

Temporary copies are taken to share certain characteristics of permanent and durable copies, in that the ephemeral copy indirectly enables the work to be perceivable to the human mind. The user, then, accesses one or more temporary copies rather than the original.[19] This position is not reconcilable with the fact that communication and reproduction are two distinct acts. If followed, it will have grave consequences for the status of the public domain paradigm. The ordinary meaning of the term 'reproduction', was to produce something that replaces the original. A copy, therefore, must fulfil a certain function, which lies in the fact that it enables a different source of communication rather than a communication as such. In relation to traditional copyright, the notion of a broad reproduction

right then extends to all types of digital uses which necessitate ephemeral copies, and this includes every reception of the work – and, of course, the information contained therein – via electronic means. The communicative act is the very same as reading a book or looking at a painting. Conversely, copies generated during the act of transmission simply assist in carrying out the communication.

So why did such a broad notion enter the legislative process? In relation to software protection, the initial purpose is that the owner of software copyright is given a right to control typical uses. Since software cannot be communicated in a traditional sense, the right to control temporary copies can be translated into a right to control individual uses of a discreet set of software, in particular in larger companies, since otherwise the software could be accessed from a number of connected computers once stored on a central server. The intention was to protect the return of investment[20] via copyright law, not a personality right. Since an international consensus on reciprocal protection could more easily be achieved under the Berne Convention, the reproduction right had to be extended so as to cover typical software uses, and because software cannot be communicated, utilizing the reproduction right to cover the running and loading of computer programs provided for both some reconcilement with the Berne requirements and, simultaneously, a tool to practically provide protection where needed. Yet from a copyright purist's perspective, the notion of control over temporary and, essentially, valueless copies remained unnatural, and perhaps the best explanation is to understand transient copying as a metaphor for what would otherwise have simply been coined an industrial property use right. Despite this, the text of the Software Directive was repeated in the Database Directive,[21] and finally matured into an uncontested consensus under the *acquis communautaire*. The Information Society Directive takes a rather unsatisfactory stance which is not precipitated by the 1996 WIPO Treaties. Whilst the text of both the Software and Database directives is repeated by extending the exclusion so as to cover every form of 'copy' (direct or indirect, permanent or temporary), Article 5 (1), in the fashion of a mandatory exception to the transient reproduction right, exempts certain ephemeral copies provided they facilitate electronic transmission.[22] The most compelling feature of this legislative technique – which at least reflects some doubts on behalf of the Commission – is that the exemption only applies if the use has no economic significance, and this is elaborated in Recital 33 so as to mean the absence of a lawful *use.* In turn, lawful uses are those which are not prohibited by law or a licensed use and accordingly require consent.[23] The inference is that the copyright owner may resurrect transient copying as economically significant as a basis for infringement if he had not consented to the electronic transmission of the

work.[24] The effect is that the electronic communication, which under Article 2 b) of the same directive must reach the public, is subject to control via the reproduction right.

It may be suggested that the European stance had profound influences on the treatment of temporary copies under the 1996 WIPO treaties, though the conference produced only a marginal definition,[25] under which the reproduction right encompasses any direct or indirect, permanent and temporary copy.[26] Article 7 (2) of the Basic Proposal allowed for certain exceptions in relation to transient or incidental copies, which were to be based upon the three-step test under Article 9 (2) of the Berne Convention[27] and dependent upon the author's consent.[28] The provision did not make it into the final text though an agreed statement was introduced,[29] which provides that the reproduction right 'fully applies in the digital environment' and that the storage of a work constitutes a reproduction, that is it covers acts occurring during online transmission,[30] though it does not articulate an international consensus.[31] The doctrinal background, under both the Directive and the Agreed Statement on the WCT, is based upon the notion that transient copies are, conceptually, fixations.[32] Yet even if one can assert a broader interpretation – indeed, nothing under the Berne Convention as such suggests that a copy must be permanent or functional – the friction with the communication rights is hardly deniable. The core absurdity is the fact that the terminology is used without any reference to communication rights, so that, via a broad interpretation, the requirement of a public present becomes redundant. Certainly, this is caused by a lack of scrutiny as to the scope of the participation interest afforded to the owner, and reflects some ignorance as to the function of the dichotomy between physical and non-physical uses. If copyright is to maintain a balance in this respect, courts will have to step back and deny protection for lack of originality.

2 Trespassing on Private Communications: The Public Communication Right

A similar interpretational problem occurs in relation to the expansion of the communication right. The distinction between physical and non-physical rights, as noted, highlights the underlying idea that, in general, the author has no specific right to prevent any private display or to control a one-to-one communication of the work, that is the committal of a defined act of communication, such as by broadcasting, and the presence of the public.[33] Normally, the public would be present simultaneously rather than successively, as is typical of digital uses on the internet. From these two principles, the traditional meaning of 'the public' is easily demonstrable. In a traditional environment, the act of publicly communicating a work would,

of course, typically reach the public. This 'public' typically consists of persons receiving the communication *simultaneously*. This view of public communication had posed, apparently, the most scrutinized topic during the genesis of the communication right: network uses do not *reach* the public in such a fashion. It is not surprising that the Directive was quick in the attempt to eradicate this view, and indeed such abolition was favoured even before the discourse on online exploitation commenced.[34]

In conjunction with the reproduction right outlined above, the effect of a making available right is threefold. First, courts will have no option to refer to a standard situation (such as a television audience) in order to assess the impact of specific uses. Second, as a consequence of the lack of a description of the act as a typically commercial one, the decisive factor is to assert what, or who, constitutes the public. Third, it follows that the term 'public' will be interpreted through the filter of each national statutory interpretation canon, which will lead to potentially diverse results[35] and cause legal uncertainty. Conversely, if harmonization is to be achieved under a smallest common denominator solution, this effects an interpretation which maintains that a communication directed to at least one 'member of the public' is sufficient; because the communication need not be simultaneous, courts need only to conclude as to whether a private relationship exists between sender and recipient,[36] and again it is improbable that such judicial elucidation is appropriate to yield common global copyright standards. As a consequence, the harmonization of laws intended causes a significant reduction of the freedom to communicate and legal uncertainty because the communication right is bereft of any implication as to a commercial exploitation.[37] Because neither the Directive nor the respective formulation under the 1996 WIPO copyright treaties acknowledge the link between the terms 'public' and 'communication,' the effect is to underpin the author's control rights with a theorized concept of a use right extending to any work, rather than providing for a specific act entailing a 'commercial' connotation. This conveniently provides a theoretical basis for asserting a general access right as a subcategory of a broad use right, which will display characteristics similar to industrial property rights.[38] In that sense, the shift in the balance from free communication to copyright control via recognition of 'use' control may pave the way for asserting an access right if technological measures have been applied.

III. CODE AS LAW: TECHNOLOGICAL MEASURES

Technological measures are protected under the WIPO Copyright Treaties, the DMCA and the European Information Society Directive. Their impact

upon the public domain requires a much more detailed discussion than is possible here, yet two aspects should be analysed.

The first is the question how such a system of protection is to be placed within the copyright architecture. This issues relates, primarily, to the question whether the circumvention must affect the interest in the specific copyright work which is technologically protected. The second issue is of a more general nature. Here, it is necessary to analyse the status of the act of circumvention in relation to the general legal framework, and the legislative roots and judicial consequences the protection measures have in the overall legal method in relation to information protection outside copyright.

The idea behind the introduction of technological controls protection is to enable right-holders to protect their works against digital copying. Such control may, possibly, enable a new economy for copyrighted works by creating artificial scarcity that would otherwise have been obtained through the price paid for purchasing a physical carrier. Protection by technological means thus enables the right-holder to immediately contract with the user. The remuneration to be paid under such a contract makes the work scarce, that is it is only accessible once a (physical) copy has been bought. In the online world, such control is difficult because, once available in digital form, the work can be endlessly copied. The author, or indeed the right-holder, will have no other means but to secure his income through artificially restraining access in order to achieve the desired scarcity of his work, which can only be accomplished through employing technical measures enabling access and use to be restricted in order to control the dissemination of the work.

Where, if at all, does the public domain paradigm come into play? The trite answer is that technological measures allow protection of unprotectable material, and also allow for contract models which restrict the user's ability to copy or resell the work. In short, it may create an information monopoly by safeguarding information possession.

Legislators have indeed observed that a certain tension between extensive control and freedom of information exists. The response to – this rather trivial insight – differs between EU member states, though the general pattern, as followed by all countries implementing the EU Copyright in the Information Society, is the same: the act of circumvention as such is not subject to the usual copyright test. Information access needs to be maintained, yet only at the level of specific limitations, a list of which has been introduced under Article 5 (2) of the Directive. In Europe, some jurisdictions have opted for administrative procedures to be initiated by beneficiaries of certain specific limitations – a time-consuming procedure the beneficial effects of which are more than dubious.[39]

1 An Access Right?

The idea of 'access' stems from the notion that the copyright owner, just as the owner of physical property, has a right to erect 'electronic fences', a proposition which equates intellectual and real property. The idea is placed upon a 'code as code' solution – technological opportunities additionally protected under tort law. In that sense, the establishment of provisions concurrently prohibiting the circumvention (and thereby even access to free information) is a legal continuance of a regulation by code rather than law. Courts have already held that removing technological measures amounts to a tort in its own right, and thus courts are not to conduct a copyright infringement test.[40] This instigates an interpretation which eradicates any judicial freedom of movement in relation to a preference of information freedom.[41] Hence, the act of applying measures, as such, would provide the owner with an all-embracing control right. This has been, *obiter dicta*, confirmed in *Reimerdes*.[42] Legal control is offered over the original work but also extends to information as such. In that sense, it presents a different problem from the use right as introduced by the amendments of economic rights because copyright infringement cannot occur if the object is insufficiently original.

There is certainly a much more subtle notion which is directly linked with the public interest complexity, which concerns both access to, for instance, unprotected scientific data or the ability to freely circulate protected works. There will be very few occasions where an end user actually circumvents – only few will have the knowledge and technical aptitude. In that respect, the discourse seems, in reality, overestimated. Likewise, unlawfully acquiring access to information as such, already may constitute a tort or even criminal offence in different legal areas.[43] But because the code is then flanked by legal safeguards in the much wider and important area of *copyright*, the ultimate consequence will be a notion of preference of intellectual property – and perhaps even information possession – over property or other positions under human rights law which never used to be contested by copyright. The ordinary end user will instantly become acquainted with a belief of overreaching protection for copyrighted works, and a concurrent legal preference for Intellectual Property, even in cases where works have been purchased on tangible carriers.[44] Whereas, in relation to traditional works, the exhaustion principle provided the opportunity for free circulation (that is loss of control over distribution chains), works in digital form which restrict access and use will become standard.[45] Copyright control can be exerted over private uses. As users become increasingly familiarized with use restrictions, 'digital' copyright provides an ever broadening line of reasoning for progressively more obliging licensing clauses even on tangible

carriers. And because copyright doctrine is indifferent as to the type of subject matter, the very same case can be made by owners of a 'thin' copyright – ultimately permitting legal control over access to free information. The implications of a proprietary protection which actually allows the emergence of information monopolies are, however, far from clear. The true aim – protection for the music and film industry – might transgress in a doctrinally tenable impression of some information property dogma, at least within the confines of copyright.

The doctrinal implications are grave. Coupled with the notion of a use right by which communications can be controlled, an uncontested right to regulate access will certainly spawn a shift in the methodological way the public domain intercepts with information access under copyright. It is trite that the public domain, as a copyright-specific metaphor for freedom of information, will not lose its importance. Conversely, it will attract more attention because the control provided has the potential to monopolize information – if the conflict cannot be resolved within copyright, it will have to be moved under a different, yet functionally equivalent, heading. Apart from mechanisms in monopoly/antitrust control, this means that the preservation of the public domain can only be accomplished by applying a constitutional test.

2 Access Rights and Private Norm Setting: Copyright Control and the Constitutional Imperfection of Cyberspace Regulation

This puts the access right discourse into the context of a wider framework of constitutional defects in internet regulation, specifically the reality that private norm setting – the infamous code – prevents detailed legal reasoning.[46] Thereby, constitutional norms, which in traditional judicial review impact on the legal interpretation, derived from fundamental balances and variations of the law, are likewise excluded.

This is a common problem of internet (or, better, communication) regulation, and the issue is closely interwoven with the general problem as to how constitutional implications influence internet regulation. Internet regulation can be described as a process which is strikingly different from statutory norm setting. It relies on the initiative of private actors and is, therefore, radically bereft of a sound constitutional framework. This lack of an opportunity to rely upon constitutional norms, and in particular human rights, may occur both at a formal and substantive level. In relation to formal requirements, institutions which allocate rights are often established following a non-constitutional process, which makes it difficult to entreat the recognition of basic principles. Internet-specific institutions are therefore not subject to obligations which maintain constitutional principles. The prime

example is the way in which ICANN allocates domain mains. But there is an important distinction between technological access control in copyright law from, for instance, the complexities involved in domain name allocation through private bodies.

The recognition of an access right can rely on the existing subtext of an apparently revised copyright architecture, that is a right to control uses embedded into a copyright concept: the notion of a 'use right' forms a fundamental argumentative pattern to legitimate an additional notion of 'access'. Since the grant of an access control right then relies upon – as will be discussed later – inferences drawn from formal law (in the guise of communication control through economic rights setting the standard of the participation right), the status of access control cannot easily be dismissed as private norm setting. In that sense, the problem goes beyond that in relation to an institutional lack of constitutionality, because the recognition of constitutional norms is simultaneously excluded under secondary (copyright) legislation. This makes arguments which are based on increasing horizontal effects of fundamental freedoms against biased norm setting in internet regulation[47] more difficult to plead.

Since technological access (that is the 'code') is a corollary of standard setting by private bodies – in the majority of cases, multinational entertainment enterprises – the *additional* grant of an exclusive *legal* right to control access will encroach upon the entire copyright system: a new and discrete right with an exclusive and thus proprietary character. If such a prerogative is granted in relation to 'cyberspace', it will also almost certainly alter the entire function of copyright and extend to non-digital uses. The effect, as already noted, is to equate information possession with physical property.[48] In that sense, the apparent exclusive character of copyright norms will also influence the scope of property rights to be balanced against fundamental freedoms.[49] The general arguments for regulating power in cyberspace assert the lack of norms compliant with constitutional standards. Here, the question arises whether these arguments can simultaneously be applied to legal rules which themselves are constructed upon secondary legislation apparently expressly asserting a general use.

a New copyright and internet regulation: horizontal and interpretational complexities

The constitutional problems discussed here in relation to copyright only partially reflect the general discourse on cyberspace regulation. The elements – and requirements – for a constitutionally desirable cyberspace architecture (including the exercise of the 'code' by private actors) have been identified as including, *inter alia*, the need for accomplishing a normative hierarchy and means of control over private actors' obligations to

observe fundamental norms.[50] The issue of access control in copyright even goes beyond these observations – as noted, securing the code will have a spillover effect onto the entire architecture of copyright law beyond internet-related issues, thus exceeding the problem caused by the legal safeguard of the 'code'.

Compared to the constitutional problems posed by, for example, the self-regulation policy for domain name allocation under § 12 (a) of the ICANN policy rules, copyright law itself needs to serve as a starting point. Copyright remains a body of law which sets the precedent for its own constitutional assessment. The access control problem, here, is not concerned with one individual institution but multiple owners, though it remains a problem of allocating information control for the benefit of private parties in a similar manner. The difference lies in the fact that the discourse relating to norm-setting by ICANN concerns the question whether ICANN, as an *institution*, should be obliged to observe fundamental rights and further constitutional principles.[51] In relation to *individual* copyright owners, the issue is whether access can be demanded on the grounds of an overriding 'public' interest, such as for derivative purposes or for access to information which is not protected by copyright. It is suggested, however, that there is no material distinction between the two complexes, but a methodological one. Both copyright and domain name allocation are safeguarded by a 'code as law' method. 'Constitutionalizing' ICANN as an institution would, therefore, present a much less demanding task than re-erecting norms which maintain the public domain in cases concerning copyright/access right infringement. This is so even if one asserts that access control is, itself, not exclusive in that it requires a copyright infringement test;[52] the problem persists that the premises under copyright remain unclear, precisely because the notion of a use right by way of extended economic rights still exists. In addition, the doctrinal aspects of constitutional conflict resolution will invariably differ between jurisdictions,[53] yet all fundamental norms require the balancing if the scope of protection of one right – in this case, the proprietary interest in the economic aspects of copyright – conflicts with other fundamental rights, here the right to receive and impart information with all its implications for cultural and economic progress. As noted, a system of resolving these conflicts can either be incorporated in copyright law as secondary legislation[54] or can be sustained by judicial interpretation which takes into account factors which objectively lie beyond a literary interpretation of the respective copyright statute.

It appears that the core problem here is much more closely associated with the question of normative hierarchy. The copyright system used to employ a seemingly autopoietic system in the sense that the inherent and subtle balancing mechanisms provided for a fundamental norm,[55] an orientation

figure which allowed for variations and exceptions. The answer to the resolution of the conflict must come from within a reasoning based upon the interpretation of copyright as inferred from the norms and structures of the copyright legislation in question. If that structure changes, the apparently clear legislative extension of the monopoly granted will concurrently reduce the constitutional scope of legitimately pleading conflicting fundamental norms. Traditionally, aspects of information freedom come into play as re-exceptions under the limitation heading only, and under the traditional framework these exceptions are to be interpreted narrowly.[56] In addition, these limitations are subject to further restrictions based upon safeguarding the participation right of the author. Various decisions in relation to freedom of information in authors' right have underscored that legislators are permitted to restrict the scope of protection by implementing *specific* limitations.[57] The scope of copyright as a property right in terms of a constitutional scrutiny is thereby not questioned. Copyright, just as physical property, is perceived to pre-exist in a rigid notion. The effect is a circular argument: the constitutional scope of copyright can only be specified by interpreting the respective national notion of copyright, and any amendment which extends the copyright monopoly must therefore be taken so as to simultaneously extend the scope of property protection under constitutional norms.[58]

Though it may be asserted that a safety net can be introduced by requiring a traditional copyright test, such a test can only work in jurisdictions which employ a general fair use norm. This option is not open to jurisdictions with a more comprehensive system of exceptions and limitations. Yet even if such a general fair use clause were to be introduced under international agreements, the conflict will not be finally resolved. The expansion of copyright protection affects not merely the question of copyright infringement but also has repercussions for the way in which contracts between right-holders and users are concluded. Even if one denies the existence of an access right, there is certainly some truth in the notion of a use right, and such a concept allows a wider freedom to restrict use of the work. This is already evident in the fact that works in electronic form are increasingly not sold. Instead, the purchase of a copy may contractually be defined as rental, the effect being that the distribution right is not exhausted. This means that the copyright owner is factually permitted to control any subsequent sales. If the copyright owner employs additional technological measures – for instance in order to restrict the making of copies – this may be taken as an indication for a rental rather than a purchase contract. Whether such practice which restricts the otherwise permitted use of a physical copy continues is open to debate, yet the constitutional conflict between access and freedom of information is apparent. If the exhaustion principle serves

as a watershed which allows the information contained in a work to enter into the public domain,[59] the effect of applying technological measures is equally to negate the value of the public domain in relation to contractual agreements. The key issue as to whether such contractual clauses are enforceable leads to the more general problem of whether limitations and exceptions can be contractually circumvented. Yet even if this question is not answered in the affirmative, the factual application of technological measures reveals a general predominance of information protection. This cannot be overcome by a divergent doctrinal categorization as a liability rule. It is apparent that the solution must likewise be embedded in assessing the public domain as a meta-norm for copyright protection.

b Re-conceptualizing the public domain: starting points from a human rights perspective

The notion of freedom of information as a mere re-exception which requires a formal parliamentary act[60] in order to restrict the monopoly (that is an express statutory limitation for specific cases) is, therefore, short-sighted. Freedom of information, under an autopoietic, self-referential assessment of substantive copyright law, is not limited to balancing between an existing asset and certain possible limitations. The rights afforded are subject to judicial variations of the statutory text, albeit not under an express constitutional scrutiny which actually refers to constitutional norms. It follows that, if copyright extends towards an access right, such an extension cannot simultaneously afford an initial predominance to the property right of the author. The scope of the freedom of information concept, and its interface with copyright protection must, therefore, be left intact. There are early signs that the safety nets previously inherent in the copyright structure come into play under different approaches, a development apparent in the area of competition control for 'essential' Intellectual Property facilities.

If the scope of the public domain has not been changed, the only remaining issue is how to incorporate the public domain paradigm into a copyright system which allows both the fencing in of information and the control over a number of (electronic) communication processes. The use of the public domain paradigm as a general discursive pattern in copyright seems difficult. The more secondary legislation restricts those rights that would have been available under traditional copyright – for example, the freedom to access information in order to create new works – the more the public domain paradigm will have to be applied. The problem, therefore, is not the 'withering away' of free access and use but the fact that the only option left is to take recourse to fundamental norms which are not represented in statutory law. The remaining issue is one of methodology rather than existence of a public domain paradigm.

In short, copyright assessment must rely on assessing the impact of the public domain as a meta norm for all forms of information protection. If the sole option is to employ such a meta norm through the channel of asserting fundamental human rights, this doubtless creates further methodological problems. A constitutional assessment will implicate the problem of horizontal effect, an issue very much associated with the broader complexities encountered in attempts relating to professing human rights as against private actors. Here, the underlying problem is, likewise, the general shift of norm-setting powers to private institutions, whether these are multinational enterprises,[61] internet 'authorities'[62] or private arbitration panels. The horizontal effect problem in relation to the overbroad notion of 'access' is, however, not one of recognizing the existence of human rights on an institutional level, but of recognizing a shift of power to private actors. If the tension between property and freedom of information can no longer be resolved within the statutory framework of copyright law, the idea that there is a horizontal effect problem is fallacious: if the state reduces the scope of the public domain without expressly eradicating the public domain as a fundamental concept, the same concept cannot be impeded by introducing a constitutional element.

It follows that courts will have to find new systematic concepts in copyright assessment, possibly by relying upon a somewhat tenuous meta norm, and without formal restraints following from an apparent direct effect given to constitutional norms. The scope of how a constitutional 'meta norm' affects the scope of the property rights granted will primarily depend upon a proportionality test that such a 'new' norm might impose.

If the notion that works in digital form can be controlled following a general notion of extensive control over information and ideas – as is suggested by a comprehensive interpretation of both the amended reproduction and communication rights – it is apparent that the more fundamental aspects of the public domain paradigm can be challenged as well. If it is true that the public domain idea is a reflection of constitutional standards incorporated into copyright law, the constitutionality of a norm setting a rigid standard must be challengeable as a norm of secondary legislation.

IV. CONCLUSION – A SUPERFLOUS RE-CONCEPTUALIZATION?

Although the inherent architecture of copyright might have shifted towards an all-embracing control right over information, it remains doubtful whether such shift will, in future, be upheld. The 'withering away' of the public domain, as can be experienced today, will certainly spawn a wealth

of dogmatic thinking aiming to re-conceptualize the general allocation of information. As time progresses, however, national courts will need to find ways which allow for a more refined assessment of copyright protection. Bereft of specific copyright norms and the question of information use will have to be addressed by the application of the fundamental principles to be re-introduced into the specific assessment, a shift in methodology rather than function. This casts doubt upon the very means by which digital issues are addressed at the international legislative level. The method to amend existing rights in order to reach a global consensus effects significant frictions in different national systems yet fails to deliver a harmonized solution. The true complexities – a workable global definition of the standard of copyright which is at least similar in its legislative intention and structure – have quite simply not been resolved.

NOTES

1. WIPO Copyright Treaty, adopted 20 December, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 65 (1997) [hereinafter WCT]; WIPO Performances and Phonograms Treaty, adopted 20 December 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 76 [hereinafter WPPT].
2. Council Directive 2001/29 of 22 May 2001 on the Harmonization of certain aspects of copyright and related rights in the information society, O.J. No. L167 (2001), p. 10.
3. See, in general, Jessica Litman (1990), 'The public domain', 39 *Emory Law Journal* 965; David Lange (1981), 'Recognizing the public domain', 44 *Law & Contemporary Problems* no. 4, 147 (1981).
4. See, for example, § 2 (2) of the German Copyright Act, http://www.iuscomp.org/gla/statutes/UrhG.htm.
5. See *Feist Publications v Rural Telephone Services* 499 US 340 (1991).
6. See, for example, the decision of the German Federal Court of Justice in 'Inkassoprogramm', Decision of 09.05.1985, I ZR 52/83 (1985) GRUR 1041, in which the court demanded a 'striking distance from everyday and routine' endeavours, thus denying protection for a computer program.
7. *IBCOS Computers Ltd. v Barclays Mercantile Highland Finance Ltd.*, [1994] F.S.R. 275, 302 (1994) (Jacob, J.); *Waterlow Directories v Reed Information Services*, [1992] F.S.R. 409, 411 (1997). Courts have particularly taken into account whether an intention to compete with the plaintiff's product was present, in which case courts have assumed that the substantial taking test was fulfilled and, accordingly, shifted the burden of proof to the defendant. See also Jane Ginsburg (1990), 'Creation and commercial value: copyright protection of works of information', 90 *Columbia Law Review* 1865, 1903–04.
8. For a detailed discussion, see the section on 'Trespassing on private communications' below.
9. See, for instance, § 17 (2) of the German Copyright Act; Sec 18 (3) UK Copyright, Designs and Patents Act 1988.
10. See the section on 'Reproduction'.
11. See Article 8 WCT and Art. 3 Directive 2001/29.
12. Adrian Sterling, World Copyright Law, Para 9.09 (distinguishing between rights in public performances, wireless transmissions and cabling). Under UK copyright law, there were doubts as to whether the term 'public performance' covered wireless broadcasting and cable diffusion. The German Act 1965 successively defines acts of recitation,

performance and representation (§ 19), transmission (§ 20), communication by image or sound recordings (§ 21) and broadcasting (§ 22).

13. For a critical account of the new communication right see W. Van Caenegem (1995), 'Copyright, communication and new technologies' *Federal Law Review* 322; K. Weatherall (1999), 'An end to private communications in copyright? The expansion of rights to communicate works to the public' 21 *European Intellectual Property Review* 342; G. Westkamp (2004), 'Transient copying and public communications – the creeping evolution of use and access rights in European copyright law' 36 *George Washington Journal of International Law* 1058–108.
14. See section on 'Re-conceptualizing the public domain' below.
15. Directive 2001/29, Article 2.
16. Early considerations on computer storage and retrieval can be found at the 'Report of the Executive Committee of the International Union for the Protection of Literary and Artistic Works (Berne Union)', 8 [1972] Copyright 14, 15.
17. See Herman Cohen Jehoram (1994), 'The EC copyright directives, economics and authors' rights' 25 *International Review of Industrial Property and Copyright Law* 821.
18. Directive on the Legal Protection of Computer Programs, 250/91/EEC, Article 5 (1).
19. Cf. Legal Advisory Board, 'Reply to the green paper on Copyright and related rights in the information society', at http://europa.eu.int/ISPO/legal/en/ipr/reply/reply.html (last visited 20 June, 2004).
20. See, expressly, Recital 3 of the Computer Program Directive.
21. See Directive on the Legal Protection of Databases, 96/9, Article 3.
22. Article 5 (1) only applies to certain copies which are transient and facilitate the transmission, such as copies made on proxy servers and caches, but would not apply to the act of loading a work onto computer memory.
23. The position in US law seems less clear, 17 U.S.C. § 117 (2001) (providing exceptions for certain temporary copies made while computer is in operation); US Copyright Office, DMCA Section 104 Report 107-20 (2001), http://www.copyright.gov/reports/studies/dmca/dmca_study.html> (reproductions in RAM are 'copies for copyright purposes').
24. Some commentators take the view that the term 'economic significance' in Article 5 (1) is redundant, see M. von Welser (2002), in: A. Wandtke and W. Bullinger, (eds), Urheberrecht, Kommentar, Ergänzungsband, Munich: C.H. Beck 2002, § 44a UrhG, Ann. 14.
25. On the interpretation of the reproduction right under the Berne Convention see C. Masouyé, 'Guide to the Berne Convention for the Protection of Literary and Artistic Works', § 9.2 (1978) (right covers all methods of reproduction, including those yet to be discovered.
26. Basic proposal for the substantive provisions of the treaty on certain questions concerning the protection of literary and artistic works to be considered by the diplomatic conference', Article 7 (1), WIPO Doc. CRNR/DC/4, http://www.wipo.int/ eng/diplconf/pdf/4dc_e.pdf.
27. It should be noted that Article 5 (5) of the Information Society Directive additionally, in relation to all limitations provided for under Article 5, requires a test based upon Article 9 (2).
28. On the background, see J. Reinbothe and von S. Lewinski (2002), *The WIPO Treaties 1996: The WIPO Copyright Treaty and The WIPO Performances and Phonograms Treaty: Commentary and Legal Analysis*, London: Butterworth, p. 41; Tani Freedman, 'Global copyright treaties slammed by US lobby' (5 December, 1996), http://www.public-domain.org/wipo/dec96/dec96.html.
29. WCT, Agreed Statement concerning Art. 1(4).
30. Reinbothe/von Lewinski, op.cit., pp. 42–43; Mihály Ficsor (1997), 'The Spring 1997 Horace S. Manges Lecture: Copyright for the Digital Era: The WIPO "internet" Treaties', 21 *Columbia-VLA Journal of Law & The Arts* 197, 204.
31. J. Ginsburg (2003), 'Achieving balance in international copyright law' *Columbia-VLA Journal of Law & The Arts* 201, 208.

32. However, the Agreed Statement only refers to the 'storage' of works rather expressly detailing that transient and ephemeral copies constitute reproductions. In favour of such reading, see J. Reinbothe and S. von Lewinski, op.cit. p. 44; see further Julie S. Sheinblatt (1998), 'The WIPO Copyright Treaty' 13 *Berkeley Technology Law Journal* 535, 550; Sam Ricketson (2002), *The three-step test, deemed quantities, libraries and closed exceptions* Centre for Copyright Studies 49–50; J. Reinbothe and S. von Lewinski, op.cit., pp. 42–44; J. Ginsburg, op.cit. 207.
33. See, for example, § 106 (4) US Copyright Act. This follows automatically from the use of the term 'public' in statutory law and the concurrent use of sub-categories relating to specific forms of communication which are typically commercial in nature.
34. See, for example, Gerhard Schricker (1999), 'Einleitung', in *Urheberrecht: Kommentar*, para. 21, at 10 (2nd edn); Joachim von Ungern-Sternberg (1999), in Schricker (ed.), *Urheberrecht: Kommentar*, § 15, annotation. 4–10 (2nd edn).
35. See *Duck v Bates*, 13 Q.B.D. 843 (1884) (Eng. C.A.) (finding no copyright infringement when a protected dramatic work was performed before a small audience at a hospital without charge because the performance was not 'public').
36. See, in general, Kurt Kemper (1995), 'The concepts of "Public" and "Private" in the digital environment', in *WIPO Worldwide Copyright Symposium on copyright in the global information infrastructure* 195; Ysolde Gendreau (1990), *The Retransmission Right: Copyright and the Diffusion of Works by Cable*, ESC, Oxford. This would follow the WIPO definition. Cf. WIPO Glossary of Terms, in The Law of Copyright and Neighbouring Rights (1980) (under 'Public').
37. *Rangers F.C. Supporters* Club, [1975] R.P.C. at 626. *Ernest Turner Elec. Instruments, Ltd. v Performing Rights Soc'y, Ltd.*, [1943] 1 Ch. 167 (C.A.) (finding infringement when employer broadcast copyrighted radio programming to its factory workers); *Jennings v Stephens*, [1936] 1 Ch. 469 (C.A.) (finding infringement when performed before audience of dues-paying club members).
38. Art. 9 (2) provides that the reproduction may only be permitted if it does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author. For a discussion of Article 9 (2).
39. § 1201 (d) Copyright Act 1976 (as implemented by the Digital Millennium Copyright Act) does not impose any such restrictions but contains several limitations. See further Guido Westkamp (2003), 'Towards access rights in UK copyright law: some remarks on the proposed implementation of the EU Copyright Directive', 1 *Computer Law Review International* 11–17.
40. See, for example, *Universal City Studios, Inc. v Reimerdes*, 82 F. Supp. 2d 211, 217 (S.D.N.Y. 2000) (distinguishing violations of the Digital Millennium Copyright Act (DMCA) from copyright infringement); *RealNetworks, Inc. v Streambox, Inc.*, No. 2:99CV02070, 2000 WL 127311, at *6 (W.D. Wash. Jan. 18, 2000) (same).
41. Pamela Samuelson (1999), 'Intellectual property and the digital economy: why the anti-circumvention regulations need to be revised', 14 *Berkeley Technology Law Journal* 519, 534–37.
42. *Universal City Studios v Reimerdes* 111 F.Supp.2d 294.
43. See, for instance, EC Directive on Conditional Access, Art. 3 (1).
44. The types of restrictions seem endless. Already, the music industry has started using means which restrict the number of copies which can be made, or the number of times a song purchased can be listened to.
45. A complex issue arises in relation to conflicts between anti-circumvention measures and lawful user rights, as required under Article 5 (1) of the Computer Program Directive, Article 6 of the Database Directive and Article 5 (1) of the Information Society Directive. In some member states, the meaning of lawful user encompasses the purchaser, provided that the distribution right in relation to the purchased copy had been exhausted. Exploiters may now circumvent this by concluding rental rather than purchasing agreements. It can hardly be denied that the notion of 'rental' can now be successfully argued if, for instance, the number of times the work can be accessed is restricted by technological measures. A similar problem will occur under Sec. 56 (1) CDPA 1988, which deals

with purchases of works in electronic form. In short, the industry is enabled to raise the very concept of access control to ultimately thwart even the occurrence of exhaustion, thus licensing the use of a work rather than selling copies – from a doctrinal point of view, this effects a situation in which courts would not be allowed to scrutinize a conflict between exhaustion and copyright control.

46. G. Teubner (2003), 'Globale Zivilverfassungen: Alternativen zur staatszentrierten Verfassungstheorie', *Zeitschrift für Ausländisches öffentliches Recht und Völkerrecht* 63, p. 1.
47. See J. Boyle (2002), 'Fencing off ideas', *Daedalus*, **13** (2) 13–25.
48. Outside the confines of copyright law, information law scholars have suggested the creation of proprietary rights on the basis of 'mixing' data so as to create a parallel to property acquisition in relation to physical objects, see (tentatively) Jean Nicolas Druey (1995), *Information als Gegenstand des Rechts,* Schuttess: Zürich, p. 99; Pierre Catala, 'Ebauche d'une théorie juridique de l'information', *Recueil Dalloz Sirey* 1984, *Cahiers Chronigues*, **16**, 97, 101. See further, arguing against the notion of information property, Guido Westkamp (2003), 'Protecting databases under US and European law: methodical approaches to the protection of investments between unfair competition and intellectual property concepts' 34 *International Review of Industrial Property and Copyright Law* 772, 782.
49. Paul Schiff Berman (2000), 'Cyberspace and the state action debate: the cultural value of applying constitutional norms to "Private" Regulation', 71 *University of Colorado Law Review* 1263, 1302–05; on formal constitutional requirements in the US see Thomas Nachbar (2004), 'Intellectual property and constitutional norms', 104 *Columbia Law Review* 272.
50. G. Teubner (2003), 'Globale Zivilverfassungen: Alternativen zur staatszentrierten Verfassungstheorie', *Zeitschrift für Ausländisches Öffentliches Recht und Völkerrecht* 63, p. 1.
51. See, in general, A. Goldstein (2002), 'ICANNSUCKS.biz (and why you can't say that): how fair use of trademarks in domain names is being restrained', *Intellectual Property, Media and Entertainment Law Journal* 1151, 1175.
52. *The Chamberlain Group*, *Inc. v Skylink Technologies Inc*. No. 02-C-6376 68 U.S.P.Q.2d (BNA) 1009, 2003 U.S. Dist. LEXIS 15298 (N.D. Ill. Aug. 29, 2003).
53. The question of the scope given to either aspect of the conflict can only be answered by reference to the underlying recognized function copyright has in a particular jurisdiction. In jurisdictions which generally place more emphasis upon originality the answer will have to be inferred from a notion of personality protection as the core comparative item, whereas in jurisdictions based upon an investment scheme the answer will perhaps be inferred from a commercial nucleus of protection. The same is true for those aspects which influence the determination of the public interest, hence whether a work is protected so as to give an incentive to publication (that is whether information freedom is a response to utilitarian notions) as under the US Constitution. It is apparent that this leads to divergent scopes of both conflicting rights, and therefore the initial starting point will vary considerably.
54. In that sense, see *The Chamberlain Group*, *Inc. v Skylink Technologies Inc*. No. 02-C-6376 (N.D. Ill. 11/13/03). ('A copyright owner seeking to impose liability on an accused circumventor must demonstrate a reasonable relationship between the circumvention at issue and a use relating to a property right').
55. This is derived from H. Kelsen, *A General Theory of Law and State*, Harvard University Press, 1945, p. 116 (explaining the relationship between the 'highest' constitutional norm to an unwritten fundamental rule). See further G. Teubner, 'Globale Zivilverfassungen: Alternativen zur staatszentrierten Verfassungstheorie' 63 [2003] *Zeitschrift fuer anslaendisches offenthches Recht un Voelkerrecht*.
56. BVerfGE 31, 229.
57. Federal Constitutional Court, BVerfGE 31, 229 in relation to an exception for the use of musical compositions in schools and churches.
58. This is perhaps one of the weaknesses of the underdeveloped area of copyright in constitutional law. Even in relation to physical property, the German constitutional

court employs a definition different from that under secondary legislation, in this case § 903 of the Civil Code.

59. See, for instance, § 12 (2) of the German Authors Right.
60. This view is still pertinent in German copyright scholarship and doctrine. The German Federal Constitutional Court has consistently held that, whilst the legislator is permitted to introduce exceptions, these must be narrow and definable. See Federal Constitutional Court BVerfGE 31, 229, 240 – Kirchen- und Schulgebrauch; BVerfGE 49, 382, 392, 394, 400 – Kirchenmusik; BVerfGE 77, 263, 270 f. – 'Zeitschriftenauslage'; BVerfGE 79, 29, 40 'Vollzugsanstalten'.
61. Peter Muchlinski (2001), 'Human rights and multinationals: is there a problem?' 77 *International Affairs* 31–48; D. Sciulli (1994), *Corporate Power in Civil Society: an Application of Societal Constitutionalism*, New York, pp. 27ff.
62. Mueller, Milton (2002), *Ruling the Root: Internet Governance and the Taming of Cyberspace*, MIT Press, pp. 245, 247; Keith Blackman (2001), 'The uniform domain name dispute resolution policy: a cheaper way to hijack names and suppress critics', 15 *Harvard Journal of Law & Technology*, 211–56.

PART V

IPRs and geographical indications

15. Geographical indications and TRIPS

Michael Blakeney

THE TRIPS REGIME

The inclusion of geographical indications as part of the minimum IP standards prescribed for WTO Members by the TRIPS agreement has been particularly problematic. Unlike the other categories of IP rights, the US and EU, the main proponents of the TRIPS agreement, were divided on this subject. This division has been reflected in the subsequent discussions in the TRIPS Council and has culminated in the request by the US and Australia, for Dispute Panels to consider whether the European regime for the protection of geographical indications, infringes TRIPS standards. At the same time divisions also exist among other developed countries and among developing countries.

The TRIPS agreement provides a basic standard for the protection of geographic indications. Article 22 defines geographical indications as: 'indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.'

Article 22.2 of the TRIPS agreement requires that Members 'shall provide the legal means for interested parties to prevent the use by any means in the designation or presentation of a good that indicates that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of goods'. The TRIPS agreement does not specify the legal means to protect geographical indications. This is left for Members to decide. Article 22.2 also prohibits any use which 'constitutes an act of unfair competition' under Article 10*bis* of the Paris Convention. The ambit of Art 10*bis* is extended to a geographical indication 'which, although literally true as to a territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Additional protection is accorded geographical indications for wines and spirits by Art. 23. This additional protection has two components. First, protection for each geographical indication for wines, in the case of homonymous indications. Secondly, the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

REVIEW OF THE TRIPS REGIME

Article 24.1 of the TRIPS agreement obliges Members 'to enter into negotiations aimed at increasing the protection of individual geographic indications under Art. 23'. Although Art. 24 contains a number of paragraphs excepting certain matters from protection as geographical indications, Art. 24.1 disallows Members from using these exceptions as an excuse for the refusal to conduct negotiations. Also in implementing this negotiation obligation, Art. 24.3 requires that a Member 'not diminish the protection of geographical indications' which existed in that Member prior to the date of the entry into force of the WTO Agreement. The Council of TRIPS is obliged under Art. 24.2 to monitor the application of the above provisions and to conduct a review within the first two years of entry into force of the WTO Agreement. Matters concerning compliance with the obligations of Members under these provisions may be drawn to the attention of the Council, which 'at the request of a Member shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral and plurilateral consultations between the Members concerned'. The Council is given a general power 'to take such action as may be agreed to facilitate the operation and further the objectives' concerning the protection of geographical indications envisaged under the TRIPS agreement.

The TRIPS Council confined its initial efforts in relation to the review of geographical indications to a suggestion for a multilateral register of geographical wine indications. Prior to the Seattle Ministerial, a submission by Turkey of 9 July 1999 proposed the extension of geographical indications in TRIPS beyond wines and spirits,[1] this was endorsed by the African group of countries who requested that the protection of geographical indications be extended 'to other products recognizable by their geographical origins (handicrafts, agro-food products)'.[2] This proposal was also taken up by Cuba, the Czech Republic, Dominican Republic, Honduras, India, Indonesia, Nicaragua, Pakistan and Sri Lanka, Uganda and Venezuela.

At the TRIPS Council meetings in 2000, the President sought to separate the discussion of the establishment of a multilateral register from the

question of the extension of protection to avoid confusion. A proposal from Bulgaria, the Czech Republic, Egypt, Iceland, India, Kenya, Liechtenstein, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey was that the extension of geographical indications to products other than wines and spirits be included as an extension of the built-in agenda.[3] Opposing the proposals for an extension of the protection of geographical indications for wines and spirits under TRIPS to all products, was a communication sent to the TRIPS Council on 29 June 2001, by Argentina, Australia, Canada, Chile, Guatemala, New Zealand, Paraguay and the United States.[4] The communication pointed out that proposals for the extension of the TRIPS wines and spirits provisions to all products had insufficiently addressed the costs and administrative burdens of this extension. However, Clause 18 of the Doha Declaration has expressly opened the possibility of the extension of the additional protection, through a multilateral system of registration, to products other than wines and spirits.

Given the divisions within the TRIPS Council, no consensus has been reached on the nature of the mandate for further negotiations. The Draft Ministerial Text submitted to the Ministers in Cancun, merely proposed the continuation of negotiations.[5]

In relation to the negotiations on the multilateral register, at one extreme is the position of the EU that participation in the multilateral system should be mandatory for all WTO Members and that registrations should have binding effect.[6] The opposing position, taken by Australia, Argentina, Japan and the USA is that there should be voluntary participation in the system in which the register would function as a database which could be consulted by Members in taking decisions on the protection of geographical indications in their countries.[7]

On the question of the extension of the additional protection of Art. 23 of the TRIPS agreement to products other than wines and spirits, the dividing line is perceived to be one between emigrant countries urging extension (Europe, Africa and part of Asia)[8] and immigrant countries which are resisting extension (Australia, Latin America and the USA).[9]

THE HISTORY OF GEOGRAPHICAL INDICATIONS

Historically, signs indicating the geographical origins of goods were the earliest types of trademark.[10] Prior to the Industrial Revolution in Britain, which commenced in the eighteenth century, industrial production was on a small scale. The corporate form of industrial organization did not yet exist. For this reason, it was unnecessary for the law to develop the notion of protectable goodwill. Until this time, the principal products, which

entered international trade, were primary products, such as minerals and agricultural produce and simple manufactured goods, such as pottery and woven fabrics. In the competition to earn revenues from the international trade, which was developing at that time, it became apparent that the products of particular regions were more saleable than comparable products from other regions, because of their superior quality. This superior quality resulted either from natural geographic advantages, such as climate and geology (for example Seville oranges, Kentish hops, Burgundy wine); recipes and food processing techniques, local to a region (for example Kyoto bean cakes, Malmesbury mead, Frankfurter sausages) or indigenous manufacturing skills (for example Toledo steel, Delft ceramic ware, Korean celadon ware).

To take advantage of the commercial attractiveness of these local reputations, merchants branded their goods with marks which designated the place of origin of these products. These brands utilized depictions of local animals, landmarks, buildings, flags and heraldic signs, or the depiction of well-known local personalities. These brands were tantamount to a warranty of the quality of these goods. To protect the commercial reputation of these goods, local legislators passed laws to prevent the adulteration of local produce by the addition of inferior introduced goods or ingredients. These laws punished the adulteration of goods and established systems of marking approved local goods with marks certifying their quality (for example wool marks for cloth, and hallmarks for goods made from precious metals). Where the reputation of local goods was attributable to the skills and technology of local artisans, associations, or guilds, of masterworkers developed. The taxing authorities saw an advantage in preserving the skills and revenue-earning capacities of these guilds and conferred upon them a monopoly of manufacture. To regulate this monopoly, the guilds developed service marks, or heraldic-type designs which were placed upon goods produced by guild members.

The legislation which sought to protect the commercial reputation of traders in discrete geographical localities evolved principally in Europe into systems for the protection of geographical indications.

The Industrial Revolution, which commenced in Britain in the eighteenth century, saw the emergence of the modern trademark. The development of large-scale industrial production led to the desire of individual producers to identify themselves as the place of origin of goods, as a warrant for the quality of those goods. The registered trademarks system was thus developed to permit individual traders to enforce their marks as a private proprietary right. This contrasted with the system for the protection of geographic indications which conferred public rights upon producers in defined localities.

The evolution of the private trademark system did not result in the disappearance of geographic marks. Particularly in Europe, substantial processed foods markets and markets for alcoholic beverages are dependent upon the continued recognition of geographical marks.

THE ECONOMIC IMPACT OF GEOGRAPHICAL INDICATIONS

There is an extensive and growing literature which tests the thesis that intellectual property protection is necessary as an incentive for invention and creativity. Article 7 of the TRIPS agreement, which is headed 'Objectives' states that 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare'.

It has been suggested that geographical indications may be of particular interest to those developing countries which have, or might be able to achieve, a comparative advantage in agricultural products and processed foods and beverages.[11] For these countries, seeking and enforcing protection for geographical indications abroad may have economic gains. However, these benefits have to be weighed against the expense of enforcement actions, as well as the expense of protecting the geographical indication in the country of origin. These expenses include those of establishing a protection system, for example a register, the transaction costs involved for producers in registration and the deployment of resources by organizations and associations representing producers to ensure that the required quality, reputation or other characteristics of the product covered by the geographical indication are developed and maintained.

Similarly for consumers, geographical indications can act as a source of information which links the particular qualities of a product with its area of geographical origin. For a number of countries, this association between product qualities and the area of geographical origin is not arbitrary. Evidence from the Lisbon Agreement, which is the international system of protection administered by the World Intellectual Property Organization (WIPO) for the protection of appellations of origin, Suggests that Cuba accounts for all the protected appellations for cigarettes and the Czech Republic 93 per cent of the appellations in beers and malt while France holds over 80 per cent of the wine and spirit appellations.[12] Within the EU, the countries holding leading share of indications in cheese are France (28 per cent), Italy (20 per cent) and Greece (13 per cent), in meat-based products it is Italy

(41 per cent) and Portugal (22 per cent) and in beers it is Germany (80 per cent) and the UK (20 per cent).[13]

On the costs side, geographical indications may be seen as a barrier to market entry erected against producers outside the relevant geographical area. The Trade and Agriculture Directorates of the OECD have undertaken an analysis of the legal and economic theory underpinning geographical indications.[14] It was noted that the policing of geographical indications in relation to agro-food products invariably entailed some degree of coordination among the actors involved. The most frequent reason was the need, at the end of the processing stage, to arrive at a product with specific characteristics. This coordination produced the dangers of: monopolistic cartels, obstacles to new market entrants, and over-administration and over-regulation. In a number of competition law cases, it was found that groups had taken measures to control total supply, through the allocation of production quotas.[15] Direct price control measures were occasionally found, either in setting price ceilings for purchasing raw materials or in imposing minimum resale prices on distributors.[16] In most cases the groups or consortia argued unsuccessfully that supply controls were essential for quality control.

The OECD report concluded that 'from the cross-border perspective, . . . as long as it is a geographical name that is being protected, and not a generic name, there is insufficient evidence to consider appellations of origin as non-tariff barriers to trade.'[17]

Within the TRIPS Council,[18] WIPO[19] and UNCTAD,[20] it has been proposed that more cost analyses be undertaken of the likely impact of introducing a European style registration system. The UK Commission on Intellectual Property Rights added its request that financial analyses be undertaken of the developmental role of geographical indications. [21]

RURAL DEVELOPMENT

As the Economic and Social Committee notes in its opinion on the Proposal for a Council Regulation amending Regulation 2081/92,[22] '[b]y virtue of their intrinsic character and production methods, traditional products can play a key role in the development and promotion of rural society.' The ESC goes on giving credit to traditional products as they help in conserving and improving the natural environment, as they 'respect existing ecosystems, biodiversity and the gene pool by using local varieties and breeds; represent the culture and tradition of an area or region'. In its opinion on the proposal for amending Regulation 2081/92, the ESC considers that the scope of application of the Regulation on geographical indications could be

extended to other agricultural products, and that 'a legal framework to protect non-agricultural products with special characteristics linked to a particular geographical area' could be created.

One of the guiding principles and objectives of EEC 2081/92 is the protection of 'provenance' as a means of promoting rural development, 'whereas the promotion of products having certain characteristics could be of considerable benefit to the rural economy, in particular to less-favoured or remote areas, by improving the incomes of farmers and by retaining the rural population in these areas'.

Most of the geographical indications which have been registered under the European Regulation reflect strong historical and symbolic links between place and product.[23] Thus Moran states that,

> Geographical indications are much more than the identification of a product with a place. As a type of intellectual property that is attached to territory, they are a means for the social and industrial groups with rights to them to protect and distinguish their products. Small local producers are able to use them to enhance their reputations, and to sell directly to final demand, thus competing more effectively against large corporations.[24]

There may be other economic benefits from protecting geographical indications, as they serve also 'to publicise the localities and regions that they use for their names: Burgundy gives its name to one of the best known wines in the world but at the same time the region of Burgundy becomes known because of its wine'.[25]

PROTECTION OF GEOGRAPHICAL INDICATIONS IN EUROPE

The European system for the protection of geographical indications is offered as a useful prototype for other countries. EEC Regulation No. 2081/92 *on the protection of geographical indications and designations of origin for agricultural products and foodstuffs* provides for the protection of designation (appellation) of origin and geographical indications. Designation of origin is defined as

> the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff originating in that region, specific place or country, and the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area.[26]

Geographical indication is defined as

> the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff originating in that region, specific place or country and which possesses a specific quality, reputation or other characteristics attributable to that geographical origin and the production and/or processing and/or preparation of which take place in the defined geographical area.[27]

The Regulation provides for two different levels of link between product and geographical origin. For the designation of origin the link is essential, and the entire production process must take place in the defined geographical area, but for the geographical indication it is sufficient that either production, processing or preparation take place in the area specified.

Following voluntary initiatives by groups of producers, Member States forward applications for registration to the European Union after conducting national checks that they comply with the criteria set down in Regulation (EEC) 2081/92. Once a product has been recognized as a protected designation of origin (PDO) or protected geographical indication (PGI), it is automatically recognized and protected in all EU countries against misuse of any kind. Protection relates to the name in itself and applies throughout the EU countries, without reference to reputation or to any loss to consumers. To qualify for registration, producers must form groups and show the relevant national body proof of the link between product and geographical area, and product specifications which strictly regulate the production process (from raw materials to processing and packaging), and which they undertake to observe in order to make use of the registered name. Compliance with the specifications has to be monitored by an independent, objective and impartial structure.

The EU has been the principal advocate for wider global protection of geographical indications. This is attributed to those Mediterranean states, such as France, Italy, Portugal and Spain 'where traditional, small-scale, non-commoditised agricultural practices remain relatively commonplace with a fair degree of commercial processing'.[28] In this agricultural environment the links between the position which the EU takes on geographical indications and its agricultural policies are probably self-evident,' just as the opposition to the extension of geographical indications by the USA and the New World countries is explicable by reference to their large-scale agricultural production methods and their common adoption of European geographic terms as generic product descriptors.[29]

A number of TRIPS Members have argued that the EU scheme for the protection of geographical indications is TRIPS-deficient in a number of areas. For example, the statement of the United States (US) to the WTO on the WTO trade policy review of the European Union expressed the concern

that 'foreign persons wishing to obtain protection for their GIs in the EU itself face a non-transparent process that appears to come into some conflict with the EU's TRIPS obligations' and that 'EU rulemaking processes are often perceived by third countries as exclusionary, allowing no meaningful opportunity for non-EU parties to influence the outcome of regulatory decisions'.[30]

On 1 June 1999, the United States requested consultations with the European Communities (EC) pursuant to Article 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU) and Article 64 of the TRIPS agreement regarding EC Council Regulation No 2081/92.[31] The United States and the EC held consultations on 9 July 1999, and thereafter, but these consultations failed to resolve the dispute. Following additional consultations on 18 August 2003, the US asked the DSU to establish a panel.[32] It claimed that: Regulation 2081/92 did not extend national treatment to WTO Members; that it diminished the legal protection for trademarks (including preventing the use of an identical or similar sign that is likely to confuse, and adequate protection against invalidation); that it did not provide legal means for interested parties to prevent the misleading use of a geographical indication; that it did not define a geographical indication in a manner that is consistent with the definition provided in the TRIPS Agreement; that it was not sufficiently transparent; and that it did not provide adequate enforcement procedures. On 18 August 2003, Australia asked the Dispute Settlement Body of the WTO to establish a panel on the same grounds.[33]

GEOGRAPHIC INDICATIONS: YES OR NO

The principal argument against the expansion of the EU-style regime for the protection of geographical indications is that its primary beneficiary is obviously going to be those countries of the EU that have long-established geographical indications, which over the years have established a market reputation. Other countries would only be able to establish similar commercial advantages after considerable investment in the promotion of their local brands, at the same time as carrying the administrative burden and expense of protecting the established European brands.

On the other side of the coin developing countries, in particular, with their smaller scale agricultural production are probably closer in agricultural ethos to the EU. In the package of intellectual property norms, which the TRIPS agreement imposes, arguably, geographical indications protection comes closest to their policy interests. The imposition of production standards and commensurate quality controls is criticized as inhibiting

agricultural innovation. On the other hand, such controls may be a necessary means of introducing those quality control techniques which are necessary to establish commercial reputation.

An area where geographical indications might be able to play a useful role for developing countries is in relation to the protection of traditional knowledge. Currently, effective international protection does not exist for traditional knowledge, despite increasing calls from developing countries for such protection.[34] The difficulty of framing protection for traditional knowledge results mainly from the nature of such knowledge. Traditional knowledge is generally elaborated by groups of persons or communities, whereas intellectual property rights are generally owned by individuals. The purposes of intellectual property protection include the promotion of inventive activities and the reduction of transaction costs for the transfer of technology.[35] The protection of traditional knowledge often relates to the need to preserve a knowledge that is often oral and this sometimes involves keeping matters confidential and protecting them from exploitation.

In the absence of an elaborated system for the protection of traditional knowledge, geographical indications protection may provide a second best solution. WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has indicated that it is possible that the cultural value of handicrafts might be protected through geographical indications.

In the absence of a reliable economic assessment, it is difficult to evaluate the merits of both sets of arguments. They also, of course, reflect differences in perceived economic interest between both developed and developing countries. A few countries, for example Egypt and Paraguay, have already indicated that the additional protection for geographical indications for wines and spirits will be made available under their national laws for other products.[36] It will be interesting to see whether providing such comprehensive additional protection leads to significant additional costs or benefits, in the absence of international recognition.

NOTES

1. WTO Doc No WT/GC/W/249, 13 July 1999.
2. *Preparations for the 1999 Ministerial Conference the TRIPS Agreement Communication from Kenya on Behalf of the African Group*, WTO Doc WT/GC/W/302, 6 August 1999.
3. WTO Doc. IP/C/W/204/Rev.1.
4. WTO Doc. IP/C/W/289.
5. WTO Doc JOB(03)/250/Rev 1 of 24 August 2003, §12.
6. See WTO Doc TN/IP/W/3 of 24 June 2002, signed by Bulgaria, Cyprus, the Czech Republic, the EU, Georgia, Hungary, Iceland, Malta, Mauritius, Moldova, Nigeria, Romania, the Slovak Republic, Slovenia, Sri Lanka and Turkey.

7. See WTO Doc TN/IP/W/5 of 23 October 2002, also signed by Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Namibia, New Zealand, Philippines and Chinese Taipei.
8. See IP/C/W/204/Rev.1; IP/C/W/247/Rev.1; IP/C/W/308/Rev.1; IP/C/W/353.
9. See F. Addor and A. Grazioli (2002), 'Geographical indications beyond wines and spirits – a roadmap for a better protection for geographical indications in the WTO TRIPS agreement', *Journal of World Intellectual Property* 893.
10. Generally, on the history of trademarks and geographical indications see: F. Schechter (1925), *The Historical Foundations of the Law Relating to Trade-Marks* New York: Columbia University Press; S.A Diamond (1983), 'The historical development of trademarks' 73 *Trademark Reporter* 222; J.T. McCarthy and V.C. Devitt (1979), 'Protection of geographical denominations: domestic and international' 69 *Trademark Reporter* 1979; M.G. Coerper (1990), 'The protection of geographical indications in the United States of America, with particular reference to certification marks; July/August, *Industrial Property* 232.
11. World Bank (2001), 'Global economic prospects and the developing countries 2002: making trade work for the world's poor', World Bank, Washington DC, 143–4.
12. See D. Rajnekar (2003), *The Socio-Economics of Geographical Indications A Review of Empirical Evidence from Europe*, Geneva: UNCTAD/ICTSD, 10–11.
13. Ibid., Annex 1.
14. COM/AGR/APM/TD/WP(2000)15/FINAL.
15. E.g. in relation to the production of Cantal cheese (France, Competition Council Decision No. 92-D-30 of 28 April 1992); Parmigiano Reggiano and Grana Padano cheese (Italy, Competition Council Decision No. 4352 of 24 October 1996); Gorgonzola cheese (Italy, Competition Council Decision No. 6549 of 12 November 1998).
16. E.g. Parma and San Daniele ham (Italy, Competition Council Decision No. 3999 of 19 June 1996); Label-scheme poultry sector (France, Competition Council Decision No. 94-D-41 of 5 July 1994).
17. N.9 *supra* at para 82.
18. 'Issues for discussion in the negotiations under TRIPS Article 23.4', US submission to the TRIPS Council, 10 April 2002, WTO Document No. TN/IP/W/2.
19. Argentina, Sudan, Malaysia and Mexico. WIPO Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications, Seventh Session, December 2001. WIPO Document No. SCT/7/4 Prov.2.
20. See D. Rangnekar (2002), *Geographical Indications: A Review of Proposals at the TRIPS Council*, Geneva: UNCTAD/ICTSD.
21. CIPR (2002), *Integrating Intellectual Property Rights and Development Policy*, London, September, at 101.
22. ECOJ 7.10.2002 C 241, pp. 57–61. The subject-matter of Regulation 2081/92 is 'the protection of geographical indications and designations of origin for agricultural products and foodstuffs'.
23. See L. Bérard and P. Marchenay (1996), 'Tradition, regulation and intellectual property: local agricultural products and foodstuffs in France' in S.B. Brush and D. Stabinsky (eds), *Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights*, Covelo, CA: Island Press, 230–43.
24. W. Moran (1993), 'Rural space as intellectual property', 12 *Political Geography* 263.
25. Ibid., 267.
26. Council Regulation (EEC) No. 2081/92, Article 2, para. 2.
27. Ibid.
28. See W. van Caenegem (2004), 'Registered GIs: intellectual property, agricultural policy and international trade', 26 *European Intellectual Property Review* 170 at 172.
29. Ibid., at 173.
30. WTO Trade Policy Review of the European Union, Statement by the United States to the WTO, 24 July 2002, http://www.state.gov/e/eb/rls/rm/2002/12242.htm.
31. WTO Doc., WT/DS174/1.
32. WT/DS174/20.

33. See WT/DS290/18.
34. See M. Blakeney (2000), 'Protection of traditional knowledge under intellectual property law' *European Intellectual Property Review* 251.
35. See WIPO/CGRTKF/IC/4/8 dated 30 September 2002, prepared for the Fourth session of the CGRTKF, Geneva, December 9–17, 2002, p. 8 (citing WIPO/CGRTKF/IC/3/7).
36. WTO Document No. IP/C/W/278/Add.1 Source: http://docsonline.wto.org/DDFDocuments/t/ip/c/w278a1.doc and IP/C/W/231 Source: http://docsonline.wto.org/DDFDocuments/t/ip/c/w231.doc.

16. The treatment of geographical indications in recent regional and bilateral free trade agreements

David Vivas Eugui and Christoph Spennemann

I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) represents an important step toward the universal recognition of geographical indications (GIs) protection. While previous agreements concluded under the auspices of the World Intellectual Property Organization (WIPO) including the Madrid[1] and the Lisbon[2] agreements have already regulated related legal figures such as indications of source and appellations of origin, the TRIPS agreement is today the standard subscribed to by all Members of the World Trade Organization (WTO) and therefore the one with widest international recognition. The TRIPS agreement contains some minimum standards for the protection of geographical indications, including definition, scope, legal means, exceptions and international negotiations. It is also important to mention that the TRIPS agreement is subject, as any other WTO agreement, to the dispute settlement understanding of the WTO, making its standards 'enforceable' among Members.

GIs have been under the spotlight of international trade discussions since the adoption of the TRIPS agreement. These discussions have proved to be very controversial in the WTO as well as in other forums. Interestingly, unlike other cases such as discussion on public health there is not a North–South divide but different groups of countries – inclusive of developed and developing countries alike – holding different positions on several critical issues.[3] This situation is the reflection of different cultural settings, legal traditions, economic value attached to GIs and trademarks, implications of GIs for the protection of the local economy and trade interests including imports and exports opportunities.

Discussions on GIs in the last decade relate mainly to three clusters of issues, two being developed at the multilateral level and one at the regional and bilateral levels. These are the following: a) implementation of TRIPS

obligations and implementation-related issues, b) negotiations of a multilateral system of notification and registration of wines and spirits in the TRIPS Council of the WTO and c) the new generation of TRIPS-plus GI and trademark standards being developed through regional and bilateral free trade agreements.

Implementation of TRIPS Obligations and Implementation-related Issues

GIs were historically developed in continental Europe, and before the 1980s they were mostly unknown in many countries especially in those of common law tradition.[4] The adoption and implementation of the TRIPS standards required some legal and administrative reforms for setting GI protection in various countries, including leading economies such as the United States and Canada. However, in most cases countries without an independent GI regime simply reformed their trademarks regime as to accommodate the new TRIPS obligations. Even in countries where some GIs or appellation of origin protection existed, such as Latin American countries, the standards provided by the TRIPS agreement implied reforms, especially in relation to enforcement measures. Implementation of the TRIPS agreement standards has been subject to examination by the TRIPS Council since 1996. Currently, all developed countries and many developing countries have already concluded this examination process, by notifying their legislation to the WTO Secretariat and responding to other Members' questions in the TRIPS Council.

Various countries, including Switzerland, India, Sri Lanka and some Eastern European countries, expressed in the WTO General Council concerns over the problems they were facing in implementing WTO obligations, including those under the TRIPS agreement. In relation to GIs these countries called for the protection already granted by Article 23 of the TRIPS agreement to wines and spirits to be extended to other products, and affirmed that having two levels of protection did not reflect their commercial interest, leaving aside products such as tea, rice, coffee, handicrafts, and so on. As a consequence of this debate, the Doha Ministerial Declaration instructed Members to address implementation issues in the relevant body of the WTO following the procedure set in paragraph 12 of the same Declaration.[5] This procedure is complemented by the Decision on Implementation Issues and Concerns[6] and with the Outstanding List of Implementation-Related Issues. The latter document indicates as one of the outstanding implementation issues: 'Negotiations to extend protection of geographical indications to other products than wines and spirits'. Since then the issue of extension of GI protection to other products has been included in the agenda of the TRIPS Council

under implementation issues without any specific outcome being reached so far.[7]

Negotiations of a Multilateral System of Notification and Registration of Wines and Sprits in the TRIPS Council of the WTO

The TRIPS agreement not only sets some minimum standards, but according to Article 23.4, calls for negotiations for the 'establishment of a multilateral system of notification and registration of geographical indications for wines and spirits eligible for protection in those Members participating in the system'. Negotiations for such a multilateral system were part of the built-in agenda (unfinished business of the Uruguay Round) and were taken as part of the Doha Development Round. According to the Doha Ministerial Declaration, paragraph 18, Members have agreed to 'negotiations for the establishment of a multilateral system of notification and registration of geographical indications by the Fifth Session of the Ministerial Conference'. Negotiations on a multilateral system of notification and registration of GIs for wines and spirits are currently underway in the special (negotiating) session of the TRIPS Council. While WTO Members have generally agreed in the discussions that the system should not increase the level of protection that currently exists for covered products, they remain divided over whether countries should be obliged to protect the GIs to be covered through the multilateral system – as advocated by the EU and Eastern European countries – or whether it should be left to each country to decide at the national level – as favoured by Australia, Canada, Japan and the United States.[8] This latter group of countries envisage a multilateral system functioning essentially as a database. Similar divisions are also apparent with regard to participation, legal effects and opposition/dispute settlement procedures in the system.

Regional and Bilateral Negotiations Resulting in GI Obligations

Intellectual property rights (IPRs) have increasingly become the subject matter of regional and bilateral trade agreements (RTAs).[9] Since 1994 more than 175 new regional or bilateral trade agreements have been signed[10] and many of them contain detailed chapters on intellectual property rights. There are currently concerns over how these RTAs will impact existing rights and obligations under the TRIPS agreements, due to the fact that in many cases the new regional or bilateral obligations can go further than what is already established in the TRIPS agreement[11] or inconsistencies could arise in their implementation. This situation becomes even more worrisome when it is linked to the expansive effect that Article 4 d) of the

TRIPS agreement (Most-favoured-nation/MFN clause) has on all TRIPS-plus obligations subscribed after 1995.[12]

As it was mentioned the TRIPS agreement does not include substantive obligations, but also contains in-built negotiating mandates. Article 24 of TRIPS indicates that 'Members agree to enter into negotiations aimed at increasing protection of individual geographical indications under Article 23. The provisions of paragraph 4 through 8 below (exceptions) *shall not be used by members to refuse to conduct negotiations or to conclude bilateral or multilateral agreements'* (emphasis added). While this article creates a mandate to keep negotiating increased protection of GIs, it seems that the drafters encouraged not only negotiations at the multilateral level but also potential bilateral agreements. In that sense existing exceptions under Article 24 cannot be considered an excuse to refuse further negotiations toward higher levels of protection. This type of encouragement of having recourse to FTAs is unusual in the WTO context, as most WTO agreements seek to achieve results at the multilateral level and most regional and bilateral agreements can only be exempted from the MFN clause under certain conditions. In the particular case of the TRIPS agreement, treaties subscribed after 1995 are not exempted from MFN treatment.

Most last generation regional or bilateral free trade agreements or partnership agreements to which the European Union or the United States are one of the signatory parties include fully fledged intellectual property chapters. Also in almost all of them there are subsections on GIs and rules on market access-related issues. In only a few have GIs been included as part of the trademark chapter. Among the regional agreements that include GI rules we can identify the North American Free Trade Agreement and Andean Decision 486. Examples of bilateral agreements with GIs and trademark-related rules are the bilateral/partnership agreements of the EU on the one side, and Australia, Chile, Lebanon and Mexico on the other; or between the United States and Australia, CAFTA, Chile, Jordan, Morocco and Singapore. The type of protection that can be found in many of these agreements includes, among other obligations, expanded definitions of GIs, wider scope, incorporation of exclusive rights, simplification of formalities, transparency regulations, GI and trademark registration, relationship with trademarks and mutual recognition of protection, among other features.

The objective of this chapter is to analyse the treatment of GIs in this new generation of RTAs as well as the content of the new standards being set. The chapter has been structured as follows. First, it briefly recalls the main TRIPS obligations under the GI section as to permit comparison with the new RTAs obligations. Second, it explores the approaches of the European Union and the United States in these regional and bilateral agreements. For that purpose, it will analyse at the regional level the NAFTA and at the

bilateral level the agreements signed by the United States with Chile, Morocco and Australia, and by the European Union with Australia, Chile, Mexico and South Africa. Finally, from that exploratory work it draws the main lessons learned for the regional and bilateral processes in the field of GIs and presents some conclusions.

II. THE TRIPS STANDARDS

1. Definition

'Geographical indications' (GIs) are dealt with under Articles 22–24 of the TRIPS Agreement ('Section 3: Geographical Indications'). GIs are defined in Article 22.1 TRIPS as 'indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.'

A GI under this definition is broader than a mere *geographical name* (for example 'Champagne', 'Tequila' and 'Parma'). It is sufficient if the indication helps the consumer *identify* the good as originating in a certain place (for example the symbol of the Eiffel Tower to designate famous French products, or the Chilean flag to identify wines of certain quality or reputation).[13] Thus, a word may qualify for GI protection by *evoking* a certain territory, without itself being the name of the territory.[14]

In order for an indication to qualify for protection under TRIPS, there has to be a link between the designated product's characteristics and its place of origin. The 'given quality, reputation or other characteristic of the good' must be 'essentially attributable to its geographical origin'. While the notion of 'quality' appears to refer to some objectively measurable, physical characteristics, the separate reference to 'reputation' makes clear that indications may qualify for protection even where the link between the designated good and its geographical origin does not result in any objectively measurable characteristic but merely creates certain goodwill or reputational associations with consumers.[15]

The reference in Article 22.1 TRIPS is to quality, reputation, 'or other characteristics' of the good. It has been observed that while quality and reputation carry a positive implication, the term 'characteristics' may comprise attributes such as colour, texture or fragrance that might be considered more neutral or even unfavourable by consumers, yet still providing the producing territory to protect the name.[16]

Finally, GIs may be distinguished from other intellectual property rights by their *shared character*. GIs are not necessarily held by one single

right-holder but may be used by all producers in the indicated area. The absence of a particular owner distinguishes GIs from trademarks.[17]

A consequence of their shared character is that GIs cannot be assigned to parties producing outside the indicated area.[18]

2. Scope of Protection

Article 22.1 TRIPS as quoted above refers to goods, thus excluding services from the scope of protection. On the other hand, protection is not limited to a particular category of goods; the *lex specialis* of Article 23 TRIPS specifically addresses wines and spirits (see below), but the general provision of Article 22 covers any good, such as all agricultural products.

3. Level of Protection

The TRIPS provisions on GIs provide for two different levels of protection: the basic level of protection accorded to any GI under Article 22, and an advanced level of protection under Article 23 accorded specifically to GIs for wines and spirits. For those, Article 23 constitutes a *lex specialis*, excluding wines and spirits from the more basic provision of Article 22.

Article 22, which is applicable to all GIs except those for wines and spirits, obligates WTO Members to provide the legal means for interested parties to prevent:

- Presentation or designation of a good that misleads the public as to the geographical origin of the designated good (Article 22.2 (a));[19] *and*
- Use of the GI that constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention for the Protection of Industrial Property (Article 22.2(b)).

The 'legal means' to be made available refer to a variety of statutory, administrative or common law methods of protection, encompassing protection under the doctrines of unfair competition, passing off, registration of GIs and appellations of origin, and registration of collective and certification marks.[20]

As to Article 22.2 (a) of the TRIPS agreement, the owner of the protected GI has to prove that a third party, by designating or presenting a good, misleads the public into believing that the third party's goods originate in the same place as his protected GI. The TRIPS agreement contains no definition of the 'public'[21] or of the degree of confusion required to

trigger the obligation to protect the GI in question. This provides WTO Members with considerable flexibility for the implementation of their Article 22 obligation to protect GIs.

As to Article 22.2 (b) of the TRIPS agreement, the owner of a protected GI has to prove that the use of an indication by a third party constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention.[22] Arguably, Article 22.2(b) TRIPS in conjunction with Article 10*bis* (3), third indent of the Paris Convention, extends the protection available under Article 22.2(a) TRIPS: while the latter covers cases of consumer confusion about the *origin* of the indicated good, the former addresses cases where the public is aware of the true origin, but is misled with respect to the good's *nature, manufacturing process or characteristics*.[23]

Additional protection for GIs for wines and spirits is provided under Article 23 TRIPS. Under this provision, third parties may not use a protected GI for the designation of their own products, even where the consumer is not misled as to the true origin of the third party product.[24] This considerably facilitates the GI owner's task of proving GI infringement: it is sufficient to show that the third party product using the protected GI does not originate in the indicated area, without the requirement to prove consumer confusion or an act of unfair competition.

However, even the additional protection for wines and spirits is not absolute: Article 24 TRIPS provides for a number of important exceptions that grandfather certain uses of GIs or trademarks normally prohibited by Article 23. It is important to note at the outset that the elimination of these exceptions has been one of the objectives of the European Union's bilateral free trade agreements, as illustrated below.

Article 24.4[25]

Where in one country A producers use a GI similar to a GI already protected in another country B, country A is not required to prevent continued and similar use of the GI, provided the GI has been used continuously, and with regard to the same or related goods or services, at least since 15 April 1984 (that is 10 years preceding 15 April 1994, date of adoption of the Uruguay Round agreements at Marrakesh), or that the GI has been used in good faith prior to 15 April 1994.[26] These exceptions make clear that the Article 23 protection for wines and spirits GIs applies to future rather than to past practices.

Article 24.5[27]

This provision provides an exception to Articles 22.3 and 23.2 TRIPS, according to which the registration of trademarks similar to GIs shall not

be admitted or refused under certain conditions. Article 24.5 TRIPS exempts from this rule trademarks

- applied for or registered in good faith, or acquired through use in good faith (this could include common law marks[28]),
- before the entry into force of the TRIPS Section on GIs in the relevant country (for example 1 January 2000 for developing countries), *or*
- before the GI was protected in its country of origin.

It may be observed that the TRIPS agreement, through Articles 22.3 and 23.2 on the one hand, and the above exception on the other hand, seeks to balance competing GIs and trademarks. In their respective bilateral trade agreements, the EU and the USA both shift this balance, either in favour of GIs or trademarks, according to their domestic legal tradition (see below).

Article 24.6[29]

In essence, this provision takes account of the fact that a certain indication protected as a GI in one country might be a common or generic name for the designated product in another country. The latter country is exempted from the obligation to grant GI protection to such a term, which would limit the use of words that have become part of the country's everyday language.[30] The second sentence of the provision establishes a similar rule with respect to customary names of grape varieties.[31]

Article 24 TRIPS contains two other exceptions under paragraphs 8 and 9. These are, however, less relevant in the bilateral context.[32]

III. THE APPROACH UNDER EUROPEAN UNION BILATERAL FREE TRADE AGREEMENTS

GIs protection has a long tradition in continental Europe, and most GIs worldwide are European.[33] The EU has legislated extensively on GIs on the domestic level.[34] This legislation in several respects goes beyond the TRIPS minimum standards of protection. In particular, GI protection provided by the EU for agricultural products is stronger than the protection provided by Article 22 of the TRIPS agreement.[35] Box 16.1 presents the main features of the EU domestic system for the protection of GIs.

In its relations with third countries, the EU is seeking to come to a level of protection comparable to its domestic system. In the context of WTO commitments to reduce export subsidies for EU farmers, advanced protection of European GIs represents an alternative strategy to maintain

BOX 16.1 THE EU DOMESTIC SYSTEM FOR THE PROTECTION OF GIS

In the EU, GIs are protected through two separate regulations:

- Council Regulation (EEC) No 2081/92 on the protection of geographical indications of origin for *agricultural products and foodstuffs* (OJ L 208, 24 July 1992, p. 1).
- Council Regulation (EC) No 1493/1999 on the common organization of the *market in wine* (OJ L 179, 14 July 1999, p. 1).

Regulation 2081/92 comprises two categories of registered denominations:

- 'protected designations of origin' (PDO)
- 'protected geographical indications' (PGI).

The first category (PDO) is narrower than the GIs definition under Article 22 of the TRIPS agreement. It corresponds to the definition of 'appellation of origin' under the Lisbon agreement (see above). The link between the product and the geographical area has to be very close: quality or characteristics must be primarily or exclusively due to the geographical area, including natural and human factors. This means not only that the designated product has to be produced in the respective area, but also that the ingredients of the protected product have to originate in that area.[36]

The second category (PGI) corresponds to the definition in Article 22 TRIPS. The link between the product and the geographical area may be less close than in the case of a PDO, and may simply consist of the reputation of the area for the production of certain foods. The production/manufacture of the product must take place in the designated area, but the ingredients do not necessarily have to originate in that area.[37]

Regulation 1493/1999 deals broadly with the wine industry and includes in Chapter II (Description, Designation, Presentation and Protection of Certain Products) rules on the protection of GIs and labelling. The level of protection accorded corresponds to Article 23.1 of the TRIPS agreement.

European market shares throughout the world.[38] The EU has three major negotiating objectives:[39]

- The establishment of a multilateral register for geographical indications (see above, in the introduction);
- The extension of the additional GI protection for wines and spirits to other agricultural products (see above, in the introduction);
- Multilateral acceptance and enforcement of a list of selected European GIs. The latter would imply a state's obligation to remove prior conflicting trademarks and to grant protection to EU GIs that have become generic. Such obligations would effectively erase the exceptions available under Article 24 TRIPS (paragraphs 4, 5 and 6). Since the EU has thus far not been able to make such an obligation acceptable on the multilateral level, the Article 24 exceptions have increasingly become the target of its regional and bilateral agreements.

While the first two objectives are pursued on the multilateral level, the recognition of selected European GIs has been a major focus of a number of bilateral agreements between the EU and third countries, such as Australia, Chile, Mexico and South Africa. All of these agreements concern particularly GIs for wines and/or spirits.

1. Definition, Scope and Structure

The EU–Chile Agreement on Trade in Wines[40] for defining 'geographical indications' refers to Article 22.1 of the TRIPS agreement (see Article 3(b)). The 1994 pre-TRIPS EU–Australia Agreement on Trade in Wine,[41] like Article 22 TRIPS refers to 'a given quality, reputation or other characteristic' of the wine that is 'essentially attributable to its geographical origin'.[42]

Both agreements are limited to GIs for wines. With Chile, the EU has concluded another agreement covering GIs for spirit drinks and aromatized drinks.[43] Likewise, the EU and South Africa concluded two separate agreements covering GIs for wines and spirit drinks, respectively.[44] On the other hand, the EU and Mexico agreed on the mutual recognition and protection of GIs for spirit drinks, but not for wines.[45]

All of the above agreements on wine GIs basically follow the same structure: after some general provisions (particularly on objectives, scope and coverage and definitions), each agreement contains two separate titles on the substantive protection of wine names and oenological practices, respectively. Other titles of these agreements deal with import certification

requirements, mutual assistance between control authorities, management of the respective agreement, and finally some general provisions (such as on dispute settlement and the marketing of pre-existing stocks). The EU–Chile agreement in addition contains a separate title on sanitary and phytosanitary measures, basically referring to the WTO Agreement on Sanitary and Phytosanitary Measures.

2. Level and Means of Protection

All of the examined agreements follow the approach taken under Article 23 TRIPS, as described above (that is protection against false use of GIs, irrespective of actual consumer confusion or the existence of an act of unfair competition). While the agreements in general refer to the Parties' obligation to provide the 'appropriate legal means' to ensure effective GIs protection,[46] all of them subject use of protected GIs to the conditions laid down in the laws and regulations of the Party in which the respective GIs originate.[47] This requirement goes beyond the general obligation under TRIPS to provide for the legal means to protect against certain uses of GIs, because it obligates each Party to follow the domestic system for GI protection as existing in the other Party. For instance, EU domestic legislation provides that trademarks identical with wine GIs may in general not be used, or may only be used until 31 December 2002.[48] Through the above provision in the bilateral agreements, this condition for the use of GIs is imported into the obligations for the EU's bilateral partners. For the latter, this could lead to conflicts with domestic or third country trademarks incorporating the protected European GI. As will be shown below, the USA in its bilateral free trade agreements has recently promoted the protection of GIs under trademark law, giving trademarks priority over GIs in case of preexistence of the trademark. A country party to bilateral agreements with both the USA and the EU might find itself caught between opposing obligations in the case of a conflicting European GI and a US trademark that is similar to or incorporates that European GI. This situation is becoming more common as the number of bilateral agreements with IPR provisions increases, while a multilateral solution is still frozen in the TRIPS Council of the WTO.

3. The Accordance of Automatic Protection

All of the agreements referred to above obligate the Parties to ensure 'reciprocal'[49] or 'mutual'[50] protection of particular GIs that are enumerated in a number of lists attached to the agreements. This approach goes beyond the TRIPS minimum standard of providing 'legal means' for the protection

of GIs. Under the latter, a country is not obligated to accord *automatic* protection to a foreign GI. Rather, its authorities maintain the discretion to examine whether the GI at issue actually meets the basic eligibility requirements under Article 22.1 of the TRIPS agreement (that is whether the given GI identifies a particular geographical area, whether there is a particular link between the quality, reputation or other characteristic of the product and its geographical origin, and whether any of the Article 24 exceptions apply). The obligation under the above bilateral agreements to 'take all necessary steps in accordance with this Agreement to ensure mutual protection'[51] of the names referred to in the attached lists takes away such discretion. The concrete obligation to ensure protection of particular, listed foreign names means that a country's authorities have to recognize the examination by a foreign authority as sufficient for domestic purposes. They will have no opportunity to argue that the respective foreign GI does not meet the basic Article 22 TRIPS requirements, or that an Article 24 exception applies.[52] The protection accorded through the bilateral agreements under examination is therefore 'automatic'. This interpretation is supported by the fact that each of the examined agreements except EU–Mexico expressly states the obligation to reserve the listed names exclusively for the products originating in the Party to which they apply.[53]

4. Exceptions

As mentioned above, the TRIPS agreement in Article 24 provides a number of exceptions that considerably limit the obligation to provide protection to wine and spirits GIs under Article 23. All of the bilateral agreements under examination eliminate the exceptions with respect to continued and similar use in good faith of a similar GI and use of designations that have become generic.[54] This is not done in a uniform manner. While the EU–Mexico agreement on spirit drinks expressly refers to the TRIPS agreement exceptions,[55] the other examined agreements obligate the Parties to accord exclusive protection to a list of designations annexed to the respective agreement, without reference to any exceptions. This means that a given designation may only be used by producers located in the respective Party for which it has been listed.

All except the EU–Australia agreement are post-TRIPS treaties, and may therefore alter the obligations taken by the Parties under the TRIPS agreement.[56] For instance, the EU–South Africa agreement on trade in wine in its Annex II contains a list of wine names, among which there is reference to 'Porto/Port(2)/Oporto/Portwein/Portvin/Portwijn'. Even though this designation has been used in a generic manner for a long time in South Africa,[57] the latter is obligated to phase out its use locally within 12 years from

1 January 2002, within eight years in the Southern African Development Community (SADC), and within five years internationally. The same obligation applies to the name 'Sherry', which also was a generic name in South Africa. Responding to the new legal situation, South African producers have started renaming their products: 'Tawny' instead of Sherry, and 'Ruby' instead of Porto.[58]

In addition, South Africa is obligated to phase out within five years from the entry into force of the agreement the use of the specific European denominations 'Grappa', 'Ouzo', 'Korn', 'Kornbrand', 'Jägertee', 'Jagertee', 'Jagatee', and 'Pacharan'.[59] These particular names are not 'geographical' in the sense that they do not match with the name of a particular region or locality, nevertheless it is important to recall that a GI identifies a product as originating in a particular region or territory. There are names that while not being 'geographical' in a strict sense are used to identify the products of a particular region or a territory. A typical example is the case of 'Feta' cheese, which literally means, 'slice', but it is used in Europe to identify a particular goat or sheep's cheese from Greece.

Transitional periods for the phasing out of the use of European names are also provided in the other EU agreements. All of the examined agreements contain a provision on the marketing of pre-existing stocks of wines or spirits. This concerns wines or spirits that, at the date of or prior to the entry into force of the respective bilateral agreement, were produced, described and presented in accordance with internal legislation of a Party, but in a manner prohibited by the bilateral agreement. All of the examined agreements provide the right for retailers to market such products until stocks are exhausted.[60] Wholesalers are accorded a 3-year transition period (counted from the entry into force of the respective agreement), except under the EU–Mexico agreement, which provides for only 1 year.

The EU–Australia agreement on trade in wine constitutes a particular case, as it entered into force on 1 March 1994, that is before the entry into force of the TRIPS agreement (1 January 1995). Since the EU–Australia agreement obligates the parties to protect a specific list of names, without referring to any exception, there might be a conflict with the TRIPS agreement provisions on GI exceptions. Should this be the case, the later-in-time-rule of the Vienna Convention could be relevant in dealing with those provisions in the bilateral agreement that conflict or are incompatible with the TRIPS agreement.[61]

Unlike the other exceptions, the examined bilateral agreements do maintain the TRIPS flexibility with respect to the protection of homonymous GIs.[62]

5. Relationship with Trademark Protection

Article 24.5 TRIPS as discussed above authorizes the good faith registration and use of trademarks similar or identical to a GI, subject to certain temporal conditions. Not all of the examined agreements address this issue in the same way. The most straightforward approach is taken in the EU–Mexico agreement on spirit drinks. Article 4.4 of that agreement expressly excludes the applicability of Article 24.5 TRIPS in the bilateral context. On the other hand, the EU agreements with Chile on trade in wine and in spirits, without referring to Article 24.5 TRIPS, flatly state that registration of a trademark that is identical with, or similar to a protected GI shall be refused. Existing Chilean trademarks that are listed in appendices to the respective agreements shall be cancelled within 12 years from the entry into force of the agreements (that is 1 February 2003) for domestic use, within five years for use for export, and immediately upon entry into force for small quantity exports.[63] There is no reference to the good faith exception under Article 24.5 TRIPS. Therefore, all trademarks included on the lists will have to be cancelled, even if they meet the requirements under Article 24.5 TRIPS.

Finally, the EU's wine agreements with Chile and with Australia both extend the protection accorded to GIs against identical or similar trademarks to traditional wine expressions (for a definition, see below). A number of listed Chilean trademarks had to be cancelled with the entry into force of the agreement.[64]

6. Traditional Expressions

The EU Agreements with Chile and Australia on the protection of wine GIs contain an obligation to protect 'traditional expressions'. According to Article 3 (c) of the EU–Chile agreement, the term 'traditional expressions':

> means a name traditionally used to refer, in particular, to the production or ageing method or the quality, colour, type of place, or a particular event linked to the history of the product concerned of wine that is recognised by the laws and regulations of a Party for describing and presenting a product originating in that Party.

Examples include expressions such as, for example, 'Vino dulce natural', 'Eiswein', 'Grand Cru', 'Ruby' and 'Tawny' on the side of the EU,[65] and 'Chateau', 'Reserva o Reservas' and 'Noble' on the Chilean side.[66]

The EU–South Africa Agreement on trade in wines does not contain any reference to traditional expressions. On the other hand, South African wine exports to EU countries will be subject to the EU's wine labelling

regulation, conditioning the use of traditional expressions on the respect of certain requirements.[67]

The obligation to accord protection to traditional expressions goes beyond the TRIPS minimum standards of GIs protection. Traditional expressions do not constitute GIs within the meaning of the TRIPS agreement, because they do not indicate a geographical area. In this sense, they are of less exclusive character than GIs: any producer respecting certain production or ageing methods and other conditions may use the corresponding traditional expression. For example, the expression 'Eiswein' or 'Icewine' is not limited to any region, but may be used by any producer following the specific harvesting requirements. The obligation to accord protection to the traditional expression 'Eiswein' means that in the Parties to the respective agreement, only those wines meeting certain production standards may be marketed as 'Eiswein'. Box 16.2 describes the

BOX 16.2 THE REQUIREMENTS FOR THE TRADITIONAL EXPRESSION 'EISWEIN'/ 'ICEWINE'

Eiswein in Germany, or Icewine in Canada, is a *late-harvest wine* made from grapes pressed while frozen. Only three varieties of *vinifera grape* and Vidal may be used but usually it is made from *Vidal and Riesling* grapes.

To make Icewine, the grapes are left on the vine until after the first frost hits. These grapes are harvested after being frozen in the vineyard and then, while still frozen, they are pressed. They must be picked early – before 10 am. During both of these processes the temperature cannot exceed −8°C. At this temperature (−8°C) the berries will freeze as hard as marbles. While the grape is still in its frozen state, it is pressed and the water is driven out as shards of ice. This leaves a highly concentrated juice, very high in acids, sugars and aromatics.

In Ontario and in Germany, Eiswein/icewine is defined as naturally frozen. This means that in both countries, no other method of making Eiswein/icewine is allowed other than the natural method. No artificial freezing method constitutes Eiswein/icewine by definition or label.

Source: http://www.ontariograpes.com/icewine.html (The Southwestern Ontario Vinters Association).

production requirements for the protection of the traditional 'Eiswein'/ 'Icewine'.

However, the EU wine labelling regulation used to differentiate between traditional expressions that could be used by third country producers and those that were exclusively reserved to EU wines. The latter category included expressions such as 'tawny', 'ruby', 'vin jaune', and 'amarone'. This entailed difficulties for those third country producers that, in an effort to avoid European GIs, had started producing wines under generic indications such as 'tawny' and 'ruby' (see above, for South Africa). In 2004, however, the EU adopted a set of amendments to its wine labelling regulation, merging the two categories into one and making it possible for all traditional expressions to be used by third country producers, provided certain requirements are met.[68]

The EU–Chile agreement on trade in wines mirrors the former EU legislation, as it contains two categories of expressions to be protected. Expressions like 'Eiswein' (List A) may be used by Chilean producers, provided the production requirements are met. By contrast, the expression 'Tawny' is exclusively reserved to particular European producers (List B). On the other hand, Chilean producers have the exclusive right to use the expression 'Noble', for example. It remains to be seen whether the Parties adapt the agreement to the more flexible new EU domestic legislation.

7. Recapitulatory Table

A recapitulatory table (Table 16.1) has been prepared to facilitate the understanding of the main differences in the EU's FTAs regarding GI protection. The table follows the features of GI protection subject to analysis in this section.

IV. THE APPROACH UNDER UNITED STATES REGIONAL AND BILATERAL FREE TRADE AGREEMENTS

The United States (USA) has included chapters on IPRs in all of its latest FTAs. This situation is not surprising, the United States being a knowledge-based economy and its corporations having deep strategic interests in consolidating TRIPS protection as well as improving current standards at the global level. The strategic interests of the United States in the IPR field are close to those of the pharmaceutical, agrochemical, entertainment and software industries. While use of regional and bilateral agreements has always been preferred by United States commercial diplomacy, the regional

Table 16.1 Comparative analysis of GI protection of selected EU bilateral agreements

	EU–Chile	EU–Mexico	EU–South Africa	EU–Australia
Separate agreement	No. Both agreements (trade in wine and trade in spirits) are Annexes to EU–Chile Association Agreement.	Yes. Agreement on the mutual recognition and protection of designations for spirit drinks.	Yes. Agreement on trade in wine and Agreement on trade in spirits supplement the Trade, Development and Cooperation Agreement (TDCA).	Yes. Agreement on trade in wines.
Type of protection	No particular reference to any specific system of protection → through both GIs or trademarks.	No particular reference to any specific system of protection → through both GIs or trademarks	No particular reference to any specific system of protection → through both GIs or trademarks.	No particular reference to any specific system of protection → through both GIs or trademarks.
Definition of GIs	1. Wine Agreement: yes, reference to Article 22 TRIPS 2. Spirits Agreement: no	No	Yes: reference to Article 22 TRIPS, including appellations of origin.	Yes: language similar to Article 22 TRIPS, including appellations of origin.
Legal means of protection	'Appropriate legal means referred to in Article 23' of TRIPS	As Article 23 TRIPS	As Article 23 TRIPS	As Article 23 TRIPS
Conditions of use of protected names	Only under conditions laid down in laws and regulations of the Party where the name originates.	Only under conditions laid down in laws and regulations of the Party where the name originates.	Only under conditions laid down in laws and regulations of the Party where the name originates.	Only under conditions laid down in laws and regulations of the Party where the name originates.

Table 16.1 (coninued)

	EU–Chile	EU–Mexico	EU–South Africa	EU–Australia
Exceptions (Article 24 TRIPS)	No: names on lists are *exclusively reserved* to one Party; no reference to exceptions; later in time than TRIPS.	No: express exclusion of Article 24 TRIPS.	No: names on lists are *exclusively reserved* to one Party; no reference to exceptions; later in time than TRIPS.	No: names on lists are *exclusively reserved* to one Party; no reference to exceptions; earlier in time than TRIPS.
Transitional period for phasing out of certain names	Marketing of pre-existing stock: – 3 years (as of entry into force) for wholesalers; – until stocks are exhausted for retailers.	Marketing of pre-existing stocks: – 1 year (as of entry into force) for wholesalers; – until stocks are exhausted for retailers.	1. Marketing of pre-existing stocks: – 3 years (as of entry into force) for wholesalers; – until stocks are exhausted for retailers; 2. Porto and Sherry: within 5 years for exports; – within 8 years for exports to SADC countries; – within 12 years for domestic market. 3. Grappa, Ouzo, Korn, Jägertee, etc.: within 5 years.	1. Marketing of pre-existing stocks: – 3 years (as of entry into force) for wholesalers; – until stocks are exhausted for retailers; 2. Three agreed dates for the phasing out of listed particular European names used by Australian producers (31 December 1993; 31 December 1997; last date to be determined by Parties).

Protection of wines beyond GIs	Yes: obligation to protect not only GIs, but also: – traditional expressions – oenological practices and processes and product specifications.	No wine agreement	Yes: obligation to protect not only GIs, but also: – oenological practices and processes and product specifications. No separate obligation to protect traditional expressions on domestic level. But exports subject to EU labelling regulation.	Yes: obligation to protect not only GIs, but also: – traditional expressions – oenological practices and processes and compositional requirements for wine.
Relationship GIs and trademarks	1. Wine Agreement: – No registration of TMs identical with or similar to other Party's GI or traditional expression; – list of existing Chilean TMs to be cancelled within: – 12 years for domestic use; – 5 years for exports; – as of entry into force of Agreement for small quantity exports and those TMs conflicting with EU traditional expressions. 2. Spirits Agreement: – Like wines	No reference to TMs. But exclusion of Article 24.5 TRIPS (good faith registration/ use of TMs).	Cases of conflict between GIs and TMs to be settled by a Joint Committee.	No registration of TMs containing or consisting of protected GIs or traditional expressions.

Table 16.1 (coninued)

	EU–Chile	EU–Mexico	EU–South Africa	EU–Australia
	In addition: – TMs identical with or similar to protected EU GI may not be invoked against use of such a GI; – existing Chilean TMs not included in attached list may be used or requested for registration even if similar to protected EU GI (within 2 years from entry into force of agreement).			
Mutual recognition of certain GIs	Obligation to accord mutual protection to particular names as contained in lists attached to the agreements. No discretion for national authorities to refuse protection.	Reference to a list of protected names as contained in lists attached to the agreement. No discretion for national authorities to refuse protection.	Obligation to accord reciprocal protection to particular names as contained in lists attached to the agreements. No discretion for national authorities to refuse protection.	Obligation to accord reciprocal protection to particular names as contained in lists attached to the agreement. No discretion for national authorities to refuse protection.

and bilateral track has been emphasized even further since the failure of the WTO Cancun Ministerial. This trend is illustrated by the lack of high-level officials attending the TRIPS Council and the heavy bilateral trade agenda, which includes an increased number of developing countries. Some of the last bilateral initiatives include negotiations, among others, with some Andean countries, Thailand and Sri Lanka. IPR chapters in the United States so far negotiated in FTAs tend to be very detailed and contain many TRIPS-plus features and new forms of intellectual property.[69]

In the case of GIs the interests of the United States do not necessarily match those in other IPR areas. While the United States could gain protection for certain agricultural and agro-industrial products, US negotiators see little or no interest in their own industry as a whole for enhanced protection of GIs whether at the multilateral, regional or bilateral level. Nevertheless, some of the agricultural producers in the United States have become more active in expressing potential interest in GIs/trademark protection for the local products (for example Napa valley producers are starting to join European and third country producers in pro-GIs lobbying activities).

During the Uruguay Round the United States was very reluctant to create a new IPR category to protect GIs at the multilateral level that could fall outside the trademarks field. In 1990, it put forward a proposal to the Trade Negotiation Group indicating that, 'Contracting Parties shall protect Geographical indications that certify regional origin *by providing for their registration as certification or collective trade marks*' (emphasis added). This proposal illustrated the United States' preference for protecting GIs through the trademarks system. The preference of the United States regarding trademarks has a lot to do with its own internal legal tradition and its consideration of GIs as private rights and not rights of 'public nature' that could not be licensed or sold.

The GI sections of the FTAs subscribed by the United States tend to vary in size and content. The GI chapters have changed over time and evolved from an independent GI protection system to a convergence toward trademark protection covering GIs. Initially, in cases such as the NAFTA, most of the rules were very close to the existing TRIPS standards with independent GIs and trademarks sections. In the latest FTAs, GI sections have, depending on the counterpart, included a dual system of protection GIs/trademarks, as in the case of the bilaterals with Chile and Morocco, or a unique protection system based in the incorporation of GIs as a form of trademarks, as in the recent bilateral with Australia. A reaffirmation of this tendency can be clearly seen by comparing the title of the sections of the NAFTA, the USA–Chile and USA–Morocco agreements on one hand where there are separate sections on trademarks and on GIs; and the

USA–Australia agreement on the other, where there is only one single section on 'trademarks, including geographical indications'.

While it is acceptable for the United States that other countries choose a different system to protect GIs (for example systems closer to appellations of origin or *sui generis* systems), the USA provides protection in a variety of ways including unfair competition law, common law recognition of marks, certification trademarks, collective trademarks, and some especial regulatory norms regarding advertisements and labelling.

GIs can be protected by three main categories of protection. These categories are enumerated in Box 16.3.

Some examples of certification trademarks linked to a geographical area registered in the United States are 'Napa Valley Reserve' and 'Ohio river valley' for wines, 'Idaho' for potatoes and onions, 'Real California Cheese'

BOX 16.3 CATEGORIES OF PROTECTION FOR GEOGRAPHICAL INDICATIONS

Regulations Focusing on Business Practices

The basic issue under these regulations (such as unfair competition, consumer protection, trade descriptions, labelling and food standards) is not whether the geographical indication as such is eligible for protection but, rather, whether a specific act involving the use of a geographical indication has contravened standards contained in laws covering such acts.

Trademark Law

Trademark law may provide two types of protection for geographical indications: against the registration and use of geographical indications as trademarks, or through collective, guarantee or certification marks.

Sui Generis Protection

A third category of regulations comprises laws and regulations specifically dedicated to the protection of geographical indications.

Source: *Protection of Geographical indication in Caricom Countries*, Correa, 2002.

for cheese, 'Washington' for apples and 'Pride of New York' for various agricultural products'.[70] Also the so-called 'common law trademarks' have been used to protect GIs in particular cases such as 'Cognac'[71] and 'Black Hills' Manufacture for gold jewellery.[72] It is important to note that protecting GIs through trademarks is not incompatible with the TRIPS agreement provided that its minimum standards are met. The TRIPS Agreement specifically indicates in its Article 1 that 'members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice'.[73] Even USTR high officials have indicated in the not yet publicly disclosed panel report in 'European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs'[74] that the panel clearly upheld the coexistence between GIs and trademarks and that trademark protection for GIs was in conformity with WTO rules.[75]

There are various TRIPS-plus standards in the RTAs recently subscribed by the USA. Most of the new standards relate to the incorporation of trademark law principles into the GI sections or by incorporating GIs in a trademark section. These new standards have broadened the scope as well as the means of protection of GIs provided they are protected by trademarks. For the purpose of facilitating the analysis we have organized the structure of the obligations covered by the GIs section of the IPR chapters of pre-selected FTAs according to the following features:

1. Definition and Scope

The GI definition of Article 22 of the TRIPS agreement has been directly incorporated in the case of the bilateral agreements between the USA and Chile and in the USA–Morocco agreement. Nevertheless a new sentence has been added to this definition making it a broader one.[76] Articles 17.4.1 of the USA–Chile agreement and 15.3.3 of the USA–Morocco agreement indicate that 'Any sign or combination of signs (such as words, including Geographical and personal names, as well as letters, numerals, figurative elements and colors including single colors[77]) in any form whatsoever shall be eligible for protection'. This sentence basically adds to the GI definition part of the definition of trademarks, making it possible for GIs to be also protected through trademarks.[78] This situation reduces the differences between GIs and trademarks as set by the TRIPS agreement. While some WTO Members could consider this situation positive, it could also be considered as undermining the intention of the drafters of the TRIPS agreements, which specifically established two different categories of IPRs.

In the bilateral between the USA and Australia, the tendency toward merging GIs and trademark protection is almost consolidated. As was

mentioned above, this bilateral does not have a section on GIs or even a GI definition. There is just an obligation in Article 17.2.1, indicating that, 'Each Party shall provide that marks shall include marks in respect to goods and services, collective marks and certification marks. Each Party *shall also provide that GIs are eligible for protection as marks*' (emphasis added). This article basically considers 'GIs' as a type of mark without any differentiation. Another interesting feature of the protection provided in this bilateral is that the scope of trademarks (including GIs) covers goods as well as services. While this is a common feature in trademark law, the GI protection provided by the TRIPS agreement only applies to goods (see above, under section II on the TRIPS standards).

2. Legal Means of Protection

The legal means of protection contained in Articles 22.1, 22.3 and 23.1 of the TRIPS agreement are not explicitly mentioned in any of the FTAs under study, except in the case of NAFTA where the basic rules of the GI section of the TRIPS agreement are directly incorporated. However, this seems not to be a problem for the USA–Chile FTA due to the incorporation of a non-derogation clause in Article 17.1.5 of that agreement. This non-derogation clause indicates that, 'nothing in this chapter concerning intellectual property *rights shall derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement*' (emphasis added). In the case of the USA–Australia FTA, there is a reaffirmation of the rights and obligations under the TRIPS agreement in Article 17.1.3. Regarding the USA–Morocco FTA, there is neither a non-derogation clause nor a specific reaffirmation of rights and obligations under the TRIPS agreement. This could raise concerns over potential conflicts of obligations or rights derived from the TRIPS agreement in case of inconsistencies with particular provision of this bilateral.

A new legal means of protection has been added in the three bilateral agreements[79] under study by recognizing exclusive rights over 'GIs' that are protected through a trademark. In the Trademark sections of these bilateral agreements the following text has been included in a similar manner:

> Each Party shall provide that *the owner of a registered trademark shall have the exclusive rights to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs, including geographical indications,* for goods and services that are related to those goods or services in respect of which the owner's trademark is registered, *where such use would result in a likelihood of confusion* (emphasis added).

For this exclusive right to operate, there must be likelihood of confusion. The law of the Parties is the one that determines when 'likelihood of

confusion' occurs. In the case of the USA–Australia and USA–Morocco agreements, a sentence has been added to clarify that in case of the use of identical signs confusion shall be presumed. The expansion of exclusive rights of trademarks to cover also 'GIs' protected through trademark is another element that shows convergence towards trademark law in United States bilateral agreements.

The three bilateral agreements also contain rules to protect well-known trademarks that are also applicable to 'GIs' protected through trademarks. The protection granted is similar to the one provided in Article 16.3 of the TRIPS agreement and the one provided by Article 6*bis*[80] of the Paris Convention. In the particular case of the USA–Chile agreement, there is a provision on well-known marks protection that goes beyond the TRIPS agreement or the Paris Convention[81] requirements. Article 17.2.7 of the USA–Chile FTA indicates that

> Each Party shall, according to their domestic law, provide for appropriate measures to prohibit or cancel the registration of a trade mark [that may include 'GIs' in light of Article 17.2.1], *identical or similar to well known trademarks, if the use of the trademarks by the registration applicant is likely to cause confusion, or to cause mistake, or to deceive or risk associating the trademark with the owner of the well known trademark, or constitute unfair exploitation of the reputation of the trademark*.

Similar provisions were not found in the other two bilateral agreements.

3. Relationship with Trademarks

One provision that calls the attention in two of the bilaterals under study (USA–Chile and USA–Morocco)[82] is incorporation of a provision with special grounds for refusing protection of GIs by favouring pre-existing trademarks. The following text was found with similar drafting in Article 17.4.10 of the USA–Chile and 15.3.2 of the USA–Morocco agreement:

> Parties shall provide that each of the following shall be a ground for refusing protection or recognition of a geographical indication:
>
> *(a)* the geographical indication is likely to be confusingly similar to a trademark that is subject to a good-faith pending application or registration;
> *(b)* the geographical indication is confusingly similar to a pre-existing trademark, the rights to which have been acquired in the territory of the Party through use in good faith.

The provision basically transfers the 'first in time, first in right' maxim applicable in most trademark laws. It provides that the countries party to

this bilateral may not register geographical indications in the face of prior trademarks.[83] The principle of '*first in time, first in right*' does not mean the first in time '*anywhere*'. It is subject to the overarching principle of territoriality, typical of industrial property and trademark law, meaning that *first in time* has to have happened in the same country where the application for a trademark is pending or was previously registered.

By adopting this provision, GIs are positioned at the same level as any other trademark for the purposes of asserting rights in an application procedure. Nevertheless, we need to recall that this is not the only situation where a trademark application might be refused. Article 22.3 of the TRIPS agreement indicates that 'Members shall, ex officio if legislation permits or by the request of the interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated'. The refusal or invalidation in this case only operates if the use of the indication misleads the public as to the 'true place of origin'. Here the 'true place of origin' could be in another country and the refusal or invalidation is not subject to the principle of territoriality.

4. Exceptions

NAFTA has basically reproduced the exceptions contained in Article 24 of the TRIPS agreement. The reason why NAFTA reproduces most of the provisions of the TRIPS GI Section is that it was signed only some months after the final adoption of the Uruguay package and little experience was developed in implementing these provisions. The USA–Chile agreement and the USA–Morocco agreement do not include the TRIPS exceptions or new exceptions on GIs. In the case of the USA–Australia FTA, the Trademark section, including GIs, contains a reference to exceptions regarding the rights conferred by a mark including fair use of descriptive terms, provided those exceptions take into account the legitimate interest of the owner of the trademark of third parties. This exception is normal in trademark law and applies to marks that also cover descriptive terms of the goods or the services identified in the mark.

At the time of writing the WTO panel report on 'European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs'[84] between the EU on the one side and Australia and the United States on the other side regarding geographical food names had not yet been made available to the public. However, an interim panel report was issued to the parties to the dispute on 16 November 2004, which reportedly supports Australian and US claims of TRIPS inconsistencies of the EU Regulation 2081/92 on the protection of geographical

indications of origin for agricultural products and foodstuffs.[85] In particular, the panel observed that the EU's approach in the regulation of protecting GIs that are confusingly similar to existing trademarks is not covered by the fair use exception under the TRIPS trademark provisions (Article 17). Also, the panel reportedly considered the regulation to be inconsistent with the obligation in Article 4 of the TRIPS agreement to provide unconditional MFN treatment to foreign IP holders, as it subjects the protection of third country GIs in the EU to a requirement of reciprocal protection of EU GIs in the country of origin.[86]

In the same context, press releases of the United States Mission mentioned that the panel report emphasized that the exceptions under the GI chapter of the TRIPS agreements were narrow and limited to the actual GI name 'as registered'. These last words implied that while linguistic variations (translations) of GIs might give concerns to certain producers, only the words in the original language were covered by the TRIPS agreement.[87]

5. Some Procedural Features

The USA–Chile and the USA–Morocco bilateral agreements have included various provisions designed to facilitate filing procedures and protection of GIs that go beyond the TRIPS agreement. These provisions include the following features:

- Simplification of formalities for the protection of registration of GIs;
- Incorporation of various transparency rules such as making available regulations governing filing procedures or publication of GIs for the purposes of opposition procedures;
- Provision of procedures for opposition and cancellation of registration.

As the USA–Australia FTA does not have a section on GIs, all the procedural and transparency rules of the trademark chapter apply to all GIs protected through trademarks. These include all the features mentioned above plus obligations for providing for electronic filing procedures. The USA–Chile FTA also has this obligation in the trademark chapter and this obligation is also applicable to GIs protected through trademarks.[88]

6. Links with Market Access Rules

In certain RTAs we find mutual protection clauses for particular geographical names. They have covered so far only certain geographical names for spirits and wines. We have only found mutual protection clauses in the

NAFTA and in the USA–Chile FTA. This calls attention to the question why in the bilateral agreements between the USA and Australia or the USA and Morocco, such clauses were not included. One speculative argument could be that in the case of the USA–Australia agreement there is no need due to the fact that trademark law is the main form of protection for 'GIs' and that there are no important limitations for trademark registration in both countries. In the case of the USA–Morocco FTA, there were possibly no protectable geographical names for wines and spirits in Morocco or there was little interest in exporting this type of product to the Moroccan market by the United States.

The mutual protection clauses are part of the market access chapters and not of the GIs or trademark sections of the IPR chapters. The main obligations derived from these clauses are the following:

a. Recognition of certain geographical names as 'distinctive products'. A definition of 'distinctive product' was not found in the US RTAs. As this clause was found in the market access chapter this definition may have an impact in the breakdown of the tariff lines where these special products are listed as to facilitate trade.
b. Protection against sale of any products with those names within the territory of the Parties, unless they are manufactured within the territory of the other Party in accordance with domestic laws and regulations governing the manufacture of those products. The obligation establishes a ban to sell products using the protected names unless they fulfil territorial and manufacturing regulatory requirements applicable to the protected geographical names. These territorial and manufacturing regulatory requirements fit in a general manner in the definition of GIs of the TRIPS agreement and the definition of certification trademarks in United States law.

The protected geographical names affected by the mutual recognition clause are limited. They include so far: Bourbon and Tennessee Whiskeys (United States); Canadian Whiskey (Canada); Tequila and Mezcal (Mexico); Chilean Pisco, Pajarete and Vino Asoleando (Chile).

7. Recapitulatory Table

A recapitulatory table has been prepared as to facilitate the understanding of the main differences in the US RTAs regarding GI/trademark protection. Table 16.2 follows the same features of GI protection subject to analysis in this section.

Table 16.2 Comparative analysis GI protection of selected US regional and bilateral agreements

	NAFTA	USA–Chile	USA–Morocco	USA–Australia
Independent GI section	Yes	Yes	Yes	No, GIs are covered in trademark chapter. There is not an independent GI chapter.
Type of protection	As GIs or trademarks (including collective or certification)	As GIs in the case of Chile or as trademarks (including collective or certification TMs) in the case of the United States	As GIs or trademarks (including collective or certification) TMs)	As trademarks (including collective or certification)
Definition of GI	Not included	Yes	Yes	Not included. They are covered by the definition of trademarks. GIs are eligible for TM protection.
Indication that 'signs' are eligible for GI protection	Not mentioned	Yes	Yes	Yes
Scope	Goods. Goods and services if protected through TMs.	Goods. Goods and services if protected through TMs.	Goods. Goods and services if protected through TMs.	Goods and services. They are protected through TMs.
Legal means of protection	Same as Articles 22 and 23 TRIPS.	Same as Articles 22 and 23 TRIPS. It recognizes exclusive rights when GIs are protected by a trademark	Same as Articles 22 and 23 TRIPS. It recognizes exclusive rights when GIs are protected by a trade mark	Same as Articles 22 and 23 TRIPS. It recognizes exclusive rights when GIs are protected by a trademark Applies well-known mark protection
Exceptions	Same as Article 24 of TRIPS	Not covered	Not covered	Include exceptions related to TM law such as fair use and descriptive terms.

Table 16.2 (continued)

	NAFTA	USA–Chile	USA–Morocco	USA–Australia
Incorporation of grounds for refusing protection of GIs by favouring pre-existing TM	Not covered	Yes	Yes	Yes
Establishment of opposition procedures	Not covered	Yes	Yes	Yes
Electronic filing	Not covered	Yes	Not covered	Yes
Rules dealing with simplification of procedures	Not covered	Yes	Yes	Yes
Rules on transparency	Not covered	Yes	Yes	Yes
Creation of a TM/GI database	Not covered	Not covered	Not covered	Yes
Links with market access rules and mutual recognition of certain GIs/TM	The GIS protected are on the side of the United States, Bourbon and Tennessee whiskeys; on the side of Canada, Canadian whiskey and on the side of Mexico, Tequila, Mezcal.	The GIS protected are on the side of the United States Bourbon and Tennessee whiskeys; and on the side of Chile Chilean Pisco, Pajarete and Vino Asoleando.	Not covered	Not covered

Note: 'Yes' = covered by the FTA in question.

V. CONCLUDING REMARKS: SOME LESSONS FROM GIS PROTECTION IN REGIONAL AND BILATERAL AGREEMENTS

The new generation of RTAs/FTAs is rapidly changing the type, scope and content of international obligations on intellectual property under the TRIPS agreement. These obligations are being multilateralized through the expansive effect of the MFN clause of the TRIPS agreement, generating a strong upward protection effect that could be consolidated later at the multilateral level. In the case of the subchapters or agreements on GIs, while levels of protection are increasing, standards are divergent in orientation and common features are rare. The most important lessons that could be learnt from a comparative analysis of standards in the RTAs of the EU and the USA are the following:

1. Different Economic Interests

The chapters/agreements are clearly the reflection of two different economic interests. The EU seeks to use GIs as a tool to consolidate the reputation and market niche of certain agricultural products as well as maintaining its level of agricultural exports in both quantities and value. GI protection tends to be seen as potential political and economic 'counterweight' to the threat that subsidies reduction and increased market access commitments could represent to its agricultural production. In the case of the United States, interest focuses on increased market access for agricultural products, and GI protection is seen as a potential 'protectionist' barrier to such products. The different economic interests have been the main drivers of political positions in all RTAs, but also at the multilateral level.

2. The Issue of Legal Tradition

Legal tradition in the EU and the USA has generated different forms of implementing TRIPS obligations in respect of GIs. Some WTO Members have chosen to protect GIs by using the 'appellation of origin' model (based on the model of the continental system, that is a public law conception) while others have given preference to the trademark system (based on the model of the common law system, that is a private law conception).[89] In the bilateral between the USA and Chile, the duality of conception can be seen very clearly in some provisions. Articles 17.4.2 and 17.4.3 of this bilateral indicate in the GI section that Chile has to provide legal means to protect US 'persons' and Chile and the United States have to provide legal means

to protect 'Chilean GIs' that meet the criteria in the common definition of GIs. The difference resides in the use of the concept of 'person', which in the case of the United States can be a natural person or a corporation. In the case of Chile the titleholder is technically the Chilean state.[90] In some FTAs such as the Andean Community of Nations, Decision 486,[91] there is legal protection for both GIs and certification trademarks (CTMs). This type of dual system permits the protection of foreign GIs as GIs/appellations of origin and foreign CTMs as CTMs. In this case, cross protection is not allowed, because this is considered to be based on two different legal categories of intellectual property.

In the negotiations of recent RTAs/FTAs, both the EU and the USA intend to promote their own legal system and incur the minimum legislative adjustment costs in the implementation of their obligations. In the specific case of the United States, it is very unlikely that this country would include any legal structures in its FTAs that do not have internal recognition or that recognize property rights of a public or mixed nature that are strongly influenced by the state.[92]

3. Divergence in Legal Means of Protection

It is clear that the EU privileges GIs as a distinctive category of intellectual property. The EU's FTAs reaffirm this distinction and even go toward deeper protection. As mentioned above, the protection in the EU FTAs implies that GIs are subject to the conditions laid down in the laws and regulations of the Party in which the respective GIs originate. This obligation generates in practice the application of the standards of the Party granting the higher-level protection. It could be argued that this level is only applicable to the GIs originating in the respective counterpart in a particular FTA. Nevertheless the MFN clause in the TRIPS agreement would expand the protection accorded to the party in such an FTA to other parties. In some cases the EU FTAs grant exclusive protection to GIs listed in the particular agreement.

In the case of the US FTAs, levels of protection for 'GIs' are higher, provided they are protected through trademarks, certification or collective trademarks. It could also be said that in those FTAs, there is just an expansion of the applicability of the trademarks rules, which have higher levels of protection in certain cases than a *sui generis* system of GI protection. In cases of FTAs where dual protection exists, meaning coexistence of GIs and trademarks, such as the case of Chile and Morocco, some additional protection is provided in relation to procedural, filing and transparency features.

4. Differences in Scope

While the US agreements apply to any product eligible for protection under the definition of Article 22 of the TRIPS agreement, the examined EU agreements concern exclusively the protection for wines and/or spirits GIs. As to wine GIs, some of the EU bilaterals do not only cover GIs but have added protection of 'traditional names'. In the case of the US RTAs, the scope of protection is expanded when the GIs are protected through trademarks, certification or collective trademarks. In cases where the GIs are protected through trademarks, both goods and services are covered. In the case of the section dealing with mutual recognition agreements, emphasis is placed on spirits, but in some cases also wines.

5. Exceptions

In general terms, while the USA in its agreements treats GIs as another form of trademark, thus emphasizing the exceptions clause under Article 24.5 of the TRIPS agreement, the EU on the other hand seeks to establish, through bilateral agreements, a *sui generis* form of GIs protection that clearly prevails over conflicting trademarks. Thereby, the EU eliminates the Article 24.5 exceptions available under the TRIPS agreement.

This difference in approach may equally be observed with respect to the other exceptions under Article 24 TRIPS. In the case of the US RTAs, the situation may vary; either TRIPS exceptions are explicitly included, or are covered by the non-derogation clause and in one case the trademark exceptions are also applied. The EU agreements, on the other hand, explicitly or implicitly eliminate TRIPS exceptions such as the one referring to continued and similar prior or good faith use of GIs or to the free use of generic terms.

The EU thus follows a GI TRIPS-plus agenda, whereas the USA is rather seeking to introduce 'TRIPS-minus' provisions in this respect, eliminating to the greatest possible extent domestic *sui generis* GI systems of protection and replacing them with regular trademark systems of protection.

6. Mutual Recognition Agreements

As observed above, the mutual recognition in RTAs/FTAs of certain designations as belonging exclusively to producers in one of the parties to the agreement provides a form of automatic protection of these designations in the other party, taking away any discretion of national authorities to subject a protected foreign GI to an examination of the qualification requirements in Article 22 of the TRIPS agreement. The EU in its bilateral

agreements has made extensive use of such clauses of mutual/reciprocal recognition. The USA, on the other hand, has expressly taken such an approach only in NAFTA and in the USA–Chile FTA. In addition, the lists of protected names are rather short in the case of the US agreements, but of considerable length in the case of the EU agreements. In the US agreements, both the USA and Mexico currently protect two designations through mutual recognition, Chile three, and Canada one. On the other hand, the list covering names for Community wines in the EU–Chile agreement on trade in wines comprises 78 pages, covering hundreds of protected European designations (as compared to two-and-a-half pages of Chilean protected wine names). Again, this difference in approach may be explained by the divergent economic interests of the EU and the USA, respectively, and the important difference in number and value of their traditionally protected designations.

7. Conclusion

The EU and US RTAs may serve as good illustrations of the recent shift in international IP policy-making away from the multilateral (WTO/WIPO) forum to the regional and bilateral levels. The examined agreements on GI protection considerably alter existing TRIPS obligations and flexibilities. The case of GIs in these RTAs shows a lack of coherent approaches by leading economies and even increasing divergence in views. This lack of coherence in the case of GIs protection is one example of how RTAs can negatively impact the multilateral trading system and create a race for locking up the regulatory IP framework with close trading partners.

New bilateral or regional commitments in the GIs field are reducing options for common understanding at the multilateral level. Developing countries, before committing themselves, should carefully assess whether the ensuing obligations correspond to their economic and societal priorities. While cultural aspects and legal tradition might be important, long-term policy goals and coherence with multilateral obligations need to be taken into account when dealing with regional and bilateral negotiations.

NOTES

1. Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods (adopted in 1891).
2. Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (adopted in 1958).
3. Dwijen Rangnekar (2004), 'The socio-economics of geographical Indications', Issue paper No 8, UNCTAD/ICTSD, (hereinafter Rangnekar, 2004).

4. Stephen Sterns (2004), 'The conflict between geographical indications and trademarks', Intellectual Property Society of Australia (hereinafter 'Stern').
5. See WT/MIN(01)/DEC/W/1 of 14 November 2001.
6. See WT/MIN(01)/W/10 of 14 November 2001.
7. *Doha Round Briefs – Intellectual Property*, ICTSD, 2002, 2003 and 2004. See www.ictsd.org.
8. Ibid.
9. The acronym RTA has been used because under WTO law regional trade agreements include both regional and bilateral agreements.
10. *WTO Secretariat and Regionalism*, World Trade Organization, 2000. The total of regional and bilateral agreements notified to the WTO since 1950 were more than 250 in 2004.
11. For a TRIPS-plus definition see David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS plus World: the Free Trade Area of the Americas'*, QUNO/QUIAP/ICTSD, 2003 (hereinafter Vivas-Eugui).
12. Ibid.
13. Examples taken from Sergio Escudero (2001), *International Protection of Geographical Indications and Developing Countries*, Working Paper No. 10, South Centre, Geneva, p. 5 (hereinafter Escudero).
14. See UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Chapter 15 (Geographical Indications), Sections 1 and 3 (Cambridge University Press, February 2005; a previous version is available at <http://www.iprsonline.org>; hereinafter UNCTAD-ICTSD Resource Book). Note that in this respect, the notion of GIs under TRIPS is wider than the notion of 'appellations of origin' as laid down in Article 2 of the 1958 Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (hereinafter Lisbon agreement). Under the latter, the name of the product and the geographical name have to be identical (Escudero, p. 4).
15. Note that this is another aspect where the definition of GIs under TRIPS is broader than the notion of 'appellations of origin' under the Lisbon agreement. Appellations of origin are limited to the 'quality and characteristics' of the designated product (Article 2, Lisbon agreement). Mere reputation alone is not sufficient to confer protection.
16. UNCTAD-ICTSD Resource Book, Chapter 15, Section 3.
17. UNCTAD-ICTSD Resource Book, Chapter 15, Section 1, noting the particularity of *collective trademarks*: these also involve shared ownership, but other than GIs, which are available to all producers in a region, a collective trademark is typically limited to a pre-defined group of owners.
18. This is another aspect in which GIs differ from trademarks. The latter may be assigned or licensed to any third party; see Article 21 of the TRIPS agreement.
19. See Article 22.2 (a) TRIPS: '2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

    (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;'

20. For more details on the different ways of protecting GIs under national laws see UNCTAD-ICTSD Resource Book, Chapter 15, Section 2.1.
21. For instance, the 'public' might be understood as comprising the general consumer with limited knowledge, or rather a more specialized group of consumers with advanced knowledge on the relevant product (UNCTAD-ICTSD Resource Book, Chapter 15, Section 3).
22. Article 10*bis* Paris Convention reads as follows: 'Unfair Competition

    (1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.
(3) The following in particular shall be prohibited:

1. all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;
2. false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;
3. indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.'

23. For instance, in the case of 'Californian Chablis', consumers are aware of the non-French origin of the drink, but might nevertheless associate with that product certain characteristics typical of the famous French 'Chablis'. See Dwijen Rangnekar (2003), 'Geographical indications – a review of proposals at the TRIPS Council: extending Article 23 to products other than wines and spirits, UNCTAD-ICTSD, Issue Paper No. 4, Geneva, page 14 (hereinafter Rangnekar, 2003).
24. Article 23.1 TRIPS reads: 'Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, *even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like*. [footnote omitted, emphasis added]'
25. Article 24.4 TRIPS reads: '4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (*a*) for at least 10 years preceding 15 April 1994 or (*b*) in good faith preceding that date.'
26. For a discussion of the good faith criterion see UNCTAD-ICTSD Resource Book, Chapter 15, Section 3.
27. Article 24.5 TRIPS reads: '5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or
(b) before the geographical indication is protected in its country of origin;

measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.'
28. The term 'common law' trademark indicates that the trademark rights that are developed through customary use are not governed or derived by statutory norms. Common law trademark rights have been developed under a judicially created scheme of rights governed by common law. Registration is not required to establish common law rights in a mark. However, formal registration usually gives a trademark titleholder additional rights not available under common law.
29. Article 24.6 reads as follows: '6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of

the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO agreement.'

30. Rangnekar, 2003, p. 33, in this context refers to former GIs such as 'Arabica coffee', 'Indiarubber', 'chinaware', 'Cheddar cheese', and 'kiwifruit'.
31. For a detailed analysis of the ambiguous language of the second sentence, see UNCTAD-ICTSD Resource Book, Chapter 15, Section 3.
32. Article 24.8 TRIPS addresses the situation where a personal name, which is used for business purposes, is also a GI. Article 24.9 TRIPS stipulates that GIs lacking protection in their country of origin do not need to be protected under TRIPS.
33. Rangnekar, 2003, p. 11, refers to a total of over 6000 protected European indications. Most of those concern wines and spirits; according to F. Vital (1999), 'Protection of geographical indications: the approach of the European Union', in: *Symposium on the International Protection of Geographical Indications*, Somerset West, Cape Province, South Africa, 1–2 September, 1999, World Intellectual Property Organization, Geneva 2000, (hereinafter Vital), p. 53, there were 518 European denominations registered in the area of agricultural products and foodstuffs as of 1 August 1999.
34. See Council Regulation (EEC) No. 2081/92 of 14 July 1992 on the protection of geographical indications of origin for agricultural products and foodstuffs and Council Regulation (EC) No. 1493/1999 of 17 May 1999 on the common organization of the market in wine. See UNCTAD-ICTSD Resource Book, Chapter 15, Sections 2.1 and 3.
35. The protection offered under Article 13 of Regulation 2081/92 is comparable to the advanced protection for wines and spirits GIs under Article 23 TRIPS, see above.
36. Vital, p. 52, refers as example to the French cheese 'Comté', which is produced exclusively from a particular cow breed, which in turn feeds only on a delimited area in the French Jura mountains. In addition, the specific climate conditions and the particular producers' skills are said to confer on this cheese its unique characteristics among other cheeses.
37. Vital, p. 53, refers as example to the Spanish meat product 'Sobrasada de Mallorca', which is manufactured on the island of Mallorca. However, the pigs used in the production do not necessarily originate in Mallorca.
38. While the EU considers this strategy a shift from protectionism to competition ('compete internationally on quality rather than quantity', see 'Why do Geographical Indications matter to us?', available at the EU website at http://europa.eu.int/comm/trade/issues/sectoral/intell_property/argu_en.htm), others regard this as just another form of protectionism (see S. Laing, 'EU on GIs: Free Trade or Protectionism?', Trade Law Centre for Southern Africa (tralac) Trade Briefs 2003, available at http://www.tralac.org/scripts/content.php?id=1999).
39. See 'Why do Geographical Indications matter to us?', available at the EU website at http://europa.eu.int/comm/trade/issues/sectoral/intell_property/argu_en.htm.
40. Agreement on Trade in Wines, available at http://europa.eu.int/comm/trade/issues/bilateral/countries/chile/docs/euchlagr_x.pdf.
41. Agreement between Australia and the European Community on Trade in Wine, available at http://europa.eu.int/comm/trade/issues/bilateral/countries/australia/docs/wine_agr.pdf.
42. Note that this formula was also part of an EC proposal with respect to the protection of geographical indications during the Uruguay Round of Multilateral Trade Negotiations. See UNCTAD-ICTSD Resource Book, Chapter 15, Section 2.1.
43. Agreement on Trade in Spirit Drinks and Aromatised Drinks, available at http://europa.eu.int/comm/trade/issues/bilateral/countries/chile/docs/euchlagr_xii.pdf.
44. Agreement between the European Community and the Republic of South Africa on trade in wine, see http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_028/l_02820020130en00040105.pdf. Agreement between the European Community and the Republic of South Africa on trade in spirits, see http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_028/l_02820020130en01130125.pdf.
45. Agreement between the European Community and the United Mexican States on the

mutual recognition and protection of designations for spirit drinks, available at http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=21997A0611(01)&model=guichett.

46. See for instance Article 5.1 of the EU–Chile Agreement on Trade in Wines.
47. See for instance Article 4.1 of the EU–Mexico Agreement on Spirit Drinks, according to which in Mexico, 'the protected Community [i.e. EC] names:
– may not be used otherwise than under the conditions laid down in the laws and regulations of the Community.
48. See Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organization of the market for wine, OJ L 179/1, Annex VII, lit. F, paras. 1 and 2.
49. See, for instance, Article 5.1 of the EU–South Africa agreement on trade in spirits and Article 4.3 of the EU–Mexico agreement.
50. See Article 5.1 of the EU–Chile agreement on trade in wines. The terms 'mutual' and 'reciprocal' may be used interchangeably, as is made clear by the EU–Mexico agreement, which in its title refers to 'mutual recognition and protection' and then uses the term 'reciprocal protection' in its substantive part (Article 4.3).
51. Article 5.1 of the EU–Chile agreement on trade in wines.
52. On the exclusion of the Article 24 TRIPS exceptions through the bilateral agreements, see also in the next, separate section.
53. The EU–Mexico agreement uses different language in this respect. It provides in Article 3: 'The following designations are protected:
    (a) as regards spirit drinks originating in the Community, the designations listed in Annex I;
    (b) as regards spirit drinks originating in the United Mexican States, the designations listed in Annex II.'

    The terms 'are protected' imply that domestic authorities have no discretion to refuse protection. Thus, the accorded protection is equally automatic, like under the other agreements.
54. For the trademark exception, see the separate section, below. As noted in the introduction, the TRIPS agreement in Article 24.1 authorizes such a TRIPS-plus approach in bilateral or multilateral agreements: 'The provisions of paragraphs 4 through 8 below [i.e. the provisions on exceptions] shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.'
55. See Article 4.4 of the EU–Mexico agreement on the mutual recognition and protection of designations for spirit drinks: 'The Contracting Parties will not deny the protection provided for by this Article in the circumstances specified in paragraphs 4, 5, 6 and 7 of Article 24 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.'
56. See Article 30.3 of the Vienna Convention on the Law of Treaties: 'When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty.' The lack of reference in the bilateral agreements to any exceptions means that those exceptions have not become part of the Parties' treaty rights.
57. See Susan Laing, 'More port anyone?', available at http://www.derebus.org.za/archives/2003Jul/articles/port.htm (hereinafter Laing, More port anyone?).
58. See Laing, More port anyone? page 4.
59. See Articles 6 (iii) and 7 of the EU–South Africa agreement on trade in spirits.
60. See, for example, Article 25 of the EU–Australia agreement.
61. Negotiations on outstanding issues of the EU–Australia agreement have resumed in April 2004. See http://www.dfat.gov.au/geo/european_union/review_04.html.
62. See for instance Article 5, paras 4 and 5 of the EU – Chile Agreement on Trade in Spirit Drinks and Aromatised Drinks. The relevant TRIPS provisions are Articles 23.3 and 22.4.

63. See Article 7 of both agreements.
64. See Article 10.4 of the EU–Chile agreement on trade in wine.
65. See lists A and B in Appendix III to the agreement.
66. See lists A and B in Appendix IV to the agreement.
67. See Commission Regulation (EC) No 753/2002 of 29 April 2002 laying down certain rules for applying Council Regulation (EC) No 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products, OJ L 118, pages 1–54 (hereinafter wine labelling regulation). For more information on this regulation, see below.
68. See '*EU amends wine labelling rules: "*traditional expressions" can be used by third countries', available at: http://www.delaus.cec.eu.int/pressandinformation/winelabeling.pdf.
69. Vivas-Eugui, 2003.
70. Beresford Lynne (1999), 'The protection of geographical indications in the United States of America', *Symposium on the International Protection of Geographical Indications*, WIPO, (hereinafter 'Beresford').
71. *Institut National des Appellations v Brown-Forman Corp*., 47 USPQ2d 1875 (TTAB 1998). See http://www.uspto.gov/web/offices/dcom/olia/globalip/geographicalindication.htm.
72. Beresford, 1999.
73. For a detailed analysis of this provision, see UNCTAD-ICTSD Resource Book, Chapter 2 ('Nature and Scope of Obligations').
74. See WT/DS174/21 and WT/DS290/19 of 24 February 2004, Constitution of the Panel Established at the Requests of the United States and Australia (hereinafter 'EC – Protection of Trademarks and GIs).
75. US Mission to the United Nations in Geneva. Press release: 'United States wins WTO case against EU over food names', 12 December 2004. Hereinafter 'US mission press release'.
76. In the case of the USA–Chile agreement a dual approach was taken. In this case the United States will protect GIs through trademarks and Chile through its own GI system, which is closer to the 'appellation of origin' model. For a precise analysis see Pedro Roffe, 'Regional and bilateral Agreements and a TRIPS-plus world: The Chile–USA Free Trade Agreement, QUNO/QUIAP. 2004. Hereinafter Roffe, 2004.
77. The phrase 'Single colours' is not mentioned in the FTA between the USA and Chile.
78. Roffe, 2004.
79. In this case we refer to the USA–Chile, USA–Morocco and USA–Australia agreements.
80. Article 6*bis* of the Paris Convention provides:
'(1)The countries of the Union undertake, ex officio if their legislation so permits, or at the request of an interested party, to refuse or to cancel the registration, and to prohibit the use, of a trademark which constitutes a reproduction, an imitation, or a translation, liable to create confusion, of a mark considered by the competent authority of the country of registration or use to be well known in that country as being already the mark of a person entitled to the benefits of this Convention and used for identical or similar goods. These provisions shall also apply when the essential part of the mark constitutes a reproduction of any such well known mark or an imitation liable to create confusion therewith.
(2) A period of at least five years from the date of registration shall be allowed for requesting the cancellation of such a mark. The countries of the Union may provide for a period within which the prohibition of use must be requested.
(3) No time limit shall be fixed for requesting the cancellation or the prohibition of the use of marks registered or used in bad faith.'
81. Roffe, 2004.
82. In the case of the USA–Australia agreement there was no need due to the fact that this obligation is already part of its trademark principles.
83. See Stern, 2004.
84. See WT/DS174/21 and WT/DS290/19 of 24 February 2004, Constitution of the Panel Established at the Requests of the United States and Australia (hereinafter 'EC – Protection of Trademarks and GIs')'.

85. See 'Interim Report Out on GIs', *Bridges* November 2004, page 7, ICTSD, 2004 (available at http://www.ictsd.org/monthly/bridges/BRIDGES8-10.pdf).
86. For more details on this EU legislation, see UNCTAD-ICTSD Resource Book, Chapter 15, Section 2.
87. Hereinafter US Mission press release.
88. Roffe, 2004.
89. For a comparison between GIs and certification trademarks models, see Vivas, 2000 and Rangnekar 2004. David Vivas-Eugui, 'Negotiations on geographical indications in the TRIPs Council and their effect on the WTO agricultural negotiations: Implications for developing countries and the case of Venezuela', UNCTAD, 2000, Rangnekar, 2004.
90. See Roffe, 2004.
91. Andean Decision 486 on Industrial Property, 14 September 2000.
92. Vivas-Eugui, 2000.

17. Geographic indications, trade and the functioning of markets

Phil Evans

The issue of the interface between food policy and trade policy has been an area fraught with controversy for some considerable time. While food safety issues and their possible misuse as barriers to legitimate trade have been with us since the onset of the GATT in the late 1940s, other food issues have begun to grow in importance. One of the most interesting, and contentious, issues is that of Geographic Indications.

What is particularly interesting about the debate around GIs is that almost all the main protagonists in the argument have some form of protection for them, but none agree about how far they should go, or perhaps more importantly how they should affect trade. It would not appear to be a debate about principle but rather of degree.

What is also interesting is the degree to which the debate has avoided discussion of competition issues in agricultural markets. This is, in part, because of historical provisions excluding many agricultural markets from competition overview, most notably in the EU. The role of the Common Agricultural Policy and general 'exception' afforded agriculture in competition law is neither new nor surprising. It should be remembered that competition policy in its modern form first emerged in the USA, Canada and Australia as a rural revolt against urban 'trusts' that were seen to be doing down the farm communities.[1] This original rural revolt has affected the manner in which competition law has been framed and how it has viewed agricultural markets. In particular the role of agricultural cooperatives and farmer groups has been a difficult one for most competition bodies.

However, the restrictions that GIs impose on their members and on those that do not possess the required standard are such that a combined analytical approach is needed. If we rely solely on trade policy to analyse the GI issue we are left with little real room to question the basic structures of the systems on offer and why they emerged. This limited focus allows disputes to occur, but only insofar as issues impinge on basic trade rules. The fundamental structure of GI systems does not fall easily into trade policy analysis. Conversely competition policy allows us to question the structure

of GI systems at the national or regional level. It allows us to deconstruct the incentive structures that GIs create in agricultural markets and to discuss the impact that GIs have on competition in product markets. Combining a trade and competition policy approach allows us to engineer some form of approach that could minimize trade tensions while maximizing product market competition and protecting legitimate producer interests. The only remaining piece of the puzzle lies in a socio-historical review of how current food cultures and production processes came to be. Only through seeing where food cultures came from can we hope to frame the discussion of possible ways forward for the global GI debate.

WHO DOES WHAT?

The USA has a system of certification for geographic product claims that has allowed 100 per cent Kona Coffee, Vidalia Onions and Wisconsin Real Cheese to be offered a form of trademark protection under a certification scheme. Part of that trademark protection is based on the producers of the product being within a specified geographic region. The US trademark system allows US and foreign producers to register a trademark and apply it for geographically specific products. However, it defines some products that have such protection elsewhere, such as champagne or feta cheese, as being generic terms. As such they are incapable of being granted a trademark in the USA.

The US certification scheme states that:

> A certification mark is defined as any word, name, symbol, device, or any combination, used or intended for use in commerce with the owner's permission by someone other than its owner, to certify regional or other geographic origin, material, mode of manufacture, quality, accuracy, or other characteristics of someone's goods or services, or that the work or labor on the goods or services was performed by members of a union or other organization. (Section 1127, 'Construction and Definitions,' of the Trademark Act of 1946 ('Lanham Act') as amended. US Patent and Trademark Office 2003)

The US system also has some flexibility in having state-sponsored agricultural certification programmes, such as, 'Idaho Preferred', 'A Taste of Iowa', 'Fresh from Florida', and 'Get Real Get Maine'. For example, Vidalia onions is a certification actually owned by the State of Georgia who allow it to be used in a specified area of the State. Indeed many state-owned certification schemes exist, but tend to be rather broader in nature than product-specific geographic indications, or the sort of scheme operated in Europe. However, again one is struck by an issue of degree rather than principle operating. All geographic origin labels have some defined geographic

area and products; one has to ask if having a state scheme, national scheme or local scheme has a significant bearing on the product itself.

This flexibility in the US system even allows the US to protect some European GIs without formal certification. For example, Cognac is used as an example in the USA of a product that would not pass the general use test that champagne or feta would. This is justified on the basis of US consumer understanding that Cognac is inextricably linked to the Cognac region of France and nowhere else. Again the lack of ideology and persistence of pragmatism arises.

The European Union scheme also operates in addition to trademark protection. The 1992 EU Council Regulation on the Protection of Geographical Indications and Designations of Origin (2081/92) created two forms of certification: Protection of Designations of Origin (PDOs) and Protection of Geographic Indication (PGIs). To get a PDO a product must be produced, processed and prepared within a specific area and its characteristics must be 'essentially due to the area'. A PGI is accorded a product produced, processed or prepared in a specific area whose quality, reputation or other characteristics are some way attributable to that area and that area alone.

The EU scheme, unlike the US system, effectively creates collective trademarks for regions or groups of producers. While a particular company, or State, may have a certificate that it then uses, the EU scheme aims to bring together groups of producers to set quality standards for products. Each scheme has to be independently certified to gain the PDO or PDI. This is often done by governmental bodies.

The variation in schemes was of little real relevance prior to the Uruguay Round. The hybrid trademark/certification/common law system in the USA could live alongside the more rigid EU system without too many serious legal arguments. However, the incorporation of intellectual property rights rules into the WTO placed GIs firmly on the international agenda. Article 22 of the TRIPS: Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation, or other characteristic of the good is essentially attributable to its geographical origin.

The incorporation of GIs into the WTO system both highlighted the issue and focused on what were likely to be future trade disputes.

WHERE DO GIS COME FROM?

The right to know from whence a particular product has come has grown in importance as a role of consumer protection. While origin labelling is

a particularly complex area of law it is less of a problem in a good deal of consumer protection labelling. The principle of such labelling has tended to be that if a product claims some form of geographic link, then that claim must not be misleading or deceptive. This motivation fits neatly into the basic consumer protection role of dealing with deceptive practices. However, how this is applied nationally has varied somewhat. In the UK, for example, the principal tended to be that if a product, such as mozzarella, was produced in a country other than Italy it had to be labelled as such. The potential deception was removed by requiring a manufacturer to place wording on the label clearly showing that the mozzarella was from Denmark, for example. Thus the consumer was not deceived, while the market was protected from potential competition problems that can arise from restricting a label to a limited number of producers.

The idea of geographic indications as a protector of consumers and its link to trade was enshrined in a number of international intellectual property treaties. For example, the Paris Convention for the Protection of Intellectual Property and the Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods both have specific provisions relating to border measures that could be used to halt trade in goods whose geographic origin was deceptively identified.

It is interesting to note that many consumer protection laws also contain provisions about what is termed 'unfair competition'. While such provisions can be controversially applied to things such as below cost selling or indeed to firms negotiating discounts on volume purchases, the form of deception that GIs seek to deal with is quite naturally aligned with such provisions.

Article 22.2(a), and Article 22.4 of The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) specifically deal with the 'deceptive' use of GIs. The wider protection for wines and spirits enshrined in the TRIPS agreement was effectively a Trojan Horse for wider protection for all GIs. The wine provisions, most notably in Article 23.1, provided both a higher level of protection and remove motivation from deception. While the broader use of GIs involves an appeal to deception as a driver of usage, in wine an indication simply cannot be used if it does not come from a specific region.

EXEMPTIONS, EXCEPTIONS AND HISTORY

One of the greatest difficulties with the use of GIs is in cases where other producers have used them for some time, or indeed have only recently started using them. The problem is further complicated if a producer has

a trademark in one country that is a GI in another. While demanders of greater protection for GIs point to such problems as evidence of their case, the reality of the differential application of GIs is more complex.

It is no coincidence that the main protagonists in the GI debate are countries that, on the one hand, experienced large-scale emigration, and those, on the other hand, that were the recipients of that emigration. In essence, on the one side is Europe and on the other former colonies of Europe. In culinary terms Europe was very much the motherland to many communities that grew up in the USA, Australia, Canada and elsewhere in the world. With emigration communities took with them the culinary traditions and recipes of their homeland. If we look at cheese as an example we find that

> (m)ost of the cheeses produced in the United States originated in another country and then traveled here with immigrants. Mozzarella, one of the most popular cheeses in the US today is an example of a cheese that emigrated; taking on a different character as cheesemakers modified the product for new markets.[2]

The tale of mozzarella exemplifies the problems that many countries have when faced with a demand from the 'homeland' that they cease calling 'their' products by the names they recognize.

Early US attempts to make Italian-style cheeses were hampered by inefficient water supplies, poor dairy quality and a simple lack of knowledge about how to make cheese. The need to make such cheese in the USA was underlined by the fact that transportation was so long and hazardous (to the cheese) that importing from the 'homeland' was prohibitively expensive and impractical. US Italian migration, particularly after the turn of the 20th century led to the development of a domestic cheese industry. The early efforts to make mozzarella in the USA centred on cow's milk mozzarella. Around the same time in Italy efforts were being made to reintroduce Buffalo milk mozzarella after they too had moved to cow's milk mozzarella. However, mozzarella cheese in the USA evolved; 'after changes in the manufacturing procedure, most mozzarella evolved into a firmer, less sour, milder flavored cheese, better suited for transport and cooking – especially pizza pies.'[3] US mozzarella increasingly was produced using part-skimmed milk. The reasons for this are unknown but are believed to be related to the premium paid for buttermilk. What is clear, however, is that mozzarella in the USA was very much a home grown variant adapted to the growth of the dairy industry in the USA. The mozzarella produced, being harder, firmer and milder than Bufala mozzarella is thus similar to Danish mozzarella in Europe. The cheese was initially formulated to be mainly used in cookery, most notably on pizzas.

One has to ask how GIs can deal with this development. Mozzarella as a product is far from alone in having different trajectories depending on where in the world the producer is. The growth of the Australian, Chilean and US wine industries shows just how imported grape varieties can develop into perfectly serviceable products. It is perfectly possible, if not likely, that the manner of protection chosen for GIs in different countries bears a close resemblance to the development of their food economies and indeed the role of food manufacturers in it.

If we accept that most countries have generally developed foodstuffs in good faith, a key number of which are imported food types brought into the country by immigrants, then we have to look to the means by which potential conflicts can be dealt with. Under the TRIPS agreement Article 24.4 allows the 'continued and similar use' of GIs for wines and spirits by 'nationals or domiciliaries who have used that geographical indication in a *continuous* manner with regard to *the same or related* goods or services'. Of course the definition of 'same or related' leaves a good deal of room for manoeuvre.

Other possible routes to conflict resolution rest on challenges to trademarks. As the GI lobby in Europe is keen to point out, a private firm has a trademark on Parma ham in Canada. Most trademark systems have options for challenge, and given the preponderance in international IP law on limiting deceptive practices one wonders why this trademark has not been challenged.

The problem of correctly defining both the production process and those firms able to meet the standard is an increasingly important one for GI producers. The initial wave of GIs appeared to be based on relatively defensible and well established standards for a specific product. However, as the net has been spread the authenticity of some standards has become questionable. The recent debate around the Melton Mowbray pie in the UK is interesting in this regard. In 1999 the Melton Mowbray Pork Pie Association (MMPPA) applied to the EU to get a GI for Melton Mowbray pies. Melton Mowbray is a small town in Leicestershire whose name has become a marketing standard for pork pies. The body sought and received backing from the UK government department responsible for applying for EU GI status, but was attacked by Northern Foods who produced pies under the Melton Mowbray name elsewhere in the country. There was great debate over whether the pie should have pink or grey meat, with the MMPPA demanding pink meat which they argued came as a side effect of pigs being fed on whey from stilton production.

The immediate problem that the MMPPA had was that there was only one firm that produced pies in Melton Mowbray, and that firm had a lot of its products produced elsewhere in the area. The solution they came to was

to define Melton Mowbray to include all premises within a radius of 20 miles. Unfortunately this excluded one producer who made pies to exactly the quality and compositional standard required by the MMPPA. This producer was 40 miles away in Nottinghamshire, not Leicestershire. The response was to extend the boundary to include this producer and to include other producers that followed the production process but were nowhere near the town that bore the name.

The Melton Mowbray case illustrates the problem of differentiating recipe-based products that have a geographic designation in their name and geographic indications that also have a specific recipe component. It also indicates just how artificially restrictive a GI can be. It would be interesting to see how many GIs are awarded to bodies whose membership has a flexible boundary or whose boundary is artificial; even Parma ham is not produced in Parma, but in a valley near Parma.

GIS, TRADEMARKS, LICENSING AND COMPETITION

One of the most interesting elements of the GI 'problem' is the collective versus individual nature of the protection offered. In this respect it poses particular problems for competition analysis. While existing trademark law fits relatively neatly into competition law in terms of abusive practices and dominance issues, GIs sit in a rather awkward position. The collective nature of the GI requires members of the GI to meet and discuss 'standards' for the awarding of a label. Such a practice is normally viewed at the very least with suspicion by competition regulators. One would indeed expect any agreement that, at its core, restricts production and excludes existing producers from the market, to have to seek an exemption from competition law. Given that the most advanced system of GI protection and the authority with the majority of GIs registered and enforced is Europe, it is worth asking a few questions about the interface between GIs and competition rules.

The normal process for deciding whether an agreement is anti-competitive is to look to Article 81(1) of the Treaty Establishing the European Community (as amended by subsequent treaties) It prohibits agreements that:

1. directly or indirectly fix purchase of selling prices or any other trading conditions
2. limit or control production, markets, technical development, or investment
3. share markets or sources of supply

4. apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage
5. make the conclusion of contracts subject to the acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

However, agreements that do breach any of these conditions can be allowed to continue provided that they meet two criteria – firstly, they can be exempted from the provisions of Article 81(1) if they meet all four criteria of Article 81(3).

Under this article the agreement must:

1. improve the production or distribution of goods or lead to a technical improvement or advance economic progress
2. offer a fair share of the benefits gained to consumers
3. have no dispensable restrictions
4. involve no substantial elimination of competition.

To receive clearance any agreement must meet all four conditions. Of course the jurisprudence spelling out how these four factors will be assessed is complex and evolutionary. However, agreements that eliminate competition, have restrictions that can be achieved in another less anti-competitive manner and that offer few obvious benefits to consumers are unlikely to pass muster.

The second set of conditions that must be met are that the agreement does not

1. 'impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives
2. afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.'

Of course, agriculture is 'different'. The rules outlined above apply to 'normal' sectors of the EU economy. The EU competition regime applies to agriculture in the same sense that for many years the rules of the General Agreement on Tariffs and Trade (GATT) applied to agriculture; theoretically and in very limited circumstances. While the WTO Agreement on Agriculture (AOA) finally incorporated some coverage of agriculture into the trading system, the same cannot be said to have happened to domestic governance of European agriculture.

The position of agriculture in European regulation is of course anomalous in many ways. The encumbrance that is the Common Agricultural Policy signals the importance of a minor part of the EU economy to European rule makers. The original EC Treaty, in Articles 32 to 38 specifically,

singles agriculture out for special treatment. Agriculture is essentially governed by different rules from those for non-agricultural markets, and Article 36 specifically states that competition policy will only have an impact upon agriculture in specific circumstances to be decided by the Council. The main provision excluding significant parts of European agriculture from competition regulation is Council Regulation 26 of 1962.[4]

This Regulation applies a number of conditions to the application of Articles 81 and 82 of competition law. The regulation lists a number of agricultural products in Annex II which can only be dealt with by competition law under limited conditions. The Regulation is reasonably straightforward. The first article states that competition law applies to agricultural products listed, except for Article 2 limits. Those limits are essentially of two types, although a third is used for illustrative purposes. Those two general exemptions are for activities carried out under the Common Agricultural Policy (including the desire to allow farmers a reasonable income). The second specific exemption is for activities integral to national market organizations.

While the exemption for national market organizations has been rather overtaken by events, with a large number of them disappearing, the exemption for activities in line with the CAP is both broad and very much alive. The objectives that are thus effectively exempt from Article 81 are covered by roughly five headings; increasing agricultural productivity, ensuring a fair standard of living for farmers, stabilizing markets, ensuring the availability of supplies, and ensuring that consumers get access to agricultural produce at reasonable prices.

It is fairly obvious that the five conditions laid out for the CAP are incompatible with normal competition law. The only condition that remotely approaches normal competition law conditionality is the provision on consumer interests – but even here fair prices (whatever they are) is used rather than a fair share of any benefits.

The last exception built into Article 26 is one for the activities of cooperatives. This exception covers agreements between farmers or groups of farmers that cover either production or sale of agricultural produce or provide joint facilities for storage, treatment or processing of agricultural products. Such an exemption almost exactly describes a body such as the Parma ham consortia. There are limits to the cooperative exception. These include no allowance for price fixing, it does not apply to abuse of dominance cases, and it only applies to cooperatives within a member state.

While the Director General for Competition have always tried to put a brave face on the agricultural exemption it is clear that they have managed to do little but nip at the heels of agricultural protectionism and anti-competitive behaviour. The position at the national level is, however, potentially more interesting. To take but one relevant country, Italy, activity

against certain agricultural organizations has been more evident than one would assume, given the politics of food in that country. The Italian competition authority (the Autorità Garante della Concorrenza e del Mercato) have conducted a number of investigations into different agricultural groupings. These include IGOR, the consortium for producing gorgonzola cheese in 1998, the prosciutto di Parma and prosciutto di San Daniele, Parmigiano Reggiano cheese and Grana Padano in 1998 and the Grano Padano again in 2003 and 2004.

The number and focus of investigations at a national level illustrate a number of points about the potential impact of GIs administered by consortia. It is these consortia that are at the heart of the problem of the competition impact of GIs. Where trademark systems enable a single firm to register a name or designation, the GI system rewards a group of producers that can define its own borders. It should be noted that the US system, among others, allows group registrations of trademarks.

With single trademark owners there is considerable experience for competition regulators to deal with potential competition abuses. There are well tested mechanisms, such as licensing, that can be used to stop the abuse of the monopoly right that trademarks confer. However, with consortia the problem is more intractable. If one part of the European Commission wishes to use agricultural cooperatives and consortia as a means of advancing elements of the Common Agricultural Policy, then the ability of another to reform that is limited. The other major problem with consortia designed for one purpose, in this case quality regulation, is their tendency to carry out other activities. The Italian competition authority cases have tended to focus on efforts of the GIs bodies to restrict production to maintain and indeed increase prices.

The tendency of consortia to discuss matters other than quality is hardly surprising, nor is the idea new. As Adam Smith pointed out:

> People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices. It is impossible indeed to prevent such meetings, by any law which either could be executed, or would be consistent with liberty and justice. But though the law cannot hinder people of the same trade from sometimes assembling together, it ought to do nothing to facilitate such assemblies; much less to render them necessary.[5]

The natural scepticism of consortia is played out in the experience of the Italian authorities in which almost every case they took involved consortia members discussing matters other than quality standards. Indeed most inquiries concerned production limits imposed by GI bodies. The limits were claimed to be for 'quality' purposes.

Even where discussions do not stray beyond the quality standards that the bodies are supposed to develop, the very nature of consortia makes anti-competitive agreements more likely. Giving a group of producers a monopoly on a particular product and its composition immediately imbues them with market power. Allowing that body to discuss and set production limits makes price rises extremely likely. Any body that controls production and has a good understanding of demand can limit production to raise prices. Irrespective of the rationale for the group an anti-competitive impact is almost certain.

At such a point one would assume two sorts of action. Firstly, one would expect an investigation by a relevant competition authority and secondly, one would expect an industry to seek an exemption from normal competition law. Of course in the case of agricultural consortia the law is stacked in their favour. While price fixing is not strictly allowed, all activities that would lead to the effect of price fixing appear to be blessed. If we are to address the problem and issues of GIs it is precisely at this level that we must start.

WHERE CAN WE GO FROM HERE?

The European Commission wishes to see all WTO members adopt the EU system of Geographic Indications.[6] They want an almost exact replication of the EU system to apply everywhere; everyone will have to produce a catalogue of registered GIs. For other countries this is seen as tantamount to foodie-imperialism and will require a number of existing trademarks to be rescinded and indeed will require a number of established players to rename their existing products.

What is clear is that the manner in which the European GI regulations are structured is antithetical to normal practice in non-agricultural markets. Granting consortia of companies a monopoly on a certain product with the right to restrict entry and production is a rare beast outside agriculture. The fact that the Commission have extended the powers of these consortia to cover even how the products are retailed shows just how far from normal reality the GI standards within the EU have strayed. Of course a good deal of this depends on the market definition one uses for GI products. Here we have the GI bodies themselves to rely on. The handy rule of thumb in market analysis is that we need to look at the market that the firms are trying to monopolize before worrying about the strict market definition. The Parma ham consortia are seeking to monopolize Parma ham production, not all thinly sliced ham, which they themselves would argue is a different sort of product. The feta cheese firms are not trying to monopolize all cheese production, just feta production.

If there were no general exemption for agricultural produce under Regulation 26/1962 we would be able to test the individual requirements of the GI consortia by normal competition rules. We would be able to see whether a particular GI standard provided a fair share of benefits to consumers and whether the rule was indispensable to the attainment of the goal. In many ways it is this latter test that would be most interesting to run the GI standards by. It would not be too difficult to argue that consumers gained a fair share of benefits if product quality was maintained or improved. Of course this would need to be balanced against price rises and exclusion of existing firms. However, given the nature of the consumer share test in Article 81(3) we would not expect that to be a stumbling block.

The indispensability test would probably provide the most interesting element of any analysis of the applicability of competition law to GI consortia. This test would allow any competition authority to look closely at the rules of consortia to see if they are indispensable to attaining the goal of protecting the quality and provenance of a particular GI.

One could easily imagine that the following restrictions would not pass any indispensability test; production limits, membership or entry limits providing quality standards are met, self-regulation by existing members of a consortia, sales practice regulation or regulations that dictate where a product is cut or grated.

For example, the restriction on where Parma ham can be sliced would be hard put to pass an indispensability test. In a newspaper article following the Parma ham ECJ case a journalist from the *Sunday Telegraph* reported that: 'As he spoke, hams which had been cured for at least 12 months were being whisked into a machine which sliced each block into 60 slithers of ham, yielding 2000 packets an hour.'[7] It is difficult to believe that machine-slicing a product is an artisan skill only held in Parma or a skill that cannot be easily transferred to a venue away from Parma. Would having the ham sliced in Leeds really make Parma ham any less Parma ham; is the restriction indispensable to maintaining quality? In front of a competition regulator rather than a judge reading intellectual property law written especially for the purpose it is unlikely that such a measure would stand up.

The indispensability test would allow regulators to ensure that GIs were actually designed to protect the consumer rather than afford a small group of producers the opportunity to control a marketplace. If we could apply normal competition rules to claims for GIs then we would be some way to limiting their anti-competitive impact. If this were done then any attempts to apply such rules internationally could be received with less cynicism.

Such a system would also enable regulators to separate out products with a real geographic link and those where the link is artificially transplanted to enable producers to restrict the market. In short a means to tell Roquefort

from Feta. We need, however, to address other problems; the existence of disparate national food cultures, often from the same base; and secondly, the appropriation of geographic indications by producers in countries beyond the geographic region indicated.

If we accept that different nationalities have different food cultures, and further that many of these cultures are adapted forms of food cultures exported with emigrant populations, then the need to unify global food designations appears less significant. However, it is entirely legitimate for countries and their producers to seek review of any geographic indication, no matter how registered, in a foreign country, which is misleading.

Under a number of existing consumer protection laws producers are required to place a geographic designation on their products if there is a geographic component or association with their product that they are seeking to trade on. Thus one can buy Danish mozzarella or, until recently, Yorkshire feta. Consumers were not misled and were able to distinguish the 'real' from the 'pretend'.

There are also a number of provisions in domestic trademark laws that allow challenges to occur to existing trademarks. The issue in such jurisdictions tends to rest on whether a term is generic for those countries. It is difficult to argue that for American consumers the term mozzarella or feta, or indeed champagne, is anything other than generic. The immigrant food culture for these products has since evolved on a different path to that of the 'old' country. For those consumers Wisconsin is the home of cheese, not France or Italy, or even Greece. Is it reasonable, from a US consumer point of view, for a foreign producer to demand the relabelling of all 'their' home-produced products and have them replaced under the recognized name with products they do not recognize?

A situation where different groups of consumers value products differently would tend to be one suited to a market solution, rather than a regulatory one. If Greek feta is of a higher quality than US feta, then let the US consumer decide which to value more. If they choose domestic over foreign feta, is there any real loss?

However, we still face the second problem, namely that of trademark registration or geographic claims made without qualification. One can argue that geographic claims require some form of unification across the world to encourage trade. While this argument is largely theoretical there is an argument that we need to find a means to allow easier challenge of trademarks granted to products clearly from beyond the borders of the country concerned.

If we can change the GI process to make it more consistent with competition rules and law, then we are in a stronger position to deal with our second problem of inappropriate trademark registration. However, here

one has to ask the question about the relevant and appropriate tool to solve the problem. If different countries register trademarks for producers on the basis of their own food cultures, one would expect divergence. It is probably unreasonable for individual producers or consortia to police the global market for trademark registration. However, it would also appear that GIs are not a good candidate for upward harmonization (given the competition and cultural issues). It would thus appear a poor candidate for WTO inclusion. However, given the existence of the World Intellectual Property Organization (WIPO) we have a ready-made forum for registering all GIs and providing a forum for negotiation between member states regarding what may appear to be inappropriate registrations.

CONCLUSION

The claim of geographic indications for inclusion in the WTO system of trade regulation is a weak one. The initial weakness comes from the simple fact that different countries have different food cultures, complicated by the fact that many have come from the same source, Europe, but have followed different paths. The weakness is compounded by the design of EU GI regulations which eschew normal competition analysis and encourage anti-competitive behaviour by GI owners. The combined weakness is topped off by the lack of evidence of a global problem of such magnitude that a WTO solution is optimum.

If we are to reduce tension of the GI issue we must deal with each weakness in turn. The divergent food culture issues will essentially stop any global system in its tracks. The all-encompassing EU approach cannot work in other countries, and indeed it is arguable, following the feta case, that it works in the EU. The competition weakness is really the core problem that needs addressing. The current EU system encourages anti-competitive behaviour by fostering cartel behaviour. The exemption of agricultural products and cooperatives is fundamentally flawed and rests on a conception of agricultural markets that is both wrong and Panglossian. If Europe wishes to gain credibility for its system it must dismantle the blanket protection for anti-competitive behaviour in agriculture and fundamentally alter the activities of many GI-owning bodies. Removing unnecessary requirements, such as controls on where products are sliced and how they are sold, will improve the deserving GIs while removing those that are simply attempts to restrict markets.

Even if we can make the GI system more competitive we are struck with the issue of the scale of the GI 'problem', or whether we are actually dealing with the correct problem in the first place. The EU has managed to collect

a small coalition of countries in favour of greater GI protection. It has done this by dangling the carrot of protection for perhaps one or two products for developing countries. In essence it has offered enhanced margins through global market restriction. It is likely that every country can find at least one product to place on a central register, alongside the many the EU have managed to develop over the years; but is this a WTO issue? The answer is yes, but not in the context the EU are arguing for it. It is not an issue of such import that the WTO should create any rules. The WIPO is far better placed to deal with the creation of a central register and the creation of a mediation process for disputed GI/trademark awards. However, the issue most definitely is a WTO one in terms of the wider agricultural trade liberalization talks. It is difficult to believe that the emergence of the GI issue is unrelated to the increasing pressure on the EU to open its market to more agricultural trade. As most GIs are by their nature higher up the value chain, the cynical could suggest that the EU is trying to sew up the higher value chain markets for its own producers by allowing other countries to provide it with agricultural produce, as long as they are low-value items. If one looks at markets such as textiles, then one clearly sees an attempt from EU producers to move up the value chain, only to be met by producers in other countries doing exactly the same thing. By creating a restrictive system of GIs that stops new entrant countries or industries producing products with recognizable names, the EU is simply trying to use regulation to restrict the higher value markets for its own producers. This is to the detriment of all agricultural exporters. Perhaps this detriment is not immediately apparent, but as their agricultural producers evolve and try to move into more high-value products then it will evidence itself more readily.

A global system that allowed the present anti-competitive nature of the GI system to impose itself globally would also be to the detriment of consumers in Europe and elsewhere. For every arguable case for a GI, like Roquefort, with a tradition of production and quality, we are lumbered with feta, claimed by Greek producers, despite its Italianized version (fetta) of the Greek word for a slice (pheta) and a product that has been produced in many countries.

The EU does not have a strong case, or indeed, almost any case for a WTO agreement on GIs. Their agenda must be resisted if we are to see European agricultural markets properly liberalized rather than balkanized. If the EU get their way they will open the low-value markets to trade while at the same time tying up almost any product name that means anything to Europe's consumers. The food imperialism of the Commission has, however, thrown light on the profoundly anti-competitive nature of the GI system and the exemptions given to agricultural markets. These agreements

must be reformed and placed under the full rigour of competition regulation. Once the anti-competitive nature and effect of these rules has been dealt with, then the Commission has a case to persuade WIPO to develop a central database and registration process which allows for a low-cost arbitration system to stop inappropriate or misleading GI trademark or registration schemes at the national level.

NOTES

1. For more detail on the origins of competition policy see F.M. Scherer and David R. Ross (1993), *Industrial Market Structure and Economic Performance*, Houghton Mifflin.
2. Wisconsin Center for Dairy Research, *Dairy Pipeline*, December 2003, Vol. 15 No. 4.
3. Wisconsin Center for Dairy Research, *Dairy Pipeline*, December 2003, Vol. 15 No. 4.
4. Official Journal B 30 of 20.04.1962.
5. Adam Smith (1982), *The Wealth of Nations*, Book I, Chapter X, London: Penguin.
6. For example see Communication from Bulgaria, Cyprus, the Czech Republic, the European Communities and their Member States, Georgia, Hungary, Iceland, Malta, Mauritius, Moldova, Nigeria, Romania, the Slovak Republic, Slovenia, Sri Lanka, Switzerland and Turkey: Negotiations Relating to the Establishment of a Multilateral System of Notification and Registration of Geographical Indications. Submission to a special session of the Trips Council TN/IP/W/3.
7. *Sunday Telegraph*, 25 May, 2003. 'Victory tastes sweet to the Parma producers A court ruling on the slicing and packaging of the ham has dismayed British supermarkets but delighted the Italians', reports Bruce Johnston in Parma, 25 May, 2003, Sunday.

Conclusion: placing IPRs at the heart of the public discourse

Meir Perez Pugatch

One of the most straightforward conclusions of this book is that there is no single conclusion – at this point of time – on the current system of IPRs. Nor was it the intention of this book to suggest that there can be one single conclusion or one view or one approach that we should adopt when studying the field. On the contrary, if there is one thing that this book does suggest is that the debates and dispute surrounding the IP filed have not been narrowed or toned down over time, but rather the opposite.

But this also means another very important thing: IPRs – even when not treated as such – have a very real and extensive effect on our lives, including those of us who are not familiar with the IP field. Regardless of the positive or negative views expressed in this book, the different contributors seem to suggest that IPRs touch upon many aspects of our lives, from the very basic elements to the most sophisticated ones. Evidently, IPRs have an impact on the foods that we eat, the medicines that we require and the entertainment that we consume. IPRs will have an effect on the availabilty of these products, their prices and their compositions. IPRs have become an inseparable part of our knowledge-based economies and the so-called information society. IPRs affect the way in which we evaluate, commercialize and utilize different knowledge products and informational services. IPRs are an important mechanism (some would add the term crucial) in the overall process of technology transfer. They affect the magnitude, pace and direction of the exchange of information and knowledge between those who create knowledge, those who produce knowledge, and those who consume it. Finally, IPRs have also become an international issue, often a celebrated one, concerning trade and investment agreements, as well being included in the discussion and debates on the effects of globalization and the north–south divide as a whole.

The book also leads to some structural conclusions that one may consider as worthy of perusing in future research and publications.

First, we need to develop a more general, as well as coherent framework, to discuss IPRs. The IP field has reached a stage of maturity. As demonstrated

in this book, the level of IP expertise is extremely high and the avenues of research are rich and diverse. However, thus far the IP field has not been conceptualized or framed in a manner that would define it as an independent field of study. This is not to say that IPRs do not receive enough attention. The numerous research institutions and programmes that are dedicated to the study of IPRs, as well as the increasing role of IP themes in academic and professional curriculums are indicative of their importance and vitality. Nevertheless, the field of IP is still being viewed as a secondary subject and is still typically linked to the more established fields of study. For example, students of the law will be exposed to some of the legal aspects of IPR; students of economics will learn about the challenges of applying economic principles to public goods in the domestic and international markets; political science and political economy students will undoubtedly find some facinating material in the goal-orientated behaviour of different IP interest groups; and accounting students will learn how to evaluate intangible assets as part as their standard valuation education.

But while this is perfectly understandable, it is also long overdue to develop a framework that will treat the IP field as a primary subject and that will collect and connect different themes of the IP field into a single field of study.

Secondly, and not unrelated to the above conclusion, we need to develop and implement a more clear-cut distinction between the IP field in general and the different forms of IPRs. This is not just a matter of terminology but also of substance. To some extent this is a new development in so far as the IP field has become larger than the sum of its parts. Today, the field of IP encompasses a range of economic, legal, political scientific and social forces that shape and influence specific forms of IPRs – patents, trademarks, copyrights, GIs, and so on. The IP field is broader, and perhaps even more complex, than any single form of IPR. It can also be argued, with a certain degree of conviction, that, today, the IP field is the plain upon which policy-making is taking place. Also, this policy-making has a different effect on different forms of IPRs and on the fields of technology within each form. For example, consider the case of patents. The challenges surrounding the patent system today are enough to fill in an entire book on this issue (and probabaly more than one). Each challenge is affected by a different set of factors, or at least represents a unique combination of factors and circumstances. For example, the challenges deriving from the issue of pharmaceutical patents are not similar to those deriving from the issue of gene patenting, and both are quite different from the debates over other other fields of technology, such as the patenting of computer implemented inventions in Europe or the tension between patent protection and antitrust. Certainly all of these challenges have some underlying themes in common, but each also generates

a different debate. In other words, we need to bear in mind that any certain debate on a certain aspect of a certain form of IPR does not represent the current status of the IP field as a whole. Therefore, we need to adopt a more general and comprehensive IP perspective.

Finally, and coming back to the beginning of this book – we to need to make the history of the IP field and of IPRs known! It is puzzling that despite the very long and rich history of discussions and debates in this field, we do not seem sufficiently to recognize their implications, insights and contribution to our present time. By neglecting to do so we tend to miss the crucial evolutionary path which the IP field has travelled. We also risk repeating some of the arguments that were raised in previous discussions and which were found to be partial, unsatisfactory or even flawed. Mostly, by the time the next wave of IP debates take place (perhaps in 50 years' time), we may find our debates and our insights completely omitted from the pages of history. After all, this is what Machlup and Penrose have warned us about.

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Legal cases and publications referred to in the text are in *italics.*