



Politics of Intellectual Property

Contestation over the
Ownership, Use, and Control
of Knowledge and Information



Edited by
Sebastian Hauns
Kenneth C. Shadlen

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In February 2007, when we proposed a workshop on the “Politics of Intellectual Property” for the 2008 Joint Sessions of the European Consortium for Political Research (ECPR), we did so with a great deal of uncertainty as to whether such an issue would interest enough social scientists. After all, until recently the group of scholars – outside of the field of law – working on this issue has been extremely limited. But, to our great delight, not only was our proposal accepted, but we ended up receiving significantly more submissions in response to our call for papers than we could possibly have accommodated with just 20 spots in the workshop. We interpret this response as an indicator that the social sciences have, at last, come to realize the salience of this issue.

The workshop that took place in April 2008 in the beautiful city of Rennes proved to be extremely productive and thought-provoking. For five days, participants from four continents and with various academic backgrounds engaged in stimulating discussions of each others’ papers. In fact, the daily sessions typically extended far beyond the formal meetings, as exchange would continue in the city’s bars and restaurants. A scholarly network was formed.

This book contains significantly revised texts from roughly half of the workshop’s participants. First and foremost we wish to thank the contributing authors, who have responded promptly and thoughtfully to comments, suggestions, and repeated requests for revisions on their texts. We also wish to express our gratitude to the participants at the Rennes workshop who are not included in this volume, for this project would not have succeeded without their contributions, criticism and ideas as well. We therefore would like to thank Moses Boudourides, François Briatte, Francesco Carnesecchi, Thomas R. Eimer, Patricia M. Goff, Bryn Gay, Annika Philipps, Carolina Almeida A. Rossini, and Peter Yu for their invaluable contributions to the workshop in Rennes and, by extension, this volume. We also wish to thank the ECPR for including our panel in the 2008 Joint Sessions and the support provided to us as panel convenors.

1. Introduction: rethinking the politics of intellectual property

Sebastian Haunss and Kenneth C. Shadlen

Information and knowledge constitute the building blocks of culture, industry, and science. We use this simple observation as the point of departure in this book, where we examine the politics of information and knowledge. How conflicts over the ownership, control and use of these building blocks are resolved has consequences that are of fundamental importance in our everyday lives and, on a more macro scale, in patterns of growth, prosperity and development in the global economy. The rules on how information and knowledge are owned and controlled affect how individuals and collectivities access and use cultural products, along with media and entertainment goods. Because rules on information and knowledge influence the terms by which actors can access critical information – and knowledge-intensive goods such as books, medicines, and seeds, they affect national strategies to reduce poverty, achieve food security, and protect public health. And by affecting patterns of technological development and diffusion and the distribution of the gains from technological change, rules on the ownership and use of knowledge affect national and international trajectories of economic development.

With the importance of these issues increasingly recognized, the past decade has witnessed a veritable explosion of literature on intellectual property (IP). Analysts have explained the introduction of new and stringent IP rules in the international trading system, focusing on the establishment of the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), subsequent conflicts in the WTO over the relationship between TRIPS and public health and biodiversity, and the introduction of IP in a range of regional and bilateral initiatives (Beigbeder 2004; Bessen and Raskind 1991; Correa 2000; Drahos and Braithwaite 2003; Drahos 2005; Hein et al. 2007; Klug 2008; Maskus 2000; May 2007; Pugatch 2006; Sell 2002, 2003; Shadlen 2005, 2007a; Shadlen et al. 2005). This immense body of research has both significantly advanced the academic attention to the topic of IP and greatly enhanced our understanding of the topic.

Seen from the vantage point of political analysis, however, and at the risk of oversimplification, the current literature suffers from two weaknesses. First, the field is overly generalized, with too much attention paid to the conflicts over international (global and regional) rules and legal provisions at the expense of analysis of what is happening within countries. Certainly, international rules, whether TRIPS or the IP provisions of regional and bilateral trade agreements (RBTAs), impose constraints on national policy and establish the parameters of what sorts of policies are permissible. Yet within these parameters the questions of how actors respond to external constraints and how countries go about implementing their externally-derived obligations warrant significantly more attention than they typically receive. The prevailing focus on the international arena and on external sources of IP policy change means that we still have little appreciation and understanding of these latter sets of questions.

Scholars and students who want to learn about the global politics of IP, such as the origins of the TRIPS Agreement and the integration of IP into RBTAs, have countless texts to choose from (for example, Drahos 1995; Ryan 1998; May and Sell 2005; Sell 2003; Maskus 2000; Correa 2000; Matthews 2002; Shadlen 2005; Watal 2001). Yet scholars and students looking for analyses of IP policy-making lack such resources. In addition, most studies focus on national and international IP laws. But while laws are the solidified results of social struggles and political conflicts, understanding the law itself tells us little about the social processes that lay behind laws and even less about the social dynamics that will eventually challenge and often change them. Laws establish opportunities for action, and strictly legal perspectives in most cases say little about different actors' motivations and capacities to exploit these opportunities and how the motivations and capacities change over time (Shadlen 2007b). It is time, therefore, to reorient analysis of the politics of IP to the processes by which conflicts over the ownership, use, and control of information are manifest and resolved in regional, national and sub-national settings.

A second – and arguably more problematic – weakness of the field is that it is insufficiently theorized in a political sense: not enough attention is given to how the politics of IP may be informed by distinct dynamics and logics. Analysts of the politics of IP typically treat the issue area like any other area of political analysis: we identify actors' conflicting interests and study how these conflicts are resolved. Of course, the processes of interest formation, alliance building, and political mobilization are key aspects of politics. The analytic challenge is to see how these processes are (or are not) different when the conflicts in question are over ownership, control, and use of knowledge and information. Indeed, for most economic and legal scholarship on IP, the fundamental characteristics of knowledge and

information serve as the starting point. That is, because knowledge and information – the underlying entities that IP converts into property – are non-rivalrous and inexhaustible, or because they are typically the result of multiple producers’ efforts over considerable periods of time, or because the nature of innovation is such that it is difficult to distinguish the inputs from the outputs in knowledge generation, or because they have extremely uncertain boundaries, scholars emphasize that the economics and law of IP differ from the economics and law of tangible “normal” property (Arrow 1962; Scotchmer 1991, 2004; Helpman 1993; David 1993; Merges and Nelson 1990; Boyle 1997; Hettinger 1989; Lemley and Shapiro 2005; Thambisetty 2007; Bessen and Meurer 2008). We believe that there are good reasons to assume that the specific characteristics of knowledge and information lead to a different sort of politics as well. At least there are good reasons to probe deeper and to examine in greater depth how and under which circumstances IP politics differs from other policy fields.

Building upon the substantial body of research on the politics of IP, this book begins to address these shortcomings. The contributions discuss how rules governing the ownership, control, and use of knowledge and information are made and implemented. The authors focus on distinct areas of contestation, identify the relevant actors and the processes by which collective actors come to be, their modes of interest and preference formation and strategies of political mobilization, and analyze the mechanisms of resolving disputes between actors with conflicting interests. Importantly, the authors attempt to show where and how these processes – the basic ingredients of politics – appear different in the area of IP; and they do so with empirical studies of conflicts about the governance of information and knowledge from the developed and developing world. In this introductory chapter we present some initial and exploratory thoughts about what a more theoretically-grounded approach to the politics of IP might look like, and we provide an overview of the subsequent chapters.

KNOWLEDGE, INFORMATION, AND POLITICS

A distinguishing feature of the politics of knowledge and information is that the separation between the spheres of production and consumption is usually weak and sometimes non-existent. In processes of knowledge production, inputs are transformed – but usually not in the way tangible inputs are transformed in processes of industrial production. The scientific knowledge that is used in research projects is not fundamentally different from the knowledge that is produced in this process. Nor are there categorical differences between the knowledge authors and musicians draw

upon and the books and music that are the product of their labor. These observations are not meant to deny that new knowledge is generated, nor to negate actors' inventive and creative contributions. Yet in contrast to industrial production processes, where for example ore is transformed into iron which is then transformed into a street sign (to consider one basic segment of a single production chain), there appears to be little if any corresponding categories of raw material (such as ore), intermediate input (such as iron), and final product (such as street sign) in the process of generating scientific or cultural knowledge. The conversion of ore into iron and iron into our street sign fundamentally transforms the inputs, and additional industrial processes would then be required to restore them to their previous states. That is not the case in knowledge production: producers of knowledge are also users of the same types of knowledge. The raw materials that contribute to new music and literature are the same ideas and forms of expression that already-existing music and literature consists of; likewise, generating new computer software entails increasingly complex machinations of zeros and ones, but at the end of the day we are still left with zeros and ones. Here the notion of prosumers (Toffler 1980) is not an empty phrase but a social reality that fundamentally structures the policy field. This is true for the biochemical knowledge used to make medicines too.

The relationship between consumption and production described above appears quite different if we take into account the actual industrial processes that are used to produce tangible goods based on knowledge and information. Printing and binding forms of expression, producing CD-ROMS and DVDs, and manufacturing medicines based on biochemical knowledge, for example, all yield outputs that are fundamentally different from their inputs; and this form of industrial production does require a distinction between users and producers, as the former rarely have the capital and equipment to undertake industrial production on a commercial scale. Yet these tangible products are the delivery containers, not themselves the protected IP, and the need for capital and skills to produce the delivery containers is conditional on the prior existence of the underlying knowledge and information. To be sure, in some areas the delivery vehicles themselves have changed, so music and software can be distributed without tangible CDs and DVDs. Yet even these changes entail processes of physical and industrial transformation, such as the creation of the necessary broadband infrastructure, and these industrial transformations are separate from – and subsequent to – the transformations of the knowledge and information that yield the underlying information content. In the case of knowledge and information themselves, the lines between inputs (consumption) and outputs (production) are remarkably blurry.

It is not just the blurry borders between inputs and outputs that distinguish knowledge and information, but also the additive relationship between inputs and outputs. We know that one person's use of knowledge and information does not affect the amount available for others to use; that is, the consumption of knowledge and information is non-rivalrous. But it is more than that: the use or consumption of knowledge and information can actually increase – and not reduce – the stock of knowledge and information. Not only can knowledge and information be consumed without affecting its availability for others, but its consumption, in turn, generates more knowledge and information. Pupils and students in schools and universities do not “use up” the knowledge and information that is delivered to them. On the contrary, teaching creates more (of the same and sometimes even new) knowledge without diminishing the stock of existing knowledge. Thus, knowledge and information are not like the lighthouse that can be used by every ship off the coast; they are more like a lighthouse that, once built in one place, can provide orientation for ships off each and every coast.

These observations have profound implications for IP politics. On the one hand, given the breadth of user communities, we may expect to see broader and more fluid constituencies for IP rules that facilitate the use of knowledge and information. We may therefore expect to see unusual coalitions which will nevertheless be confronted – because of their fluidity, size, and dispersion – with familiar collective action problems. We may on the other hand expect the constituencies for restrictive IP to be fairly narrow, and therefore better able to advance their cause, an expectation that appears well supported by the many studies of industry-based mobilization during the TRIPS negotiations (for example, Drahos 1995; Ryan 1998; Matthews 2002; Sell 2003). But since we witness in some issue areas surprising outcomes of intellectual property conflicts, a closer look at the collective action dynamics is necessary (Haunss and Kohlmorgen forthcoming).

An additional and related implication of the intangible character of knowledge and information is that political conflicts over IP tend to be prone to dynamics of increasing returns. The beneficiaries of strong IP policies accumulate resources that allow them to press for further strengthening, and institutions created to implement and enforce IP tend to push in this direction as well, while those actors who are disadvantaged by strengthened IP systems often experience diminished capacity to mobilize for reforms that would loosen IP rules and facilitate use. Strong IP systems are therefore likely to generate a comparatively small group of winners who profit significantly and, in turn, have a strong interest in maintaining and further strengthening the system. In addition to what is

well known about industrial actors in biotech and content-based sectors, other especially interesting actors in this respect are patent professionals and university administrators/scientists. The former generally profit from stronger IP regimes that guarantee increased incomes, while the latter may perceive stronger IP regimes as presenting opportunities to make scientific research more profitable or may perceive them as constraining university budgets and limiting the freedom of academic research.

These dynamics are addressed by a number of authors in this book, whose chapters show in particular that opposition to restrictive IP policies is often strongest when these policies generate *immediate* negative material effects. Rising costs of medication as a result of stronger IP laws and the ensuing mobilization and resistance are one example of this phenomenon. Yet episodes of mobilization tend to be facilitated by particular conjunctures of actors and events that are far from automatic. Building and sustaining alliances to reform IP laws are extraordinarily complex and difficult processes. Indeed, many of the chapters in this volume focus on patterns of collective action in IP politics, and in particular how users and owners of knowledge often exhibit very different – and asymmetrical – patterns of political mobilization. They especially pay attention to unexpected alliances and patterns of mobilization around IP, and in doing so reveal the limitations of general mechanisms for understanding the increasingly contentious politics of IP. In Europe, for example, software programmers were able to mobilize mass protest against a project to reform patent law while consumers were unable to do so with regard to copyright enforcement.

The immaterial character of knowledge and information also makes policies that aim to restrict the use of knowledge by establishing IP and enforcing IPRs immensely challenging and thus dependent on significant regulatory efforts and expense. This unavoidable feature of IP, of course, means that the gaps between laws and reality are often immense. While analysts may be focusing on the former, actors' interests and political strategies are shaped by the latter, leading, again, to unexpected patterns of behavior. The high visibility and efforts required to enforce IP also give importance to framing processes. To the extent that restricting access to knowledge is framed as a necessary precondition to innovation and improving economic welfare, the costs and efforts of doing so may appear justified. Yet if exclusion from knowledge is framed as an obstacle to innovation, cultural flourishing, and economic development, then the costs of doing so may be more easily targeted by opponents. It is precisely for this reason that so many of the chapters in this volume focus on the process of framing and the role that epistemic communities play in altering the boundaries of IP politics.

CHAPTER OVERVIEWS

The book begins with four chapters that explore a range of conflicts over the ownership, use, and control of information and knowledge in the developing world. Kenneth Shadlen examines two sets of conflicts over patents that have emerged in most developing countries in the aftermath of the TRIPS agreement. Most governments have faced pressures to modify aspects of their IP systems regarding pharmaceutical patents, and at the same time most governments have also faced pressures to modify aspects of their patent systems more broadly related to science, technology, and innovation. In both realms we witness cross-national variation in terms of outcomes, and Shadlen's chapter points to both the cross-national differences and, moreover, over-arching cross-national similarities in the two sets of conflicts. The findings in his chapter, based largely on three Latin American cases, have broad implications for processes of interest formation and political mobilization. In particular, Shadlen emphasizes fundamental asymmetries, how beneficiaries of patent systems tend to mobilize more than those who are disadvantaged, and among the disadvantaged how resistance tends to be stronger in areas related to health and drugs than in areas related more broadly to technology, innovation, and economic development.

Gaëlle Krikorian offers one of the first in-depth political analyses of a country exploiting the flexibilities available under the TRIPS agreement. Krikorian shows how, despite an adverse global setting, Thailand issued compulsory licenses on a set of patented medications. Her chapter demonstrates the importance of understanding how political opportunity structures affect the ability of different actors to participate in and influence outcomes in conflicts over IP. In particular, Krikorian focuses on the role of the Thai Ministry of Health and health-oriented civil society organizations (CSOs), and how the government–CSO alliance was able to overcome the intense opposition of the transnational pharmaceutical sector and trade officials from the European Union and the United States of America. Krikorian's analysis has a counter-intuitive finding in that a military coup served to help CSOs advance their demands on the state to issue compulsory licenses. By focusing on the politics of CLs, the chapter also points to the limitations of work that emphasizes legal dimensions *per se*, for the real question in the Thai case was not the legality of the CLs but the country's ability to exploit its legal prerogatives. Though writing of a “successful” case, Krikorian's conclusion is decidedly less optimistic: if so many factors and conditions must come together in just the right way to make issuing CLs feasible, it would appear that the “effective political flexibilities” of the TRIPS agreement are significantly less than the agreement's formal legal flexibilities.

Ronald Herring and Milind Kandlikar's chapter on the politics of Bt cotton in India illustrates how the capacities and interests of state and non-state actors involved in conflicts over control and use of technology can be significantly more complex than suggested by conventional wisdom. The analysis points to the fundamental limitations of states' abilities to control biotechnology, and the unexpected distribution of the gains from technological innovation that may obtain in such a setting. In general, one output of government efforts to control biotechnology are biosafety regulations that slow authorization for legal use of transgenics. As Herring and Kandlikar explain, biosafety regulations can be functionally equivalent to IP regulations, in that both restrict the range of actors that can participate in technology markets. In the case of Bt cotton in India, however, biosafety restrictions have been routinely bypassed by a wide range of rural actors (entrepreneurs and farmers) that created a vibrant market for "stealth seeds". The rise of these markets and the subsequent widespread use of "stealth seeds" represents a clear case of the use of technology outpacing the regulatory terrain. Moreover, the proliferation of stealth seeds not only presents farmers with unexpected opportunities to appropriate the benefits of technological innovation but also creates new alliances of actors that demand revised biosafety regulations.

Sabil Francis's chapter on the control and use of traditional knowledge illustrates the limitations of conventional political and social categories, as well as unexpected patterns of political mobilization. As Francis shows, western concepts of ownership are unable to capture the complexities involved in analysis of traditional knowledge. Using the arogyapacha case, he shows how even well-meaning benefit sharing agreements reach their limits because the concept of intellectual property assumes a clear attribution of ownership and relies on national institutions to administer the rights. Traditional knowledge often cannot be easily attributed nor are its holders necessarily concentrated in only one national territory. Yet assigning rights to traditional communities requires that someone "speak for the tribe". Thus, Francis's chapter shows how the adoption of IP by indigenous communities necessarily creates the actors needed for the IP system to function properly, and thereby invariably changes the dynamics within local communities.

The next two chapters focus on the discursive level of recent conflicts about intellectual property rights in Europe. The authors analyze how the meaning of intellectual property is established and re-interpreted in framing processes, and how collective actors sharing a common interpretation of the issues at stake and sharing a collective action frame guiding their activities are created.

Sebastian Haunss and Lars Kohlmorgen analyze two contemporary IP conflicts in Europe, one regarding the patenting of software and the other regarding the enforcement of copyrights. The authors utilize a framing approach to explain why seemingly “weak” actors from small and medium-sized enterprises and civil society were able to prevail over a broad coalition of extremely resource-rich business interests in the case of software, while civil society actors were unable to provide significant opposition against the music industry in the case of copyright enforcement. Haunss and Kohlmorgen’s focus on discourse and framing points to the processes by which collective actors in IP conflicts are created and to the strategies that actors use to politicize ostensibly technical issues. These framing processes, the authors show, can have enduring effects on IP politics by reconfiguring constellations of actors who participate and the balance of power and influence among relevant actors. Indeed, similar processes of framing and politicization are evident in many of the IP conflicts analyzed in this book.

Ingrid Schneider analyzes the framing processes surrounding the introduction of biopatents in Europe. She shows how the involvement of non-governmental organizations and the European Parliament altered prevailing perceptions of biopatents from technical to political issues. This politicization changed the public perception of responsibility for this issue. Framing biopatents as an ethics issue brought in the parliament as an political actor, sidelining patent lawyers and technicians in the patent offices that had traditionally been perceived as being responsible for patent issues. Schneider shows how initially a frame that presented biopatents as an ethical problem managed to gain currency in opposition to industry’s alternative frame that presented patents on biological material as a strictly economic issue. But in a subsequent – and unexpected – process the ethical frame was adopted by biopatent supporters to advance their interests in a second round of the conflict.

In contrast to other chapters’ emphasis on agency and framing, Lars Bretthauer’s chapter on the politics of copyright in the Germany movie industry provides an explicitly structural perspective. Bretthauer explains how the reconfiguration of laws regulating this sector, in particular the strengthening of copyrights for digital media, is the consequence of strategic imperatives established by a neoliberal approach to seeking national competitiveness. Against the hegemony of neoliberalism, actors projecting and proposing alternative approaches to digital copyright were unable to articulate alternatives successfully. Yet Bretthauer’s analysis also points to the cracks in the hegemonic model: the widespread practice of on- and offline sharing of digital movies, the discussion on a so-called “culture flat rate”, and the provisions strengthening authors’

rights against production and distribution rights show how IP issues are embedded in ongoing social conflicts about the shape of the knowledge society.

The book closes with two contributions that take a more detailed look at patenting practices and the patent system. Hazel Moir presents an empirical analysis of the users of the patent system in the US and Australia. Drawing on data on patent applications, grants, and renewals, she shows that patent ownership in both countries is highly concentrated among a small group of companies owning hundreds or even thousands of patents whereas the large majority of patentees own only a handful of patents. Her finding that the overwhelming majority of benefits of the patent systems accrue to a tiny minority of the actors involved challenges the notion that patents serve “industry” as a whole – not to mention the effects on society more broadly. Indeed, Moir makes a valiant effort to evaluate the effects of the patent system on “patent losers”, an exceedingly difficult empirical exercise that is rarely done.

In the concluding chapter, Sivaramjani Thambisetty draws our attention to the tendency of patent systems to be subject to processes of increasing returns. In doing so, Thambisetty wed the literature from law (and a substantial amount of case law) with recent literature from political science that points to how actors that accumulate resources under given policy arrangements can use their gains to secure additional benefits, thus creating dynamics marked by self-reinforcement and increasing returns. Her insight is that patent systems have a set of attributes that make them very much subject to such processes, and she provides analysis of the doctrinal and institutional factors that underpin the propensity toward ever-expanding and ever-increasing IP rights. Thambisetty focuses on a particular set of mechanisms that perpetuate processes of increasing returns, such as the overlapping authority of courts, patent offices and other specialized IP agencies, and the idiosyncrasies of legal doctrines in the US and the UK. She also explains a critical asymmetry in patent law, that on the one hand there is a tendency toward issuing patents and allowing litigation to correct for errors in patent examination and granting, but on the other hand there are inherent biases against litigating (such as costs and inability to appropriate the benefits of successfully invalidating a patent). Together, these processes of self-reinforcement and increasing returns have been driving forces behind the continuous expansion of the breadth and scope of the patent system in recent decades. Her analysis contradicts the conventional wisdom that the expansion of the patent system would be rational from an economic perspective and points to important and so far overlooked internal dynamics of the legal system.

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2. The post-TRIPS politics of patents in Latin America

Kenneth C. Shadlen

National policies toward intellectual property (IP) underwent substantial transformation in the 1990s, as countries adopted new systems to conform to the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS-style IP regimes make patents available for more types of knowledge, grant long periods of patent protection, and endow patent-owners with strong rights of exclusion.

In this chapter I examine two different types of political mobilization and pressures for change that newly-introduced, TRIPS-style regimes became subject to by the early 21st century. Most governments have faced pressures to modify aspects of their IP systems regarding pharmaceutical patents.¹ Though the outcomes of this mobilization are not uniform across countries, the common thread has been for governments to address the consequences of stronger patent protection on the price of medicines and access to drugs. At the same time, most governments have also faced pressures to modify aspects of their patent systems more broadly related to science, technology, and indigenous innovation. Here too we witness cross-national variation in outcomes, but all around a common theme of trying to strengthen local actors' capacities to take advantage of the incentives of patent protection and creating new regulatory frameworks to link publicly-funded scientific research with private industry.

These two trajectories of mobilization and change in the areas of drugs–health and science–technology–innovation (STI) are somewhat contradictory: the first trajectory is about *reforming* the now-regnant systems of IP management, as debates in the case of drugs–health are about limiting the extent and strength of pharmaceutical patents; the second trajectory is about *reinforcing* the new systems, as debates in the case of STI are about extending more rights of private ownership over more types of knowledge. Or, to put it most simply, the utility of private rights of exclusion as tools for disseminating knowledge is questioned in one realm and buttressed in the other.

The different patterns of mobilization and policy change around TRIPS-style IP regimes prompt a set of puzzles that are the focal point of this chapter. Patent regimes that restrict the use of knowledge would seem to be of questionable appropriateness for developing countries, far removed from the technological frontier. Most experiences of national development have relied on domestic actors benefiting from minimal restrictions on their access to and rights to use cutting-edge knowledge and technologies. These hallmarks of late development – cultivation and refinement of indigenous capacities via imitation, reverse-engineering, and adaptation of foreign knowledge and technology – appear to be greatly circumscribed by TRIPS-style regimes that erect barriers on the use of knowledge by granting strong rights of exclusion to patent-holders (Kumar 2002; May 2007).

Yet, surprisingly, new patent regimes that restrict the use of knowledge have generated fairly robust constituencies for continuity and extension. In contrast to other studies that report broad-based and robust mobilization around “access to knowledge” (see Kapczynski 2008), my research on the post-TRIPS politics of patents in Latin America reveals that opposition is more the exception than the rule. Indeed, to the extent that pressures to limit patent rights have emerged, the counter-TRIPS (or “A2K”) mobilization tends to be rather narrow and limited, oriented primarily (if not exclusively) toward humanitarian dimensions of IP (such as health-drugs), rather than more traditional issues of technological transformation and industrialization (such as STI).

I explain this puzzling set of responses to TRIPS by examining how different policy arrangements generate and mobilize interests for continuity and discontinuity. I focus on how policy interventions strengthen and weaken interests, thus creating positive feedback and minimizing negative feedback, respectively. By strengthening interests I refer to the beneficiaries of a policy accumulating resources, which they can then deploy in the quest for continuity. By weakening interests I refer to those actors who are negatively affected by a policy losing resources and thus experiencing diminished capacity to mobilize in search of discontinuity. These different trajectories of interest mobilization make some sorts of policies more (or less) resilient than others, and thus more likely to undergo reinforcement (or reform).

In this chapter I use the notions of strengthening and weakening interests as analytic tools to examine the post-TRIPS politics of IP, with a focus on Latin America’s three largest and most industrialized economies (Argentina, Brazil, and Mexico).² TRIPS-style regimes strengthen interests and thereby are effective in generating self-sustaining constituencies. For the most part TRIPS-style regimes also weaken interests and thereby are effective in minimizing opposition. Distinguishing between

Table 2.1 Reform and reinforcement in Latin America

| Wave | Nature of change | Countries |
|---------------|---|---|
| Reform | Pharmaceutical patents and drugs <ul style="list-style-type: none"> ● Address public sector’s ability to secure price reductions on patented medications ● Regulate generic drug market | Late 1990s–early 2000s <ul style="list-style-type: none"> ● Argentina: 2002–03 ● Brazil: 1999–2003 ● Mexico: 2003–04 |
| Reinforcement | Science, technology, and innovation <ul style="list-style-type: none"> ● Encourage public-sector patenting and licensing ● Increase university–industry linkages | Early 2000s <ul style="list-style-type: none"> ● Argentina: 2004 ● Brazil: 2004 ● Mexico: 2002 |

the contemporary politics of IP in the realms of health–drugs and STI, however, reveals slightly different patterns. The process of weakening actors has been less pronounced in the realm of drugs–health: coalitions for discontinuity emerge, and these coalitions yield political mobilization for reform. In the realm of STI, in contrast, the strengthening of interests in favor of TRIPS-style IP has been complemented by the weakening of opposing interests: the combination of these two processes means that the winners get stronger and the losers dissipate, resulting in reinforcement.

One result of these different trajectories has been that patent policy in the area of health–drugs underwent reassessment in each country in the late 1990s and early 2000s. Though resolved differently, in each country questions of how pharmaceutical patents affect the price of essential medicines gained prominence on the political agenda. Another result of these different trajectories has been that each country has introduced changes to STI systems based on increasing domestic patenting, tightening links between public sector research and commercial enterprises, and encouraging licensing of publicly-funded research outputs. Again, the changes vary from country to country (and not all the changes regard patents and IP), yet the overall thrust, common across countries, is to amplify the role of patents and licensing (that is, private ownership of knowledge) as mechanisms to encourage innovation and technology transfer. Table 2.1 provides a simple overview of the two divergent trajectories, indicating the nature of the changes introduced and the rough dates in Argentina, Brazil, and Mexico.

STRENGTHENING INTERESTS UNDER TRIPS-STYLE PATENT REGIMES

Although the appropriateness of TRIPS-style regimes for developing countries is widely questioned, they nevertheless appear to generate significant positive feedback and thus build coalitions for continuity. What makes this possible are the mobilizing effects that TRIPS-style regimes have on actors that benefit – or regard themselves as potentially able to benefit – from the new arrangements. Five relevant sets of actors are foreign investors, state officials, local exporters, IP lawyers, and local patenting and scientific communities. Let us examine each in turn.

Foreign investors benefit from and endorse the new TRIPS-style regimes, which make patents available for more types of knowledge and strengthen patent-holders' rights of exclusion. The primary beneficiaries are firms in industrial sectors that had previously been unable to obtain patents (for example, chemicals, pharmaceuticals, foodstuffs, agro-biotech). This will come as no surprise, as we know that US, European, and Japanese firms in these sectors with concerns over the protection of "their" IP in developing countries were the principal drivers of TRIPS in the Uruguay Round (Drahoš 1995; Matthews 2002; Sell 2003). Yet the constituencies for continuity are not limited to these industrial sectors. Foreign investors' support for the new patent regimes tends to be more widespread, notwithstanding studies that reveal differing degrees of importance that IP rules have on TNCs' location and investment decisions (for example, Mansfeld 1986).

We can appreciate this breadth of support for TRIPS-style regimes by observing patterns of political mobilization of trade associations and interest groups representing foreign investors. To be sure, the associations representing transnational pharmaceutical firms (such as AMIIF in Mexico, CAEME in Argentina, INTERFARMA in Brazil³), for example, are outspoken and enthusiastic members of coalitions for continuity, supporting the new IP regimes and calling for more resources to be allocated to IP administration and enforcement; but no less active are the explicitly multi-sectoral American Chambers of Commerce. One might expect multi-sectoral associations to be agnostic, or at least somewhat nuanced and tempered, on the topic of IP, since the higher prices that local consumers pay for investors' IP-protected goods in one sector may diminish demand for investors' goods and services in other sectors where IP is less significant, but such inter-sectoral conflicts appear to be overriden by a more general conviction that the introduction of regulations offering more and stronger patent protection is indicative of a propitious environment for investment across the board. Thus, far from leaving the local pharmaceutical and biotech associations to defend their own turf,

associations such as the local Amchams continue to make IP a high priority and are critical in mobilizing foreign business communities in support of TRIPS-style policies.

TRIPS-style regimes generate positive feedback within the state too. As expected, IP officials tend to support the new systems and the dedication of additional resources to their departments and offices. And to the extent that IP affects the investment climate, which in turn affects inflows of foreign capital, the coalition of supporters comes to include those ministries and state agencies concerned with investment.⁴ Indeed, as having “modern” TRIPS-style IP essentially becomes a criterion for a country’s membership of the global economy, the advocates for continuity include a broad array of state officials involved with integration and external affairs who have come to regard increased (and increasing) IP protection as appropriate. We might expect finance ministries to be wary of arrangements that raise the costs of many goods (and thus are inflationary) and compel use of foreign exchange for royalty payments and licensing fees (and thus affect the national balance of payments), but in country after country finance ministries offered enthusiastic support for implementing TRIPS-style arrangements and, moreover, opposed efforts to reform such systems.

Among societal actors, important sources of positive feedback come from local exporters. For exporters, more and stronger IP protection is the price to be paid for secure access to critical export markets. This effect is a consequence of how IP was integrated into the global trade regime, in particular the inclusion of TRIPS in the WTO and the inclusion of IP in regional and bilateral trade agreements (RBTA). In order to have most-favored nation (MFN) access to US and European markets (under WTO) or better-than-MFN access under RBTA countries have to increase and maintain high standards of IP protection (Shadlen 2005, 2008). What this linkage and subsequent IP-market access trade-off accomplish, concretely, is to broaden and enlarge the coalition of actors who are supportive of more and stronger IP by including exporters. Exporters in many light-manufacturing sectors, for example, are unlikely to have an interest in IP policy, particularly as regards patents. But, to the extent that their access to the US and European markets depends on national IP practices, they become intensely concerned. In short, making market access conditional on the new IP policies can have the effect of transforming otherwise indifferent actors into IP proselytizers and enthusiastic participants in coalitions for continuity.⁵

The support of local IP attorneys for TRIPS-style regimes requires little explanation. Most professional IP attorneys favor more IP. After all, most IP training is about protecting IP, and more IP means more clients, foreign

and national. This is not to say, of course, that all IP attorneys and lawyers share this disposition, and in each of the countries I research I have found “public interest” patent lawyers that defend knowledge users. Yet these lawyers are minorities in each case. Local patent bars and associations of patent agents and patent lawyers are dominated by individuals with strong interests – intellectual and pecuniary – in the maintenance and expansion of IP. Legal journals published by local IP associations are strong supporters of the new IP arrangements. Indeed, in most developing countries, local IP attorneys were among the most – if not *the* most – outspoken domestic critics of pre-TRIPS IP systems. The changes introduced by TRIPS were welcomed, emphatically, and these actors are also enthusiastic and outspoken participants in coalitions for continuity.

Importantly, the TRIPS-style IP systems generate positive feedback among new societal actors too. Here the key is how local scientific communities come to defend the new systems. The introduction of new IP systems has, not surprisingly, been followed by increases in numbers of patents applied for by residents. The growth is absolute, not relative to patents by non-residents, which of course increases much more;⁶ nor does the rate of growth of residents’ patents match the rate of growth of non-residents’ patents. However, for the purpose of understanding the broadening of coalitions for continuity of new IP systems, it is the absolute growth of residents’ patents that most matters. If one examines data on applications to national patent offices made by countries’ residents, the growth throughout all of Latin American and the Caribbean from 1990 to 2005 is 70 per cent.⁷ In Argentina, in the six years after the new TRIPS-style patent law was introduced (1995–2000) the growth figure is 57 per cent; while in Brazil the rate over a similar time period (1997–2002) is 36 per cent.⁸ In Mexico, in contrast, the absolute number of residents’ patent applications shows little change since 1991, when the new TRIPS-style patent law was introduced. The coalitions for continuity include not just actual but also potential beneficiaries, such as scientists and innovators that envision their futures as patenting individuals or enterprises. Indeed, scientists (and science associations that articulate “sectoral” preferences and interests) appear to regard themselves as beneficiaries or at least potential beneficiaries under the new arrangements, and in each country I have studied they act accordingly by pressing for continuity.

To summarize, then, TRIPS-style IP regimes generate extensive positive feedback among actors in international business, the state, and local society. This positive feedback facilitates the growth of constituencies for continuity. Each of the preceding five snapshot summaries illustrates processes of increasing returns, whereby certain actors benefit from new policy arrangements, which in turn bestow these actors with resources that allow

them to mobilize in support of policy continuity. The upshot of increasing returns, then, is a tendency toward self-reinforcement in the area of IP.

WEAKENING INTERESTS UNDER TRIPS-STYLE PATENT REGIMES

Policy reinforcement is not complete, however, because of the mixed and partial presence of the other mechanism that is essential for reinforcement: weakening interests to minimize negative feedback. The issues of weakening interests and minimizing negative feedback are really questions of what disaffected actors (“losers”) do in response to new policy arrangements. In the case of IP, one response is for actors to adapt to the new regulations for using knowledge. Another response is for actors facing new rules and new incentives to disappear (that is, firms that cannot adapt close). Both responses, adaptation and disappearance, constitute “adjustment”. In both adjustment scenarios the actors who have material reasons to oppose policy stop resisting. Thus, the effect of the new rules is to weaken (if not eliminate) interests that initially presented opposition. However, not all losers adapt or disappear. A third possibility is that the disaffected remain active, demanding compensation and/or attempting to reverse the policy changes. The key point here regards the tendencies toward different types of reactions across realms of IP and sub-sets of actors.

It is in the realm of drugs–health where the third of the three responses – resistance – is most prevalent. Although some pharmaceutical firms have adapted to the new environment and changed their business models to operate in a world of patent protection, and plenty of others have simply ceased operations, most countries’ generic pharmaceutical industries retain the capacities to join coalitions of resistance to the new IP arrangements. Adjustment (adaptation and disappearance) tends to be slower in this sector, on account of how pharmaceutical patents were introduced. Developing countries had until 2000 to be in full compliance with TRIPS, and countries that did not offer pharmaceutical patents as of 1995 had until 2005 to begin doing so. And even where countries have pharmaceutical patents, opportunities for generic pharmaceutical and pharminochemical production continue to exist in older non-patented drugs.⁹

Few countries used the full ten-year transition period,¹⁰ and important differences remain as to when and how they introduced pharmaceutical patents. In Argentina patents on pharmaceutical products were not introduced until late 2000, so any drug that was in the public domain as of 2000 would continue to be in the public domain. Brazil, in contrast, introduced pharmaceutical patents in 1997 and offered retroactive protection to drugs

that were not yet on the market (that is, “pipeline patents”); yet even in Brazil, an “early” implementer in global terms, local generics producers remained sheltered from TRIPS throughout most of the 1990s, and they still could produce older, off-patent drugs. What this meant is that local pharmaceutical producers and their sectoral associations remained active, if on the defensive; they had not been “adjusted” out of political existence. Of the three Latin American countries discussed here, only in Mexico, which introduced pharmaceutical patents – including pipeline patents – as early as 1991, did something like a process of eliminating opposition through adjustment transpire.¹¹

More generally, moving from the pharmaceutical industry to the health sector as a whole, the demand for compensation and assistance can be understood as a function of the simple fact that adjustment in health is not a viable option. Most people in developing countries cannot “adapt” to the higher cost of medicines. Ceasing to use the technology is less of an option in the realm of health; actors in this sector cannot devise strategies to avoid using patented technologies when functional substitutes are absent. Patients who need drugs need drugs, or their conditions worsen and, in many instances, they die. They have to pay for the knowledge and technology, and if they cannot pay for it they lack alternatives. Of course, if those who could not get drugs died, they would cease to use the technology. This would clearly be a case of adjustment via “disappearance”, with policy arrangements weakening interests and minimizing (eliminating) negative feedback. But governments generally try to prevent this from happening, by providing health services. In fact, where the public sector provides health services it is the state, then, that feels the effects of stronger IP. So not only do the losers not go away via adjustment (neither adapting nor disappearing), but as government health bills grow, TRIPS-style IP regimes generate negative feedback in the form of health ministries facing exploding budgets on patented drugs.¹²

It is also worth noting that those negatively affected by IP in the realm of health can utilize the legal system. Patients can – and do – press their demands in courts, declaring that access to treatment is a human right or a constitutional right. Indeed, an important phenomenon that we witness in this period is patients groups and health-oriented non-governmental organizations becoming increasingly active and framing their demands in legal and constitutional terms (for example, Biehl 2007; Kapczynski 2008). When guaranteeing access to patented drugs becomes a constitutional obligation, governments may be pressed into action as well.

In sum, IP policies in the realm of drugs–health are marked by persistent negative feedback, and thus are *susceptible* to reform. I emphasize “susceptible” because reform does not look the same from place to place. In

Argentina the reform consisted of modifying a set of seemingly arcane legal provisions on preliminary injunctions in cases of alleged infringement of process patents in such a way as to favor local producers of patented medicines. In Brazil the reforms consisted of including the Ministry of Health in the examination of pharmaceutical patent applications and introducing a simpler system for compulsory licenses. In Mexico, in contrast, efforts to emulate the Brazilian approach to compulsory licensing backfired and ended up producing legislation that strengthened the rights of patent-holders (Shadlen 2009). The common thread here is that the existence of negative feedback kept the issue on the agenda and made health-related IP policy politically salient – but actual forms of resolution of these issues vary from case to case.¹³

In contrast to drugs–health, TRIPS-style IP regimes have weakened interests and thus minimized negative feedback in the area of science, technology and innovation. In this realm disaffected actors do tend to either adapt or disappear. Firms (and sectors) that in the past relied on easy use of knowledge either devised new business strategies to survive in the context of the higher cost of knowledge, or they avoided patented knowledge, or they cease to exist. Academics might still clamor about the effects of stronger IP protection on local firms' ability to use knowledge, but most local firms have stopped clamoring about it because those that still exist have figured out business strategies whereby they either pay for or avoid proprietary knowledge; and those that could not do so do not exist any more.¹⁴ Thus, within industry and science we witness little evidence of the third response: actors demanding compensation and seeking policy change. Indeed, it is not just a matter of campaigning to modify TRIPS-style IP regimes. It is rare to find people in science or industry who even articulate an argument that reforming the new IP systems and reducing the amount and strength of patent protection may be beneficial. The result, then, is that as regards science and technology TRIPS-style IP regimes face minimal negative feedback. Here, the self-reinforcing process is more complete.

To illustrate the different propensities for adjustment versus resistance and negative feedback in the realms of drugs–health and STI, consider the following contrast. In health, activist networks grew in response to concerns over how IP affects the price of drugs and thus citizens' access to healthcare. These networks can – and do – make appeals to human rights (such as the right to healthcare) and in many countries constitutional rights as well. The ability to make such appeals allows the movements to survive and, in some countries, form alliances with other societal actors (such as ministries of health, local pharmaceutical manufacturers). Yet the strategies of movement- and alliance-formation that are useful with regard

to medicines and health are less viable with regard to industry and technology. Governments do not directly bear the costs of local industrial firms' now complicated access to technologies. Nor can industrial firms that have lost access to technology on account of IP contest this new reality with appeals to human or constitutional rights: firms do not have rights to use other firms' proprietary knowledge and technology. The inability to rely on the state or to make legal and moral claims reduces the durability of users as political actors. Subsequently, coalitions for discontinuity rarely form. On the contrary, the process of adjustment leads to a progressive thinning of such potential coalitions.

The contrast between the alternatives available to knowledge users in the two realms was vividly illustrated in an interview I had with a patent attorney in Buenos Aires (November 2007), when I raised the scenario of a firm that seeks to use a patented technology but cannot reach a licensing agreement with the owner at a rate that makes using the technology feasible. In answer to my question of what recourse the firm might have, the attorney, clearly bewildered by the question itself, responded that the firm had no recourse: the exchange (in this case the exchange of money for the right to use proprietary knowledge) would or would not occur "just like any other exchange in a market economy". But a quick reflection on the case of drugs demonstrates that other sectors of the market economy operate differently. Citizens and governments do indeed demand to use others' proprietary knowledge at reasonable rates; and not only do they frame these demands in terms of their rights to do so, but claims of such rights are generally regarded as legitimate. One might maintain that industrial firms should also have rights to use other firms' proprietary knowledge, but such claims have less intuitive appeal and carry less weight. Thus, in health those negatively affected by TRIPS-style IP regimes can make appeals to constitutional and human rights that have great resonance, but not in industry.¹⁵

It is important to consider how these dissimilar patterns of political mobilization and coalition formation yield divergence in terms of the contemporary politics of IP. In contrast to the vibrant debates over access to drugs and healthcare, discussions about IP in the realm of STI tend to be thin (in terms of actors involved) and uni-dimensional (in terms of substance). Few local industrial actors express preferences regarding patents and IP. In each country where I have researched, for example, the amount of staff and resources that key trade associations give to IP is remarkably low. What few local firms and associations that do participate in political debates over IP want now is not less IP but more efficient IP systems to support their own aspirations, plans, and strategies to innovate, patent, and license. Outside pharmaceuticals and pharmachemicals, it is difficult to find local actors in industry or the scientific community that regard the

proliferation of private rights of exclusion over knowledge and technology as an obstacle to their own endeavours. Indeed, those that are at the forefront of political campaigns in the issue area are those that have their own IP, or at least regard themselves as potential creators and owners of patentable and excludable knowledge. In Brazil and Mexico, leading actors underpinning IP reinforcement in the area of science–technology–industry are private-sector associations that represent innovative research-and-development based firms.¹⁶ Ultimately, then, the actors that have survived the introduction of TRIPS-style regimes are those that can adapt to the new environments, while others who cannot – and who might provide raw materials for counter-mobilization – are gone.

Consequently, political debates regarding industry and technology are exceptionally one-eyed, about how to create more indigenous IP and how to increase national innovative capacities so that more local scientists and researchers use the IP system as knowledge owners. The result tends to be a panoply of initiatives and policies to restructure systems of science, technology, and innovation: establish funding mechanisms to increase research and development (public and private); reform higher education and vocational training systems; facilitate linkages between public sector research and private firms; enhance the capacity of university researchers to gain private rights over publicly-funded innovations; modify regulations that impede the movement of scientists between public and private sector; create new (and restructure existing) ministries of science and technology; and so on.¹⁷

The IP initiatives introduced in such a context are not so much changes *to* IP systems as changes *for* IP systems. That is, countries are not attempting to modify their IP systems to fit national scientific capacities, but rather attempting to improve national scientific capacities and national STI infrastructures to fit their new TRIPS-style IP systems.¹⁸

Consider the following. Most developing countries now have IP regimes of questionable appropriateness for their level of development. In response, a country can modify its IP regime to make it more suited to its scientific capacities (for example, restrict patenting scope, regulate licensing, facilitate the use of anti-trust measures in IP law, encourage pooling and sharing of knowledge, and so on), and a country can try to increase scientific capacities and upgrade STI frameworks and thereby “grow into” its new IP regime. In practice the latter scenario prevails: the dominant strategy is to leave TRIPS-style regimes intact and to try to “grow into” them. To the extent that changes have been introduced, these almost without exception reinforce the new TRIPS-style IP arrangements by extending the range of knowledge that is patentable and the range of actors that can obtain patents and relying on private ownership to transfer knowledge.

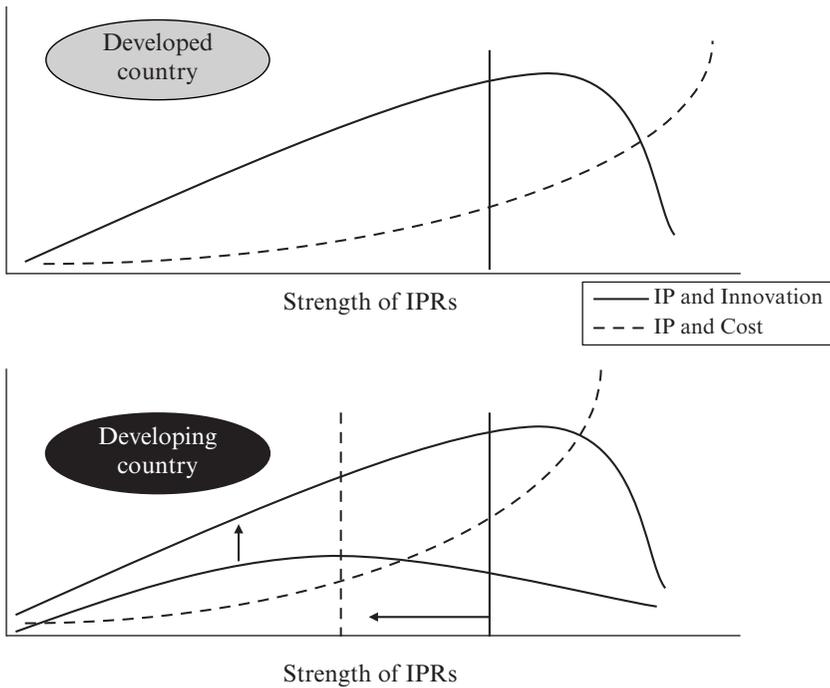


Figure 2.1 *IP and science–technology–innovation: reform or reinforce?*

The political dynamics are illustrated in Figure 2.1. The top graph presents a “developed” country with high indigenous innovative capacities. As the dark curve indicates, increased IP leads to increased innovation up to a certain point when diminishing returns kick in on account of too many inputs to further innovation becoming privately owned. The dashed curve illustrates the effect that increased IP has on costs. In such a context, a level of IP can be selected such that the benefits (innovation) exceed the costs. The bottom graph presents a “developing” country, with low indigenous innovative capacities. Here the dark innovation curve is flatter: each increment of increased IP yields less innovation, on account of less indigenous capacity, and diminishing returns set in earlier. When the same level of IPRs is introduced in such a setting, the costs exceed the benefits. The two arrows present the alternative responses noted above: reduce the level of IP to a more suitable level; change the shape of the innovation curve to look more like the innovation curve in developed countries. The reason why the latter response prevails is political: the relative absence of actors pushing to reform the IP regimes removes pressures to follow that

path, even when doing so is feasible within international obligations. Why such absence? Because the TRIPS-style regimes have weakened interests and thus minimized negative feedback, and at the same time they have strengthened the political capacities of their beneficiaries.

CONCLUSION

If a government implements a policy and the reaction is that beneficiaries demand continuity, we call that positive feedback. If a government implements a policy and the reaction is that those adversely affected demand discontinuity of the policy, we call that negative feedback. All policies tend to elicit both types of feedback, though to different degrees.

In this chapter I have used these simple insights to consider how different IP policy changes trigger contrasting patterns of political mobilization in the areas of drugs–health and science–technology–innovation. TRIPS-style regimes have generated growing constituencies for continuity, and negative feedback has been skewed. Where TRIPS-style regimes are less effective in weakening interests they are subject to reform (drugs–health), and where they are more effective in weakening interests they have undergone reinforcement (STI).

Ultimately I attribute the differences to how the “losers” react to the new IP environments. In drugs–health, those who are negatively affected by the new rules can, rather surprisingly, benefit from their inability to adjust. Governments end up bearing at least some of the costs of medicines, and actors can frequently make constitutional and also moral appeals to their rights to medicines. These conditions allow political coalitions to form and thus force some reassessment of IP policy. The realm of STI, however, tends to be marked by very different combinations of material, legal, and normative factors: firms adjust and go away, with the effects not felt directly by the state; rights to technology have little resonance in legal and constitutional settings; nor does a “right to technology” have much normative weight.

The different patterns of political mobilization lead to two very different approaches to governing knowledge. As indicated, the relationship between patents and health remains a hotly debated topic in many countries.¹⁹ In contrast, policy responses in the realm of STI have almost uniformly been about broadening, extending, and strengthening the role of patents as incentives for the creation, commercialization, and licensing of knowledge.

Assessing the effects of this latter approach is exceedingly difficult, but a few observations are in order. To be sure, national patenting rates have

increased, as indicated above. Yet this is hardly surprising. The fact that increased IP may lead to increased innovative activities and patenting is to be expected. However, more and stronger IP also increases costs and raises barriers to access. The concern is not that there are no benefits (innovation) derived from TRIPS-style regimes, but that the benefits may be outweighed by the costs (reduced ability to use knowledge). That concern may be misplaced, but one cannot argue against it simply by showing that there are, indeed, benefits. If, for example, a government raises tariffs on shoes by 100 per cent there will be more investment in shoes. One might warn that the benefits of the tariffs (increased investment in shoes) are outweighed by the costs (higher price of shoes to consumers). If one were to try to counter that argument by showing, simply, that high tariffs did indeed lead to increased investment in shoes, the argument would not be taken seriously. The emphasis on increased patenting activities without focusing on how knowledge is used and not used suffers from the same problem.²⁰

NOTES

1. The focus in this chapter is on patents, not other forms of IP such as copyrights and plant breeders' rights.
2. Throughout the chapter I draw on examples and illustrations from these three countries, but space considerations prevent extensive case studies. The three countries provide the empirical basis for my forthcoming book, *Knowledge Gaps, Knowledge Traps: The New Politics of Intellectual Property in Development*. Research in the three countries consisted of examination of archival materials and extensive interviews with key actors from state, industry, and civil society.
3. These associations are the local members of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).
4. In some countries these are one and the same. For example, the director of the PTO in Mexico was formerly the official chiefly responsible for foreign investment.
5. I call this mechanism "activating agnostics".
6. This relationship (foreign patents dominating over resident patents) holds in virtually all countries outside of the USA.
7. The data in this paragraph come from RICYT (www.ricyt.org).
8. In Argentina, the number of applications decreased after 2000 in the context of severe economic crisis, with 2000 levels re-attained in 2005. In Brazil the upward trajectory continued and the 1996–2005 growth rate amounts to 88 per cent.
9. A useful area for future research might be to examine, comparatively, the extent to which firms can continue to exist and prosper on the basis of older technologies. In pharmaceuticals, not only does the industrial sector continue to exist, but entire sub-sectors emerge around the production and distribution of older, off-patent drugs. In most of electronics, in contrast, firms using older technologies cannot compete. But how exceptional is that? In machine tools, for example, can firms continue to prosper using older technologies?
10. Among developing countries with significant capacity for pharmaceutical production, only India took advantage of the full transition period.
11. Or to put it differently, by the end of the 1990s Mexico was much further along the "pharmaceutical-denationalization" curve (Shadlen 2009).

12. Note that variation in national healthcare systems affects the extent to which governments are responsive to the growing advocates for discontinuity. The scenario that I have described (patients and healthcare activists mobilize over prices and access to drugs, and health ministry responds) is a general trait, but there are cross-national differences. For example, in Brazil, the government's commitment to universal HIV/AIDS treatment made the MoH acutely sensitive to prices on patented ARVs, much more than was the case in Mexico (Shadlen 2009).
13. The reason for this variation is that dynamics within the coalitions for discontinuity are hardly uniform. That is, among the three sets of actors – local pharmaceutical industries, health ministries, and NGOs – the relative weights and capacities of the actors who are leading the charge for reform, and the relationship among the actors in this coalition, vary from case to case. Thus, the outcome I am pointing up in this section is simply a set of underlying pressures that keep the drugs–health aspects of IP on the radar screen.
14. Measuring these changes in business strategies and industrial structure is exceedingly difficult, to say the least. Useful – though imperfect – indicators include diminished number of firms in sectors where patents have increased, size of trade associations in traditional “knowledge user” sectors, increased license fees and changing patterns of patent litigation.
15. One place to make such claims to might be competition authorities. Is it easier for governments and patients to invoke constitutional and human rights law than for firms to invoke competition law? There is also a collective action issue here. The firm that takes forward a claim against a patent owner, either in competition forums or nullification proceedings, has to bear the costs of doing so, but the benefits become available to all if the knowledge subsequently enters the public domain. For a further discussion of this dynamic as a mechanism that generates increasing returns, see Chapter 10 in this volume.
16. I refer to the National Association for Research, Development, and Engineering in Innovative Firms (ANPEI) in Brazil, and the Association of Directors for Applied Research and Technological Development (ADIAT) in Mexico. I am unaware of an analogous association in Argentina.
17. One might regard these initiatives as efforts to emulate successful “National Innovation Systems” of the OECD. They often have a “shotgun” feel to them, in that nearly every measure that has been deployed in other settings is deemed worthy of emulating locally.
18. Or to put it differently, rather than use IP policy for development, these programs are about increasing scientific capacities and improving STI frameworks (becoming more developed?) to get more out of the new IP policies.
19. In addition to the cases discussed in this chapter, see Chapter 3 in this volume.
20. Of course, this exercise is easier said than done – measuring the costs is extraordinarily difficult (see Chapter 9 in this volume). Yet however difficult it is to assess costs and benefits empirically, that does not justify failure to acknowledge both costs and benefits conceptually.

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3. The politics of patents: conditions of implementation of public health policy in Thailand

Gaëlle Krikorian

INTRODUCTION

At the end of 2006, the Thai Minister of Public Health, Mongkol Na Songkhla, made the decision to override patent protection by implementing article 51 of the Thai Patent Act on an HIV/AIDS medication, in order to generate – through import and local production – the necessary generic supplies. In doing so, he made use of a provision called *compulsory licensing*. Soon thereafter, Thailand came under attack; hailing from the American administration, the US Congress, and multinational companies, the critics were virulent. For Harvey Bale, director of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), “Compulsory licensing can be a route to commercial abuse and can put patients at risk” (Kazmin and Jack, 2007).

In recent years, most of the developing country members of the World Trade Organization (WTO) have implemented the standards of “intellectual property” (IP) protection¹ required by the organization. One of the consequences is 20-year patent protection on medicine, which forbids production, importation, or marketing of generics for this duration. Studies have highlighted the negative impact of this increased IP protection on access to health products in these countries (Subramanian, 1995; Remiche and Desterbecq, 1996; Velásquez and Boulet, 1999; Correa, 2000). In response to these concerns, and in particular in reaction to the international mobilization for access to anti-HIV medicines, the issue of how IP in pharmaceuticals affects access to medicines and public health became the subject of intense debate at the WTO. This debate led to the 2001 adoption of the Doha Declaration on TRIPS and Public Health, which recognized the right of Member states to suspend patents if they deem it necessary, using compulsory licensing. With the objective to “protect public health and, in particular, to promote access to medicines for all” (WTO, 2001),

the Declaration clearly articulates what the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) already set out in its legal language, that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (WTO, 2001).

The mobilization of the developing countries at the WTO, which led to the Doha Declaration, constituted a break in the history of international negotiations on IP. Since the signing of the TRIPS Agreement in 1994 – but also during the whole negotiating period that led to its ratification – power relations have clearly favored the strengthening of IP rights (IPRs). With Doha, for the first time, a consensus was reached on the notion that the need to implement IPRs must be balanced against concerns regarding public health. This occasion witnessed the weakening of the domination of the pharmaceutical lobby, at least temporarily.

Yet the period since Doha has seen an increase in the number of patents on medicines in developing countries,² and thus a rise in potential barriers to access. Moreover, the number of countries taking advantage of compulsory licensing by granting licenses has been minimal.³ Even when they have exercised this option – and this is most common in poor countries, most of whose pharmaceutical products are imported⁴ – they usually have tried to prevent the action from receiving publicity. Thus, even if the WTO has declared that states are free to use compulsory licensing, in practice few do and many of those who have attempted to do so have faced significant political and economic pressure (Kuanpoth, 2003: 15). Because rules like the TRIPS Agreement are “embedded in a broader context of asymmetrical power relationships between developed and developing countries, and between producers and consumers of the fruits of intellectual property” (Sell, 2007: 17), the real and effective room for maneuver for poor countries is extremely limited.

These unfavorable conditions provide the setting for the Thai case. From November 2006 to January 2007, Thailand issued three compulsory licenses. Paradoxically, the Thai government made this decision at a time that did not seem particularly propitious – while it was engaged in a process of negotiation with the US for the signature of a bilateral free trade agreement (FTA). Not only would this agreement have, in all probability, restricted the Thai government’s ability to use its TRIPS flexibilities and take such measures,⁵ but it was also rather obvious, from a diplomatic standpoint, that the United States did not want Thailand to issue compulsory licenses.

The purpose of this chapter is to present some keys to understanding this paradox and to comprehend how the Public Health Minister’s decision was made. It also seeks to open up a discussion of the governance of

IP in developing countries. IP protection is a mode of management and control of knowledge originating in the West and progressively imposed on the rest of the world, first through colonization and then in the context of economic globalization and the rise of neoliberalism as the dominant ideological system. There is no obvious answer to the question of the methods developing countries will adopt as their own IP governance modes, for the decisions the governments make and the practices they develop are not a simple implementation of legal provisions. Working in the context of restrictions imposed by international regulations and under the constant pressure of patent owners and the governments that support them, each developing nation will have to take advantage of existing options to respond to the particular set of issues it faces domestically. Thailand's use of compulsory licensing provides an opportunity to analyze this process during what can be seen as a critical trial moment, at a time when the turmoil at the WTO has largely settled and the implementation of patents has begun to set concrete limits on access to medicine – in other words, a time when developing countries have to make a choice.

My analysis of Thai policy entails two steps. First, I locate the government's decision choice in history. As Government Pharmaceutical Organization (GPO) chair Dr Vichai Chokevivat (personal communication, 4 September 2007) has said, understanding the process which led the Minister of Public Health to authorize the use of compulsory licensing requires that one take into account the history of the last few decades. Revisiting the past does, indeed, facilitate an understanding of how the Health Minister made a decision many others have been reluctant to make. More precisely, I attempt to consider the intersection of histories produced within local/national space and those drawn within global/international space, which contributed to creating conditions favorable to this decision. Second, to deepen understanding of the logic of each of the episodes that took place, I plan to take into account the players involved, the complexity of their positions and actions, and the interactions among them.

The study presented in this chapter is based on semi-structured interviews with civil servants from the Ministry of Public Health, the Ministry of Commerce, and the National Health Security Office (NHSO), Thai pharmaceutical companies, pharmaceutical MNCs, NGOs, Embassies (US, Europe, France, Switzerland), journalists, and members of the Thai Parliament. It is also based on observations of meetings, demonstrations, and conferences. The method I have adopted to develop my argument is the selection of several critical events and subsequent analysis of the alliances, tensions, and subordinations to decipher the complexity of the players' positions.

THE PLAYERS

The players arguably belonged to three discernible groups: the Thai state, the pharmaceutical MNCs – the movement for IP protection⁶ – and the movement for access to medicine. The granting of compulsory licenses in Thailand, in turn, can be presented as the end product of the interaction between these three forces at a particular point in time. Making sense of this interaction, however, necessitates accounting for the ways that each of its three parts further subdivided into different components, was inspired by various institutional cultures and motivations, and relied on different networks of influence.

The first grouping – the Thai state – consisted of a large range of players, the exact makeup of which depended on the particular period of time or situation one is considering. Until 2006, the Thai state was, above all, represented by its Prime Minister, Thaksin Shinawatra, who had been elected in 2001 and again in 2004. He shared a strong ideological connivance with President George W. Bush and was responsible for the initiation of Thai–US FTA negotiations in June 2004. For a year and a half after his resignation and the coup in September 2006, Thailand was run by a military government. Yet, the Thai state was also constituted of various ministries, each with its own agenda, each driven by its own political and administrative culture. Although it is not a powerful ministry, the Ministry of Public Health was, by definition, at the heart of the events crucial to this analysis. At the helm, its Minister is, according to law, one of the official representatives authorized to issue compulsory licenses. Of course, there were other actors under the umbrella of the Thai state, including the National Health Security Office (NHSO), which is the institution in charge of implementation of the universal health coverage adopted with the National Security Act in 2001, as well as the Governmental Pharmaceutical Organization (GPO), which manufactures generic medicine and has been involved in the production of antiretrovirals against HIV since the end of the 1990s. Since the issue was compulsory licensing, however, state actors also included the Ministry of Commerce and its intellectual property department, which grants patents and, because it has frequent relations with the industry, demonstrated a certain unity with the latter and comprehended what was at stake regarding health only under the pressure of repeated interaction with the defenders of access to medicine. Finally, at least as regards the present analysis, the state also comprised the Ministry of Foreign Affairs, which is in charge of the diplomatic activity of the government and was thereby one of the first Thai contacts to whom other governments turned – in part through the Embassies – when the compulsory licenses were announced.

Opposing the Thai state was the second group, the pharmaceutical multinationals, not only those who mobilized to defend their monopolies but also those who had placed protection of the interests of the industry on their list of priorities and have thus taken part in the pro-IP movement. Companies got involved individually, taking positions in the media or during conferences or meetings with Thai officials, but they also expressed their views through their international (IFPMA – International Federation of Pharmaceutical Manufacturers and Associations), American (PhRMA – Pharmaceutical Research and Manufacturers of America), or Thai (PReMA – Pharmaceutical Research and Manufacturers Association) representatives. The AmCham, the American Chamber of Commerce in Bangkok, was one of the agents acting locally on behalf of the industry, developing aggressive communication and raising the threat of the loss of foreign investments in Thailand. The interests and wishes of private corporations are regularly supported by Western states that have assumed the mission of protecting industries settled on their territory and of owning and exporting IP. The United States Trade Representative (USTR), following its legal mandate, promotes and protects the interests of American pharmaceutical companies (that is, those settled in the US) and, by extension, the interests of the pharmaceutical industry in general. In the Thai case, Western countries (the US, EU, France, Switzerland) acted directly through their Embassies and delegations, who were in regular contact with the companies and exerted a certain pressure on Thai institutions and officials. Industry positions were also advocated by the European Commission, notably through Commissioner Peter Mandelson, who wrote to the Thai Minister of Commerce to express his concerns.

On 10 July 2007, Commissioner Mandelson wrote to Commerce Minister Krirkkrai Jirapaet:

I am concerned by recent indications that the Thai Government may be taking a new approach on access to medicines. Your Government has announced the use of compulsory licensing for a number of patented drugs and stated that if drug companies wish to do business in Thailand, they should offer their drugs for no more than 5 percent above the generic cost. This approach is a matter of concern to the European Union and would be detrimental to the patent system and so to innovation and the development of new medicines. It risks forcing more drug companies to abandon their patents and could lead to the isolation of Thailand from the global biotechnology investment community. . . . The EU therefore encourages the Thai Government to engage in direct discussions with the right holders, in particular with Sanofi-Aventis on *Clopidogrel (Plavix)*.

Then, on 20 July 2007, US Ambassador in Bangkok, Ralph Boyce, wrote to Thai Prime Minister Surayud Chulanont:

When we spoke in late March, before my trip to the United States, I welcomed your assurance that no new compulsory licenses on pharmaceuticals would be issued. I reported this news to my Government and to the U.S. industry on my subsequent travels back to Washington which greatly eased the tension. I now fear that the compulsory licensing issue will soon reemerge. A number of U.S. pharmaceutical manufacturers are closely following the deliberations of the Ministry of Public Health ad hoc committee formed to consider pharmaceutical compulsory licenses. The Ministry of Public Health has confirmed that it is actively considering a list of additional drugs for compulsory licensing. My staff has consulted with officials from the Ministry of Foreign Affairs and Ministry of Commerce, who have not been able to reassure that no additional compulsory licenses are forthcoming.

These two letters provide interesting insight into the inner workings of this sort of pressure. Of course, as WTO members, both the US and the EU endorsed the Doha Declaration and thus formally acknowledged countries' rights to use compulsory licensing to facilitate "access for all". In fact, it is worth noting that neither the US nor the EU representative objected to compulsory licensing per se, but rather each invoked a possible new use or fear of a systematic use. The temporal proximity of the two letters – in the middle of the summer, a period of little, if any, significant activity on the Thai side – suggests US–EU coordination on the issue. The excerpt from Ambassador Boyce's letter provides a valuable illustration of the close communication between the industry and the US administration. The fact that this letter was addressed to the Prime Minister, on the other hand, is testimony to the multiplicity of levels, including the very top, of Thai government to which US representatives and pharmaceutical companies were prepared to turn to try to block the use of compulsory licenses.

Besides direct pressures such as withdrawal of medicine registrations submitted to the FDA or direct action taken by foreign governments, the pro-IP movement also resorted to more indirect threats. For example, when president of Novartis's Thai branch Sirilak Suteekul explained that "the time [is] not right to impose compulsory licensing" on Glivec (Sarnsamak, 2007), Thai Society of Hematology president Dr Saengsuree Joota declared to a newspaper that "the government should think carefully before issuing compulsory licensing to bypass patents on cancer drugs since such action may cause long-term adverse effects. . . . Issuing a compulsory licence (CL) for Glivec may adversely affect some 900 leukaemia patients who already have access to Imatinib, a generic version of the cancer drug, through a philanthropic programme" (Treerutkuarkul, 2007c). There are 34 assistance centers and 113 physicians in this philanthropic program in Thailand (Sarnsamak, 2007), all of whom could, following Dr Saengsuree's example, have taken sides with the industry for fear of retaliation.

Commissioner Mandelson's letter, on the other hand, reveals internal conflicts between the European Parliament and the Commission over TRIPS and health issues. Indeed, the Commissioner's letter appears to be in total contradiction with the EP's resolution – adopted just two days later, on 12 July 2007 – asking the European Council to support developing countries that used flexibilities included in the TRIPS Agreement (Cronin, 2007).⁷ The letter is also a useful example of the absence of homogeneity among institutions or bodies, which were supposed to represent the same country (or group of countries) and support a single position but which, in real life, often showed significant divergences.

Finally, the third major group of players consisted primarily of a variety of NGOs. Several discernible subgroups emerged to form the coalition involved in events that led to the granting of compulsory licenses. Leading the charge, of course, were Thai groups and NGOs mobilized against HIV/AIDS, such as the AIDS Foundation and the Thai Network of People with HIV/AIDS (TNP+). But these groups were also supported by international NGOs, such as Médecins Sans Frontières (MSF), whose local unit in Bangkok took part in local campaigns and financially supported several communications operations.

In addition, other groups and alliances, those less directly focused on health issues, took up the compulsory license issue and stood ready to support their HIV/AIDS counterparts. These included coalitions, such as FTA Watch, which covers 11 networks of groups opposing the FTA with the US (trade unionists, students, farmers, and so on), as well as single organizations, such as BioThai, which is dedicated to biodiversity and the protection of natural resources and traditional knowledge of local communities. The action of Thai civil society was also supported by foreign national NGOs and HIV/AIDS activists – in the US, France, Brazil, India, and so on – who got involved in solidarity with their Thai colleagues.

Lastly, Thai academic networks have collaborated with NGOs on health issues since the 1970s,⁸ and since the 1990s social movements have played a major role in the fight against AIDS in Thailand. Although relations with the Minister of Public Health rarely became seriously confrontational, AIDS organizations and networks of people with HIV/AIDS exerted constant pressure on the ministry to improve existing policies and implement new ones. They demanded and secured access to antiretrovirals on a national scale. The Access Foundation and TNP+ played a key role in collecting 50 000 signatures to submit to the parliament a legislation for national medical coverage, which was subsequently adopted by Parliament in 2001. The addition of anti-AIDS treatment to the list of medicines reimbursed under universal health coverage created the conditions necessary to generalize access – and, in so doing, contributed to putting in place a

system that ultimately necessitated the use of compulsory licensing. Each time it was necessary, these NGOs relied on the network of academics of the Drug Study Group (DSG). This alliance, reinforced by the collaboration of international NGOs such as MSF, Oxfam, and Knowledge Ecology International (KEI) (formerly CPTEch), enhanced and expanded the expertise of the AIDS activists on the issues of patents and IP.

Hence, the NGOs' actions and impact relied on both the breadth of their informal coalition and the appropriation of knowledge and expertise. Rooted in local groups, a heterogeneous network of individuals and organizations concerned with the issue of IP and access to medicines mobilized and grew from the end of the 1980s. This network's efficiency was based on its ability to address specific technical issues with a level of expertise that often exceeded that of the government, and its capacity to react extremely rapidly to situations and attacks. Local NGOs were prompt to use the media, organize rallies, go to court, and they were able to mobilize individuals all over the country when necessary. Tight connections with international experts, collaboration with organizations such as MSF, and informal relations with activist groups from other countries have proven effective in generating widespread, global support for the Thai NGOs. Whether the target was the Thai government, a pharmaceutical company, or the USTR, advocates and activists came promptly in support of their Thai counterparts through articles in the Thai media, demonstrations in front of Thai embassies, or public action against pharmaceutical companies or the US administration. The NGOs' advocacy for CL, part of a long trajectory of mobilization that grew over two decades, is one of the elements that explains how the CLs could be issued at the time when the country was run by an authoritarian government – that is, at a time when one might expect NGOs to be less influential.

One missing actor in the picture just described is the local pharmaceutical industry. Whereas the GPO has played an essential role in securing access to essential medicines in Thailand and promoting the use of generic products, their private-sector counterparts have been mostly absent from the debates over CL. This may seem surprising since Thailand does have a local industry that remains significant, even if losing market share year after year to multinationals. This industry that is focusing on producing and selling generic medicines could definitely find an interest in the use of CL and more broadly on the issue of IP and medicines, since any increase of protection will affect its ability to work on new products and relaxation of IP protections would enlarge the scope of their potential markets. However, while the Thailand Pharmaceutical Manufacturer Association (TPMA), and more precisely a couple of individuals inside the organization, saw what was at stake and participated in the discussions, local

industry for the most part ignored the issue. Whether it is because local companies are mostly focusing and fighting over their share of a shrinking domestic market, or because they see their future in licensing agreements with multinationals more than in fighting their supremacy, this element of civil society, which has proven to be very active in other countries such as India and Brazil, did not engage on the issue or show deep interest in acquiring the necessary knowledge to tackle it.

ANALYZING CHOSEN EVENTS

Two major elements combined to create the conditions necessary for the decision to use compulsory licensing in Thailand. First, a perceived need to act was fueled by the AIDS epidemic, the existence of patents on medicine, the implementation of a national treatment access policy, and the limited financing resources available to cover health products and services. Second, the social and political context at the end of 2006 and beginning of 2007 and the political pressure civil society exerted in defense of patients' lives contributed to the creation of possibilities that would otherwise have been rejected. Moreover, each element affected the other: the need to act was the movement's *raison d'être*, and it was partly the movement that compelled political leaders to respond as well. Several key events offer insight into the development and crystallization of conditions favorable to the use of compulsory licensing, as well as revealing the power relations that exist around the issue of IP in the Thai context and beyond.

October 2001 – Adoption of Universal Health Coverage

In 2001, the Thai Parliament passed the National Security Act. With its ratification, the nation instituted universal health coverage – the 30-baht universal health care scheme – intended to cover the entire Thai population. This new law was the product of intensive mobilization of civil society.⁹ Calls for the creation of national health coverage were picked up by Thaksin Shinawatra's Thai Rak Thai (TRT) party, during his campaign to become Prime Minister, and universal healthcare coverage became law shortly after his election in 2001. Its implementation by the National Health Security Office (NHSO) led, a couple of years later, to opening a debate about compulsory licensing, among institutions and with NGOs.

As a consequence of NGO campaigns, in October 2003, antiretroviral treatments, theretofore the financial responsibility of patients themselves,

became part of the universal coverage package. This led to a massive increase in the number of patients with access to medicine, from 27 000 at the end of 2003 to more than 52 500 at the beginning of 2004 (World Bank and Ministry of Public Health, 2005). One issue that emerged in the aftermath of this development was the question of access to generics for a second line or a less toxic first line treatment.¹⁰ According to WHO therapeutic recommendations, the most urgently needed drugs included efavirenz (Merck's Sustiva®¹¹) and the lopinavir/ritonavir combination (Abbott's Kaletra®¹²). It became obvious to the head of NHSO, in charge of managing the universal coverage program, that the access program was about to face a major quandary – the number of patients needing to switch treatments was not yet important, but it was steadily and irretrievably increasing. Officials from institutions dedicated to health, AIDS, and medical coverage knew that the cost of second line treatments would inevitably become an increasing burden on the national budget dedicated to access to antiretroviral drugs. The idea of relying on the compulsory licenses that were ultimately granted in 2006 and 2007 had started to take shape in the minds of some of these officials a couple of years earlier. Informal discussions were held with NGOs and academics, but also with the Department of Intellectual Property at the Ministry of Commerce. However, all were rather uncertain about how to proceed with compulsory licensing in terms of implementation.

One key problem was that Thai IP law was potentially open to interpretation regarding who should be authorized to grant the CLs. This role could be played by the heads of several different government institutions, including the Ministers of Public Health and Commerce, or the head of the Department of Communicable Disease Control, and so on. However, civil servants expressed fears about potential fallout for the individual who would grant the licenses, regardless of his or her institution. They were especially concerned about the prospect of the granting official being taken to court by pharmaceutical companies – a fear proven not altogether unfounded when, in April 2006, Pfizer took the head of the Philippine Food and Drug Administration (FDA) to court after his institution imported and gave marketing approval to a medicine whose patent was about to expire, in order to prepare for the introduction of a generic version (“Government sues US firm over patent war”, 2006). Meanwhile the economic pressure had not yet challenged the viability of the medical coverage scheme, which would have undermined the tacit new moral agreement (that is, the social contract regarding the right to medical care) that had been established between Thai society and the government when the universal coverage plan was adopted.

January 2006 – a Massive Mobilization

In January 2006, during the sixth round of negotiations of the FTA between the US and Thailand in Chiang Mai, around 10000 people took to the streets in protest. This massive mobilization far exceeded previous demonstrations against the agreement. Afterwards, Thai chief negotiator Nit Phibunsongkhram admitted he had had to escape through a back door from the hotel where the negotiations were taking place, as it had been besieged by protestors. He resigned two weeks later.

Eleven networks, from farmers to bankers, had formed a coalition. Within this mobilization, groups dedicated to health and the fight against HIV/AIDS represented an important component and played a key role. During the protest in January 2006, more than a third of the people demonstrating were members of groups of people with HIV/AIDS, from various regions of the country.

These protestors denounced the increase in the level of IP protection the agreement would impose, strengthening monopolies and impeding access to generic medicines (Krikorian and Szymkowiak, 2007). In order to reach mass mobilization, NGOs undertook an important nationwide campaign of information, popularization, and education through their networks. They managed resources as a collective – some contributed expertise, others communication capacity or financial means – in order to train themselves and their intermediaries, whose role was to spread the information across the country. An increasing number of members of networks became familiar with the most technical aspects of the impact on access to medicine the IP provisions promoted by the US were likely to have. The NGOs and activists were very resourceful, pulling every possible string. They organized workshops, press conferences, and demonstrations. They generated and distributed leaflets, brochures, and videos, denouncing the negative impacts of the agreement. In their public statements, they enjoined the government to refuse US demands, including proposed limitations on the use of compulsory licensing. The level of detail of these documents demonstrated the efficiency of the activists' education campaigns. It proved the significant role the mobilization against the FTA played in generating popular support for compulsory licensing. A sticker spread by the NGO networks proclaimed "Right to CL = Right to live". Because of the success of activist campaigns, this message, which might otherwise have seemed totally abstruse to most citizens, turned out to be understandable enough to be used on a sticker disseminated by the thousand.

This phenomenon of knowledge appropriation is borne out by analysis of Thai newspapers as well. NGOs fighting HIV/AIDS made the most of relationships they had, over the years, developed with some of the country's

journalists. NGO spokespersons and experts educated allied journalists on the issues of IP rights, free trade agreements, and compulsory licensing the same way they had once done on modes of contamination, the spread of the disease, the effects of antiretrovirals, and so on. Newspaper reporting on the demonstration against the FTA in the newspapers was widespread; never had media coverage on this issue been so extensive.

During the first half of 2006, the movement against the FTA took place at the same time as – and was sometimes included in – even bigger demonstrations against Prime Minister Thaksin. In light of corruption allegations, his popularity, unshakable since his first mandate in 2001, dwindled. For many opponents, the FTA was an emblematic example of his neoliberal politics. A questionnaire given to around 20 000 participants during an anti-Thaksin rally found the FTA cited as one of three main reasons people had come to take part in the protests (W. Lianchamroom, BioThai, personal communication, 2 September 2007). Paradoxically, the FTA negotiations helped prepare Thai civil society to declare and defend its right to use compulsory licensing.

Numerous authors have shown how the pro-IP movement was able to introduce IP protection into international trade negotiations and convince policymakers and political leaders in the US and other rich countries (as well as the public at large) of the existence of a relationship between strong IP protection and national welfare (Drahoš and Braithwaite, 2002; Sell, 2003). The convergence of actors from the private sector around a particular approach to IP and their ability to act strategically to advance this approach were critical for these actors' ability to frame the issue of IP in a way that gave them political authority and legitimacy. As a result, they managed to alter conventional wisdom and impose a new vision of the use of strong IP protection. The defense of their interests became an element of national policies that could not be ignored and binding provisions in national and international laws that had to be enforced. Beside the tactics and strategic use of institutions (such as forum shifting), resources (such as easy access to policy and decision circles) and coercion (such as the use of the USTR's "Special 301" lists), the pro-IP movement made the most of a "discursive dimension" to give a hegemonic force to its political objectives.¹³ We can observe similar efforts to reframe the issue of IP on the part of NGOs and activists in Thailand. Their potential success depends not only on shifting understanding from one framework to another – to emphasize the public-health dimensions of IP – but also on the fact that doing so allows actors to perceive the world differently. Thai NGOs and activists are involved in an effort to re-encode and re-frame the debate (see Chapter 6 in this volume; Snow and Benford, 1992: 137).

The pro-IP offensive led by the US with the FTA, in particular the radicalism of the USTR's demands and its inflexibility in the negotiations, helped to bring together a wide range of actors that formed a broad front to fight against the FTA. This collective action resulted not only in the denunciation of their opponents and the perceived negative social impacts of IPRs, but in an attempt to change the terms of the debate in the public sphere. Activists stressed the positive impacts of the use of legal provisions, thus bringing to the fore the issue of patients' lives. In doing so they linked "CL" and "Life", suggesting the idea of a legitimate right for the government to use CLs to help people stay alive. Their message relied on some aspects of the system of their opponents (such as the existence of a legal framework governing IP) but promoted an alternative interpretative frame.¹⁴

A Historical Decision

The decision of the Minister of Public Health can be understood as an event materializing at the intersection of two separate but concurrent histories. The first of these is the history of successive US–Thai conflicts over IP since the 1980s. IP protection is, indeed, at the heart of tense relations marked by recurrent threats of economic sanctions – the use of Special 301 provisions – against Thailand. In 1989, Thailand was placed on the Priority Watch List, and it was moved to the Priority Foreign Country List in 1991.¹⁵ As a result of tensions and pressures, Thailand's Patent Act was ultimately amended in 1992, instituting IP standards more restrictive than those in WTO's TRIPS Agreement, which at the time was still two years from its eventual ratification (in 1994). As a result of the same pressure process, this law was revised again in 1998. When Thailand was not under pressure from the United States government, pharmaceutical companies simply stepped in to fill the void, going on the offensive against the country's policies in favor of generic drugs.

At the end of the 1990s, Thai patients taking antiretrovirals had to pay for their treatment themselves. At the time, the price of therapy in developing countries was almost equivalent to that in Western countries, around US\$10,000 per patient per year, and Thailand did not depart from the rule. Combination or bi-therapy – then the therapeutic standard in Thailand – was out of reach for the majority of patients. This situation prompted the governmental producer GPO to get involved in the manufacture of several drugs often included in these therapeutic combinations. The pharmaceutical company Bristol-Myers-Squibb (BMS) intervened, however, and claimed exclusive rights to the patent for ddI. BMS had control of the patent of an improved version of this antiretroviral,

containing antacid to prevent the destruction of the ddI by the acidity of the stomach. GPO was willing to market a generic version its chemists had engineered using their own original process, which would have lowered the cost by approximately 40 per cent.¹⁶ Informed of the existence of the BMS patent, the manufacturer abandoned the marketing of the generic.

In response to BMS's claim of monopoly, some NGOs and public health experts suggested that the government take advantage of the flexibilities of international IP rules. In 1997, GPO submitted a compulsory license request to the patent office (Guennif and Mfuka, 2003: 144). In 1998, NGOs and the DSG organized several meetings in order to launch a national campaign. For two days, on 22 and 23 December 1999, a hundred groups of people with HIV/AIDS and many NGO activists set up tents for a sit-in in front of the Ministry of Public Health. They requested the use of compulsory licensing in order to authorize GPO to produce ddI tablets (Limpananont, 2005: 61). WHO representative to Thailand at the time, Dr E.B. Doberstyn, declared, "We recognize that compulsory licensing is one of the ways to approach this issue" (Bhatiasevi, 2000a).

However, in February 1999, PhRMA submitted its annual report for the 301 list, requesting the addition of Thailand to the Priority Watch List. The USTR published its list two months later, but PhRMA's request was not fulfilled. However, despite a new amendment of Thai law to satisfy US demands, Thailand did stay on the Watch List. If they even existed in the first place, government desires to use compulsory licensing were suppressed by threats of economic sanctions and custom duties on Thai exports to the US, particularly wood and jewelry (Boseley, 1999).

In January 2000, Thai NGOs wrote to then US President Bill Clinton, and, on 18 January around 200 people protested in front of the American Embassy. In its response, the White House implicitly recognized that the TRIPS Agreement provided for the right to use compulsory licensing, but the Thai government remained cautious.¹⁷ It rejected the option of compulsory licensing (Ramachandran, 2003) and asked GPO to limit its production to ddI powder, which was not protected by the BMS patent. In March 2000, GPO announced that it would produce a powder form of ddI, the composition of which would be different from that manufactured by BMS.¹⁸ In the meantime, health NGOs and networks of people with HIV/AIDS changed their strategy, reorienting their efforts toward a court case against BMS and the Department of Intellectual Property of the Ministry of Commerce. As a result of these two trials, BMS finally decided to relinquish its patent.¹⁹

Throughout this series of conflicts, Thai civil society acquired invaluable expertise on IP. Moreover, NGOs forged constructive new collaborations with academics, who, in turn, gained and maintained contacts with a

number of agents within governmental institutions. In a sense, American offensives resulted in the rise of organized resistance.

Thailand's announcement of the granting of the three aforementioned CLs highlighted a point where this history of tension and contention intersected with another, the personal history of Minister of Public Health Mongkol Na Songkhla. Dr Mongkol had studied at Mahidol University in Bangkok. He had been involved in student-led left movements during the 1970s and had joined the Rural Doctor Society (RDS). Named "Outstanding Rural Doctor" in 1976, he had practiced in the countryside for most of his career. He had also occupied important positions in the public health administration, including Director of Phimai Hospital, General Director of the Medical Services Department, Secretary-General of the Food and Drug Administration (FDA), and Permanent Secretary of Public Health.

When appointed Minister of Public Health in October 2006, Dr Mongkol chose as his advisors some of his former university colleagues who, like him, had been involved in the rural association.²⁰ Some had become experts on IP and had closely followed the national and international debates on this issue that had taken place during the previous decade. The General Secretary of NHSO, Dr Sanguan Nittayarumpong, had also participated in student activist efforts, had been part of the rural doctor networks, and had been involved in many consumer and civil society activities. He was in position to sound the alarm when it became obvious that the cost of second line treatment would probably cripple the national health budget.

Thus, the new Minister of Public Health and his advisors were able to rely on a set of common values, as well as on years of experience working together. It was in this context of expertise and trust that Dr Mongkol assumed his post as the nation's top health official. Immediately, he requested the collection of all necessary facts and figures to make a decision regarding the use of compulsory licensing, and he announced his decision within the month.

While such personal aspects of the Minister's trajectory may seem trivial, consider the Thai case in light of other seemingly similar countries. In many such cases, the notion of the use of compulsory licensing is systematically dismissed on account of insecurity and fear, highlighting the potentially transformative role of micro-history. The conjunction of legal expertise and a climate of confidence probably played a determinant role in Dr Mongkol's decision. Notably, such analysis of historical and biographical elements shows why this decision was not just one man's courageous choice for a policy to help the sick and poor.

September 2006 – a Military Coup

From a political point of view, the use of compulsory licensing in Thailand can be seen as the product of a very particular situation. Dr Mongkol did, after all, exercise his mandate in the context of a transitional military government. In April 2006, Prime Minister Thaksin was forced to resign, and, in mid-September, a military coup expelled the remainder of his political party. The military appointed a temporary government, creating exceptional ruling conditions from which the Minister of Health would ultimately benefit.

Indeed, the fact that, at the time, the government was the product of a coup freed the Minister from a number of constraints. First, knowing the temporary government was by definition not made to last, Dr Mongkol could make a politically precarious decision without really jeopardizing his position. However, he also benefited from greater autonomy than he would have had under a stable civilian government. After the expulsion of the existing government and the installation of temporary military rule, major national issues – such as a referendum on a new constitution, relations with the former ruling party, and the return to democracy – were at the center of the Thai political scene and kept the ruling class rather preoccupied with the search for resolution. In this context, the use of compulsory licensing to supply the country with generic medicine hardly seemed like a pressing issue for most high rank officials. It was seen as a matter that fell squarely within the Health Minister's competence. For his part, although he asked his advisors to consult with the Ministry of Commerce on legal aspects of compulsory licensing and interpretation of Thai law, Dr Mongkol made his decisions without involving other Ministries or the Office of the Prime Minister. As such, the compulsory licensing decisions were by no means the product of inter-ministerial collaboration or consultation with the Council of Ministers. This explains both why some representatives of other Ministries later implied Dr Mongkol had presented them with a *fait accompli* and why no other minister was able to thwart his edict.

Chain Reaction

Reactions to the decision of Thailand's Minister of Public Health provide a valuable lens with which to take a closer look at the alliances and hostilities playing out in the field of IP. The Thai episode shone a spotlight on forces that cooperate and conflict in complex patterns not only on the national level but also, importantly, on a more global scale.

After Thailand announced its decision to issue the compulsory licenses,

various players who had been actively involved, in one way or another, in the pro-IP movement took part in a chain reaction. The media reported on these reactions, giving them a measure of visibility. In some cases, they even contributed to the backlash, as the *Wall Street Journal* published a series of acerbic criticisms of Thailand.²¹ At the beginning of March, Abbott Laboratories announced it was withdrawing seven registration applications pending approval by the Thai FDA. On 1 May 2007, the USTR published its annual Special 301 report, moving Thailand from the Watch List to the Priority Watch List. Although USTR officials declared that the grounds for this change in status were not linked to the compulsory licenses, the report clearly states as follows:

In addition to [some] longstanding concerns with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval. (USTR, 2007)

USA For Innovation – an entity that called itself an NGO but turned out to be working for a public relations company whose most important client was Abbott – appeared on the public stage several weeks after the announcement of the compulsory licenses. Proving to be very active, the group launched a campaign against what it termed “Thailand’s Theft of American Property” and wrote to members of Congress and Secretary of State Condoleezza Rice. It also published inserts in Thai and international newspapers, calling the transitional government a “military dictatorship”, comparing it to the repressive regime in Myanmar, and questioning the quality of GPO’s products.²² Meanwhile, some members of Congress got mobilized against Thailand as well. On 20 March, several Senators wrote to USTR Susan Schwab, denouncing the country’s action. In Europe, the Trade Commissioner wrote to the Thai Minister of Commerce to share with him his concerns that compulsory licensing would come to be used in a routine way.

After all was said and done, this appeared to be a textbook case of the activation of the archetypal repression-intimidation mechanism. All protagonists who could potentially defend this type of inflexible implementation of intellectual property rights were called upon, each using the means at his/her disposal to mobilize against the offending nation. A closer look at the actions of Abbott reveals not only the violence of its assault

on Thailand's policy but also the reactions this assault subsequently provoked.

Abbott was the company to adopt by far the most aggressive attitude, notably by withdrawing its request for marketing authorization. On 23 May 2007, it sued Act Up–Paris in protest against the “netstrike” – attempts to overload the company website by multiplying simultaneous connections – that the activist group had organized in solidarity with Thai patients.²³ Meanwhile, USA For Innovation called Thailand, among other things, part of “an axis of IP evil”, resorting to rhetoric not only unreasonably extreme but downright insulting from the point of view of Thai officials.

Yet, these attacks had an effect quite the opposite from that intended by Abbott. At least temporarily, they forged a fissure in the customary unity of the pro-IP front. Abbott found itself isolated from its usual allies, who did not want to take the risk of being associated with the firm. Even such hardline adherents as AmCham, though they explained that they understood Abbott's anger, recognized the company's strategic mistake in its handling of the situation (J. Benn, AmCham, personal communication, 5 September 2007). Because the US did not want to be seen as opposed to the use of compulsory licensing, the USTR had to publicly acknowledge the lawfulness of the Thai decision.²⁴ Thus, the US Embassy did not officially support Abbott's attitude, nor did other companies (such as Merck), who focused instead on underscoring the fact that they wanted to continue dialogue with the Thai government. At first, the decision to issue compulsory licenses sparked an ongoing dialogue among the Embassies and delegations of countries housing firms affected by the licenses – or those that expected to be affected by future licenses (for example, Roche, who owned an expensive cancer drug)²⁵ – who consulted with each other and readily exchanged information. After Abbott's aggressive campaign, however, relations cooled and each of the previously cooperative countries withdrew to formulate a more individual strategy. Mindful of the yardstick of the Doha Declaration, none of these actors wanted to be seen in public opinion as IP extremists opposing access to medicine in poor countries.

These threats, sanctions and attacks, at the hands of Abbott and lobbying groups such as USA For Innovation, also reinforced solidarity between various Thai actors. This was partly a matter of a nationalist impulse, which had been triggered by the comparison of Thailand's transitional government to the dictatorship in Myanmar. These criticisms also contributed to the loss of credibility the pharmaceutical industry suffered in Thai newspapers, which were indignant at the insinuations hurled by USA For Innovation. Lastly, Abbott's lawsuit against Act Up–Paris generated a wave of reprobation. In French courts, this case was a first – a

pharmaceutical company going after a group representing people with HIV/AIDS. In reaction, an important solidarity movement developed. The European AIDS Treatment Group (EATG), together with Act Up–Paris and TNP+, requested that Abbott drop the trial and, in so doing, gave the company’s hostile initiatives publicity. It was now the Thais’ turn to take action in support of their French counterparts, demonstrating solidarity between groups from the South and North in action. Despite recent disensions among Northern activists, an international front emerged and denounced the company’s actions. The medical and scientific community got involved as well, issuing declarations and statements during various international conferences. Abbott had clearly gone too far, for everyone.

May 2007 – a Diplomatic Mission

Led by Thailand’s Minister of Public Health and including representatives from the Ministries of Commerce and Foreign Affairs, a mission to Washington, DC, was organized in May 2007. Apparently believing that, if he offered a full explanation of his policy, the US government’s concerns might be laid to rest, Dr Mongkol decided that his delegation “would attempt to make the clarification over the matter to the utmost of their abilities” (“Minister takes medicine fight to USA”, 2007). The course of this episode exposed the larger context of global confrontations on IP.

The mission’s agenda was in the hands of Thailand’s Ministry of Foreign Affairs, including the Thai Embassy in Washington, DC, who made all relevant appointments with the USTR, PhRMA, lobbying groups, members of Congress, journalists, and so on. On the whole, it proved to be a severe disappointment for the Minister and his Thai associates. The authoritarianism and closed-mindedness of US representatives stood out in sharp contrast with the effort expended by the Thai commission and the open-minded disposition of its participants. Essentially, it seemed to play out as a demonstration of the inequity between the two sides, provoking a feeling of humiliation within the Thai delegation. Meanwhile, carrying out collective tasks, as well as the need to band together in the face of adversity, reinforced relationships among actors from different Thai ministries and strengthened their solidarity.

Because it was embedded in a particular historical (the Doha Declaration), social (the existence of a strong access-to-medicine movement and international consensus to increase access in developing countries), and epidemiological (the spread of HIV/AIDS still out of control) context, this confrontation between the US and Thailand compelled players to choose sides and voice their support. In the US, some members of Congress, as well as former President Bill Clinton, expressed their

approval of Thailand's actions. Official representatives of other foreign countries – including France, the United Kingdom, India, and Brazil – did so as well. Thus, tensions over the Thai use of compulsory licensing were no longer just a clash between the US and Thailand. Rather, this case represented an international confrontation taking place in the larger context of continued conflict between the two camps – pro-IP and pro-access – on a global scale.

CONCLUSION

The way the tensions between the Thai government and the pharmaceutical companies (and their supporters) materialized and crystallized in 2007 – on the fringes of controlled diplomacy, resigning customary courtesies – speaks to the importance of the conflict that took place. The careful and deliberate manner in which USTR spokespersons explained that the reason behind Thailand's transfer to the Priority Watch List was not its decision to issue compulsory licenses – a provision whose lawfulness the USTR did not deny – indicated that the issue at stake was not a simple matter of interpretation of law. It was not, as the pharmaceutical lobby tried to frame it, first and foremost a debate to determine whether the Thai decision was lawful. On the contrary, it represented an episode of climactic confrontation between two major forces, revealing a larger underlying discord on a global scale. While one side endeavors to enforce existing WTO protections and increase IP protection standards nationally and internationally, the other struggles to curtail the negative impact these rules have on individuals, primarily (but not only) in developing countries. This particular experience is a formative one, all the more so since, with the resolve of the Health Minister and his many supporters, it has led to a shift, albeit necessarily minor, in the balance of power between the opposing forces. Within the ambit of permanent power relations, the cursor moved a touch.

Reiterated in Doha to allow access to medicine, the right to use compulsory licensing was ultimately exercised by Thailand. But the balance of power is precarious at best. On 6 February 2008, Prime Minister Samak Sundaravej took office, bringing with him a newly constituted Cabinet that included new Minister of Public Health Chaiya Sasomsab. The latter immediately announced he was launching a review of the policy of issuing compulsory licenses, including licenses on four cancer drugs his predecessor had issued prior to his departure. This questioning of the policy suggests that a reversal in the balance of power could easily take place.

One of the primary purposes of this chapter has been to reflect on developing countries' governance with regard to IP, and in particular to making an effective use of flexibilities in IP protection. Prompted by civil society, Thailand's first debates about the use of compulsory licensing to facilitate access to medicine began at the end of the 1990s. Yet, the actual use of this lawful TRIPS flexibility did not take place until the end of 2006. Here, I have attempted to determine the conditions necessary for the interests of ill people to prevail over those of patent owners. As Judith Butler points out, "Conditions are not the causes, conditions do not 'act' in the way that individual agents do, but no agent acts without them" (Butler, 2004: 9). Despite the existence of a tense political climate, a muddle of histories, both more and less recent, ultimately produced a propitious configuration. But sociopolitical configurations vary from one country to another. As such, the scenario that played out in Thailand is different from those one can observe in Brazil, South Africa, Morocco, and the like. So far, very few countries have exercised their right to issue compulsory licenses. The experience of Thailand with CL points to the difficulties that may exist for developing countries to establish and maintain the political conditions in which they can make a concrete use of TRIPS flexibilities. It also shows what it took in this country to build and sustain a civil society coalition able to frame and promote a position over IP that differs from that of the pro-IP movement.

Both the complexity and the specificity of the social, political, economic, and epidemiological factors that led to use of compulsory licensing in Thailand raise important issues. The fact that these conditions are not easily replicable calls into question the capacity of TRIPS to go beyond enforcing IP protection and actually offer countries efficient means to meet their national social needs. Reached at the end of negotiations in 1994, the consensus that led to the adoption of the TRIPS Agreement was that establishing a few key flexibilities would allow for a fair balance. Debates during the TRIPS negotiations were lively between developed and developing countries over the inclusion of these flexibilities in the agreement. If the latter managed to secure some, concrete attempts to make use of them now that the TRIPS agreement is fully implemented in most countries indicate that it is not only the scope of the flexibilities that may be a problem but also the political limitations that impede their implementation. This is where the local history of Thailand's use of compulsory licensing may collide with the broader history of international relations and thereby contribute to changing the course of international negotiations and reopening a thorny debate – one that would confront the incongruity between WTO rules and conditions in developing countries.

NOTES

1. The term “intellectual property” was devised and imposed as an ideological vehicle by the movement of private interests promoting exclusive rights through patent, copyright, and trademark (see Boyle, 2003). It is a constructed – and contested – concept and term that some actors would prefer to be abandoned since, as Stallman (2004) argued, it creates an artificially coherent category. That said, along with the other contributors to this volume, I use it because it still is the term most commonly used by social movements.
2. In the case of Morocco, for example, a search conducted on 43 pharmaceutical companies, including the biggest one, indicated that 2322 patents were granted on pharmaceutical products between 1970 and 2006 – 1562 of these between 1996 and 2006. Thus, almost two-thirds of the patents were granted within a 10-year period (Krikorian, 2007).
3. In some cases governments have used threats of issuing CLs as bargaining tools. The best-known case of this is Brazil, where the threat had credibility because of the government’s commitment to providing ARVs to all people living with HIV/AIDS and the country’s technical capacity to produce the drugs. Even in Brazil, however, the effectiveness of the threat decreased over time as the government was systematically reaching agreements with patent-holders and not issuing CLs. In 2007 Brazil finally issued a CL on efavirenz, an antiretroviral against HIV.
4. See Krikorian et al. (2008: 12–14).
5. Thailand started to negotiate an FTA with the US in May 2004. The draft of an IP chapter that was submitted by the US during the process included many provisions that require stronger IP protections than the WTO TRIPS agreement requires. They include: the expansion of patentability criteria and the limitation of exceptions to patentability, the extension of term of patent protection, the creation of linkage between patent status and drug marketing approval, the creation of exclusive rights on marketing approval data that prevent the introduction of generic versions of pharmaceutical products onto the market even in the absence of a patent, the limitation of compulsory licensing by restricting the grounds on which a compulsory license can be issued, the prohibition of parallel imports, and so on (for more specific information see Krikorian and Szymkowiak, 2007). The negotiations were suspended in 2006 but are likely to restart in the coming years.
6. In his paper entitled “The second enclosure movement and the construction of the public domain”, Boyle considers the achievements of the pro-intellectual property coalition to be tantamount to a movement. The second enclosure “movement” consists in part of “the contemporary expansion of intellectual property” (Boyle, 2003: 40); the term “movement” is used to denote a trend, an evolution, a phenomenon. In the same paper, he also argues that the environmental movement is “the appropriate model for the change in thinking” necessary in order to protect the public domain and thus counter the “second enclosure movement”. The use of the term “movement” refers here to a “social movement”. The two uses of the term differ and refer to two somewhat different realities; however, their juxtaposition in the paper raises the possibility of comprehending the actions of those arguing in favor of increasing IP protection as a form of social movement. Following Boyle’s analogy we can contemplate the use of the term “movement” to refer to the mobilization of exclusive right owners seeking to increase IPR protections and to the amorphous assembly of actors supporting them, which can both facilitate a deeper understanding of the phenomenon and offer a useful framework for analysis. Admittedly, the use of the term “movement”, which readily invokes the one of “social movement”, may seem like an odd choice when referring to the actions of an alliance consisting of a group of property owners, a network of industries, and a cartel of multinationals. However, even if the present chapter is not the ideal context for fully developing this proposition, I want to underline that there are also a number of features central to the concept of a contemporary social movement that do seem

particularly well suited to describe the pro-IP “movement” and can provide a useful analytical toolkit for the study of the mobilization of interested actors to actively strive for increased IP protection.

7. See European Parliament News: http://www.europarl.europa.eu/news/expert/info-press_page/026-9059-190-07-28-903-20070710IPR09047-09-07-2007-2007-false/default_en.htm. The resolution is available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN&language=EN>.
8. The Drug Study Group (DSG), for example, is a research group composed of academics. Created in 1975, it has since worked on issues related to public health, medicine quality and accessibility, the impact of patents, and so on.
9. A provision in the 1997 national constitution established that civil society could introduce legislation for discussion in Parliament as long as it has obtained 50 000 signatures to support it. Making use of this stipulation, the network of NGOs collected signatures and was thus able to introduce a proposal for universal medical health coverage.
10. Treatments against HIV/AIDS are made of combinations of several antiretroviral drugs. Over time, the viral strains of patients who are taking medication develop resistance to one or several components of their respective combinations, rendering this line of treatment ineffective against the spread of the disease. For this reason, they have to switch from what is called a “first-line therapy” to a new combination, called a “second line”, then a “third line”, and so on.
11. Efavirenz is one of the drugs the WHO recommends for first line treatment, because it induces fewer side effects than nevirapine, the drug used in GPO-vir, the cocktail produced by the Thai manufacturer. Nevirapine is frequently associated with toxicity reactions, including hepatotoxicity. Moreover, almost 20 per cent of the patients taking GPO-vir develop negative reactions to it and need an alternative therapy. Efavirenz can also be used for patients with comorbid HIV and tuberculosis, when nevirapine interacts with the TB treatment (MSF, 2007).
12. Kaletra® is used for second line treatments, following WHO recommendations (WHO, HIV/AIDS Programme, 2006).
13. See Sell (2006), pp. 13–16: “The discursive dimension involves agenda setting, framing and linking issues and promulgating ideas to mobilize others for change.” On the role of the construction of frames and the effect of framing processes which in collective action and social movement theories are key to understanding and explaining collective mobilizations, their actions and outcomes, see: Goffman (1974); Zald (1996); Snow et al. (1986); Snow and Benford (1988, 1992, 2000); Gamson (1988).
14. A similar example was the use of the slogan “copy = right” by Act Up–Paris in 2001 and in the following years, although it had a more radical resonance which could not make it as endorsable by a government as “CL = life”.
15. Under the GSP, the US cut import tariff privileges for 19 Thai export products, mostly agricultural goods. In 1993, Thailand was taken off the Priority Foreign Country List and downgraded to the Priority Watch List. (See Sallstrom, 1994; USTR, 1996; Markandya, 2001; *Bangkok Pundit*, 2007.)
16. For more on this issue, see Guennif and Mfuka (2003: 144).
17. At the WTO Ministerial in Seattle in December 1999, President Bill Clinton marked World AIDS Day by declaring, “Intellectual property protections are very important to a modern economy. . . . But when HIV and AIDS epidemics are involved, the United States will henceforward implement its health-care and trade policies in a manner that ensures that people in the poorest countries won’t have to go without the medicine they so desperately need” (Crispin, 2000). On 19 January 2000, the US government delivered a series of talking points to the Royal Thai government (RTG). Among other things, these points stated, “The US government has generally viewed compulsory licenses as being undesirable because they may undermine intellectual property rights. However, if the RTG determines a compulsory license is necessary to obtain the lowest price

- for ddI, the TRIPS Agreement establishes conditions that must be followed” (Love, 2000).
18. It marketed 115 mg of ddI for 26 baht, instead of the 42 baht per 100 mg pill charged by BMS (Bhatiasevi, 2000b).
 19. The AIDS Access Foundation, along with several people living with HIV, lodged an appeal in May 2001 to oppose the patent on the formulation of ddI. They accused BMS of having intentionally deleted references to dosage in the patent description after it had filed the patent at the Department of Intellectual Property, allowing it to safeguard its rights to the drug regardless of dosage. On 1 October 2002, the Thai Central Intellectual Property and International Trade Court (CIPITC) ruled that the deletion of the dosage indication extended the range of the patent beyond what it originally covered and ordered BMS and the Department of Intellectual Property to correct the patent and restore the stipulation of dosage. The second trial started the following year, when the Consumer Foundation and people living with HIV requested the revocation of the BMS patent on ddI. They invoked different types of arguments. First, when BMS filed its first patent request on 7 July 1991, the law did not permit patenting of pharmaceutical products. Second, since, at the time of the patent request, ddI was already on the market and information about it public, it could not qualify as an invention. Finally, the product did not fit the criteria for inventiveness. In December 2003, BMS put an end to the trial by surrendering its patent to the people of Thailand (Limpananont, 2005: 60).
 20. For more on the involvement of rural doctors in the development of Thailand’s health infrastructure, see Wibulpolprasert and Pengpaibon (2003: 13–14).
 21. See especially editorials and articles published in 2007, on 31 January, 9 February, 10 February, 7 March, 13 March, 14 March, 23 April, 25 April, 30 April, and 7 May.
 22. Headlined “Slouching Towards Burma: Thailand’s Radical New Regime”, the insert used the following language: “When military dictators take over by coup, the people lose. Right now, General Surayud Chulanont is steering Thailand the way of Burma. . . . Then coup leaders hastily imposed draconian measures on foreign-owned companies, like capital controls, restrictions on business advertising and surveillance of Americans working in Thailand. And now they are stealing American assets for military benefit” (USA For Innovation, 2007). For more on USA For Innovation, see <http://2bangkok.com/07/news07apr.shtml>.
 23. “[A] French judge has scheduled an Oct. 26 hearing in Abbott’s lawsuit against Act Up-Paris, which was filed in a Paris criminal court May 23, the company confirmed Monday. Abbott said the French group launched a ‘cyber-attack’ on the company’s Web site April 26 that thwarted worldwide access for ‘several hours’ on the eve of the company’s annual shareholder meeting” (Jaspen, 2007).
 24. The following are excerpts from a letter from USTR Susan Schwab, written in response to a letter sent by 22 members of Congress, asking for an end to USTR interference with the Thai compulsory licensing initiative (Allen et al., 2007): “The Administration . . . remains fully committed to the flexibilities established within global and national intellectual property regimes enabling countries to address effectively significant public health emergencies. As recognized in the 2001 Doha Declaration, these flexibilities include recourse to the issuance of compulsory licenses. . . . With respect to the recent announcement of the Thai Government, we have taken care to respect fully the Thai Government’s ability to issue compulsory licenses in accordance with its own law and its obligations as a member of the World Trade Organization (WTO). We have not suggested that Thailand has failed to comply with particular or international rules” (Schwab, 2007).
 25. Dialogue took place primarily among the European delegation and the US, French, and Swiss Embassies. In 2008, after more than a year of negotiation, the Thai government issued four additional compulsory licenses on cancer drugs (letrozole and imanitib made by Novartis, docetaxel by Sanofi-Aventis, and erlotinib by Roche) (see Treerutkuarkul, 2008).

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4. Illicit seeds: intellectual property and the underground proliferation of agricultural biotechnologies

Ronald J. Herring and Milind Kandlikar

Genetic engineering in agriculture has enabled new claims of intellectual property in seeds; novelty claimed for patent protection has likewise resonated with new claims of risk, supported by a global politics of opposition to biotechnology. Political framing of “GMOs” as bio-safety risks has produced special regulation of some seeds. Both property claims and regulation – which can function as intellectual property – increase incentives for the emergence of underground seed markets, where evasion of both regimes is possible. Contraband, “gray-market”, “brown-bag” or “creolized” transgenic seeds diffuse widely beneath the radar of both firms and states in a global pattern about which little systematic is known.

Some illicit seeds are frauds on farmers, analogous to fake medicines: *counterfeit seeds*. Others build on rural grass-roots challenges to formal intellectual property claims, and simultaneously constitute continuous challenges to states’ claims of special regulatory authority: *stealth seeds*. Stealth seeds in particular necessitate rethinking of (1) conventional wisdom on biotechnology’s effect on rural income distribution; (2) constraints on agricultural development presented by restrictive bio-safety and bio-property law; (3) political claims of both developmentalist and anti-biotechnology advocacy networks.

The spread of illicit seeds renders problematic conventional wisdom on (1) extent of diffusion of transgenic technology; (2) studies of yield effects of transgenics that fail to measure counterfeit seeds; (3) income effects for small farmers; (4) bio-safety agreements signed in cities. This chapter addresses the causes and consequences of this phenomenon, building on the case of India’s first transgenic crop – Bt cotton – to explore broader implications.

1. INTRODUCTION AND OVERVIEW

Seeds of most modern crops have been selected, bred, re-selected and re-bred over millennia, creating great diversity of crop varieties. Historically, the roles of breeders and farmers have overlapped; private intellectual property in seeds is a modern phenomenon. In the industrialized world, selection and breeding are increasingly driven by private-sector firms that lobby for strong intellectual property in germplasm. Nevertheless, a substantial fraction of seeds planted in industrialized countries are still saved by farmers. Genetically engineered (GE) seeds – “GMOs” in political parlance¹ – created a new phenomenon, legally and politically. Transgenic seeds have received stronger formal intellectual property (IP) status through gene patenting and extensive state regulation. Violations of IP, though often contested, are punished; the case of Percy Schmeiser’s transgenic canola and subsequent legal battles with Monsanto in Canada is illustrative.² Though farmers in low-income countries typically enjoy greater latitude in rights to seeds, pressure for Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the seed sector has increased globally. Intellectual property claims, in the form of “technology fees”, typically raise seed prices; regulatory strictures that apply only to transgenic seeds often make these seeds less available (Paarlberg 2001; Potrykus 2004). Governments in some low-income countries also face NGO opposition to transgenic crops domestically and in countries where their products are marketed and sold – typically the EU and Japan. The resulting uncertainty and caution have created delays in approvals, or even moratoria, on the sale of GE seeds. Where transgenic seeds are either too expensive or difficult to obtain, farmers have resorted to underground markets that have developed within and across national boundaries (Herring 2007b).

Illicit seeds cover a range of social phenomena with different effects. Counterfeit seeds are fakes. They misrepresent their genetic material by deceptive labeling or oral communication; the motive is to profit the seller by deceiving farmers. Successful counterfeit seeds exploit farmers. With the introduction of modern biotechnology, this phenomenon takes the new form of claiming transgenic status for seeds that are only conventional. Where demand for new seeds exceeds supply, counterfeit seeds fill new market niches. Stealth seeds are genuine transgenics; they fly beneath the radar screen of firms claiming bio-property and states making bio-safety regulatory claims. Both property and regulation may restrict supply as demand is increasing, leading to familiar black-market dynamics. In the stealth-seed market, the two restrictions are doubly articulated: because the seeds use novel breeding forms – rDNA techniques – they carry special claims on grounds of intellectual property (novelty, utility). But precisely

because firms claim special innovation rents for transgenic seeds, they reinforce the social construction of “GMOs” as a special category for regulation (Miller 2000). The GMO frame, though biologically meaningless, is jointly produced by firms seeking patents, advocacy networks needing issues, and states responsive to articulate urban mobilization (Herring 2008a).

Though sometimes constructed as “contamination” or “biological pollution” by opponents of biotechnology, stealth seeds reflect purposive rural agency and vigorous, though anarchic, capitalism at the grass-roots. Stealth seeds give farmers advantages they cannot otherwise obtain because of blockages in the bio-property or bio-safety regimes in which transgenic crops are embedded. Internationally smuggled seeds cross national boundaries without notification to or permission of state authorities. Examples include the spread of public-sector Bt³ cotton seeds from China to Vietnam and Thailand, transgenic glyphosate-resistant soy from Argentina to Brazil (Herring 2007b) and Bt maize from the US to Mexico (http://www.nytimes.com/reuters/world/lifestyle-biotech-crops-mexico.html?_r=1&oref=slogin). Domestic smuggled seeds move across lines of regulatory authority within the nation-state: for example, the smuggling of MECH 12 Bt cotton from Maharashtra state in India, where it was legal, to Andhra Pradesh state, where it was not, in 2006, and transgenic soy from Rio Grande do Sul in Brazil to Parana in 2003.

Illicit seeds have numerous and complex consequences. First, illicit seeds alter the distribution of gains from technological innovation. Farmers typically lose income from counterfeit seeds and gain from stealth seeds. There is also a global effect. Stealth seeds signal to seed companies that research aimed at low-income nations may not be profitable, perhaps slowing technological change in the short run, as with “orphan drugs” in the pharmaceutical industry. How strong this effect may be remains disputed (Murray and Stern 2006). Counterfeit seeds risk tarnishing a company’s image and thus sales; capitalist firms do not want to hear farmers saying: “Very expensive Monsanto seeds failed in my fields.” Inability to control seed labeling risks reputational damage to firms, and may well reduce incentives for entering markets or working on crops in the poorest places. The result could be to widen the technological divide and thus the income divide between regions and nations, typically to the disadvantage of the poor.

Stealth seeds might well reduce the ability of firms to recover costs of research and development through enforceable intellectual property rights – as seems logical – but in India the situation unfolded differently. Underground transgenic cotton generated the wave of acceptance of the new technology that enabled very profitable licensing of Monsanto’s transgene to dozens of domestic firms (see below). Moreover, private-

sector withdrawal may stimulate public-sector research in biotechnology in developmental states with sufficient capacity, beginning successfully in China, and subsequently India and Brazil. A major study by Joel Cohen and colleagues (Cohen 2005) reported transgenic crop research in 61 public research institutes in 15 developing economies.

Second, underground seeds expose state incapacity to regulate biotechnology, reinforcing arguments against transgenics on grounds of “bio-safety” from global and local NGOs (Miller 2000). Resultant bio-safety institutions are largely for urban consumption and conformity with international norms (such as the Cartagena Protocol), but can function – if enforced and effective – as *de facto* substitutes for intellectual property rights. Tightly regulated transgenics favor firms with sufficiently deep pockets and expertise to meet demanding testing protocols. Monsanto, for example, had no property rights for its Bt cotton that transformed the Indian industry, but for a time had the only legal seeds in the market: no other seeds had conformed to bio-safety requirements. There were two effects: generation of a very lucrative licensing business for Monsanto and driving the (often superior) hybrids with the Monsanto Cry1Ac construct – for example, Navbharat 151 – underground (Jayaraman 2001; 2004; Herring 2005; Roy 2006; Gupta and Chandak 2005).

Third, the phenomenon itself creates contradictions within the many transnational advocacy networks and social movements opposing biotechnology. These groups employ a narrative that posits both “monopoly power” of MNCs in the products of genetic engineering and the agronomic failure of the technology. It then becomes difficult to explain the global phenomenon of farmers’ risking prosecution to acquire and plant transgenic seeds.

Fourth, stealth seeds increase the opportunity for counterfeit seeds to enter agricultural markets. Hucksters have perennially tried to deceive farmers with fraudulent products; authenticity in seeds becomes more critical with transgenic cultivars but less obtainable. For example, the “craze” for Bt cotton in Warangal district in South India carefully and extensively documented by Stone (2007) offers a cautionary lesson: farmers were for a time confused by the plethora of new claims about seeds and intense marketing pressure. Some were duped. Some seeds marketed as Bt actually lacked the transgene, leading to increased crop failure and many reports inaccurately attributing technology failure to seeds that in fact lacked the technology.

Fifth, stealth seeds pose developmental dilemmas given the current segregation of global markets. So long as the construct “GM” remains a legal trade barrier – a matter much in dispute – agricultural exporting states have an interest in controlling what is grown where. Pollen

travels; admixture of export commodities is inevitable. To be “GM-free” constitutes a perceived national interest in many low-income countries. Moreover, if “organic” precludes molecular plant breeding, the price premium expected by organic farmers as compensation for lower yield is at risk from externalities of illicit seeds. National agricultural policy is then led in the direction of creating plans for “coexistence”, significantly increasing costs.

Finally, stealth seeds increase pressure for the development of gene use restriction technology (GURT) to enforce property claims biologically. GURT provided opponents with perhaps their most powerful dramaturgical tool. The motif of “terminator technology” framed transgenics as a bio-cultural abomination – seeds that could not reproduce (Gold 2003; Ramanjaneyula and Ravindra 1999; ETC 2007). “Monsanto’s terminator gene” was a fixture of opposition discourse. The United States Department of Agriculture and Delta and Pine Land⁴ did patent a biological mechanism for “technology protection”, but political opposition prevented its development. Since property in seeds is relational and it is hard to imagine seed police in the villages, the “monopoly” and “patent” construction of corporate power over farmers and nations presupposed the biological mechanism of terminator technology. How else could patents in seeds have power? The terminator framing outran the technology; there is today no parallel in seeds to copyright protection built into DVDs, music, and software.

2. DEVELOPMENT AND THE GENE REVOLUTION: BIO-SAFETY AND BIO-PROPERTY

The genomics revolution in biology created possibilities for conversion of nature to property on a scale unimaginable a generation ago (Tanksley and McCouch 1997; Hilgartner 2002). Early on, there was hope that these prospects potentially valorize, perhaps remunerate, both biodiversity and local knowledge.⁵ Yesterday’s pest could harbor tomorrow’s miracle gene; no one opposes a cure for cancer. Developmental theory created a normative spectrum of variable relationships between value and new forms of property, from “biopartnerships” to “bioprospecting” to “biopiracy” (Svarstad and Dhillon 2000). Bio-prospecting as a means of protecting wild landscapes through commercialization of genetic diversity largely failed to materialize; the threat of bio-piracy remained. Though there is clear evidence recombinant DNA technology is compatible with pro-poor development strategy (Herring 2007c; Lipton 2007; Zilberman et al. 2007), opponents of transgenics describe catastrophe: “genocidal seeds” in the

words of Vandana Shiva (2006). Such critiques often begin with intellectual property. Property enabled by genetic engineering in this discourse plunders genetic resources of indigenous peoples and poor nations in the South to make corporate property for the North (Shiva 1997, 2001). Poor farmers will be crushed by bondage to multinational monopolists, reduced to “bio-serfs”; monopoly power threatens re-subordination of poor nations to neo-colonial control.

Property in transgenic seeds on the ground inverts this construction. Though concentration of intellectual property in multinational firms has been important politically, there is no necessary connection with the technology itself. Global public-sector agricultural research – critical in the “green revolution” – has declined sharply, but developmental states are taking up some of the slack with national public-sector research – yielding in effect public property (Cohen 2005). Research and development costs are daunting, but large nations such as China, India and Brazil can operate at the technological frontier. There are also tested models for humanitarian transfer of biotechnology (Lybbert 2003). The direction of change suggested by India’s experience is not toward monopoly and control, but toward multiplication of actors and cultivars: legal and illegal, domestic and foreign, private and public sector. From these dynamics it is difficult to imagine seed monopoly – so long as the terminator remains in the lab – however often the idea shows up in political rhetoric.

Diffusion of agricultural biotechnology has been rapid, despite problems in the realms of bio-property, bio-safety and bio-politics (Herring 2007a). According to the most recent available data, for 2007, 23 countries have officially-approved transgenic crops growing in fields, with roughly 10 million farmers, most of them in less-industrialized countries (Herring 2008b). Despite the global political rhetoric of North vs South, the top five countries in acreage after the United States are Argentina, Brazil, Canada, India, and China. In all international institutional data, unauthorized plantings of transgenics are not counted. The AGBIOS comprehensive database on transgenic crops (<http://www.agbios.com/main.php>) does not list, for example, Thailand, Pakistan or Vietnam, yet transgenic crops are widely grown in these countries (personal communications). Stealth and evasion characterize much global seed diffusion, in parallel to the broader global illicit economy that flies under the radar of official institutions (Naím 2005).

A brief case study of illicit seeds in India will illustrate several themes of this chapter. First, the political construction of transgenic seeds as risky enables bio-safety institutions that ironically function as property institutions: Monsanto had no property rights in its transgenic seeds in India, but bio-safety regulations assured it a temporary dominance in

production and sales – and eventually licensing – of Bt cotton. These provide a choke point for opponents of biotechnology, and thus a spur to the emergence of stealth seeds; farmers cannot legally get what they want. Second, the same forces that undermine bio-safety institutions undermine bio-property institutions: farmer activism and state incapacity at the local level. Third, the success of stealth transgenic cotton spurred demand that exceeded supply, leading to opportunistic marketing of counterfeit seeds. Finally, the spread of technology from illicit seeds essentially ended the debate about biotechnology among farmers: hybrids containing the Cry1Ac transgene became ubiquitous, eventually hegemonic. Illicit seeds thus ironically prepared the way for an explosion of officially sanctioned applications of rDNA technology to cotton.

3. TRANSGENIC COTTON IN INDIA: BIO-PIRACY, STEALTH SEEDS, AND THE STATE

Indian cotton is plagued by low and unstable yields, much aggravated by depredations of bollworms (especially *Helicoverpa armigera*). The first Bt cotton hybrids contained a single transgene that produced a single protein toxic to bollworms. The leader of India's (then) largest farmer organization, *Shetkari Sanghatana*, captured best the tenor of the stealth-seed story (2001):

Through a lucky stroke a nondescript seed company managed to play Robin Hood and smuggle into Gujarat one line of anti-bollworm gene. For three years nobody noticed the difference and then came the massive bollworm rampage of 2001.

Gujarat saw all its traditional hybrid cotton crop standing devastated, side-by-side the Bt-gene crops standing resplendent in their glorious bounty. The Government was upset and ordered destruction and burning of the bountiful crop.⁶

Neither the 'Operation Cremate Monsanto' movement nor bio-safety regulators had noticed the transgenic cotton. Monsanto's partner Mahyco complained to the Genetic Engineering Approval Committee (GEAC) in Delhi that seeds sold as Navbharat 151 contained the Cry1Ac transgene. NB151 was registered with the state of Gujarat as a cotton hybrid, but not as a transgenic organism. The GEAC found Mahyco's charges to be true; NB151 contained the Cry1Ac gene in the construct of Monsanto. The head of Navbharat, Dr D.B. Desai, was eventually charged with violation of the environmental protection act (1986, Rules 1989) that regulates transgenic organisms.⁷ No transgenic crop could be legally sold or planted

without officially sanctioned tests and final approval by the GEAC. The GEAC then ordered the cotton to be burned; the farmers' organization responded: "We will burn with our crops in our fields." The state Government backed down; the orders were not carried out. The failure of the GEAC order indicated that Bt cotton was out of the hands of regulatory authorities and scientists in 2001 and in the hands of politicians and organized farmers.

The state Government of neighboring Maharashtra soon announced, under continuing farmer protests, that it would make the same hybrids available to its farmers, regardless of Delhi's rulings. On 25 March 2002, farmer representatives in the Kisan (agriculturalist) Coordination Committee threatened to launch a civil-disobedience movement if Bt cotton were not approved by Delhi immediately. Demonstrating the power of stealth seeds, they threatened to cultivate transgenic varieties whether or not the government approved. The following day, 26 March, the GEAC approved three varieties of the Mahyco-Monsanto Bt cotton, making India the 16th nation in the world to certify a genetically engineered plant for commercialization (Herring 2006).

After Navbharat 151 was banned in 2001, it became scarce, though not impossible to find; farmers sought out its parent lines for breeding. Farmers with relatives in Andhra Pradesh, and especially Kurnool district, were more successful in obtaining NB 151 seeds after they were discovered and banned.⁸ Some farmers saved their seeds after ginning and sold or exchanged or replanted the F2 generation⁹ of Navbharat 151, which was no longer available legally in the market. There is deep irony in this spread of the vigorous offspring of the "suicide seeds" as constructed by advocacy groups opposed to biotechnology. These seeds were locally called "loose seeds", straight from the ginning mill, unpackaged and unbranded. They may express less Bt endotoxin, but, according to farmers in Gujarat, offer reasonable protection at a very low price. In these early stages of diffusion, officially approved hybrids faced stiff competition from a wide variety of much cheaper stealth seeds and their progeny. On 16 August 2004, Union Agriculture Minister Sharad Pawar acknowledged in parliament that the underground seed market was flourishing and alarming. It is not known how many "Robin Hoods" – in the construction of Sharad Joshi and the BBC – were active in rural India, but a vigorous cottage industry of transgenic pocket breeding quickly grew up around descendants of the original stealth seeds – Navbharat 151.

For breeding new transgenic hybrids, farmers used the illegal Navbharat 151 seeds for the male contribution and a local variety especially well suited to their agronomic conditions as female. From this process, a new Gujarati word has been hybridized: "Navbharat variants". There are uncounted

branded and packaged Bt variants in circulation: Kranti, Luxmi, Viraat, Kavach, Sarathi, Vaman, Agni, Rakshak, Maharakshak, the generic Kurnool Bt and simply “151” playing on the original Navbharat 151, among many others. In Gujarat, these local hybrids were sold by local merchants, who sometimes guaranteed the seeds, to distinguish them from the many spurious seeds claiming Bt status in the market. To indicate transgenic character semi-covertly, some variants were labeled in English “BesT Cotton Seed”, to emphasize the Bt. There developed as well farmer-to-farmer transactions of nameless transgenic hybrids.

The tension between official seeds and stealth seeds was dynamic. When the GEAC refused approval of Mahyco-Monsanto’s new variety MECH-915 for North India, an advertisement soon appeared in a prominent Hindi daily for farmer-grown transgenic seeds: call the cell phone of Piyush Patel. In press coverage, Patel is quoted as saying: “If I live in Gujarat and go to Shimla, I will not die, so the same way these seeds developed in Gujarat will grow.” Patel offered Bt seeds for Rs 555 per packet of 500 grams, a third less than Mahyco-Monsanto’s price (*Indian Express* (Delhi) 20 April 2002). By June 2005, Herring found that locally-hybridized transgenics in Gujarat were selling for Rs 250–700 per one-acre packet; F2 transgenic seeds cost Rs 10 for the same size packet.

Jayaraman (2004) cites “industry sources” as estimating that more than half of the transgenic cotton in India at that time came from unapproved varieties; discussions with Gujarati seed producers suggested a much higher figure for that state. Data from Navbharat Seeds indicate that on an all-India basis about 34 per cent of the cotton seed packets sold were transgenic, of which 9 per cent were legal and 25 per cent stealth.¹⁰ Yet these estimates apply only to packaged and branded stealth seeds, not to “loose” (F2) seeds. Dr R.P. Sharma of the GEAC believed this to be a temporary phenomenon: farmers would eventually choose Bt cultivars from trusted seed companies and abandon the stealth transgenics: the current state of affairs simply reflected the fact that “scarcity breeds corruption”.¹¹ Scarcity, in turn, was created by banning the extremely effective Navbharat 151 hybrid because it had not passed through the GEAC’s bio-safety protocol.

The GEAC opened new incentives for stealth in 2005 by refusing to renew certification for three MMBL hybrids in Andhra Pradesh and banning use of MECH 12 in South India generally. Mahyco-Monsanto was forced to withdraw three hybrids from Andhra Pradesh. When the GEAC decided not to renew MMBL’s hybrids, they did so without any evidence on yields and performance, but at the request of the state government. One local explanation was commercial competition: Nuziveedu Seeds of Secunderabad wanted this outcome, and is politically well

connected in Andhra Pradesh. Mahyco is a firm from Maharashtra, a neighboring state, and Monsanto a much-reviled multinational from St Louis. Nuziveedu then produced two competing Bt hybrids, *Mallika* Bt and *Bunny* Bt, both popular with farmers we interviewed in Warangal district in 2006 (Herring 2008b). The first farmer Herring interviewed – in Kadipikonda, Hanumakonda mandal – introduced the new problem of illicit official seeds. To my standard question, “What cotton do you grow and why?”, he answered: “MECH 12 because of large bolls, easy picking, early flowering, bollworm resistance.” But MECH 12 was illegal in Andhra; yes, he traveled three hours by bus to Nanded in Maharashtra to get the seeds after they were removed from local markets.

In the same field trip, we discovered the continuing presence of counterfeit seeds. Could the many reports of “failure of Bt cotton in India” be related to farmers’ being fooled by counterfeit seeds? Might farmers buy seeds labeled as Bt that actually lack the Cry1Ac transgene for insect protection? How would anyone know? This hypothesis is plausible because of the “craze” for Bt cotton in the district reported by Stone (2007) and our earlier finding of shortages of Bt hybrids at the state level due to unanticipated demand. Moreover, there is no certification in Andhra Pradesh for Bt cotton seeds.

Counterfeit seeds predictably emerged from this situation: the absence of certification and regulation, shortages of preferred hybrids, commercial hype and false claims and a “craze” for the new technology. Counterfeit seeds are locally called “duplicates” (the English word is used). Duplicates are made by unscrupulous dealers who change the name on the seed packet marginally to fool the buyer. Some farmers gave us a local example: changing the printed name on the seed canister from “Mahyco” to “Mahaco”. These duplicates do not contain the Bt transgene, and therefore give no protection against bollworms. Some farmers “without knowledge” do buy the duplicates, and suffer thereby (Herring 2008b). In response, MMBL has added a holographic image to their canisters, more difficult to counterfeit.

Competing for farmer choice in Warangal were also genuinely transgenic but illegal stealth seeds. Some are known as “Kurnool Bt”, from the district in which they are grown; these are sold by farmers who grow Bt seeds for the major seed companies but leak a portion of their harvest through unauthorized channels. An alternative name was “*gudda* Bt”, from the cloth bags in which they come. The seeds sell for Rs 500–600 per packet, as opposed to Rs 750 for official seeds. They carry no guarantees; dealers are not backing them, unlike some seeds in Gujarat’s underground cottage industry. The highest yield reported to us in Warangal was from an accidental meeting with a farmer at the research station at Angrau. He had grown “Gujarat Bt”, meaning a Navbharat 151 variant, unlabeled,

and obtained what he considered a phenomenal yield: 15 *quintals*. He tried the stealth seeds after a neighbor had done well with them. Farmer exchanges of information and seeds account for gray-market seeds we discovered as well: seeds approved for cultivation in one area but not in Warangal, or seeds still under testing in the pre-approval stage. One farmer was growing Bollgard II (the two-gene stacked BGII), purchased in Nanded, Maharashtra, on three acres. On one acre he was growing the Bt hybrid Brahma, and on another MECH 12. None of these hybrids was at that time legal for growing in the state.

By 2007 India's cotton seed sector had been radically transformed. Four genetic events had been approved for insertion into hybrids, from three companies, one of which uses the Chinese public-sector genetic material and one of which is entirely indigenous, implemented by dozens of firms under licensing arrangements. Approved hybrids had gone from 3 in 2002 to 137 in 2007. No one knows the extent of stealth seeds; as prices of official seeds have come down dramatically one would expect the stealth seed market to recede. Data on the extent of counterfeit seeds are hard to come by. Dr K.R. Kranthi, a scientist with India's Central Cotton Research Institute, has estimated that "on average, 28 per cent of the illegal seed brands are non-Bt" though labeled Bt. Among samples collected and tested by CICR, only 26 per cent of the Bt cotton was true first-generation hybrid, while 46 per cent was contaminated with non-Bt cotton.¹² These observations from the Vidarbha region of Maharashtra suggest that roughly 30 per cent of Bt cotton seeds sold there were counterfeit. It is impossible to tell whether these numbers are representative of the region, let alone the state or nation. Though the great majority of Indian cotton farmers now grow some Bt hybrid or another, many must be growing hybrids without the protection they think they have bought.

4. INTELLECTUAL PROPERTY IN SEEDS: FARMERS' RIGHTS AND BREEDERS' RIGHTS

Seeds and formalized intellectual property rights have an ambiguous relationship. This ambiguity is rooted in a ground reality – seeds were, and often continue to be, produced and reproduced in farm settings, where farmers play the role of both users and breeders. Consequently, informal economies of seed production, sale and exchange have historically been a commonly shared attribute of farming communities. It is not surprising that stealth transgenic seeds emerged for multiple crops in response to demands generated within farming communities. At the same time, as private companies have garnered an increasingly large share of the seed

market, these informal arrangements have come under pressure. In most jurisdictions the relationships among seeds, farmers, and commercial firms are changing, albeit slowly, and in different ways.

Much of the contemporary pressure for change has come from the biotechnology sector, though the earliest plant patent protections in the US date to the Plant Patent Act of 1930. This act allowed for patents on asexually reproduced plants; these protections were extended to include sexual reproduction in 1970 through the Plant Variety Protection Act. Over the past two decades, products of genetic engineering and other forms of genetic modification have been incorporated into the patent regime. Following a landmark Supreme Court case (*Diamond v Chakrabarty* 1980) in the United States, any *live* organism, including seeds, that is a product of human intervention can be patented. In Europe, individual varieties are not patentable, but claims aimed at broader plant groupings are allowed, as are biological entities resulting from biotechnological processes (Le Buanec 2006). Canadian patent law does not allow patenting of higher life-forms, but allows patents on components of life-forms such as genes and cells, and processes that manipulate them (*Nature* 2003). Countries in the less-industrialized world, including India, have resisted extension of IP rights to plant varieties and seeds, but are under increasing pressure to conform to increased privatization and globalization of the seed sector.

While arrangements under TRIPS have sought to harmonize globally intellectual property protections for plant varieties, there are wide variations in how these rights are actually granted in different jurisdictions. Under TRIPS, plant varieties can be protected either by patents or by an effective *sui generis* (unique) regime. A *sui generis* system can be entirely indigenous or one based on the UPOV (International Union for the Protection of New Varieties of Plants) convention that provides guidelines for Plant Variety Protection (PVP). UPOV, first established in 1961 and subsequently amended in 1978 and 1991, grants plant breeders monopoly rights over registered varieties with a number of exemptions – such as exemptions for non-commercial uses, for research use and for breeding other varieties. India passed the Plant Variety Protection and Farmers' Rights (PVPFR) Act as *sui generis* legislation in 2001. The process lasted for more than a decade, involving multiple drafts and reviews, extensive public consultation, and significant public debate and controversy (Ramanna and Smale 2004). While the relative merits of PVPFR and UPOV legislation can be debated (Lalitha 2004), Indian PVPFR legislation departs significantly from UPOV. Farmers can sell seeds so long as they are not “branded”, where branded seed “means any seed put in a package or any other container and *labeled in a manner indicating that such seed is of a variety protected under this act.*”

Laws governing plant variety protection in India are complicated by federalism – agriculture is a state subject – and overlap with other laws. The current legislation seems to allow free exchange and sale of seeds *except* when they are labeled as being subject to the PVPFR Act. Similar exceptions apply to transgenic seeds. And all seed law may be subject to other legislation. Marketers of farmer-generated transgenic hybrids deploy this ambiguity instrumentally; they often refer on seed packages to an earlier law, the Indian Seeds Act of 1966, section 24 of which explicitly protects the farmer’s (producer’s) right to sell self-grown seed – in this case Bt hybrids. Seed companies are well aware of the weakness of plant breeders’ rights (Srinivasan 2003); the effect on the development of new varieties is difficult to disentangle.

The political debate around plant variety protection in India framed the rights of farmers against those of commercial breeders, yet what proved crucial in the illicit seeds scenario was the property-like right conferred by bio-safety regulators, not property law. Mahyco-Monsanto’s exclusive power to license the first-generation Bt cotton technology derived not from any of the strands of plant variety protection debated for India’s PVFPR; *de facto* – and temporary – monopoly derived from approval by the Genetic Engineering Approval Committee. No other seed firm had applied for such approval, and none had received it, leaving the formal-sector Bt licensing field to Mahyco Monsanto Biotech Ltd alone. The incentives of farmers and “plant breeders” (seed companies) involved in the production and distribution of illicit seed were aligned. Lowering the trait value administratively advantaged formal-sector licensees of official seeds from MMBL at the expense of both MMBL and this underground coalition of rural agents – farmers, unlicensed seed growers, distributors, sales agents and smugglers.

5. STEALTH SEEDS: WHO GAINS AND WHO LOSES

Farmers were clearly the major direct beneficiaries of the diffusion of stealth seeds in India. Navbharat Seeds benefited only temporarily since its Bt cotton sales were shut down in 2001. Among plant breeders, the greatest beneficiaries were contractors for Navbharat Seeds, and any others who managed to acquire the parental lines of Navbharat 151 and cash in on the stealth-seed boom that followed Delhi’s ban on NB151. The immediate losers were seekers of innovator rents through state protection of intellectual property – in this case Mahyco Monsanto Biotech Limited. This protection is not available in India; what made the sale of NB151 illegal was not IP regulation but the failure to gain bio-safety approval.

Farmers embraced the agrarian anarcho-capitalism of underground Bt seeds because benefits were substantial. The cost of official MMBL seeds needed per acre of planting in 2002 was \$40 (Rs 1600 per packet of 450 gm), while home-brew descendants of Navbharat 151 cost between \$6 and \$18 (Rs 250–Rs 750). Even cheaper were the NB 151 F2 Bt seeds that came from ginned cotton or were saved directly by farmers (Roy 2006). Some farmers insist that – contrary to conventional wisdom – F2s outperform F1 plants. Agronomists suggest losses of only 10–15 per cent relative to F1 Bt plants; Morse et al. (2005) found that F2 Bt varieties reduce pesticide costs but have no significant yield gains relative to non-Bt check varieties.

Bio-safety regulation can function as property if the costs of regulation are high enough to restrict entry and the monitoring regime can enforce rules. High regulatory cost burdens can delay approvals, or cause firms to withdraw the product altogether, as in the case of Bayer with GM mustard in India. Pre-approved testing, which is mandated by India's bio-safety regime, was estimated to cost US\$2 million for the initial approval for MMBL's Bt cotton.¹³ Since patent protection on intellectual property in seeds is unavailable in India, Mahyco-Monsanto favors strict bio-safety regulation. In these circumstances, regulatory restriction of official seed varieties confers property-like rights on holders of approved transgenic cultivars. Because only their seeds were legal and adjudicated bio-safe, monopoly rents became available to MMBL in licensing of their technology to the many competing seed firms. Advocates for stealth seeds accuse the GEAC of market-rigging through expensive and onerous bio-safety regulation that creates *de facto* bio-property rights.

How do farmers who use stealth seeds view abstract notions of bio-safety and intellectual property? Systematic data are limited, but the gulf between the lives of Indian cotton farmers and the global discourses around bio-safety and IP is vast. When asked why they thought stealth Bt cotton seeds were illegal, farmers in Andhra Pradesh, Gujarat and Maharashtra gave Kandlikar quite divergent explanations. These included *inter alia* Monsanto's hold over politicians, shenanigans by pesticide companies that are the only clear losers from the widespread adoption of Bt cotton, and opposition to the technology by urban environmentalists. Ideas of bio-safety or intellectual property were entirely absent. Absence of resonance with urban constructions is one of many reasons for poor institutional performance in this arena.

Stealth seed producers for their part instrumentally draw upon prior laws governing the sale of seeds (The Seeds Act, 1966) to legitimize their business. Their packages contain the warning that seeds in the packet are meant to be "exchanged" among farmers and not sold; the Act clearly gives farmers rights to save and exchange seeds. If the stealth transgenics

are not “for sale”, then their legal status is unclear. There are multiple overlapping laws and regulations that govern the sale of GM seeds – the Plant Variety Protection Act, the Seeds Act and the Environmental Protection Act – and there is no clear case law on how conflict between these laws might be resolved. Moreover, agriculture is a state subject in the Constitution; Navbharat’s defense for its Bt seeds was that NB 151 was a registered hybrid in the state of Gujarat, and therefore perfectly legal.

5.1 Indirect Economic Impacts

The direct effects in terms of revenue gains and losses from stealth seeds may be small compared with the indirect “knock-on” effects on Bt cotton in subsequent years, and more generally on transgenic crops. The tactical use of bio-safety as a tool for maintaining market monopoly is then a double-edged sword, especially if current tactics influence future regulations. Bio-safety trials mean that farmers cannot access new seeds at any price for extended periods; the seeds are simply not available in the market for the time required for regulatory approval. Both farmers and firms lose from regulatory delays. In an analysis examining the welfare impact of regulatory costs, Pray et al. (2005) provide rough estimates for the welfare costs of scenarios related to timing of approval and increased enforcement. They find that a two-year delay in approval of Bt cotton may have resulted in aggregate losses to Indian farmers of \$300 million from 2000 to 2004, while decreasing MMBL’s IRR to 45 per cent from 61 per cent. Stronger enforcement of bio-safety laws but without early approval could have resulted in losses of \$17 million for farmers, while increasing MMBL’s IRR from 45 per cent to 56 per cent.

Daunting regulation was one reason for Navbharat going straight to farmers, bypassing Delhi’s GEAC. Subsequently, as Sharad Joshi’s “Robin Hood” narrative suggests, the success of Navbharat 151 in Gujarat in the 2001 season, and the failure of Delhi’s order to burn the crop, provided the political impetus for national approval of Bt hybrids in 2002. Successful farmer protests exerted great pressure on the GEAC for approval; protests in turn were triggered by the demonstration effect from the remarkable agronomic success of Navbharat 151.¹⁴ Delhi’s approval itself probably made little difference to either stem or stimulate the diffusion of stealth seeds in India. The Government’s inability to destroy the Navbharat crop as announced signaled to all farmers and seed producers that – so long as they kept under the radar – the production and planting of stealth seeds would be officially tolerated.¹⁵ The approval, however, did make a difference to MMBL, which was then in a position to officially sell Bt seeds, make profits, and license the technology to competing seed firms.

Paradoxically, stealth seeds may actually have increased MMBL profits by accelerating this process.

Once approval was granted two competing effects come into play that influence the balance of gains from innovation. Stealth seeds, on the one hand, had a positive impact on the diffusion of Bt cotton, and so brought more farmers and seed-producing companies into the formal Bt economy; on the other hand, their continued presence reinforced the argument of opponents of biotechnology that regulation is impracticable, strengthening the case for a moratorium on new transgenics and/or stricter regulations.

5.2 Impact on Seed Companies

Bt cotton hybrids rapidly diffused across India after 2002, and by 2007 accounted (officially) for more than two-thirds of all cotton planted. Stealth varieties remain important, though uncounted. The success of Bt cotton, owed in no small measure to the success of stealth varieties, resulted in increased licensing of MMBL's approved and "bio-safe" product to more than thirty companies by 2006. By 2007, this number had increased to 137 hybrids using Bt technology from three different companies licensing their implementation of different genetic events.¹⁶

As the number of locally adapted official Bt varieties has risen, so has the use of official Bt seeds, at the expense of stealth hybrids. This may be particularly true of regions that have to import their illegal varieties. As Ramaswami et al. (2007) note, stealth seeds are a manifestation of a larger stealth economy in which networks matter. Assuring the quality of local varieties, which is critical for continued sale, may be easier since their distribution occurs through known and trusted kinship channels. Indeed, Kandlikar observed in 2005 that farmers in regions of Maharashtra bordering Gujarat were obtaining illegal/stealth seeds from kin networks from just across the border. In Gujarat, Shah (2005) found that the production and distribution of stealth seeds was rooted in a trust network involving social, credit and kinship arrangements. Regions that have no prior history of growing commercial seed may have neither the infrastructure nor the social networks to sustain clandestine operations. Finally, legal actions taken by the government of Andhra Pradesh in 2006 lowered the "trait value" of the official seeds, and thus their overall price, reducing the incentive of farmers to buy underground seeds.

5.3 Federalism and Administered Prices

Legal manoeuvres launched by the state government of Andhra Pradesh sought reduction of MMBL's monopoly rents. The government of Andhra

Pradesh lodged a legal complaint against MMBL with India's Monopolies and Restrictive Practices Commission (MRTPC) in 2006.¹⁷ In their writ, the AP government claimed that the trait value charged by Monsanto in other countries, notably China and the US, was much lower than in India. In their ruling, the MRTPC sided with the state government and agreed that MMBL was using unfair trade practices in setting its technology licensing fees. Prior to the ruling, Monsanto's trait value was set at Rs 900 (\$22) per packet, to which the sub-licensee's margins could be added. The MRTPC directed MMBL to bring the trait fee (on a per package basis) in line with those in other countries. MMBL pointed to differences in agronomic practices that made the comparison of seed costs by weight misleading; on a usage-per-acre basis the trait value for seeds in China and the USA were respectively two and three times those assessed in India. These objections notwithstanding, the government of Andhra Pradesh fixed a price ceiling of Rs 750 per packet of Bt cotton seed, and ordered all seed companies to abide by this pricing structure. Other state governments followed suit and fixed seed prices at the same level. MMBL unsuccessfully challenged the order in the Supreme Court of India.

The effect of the price ceiling on MMBL and its sub-licensees was dramatic – the premium on Bt hybrids dropped from Rs 1150 to Rs 300 – and MMBL was forced to renegotiate the trait value with its sub-licensees, which was reportedly set at Rs 150. Murugkar et al. (2007) have shown that despite the smaller premium on Bt cotton varieties, and despite licensing costs (a one-time licensing fee payment of Rs 5 million or \$125,000) and other regulatory barriers (including the need to show agronomic performance through field trials¹⁸), it still makes economic sense for seed companies to invest in the marketing of Bt hybrids.¹⁹ The effect of price reduction on the stealth-seed economy could be very large; the price differential may now be too low to sustain clandestine operations, especially since farmers are likely to choose approved seeds for which they have legal protections. F2 seeds, which need no such infrastructure, may continue to be used, but the inherent disadvantages of F2 should be self-limiting. Anecdotal evidence gathered from the Guntur region of Andhra Pradesh in 2007 also suggests that stealth Bt seeds may be on the wane in regions outside the cotton seed-growing belt. Reports from Gujarat, the birthplace of Navbharat 151, however, suggest that stealth seeds use continues unabated.

Monsanto's response to the mandated price reduction has been to introduce Bollgard II seeds that use stacked genes to resist a greater number of pests. Bollgard II seeds had themselves previously been illicit, smuggled into Andhra Pradesh in 2006 before formal approval. Bollgard II is more expensive than the single-gene Cry1Ac version, though the price of a

packet was dropped to Rs 1000 in 2007 from Rs 1400 the year before. The threat of an emerging stealth market, especially in Gujarat, and lessons from the MRTPC episode have reasonably been hypothesized as reasons. Whether the additional price premium (Rs 250) on Bollgard II will create patterns of stealth seed diffusion similar to their predecessor seeds remains to be seen.

The intervention of the Andhra Pradesh government on behalf of farmers brings into relief some important jurisdictional questions. Bio-safety laws fall under the purview of the central government under the Environmental Protection Act. In order to implement these laws, however, the center must rely on the enforcement capabilities of state governments. Farmers are large voting blocs, and the success of Bt cotton in the past few years stands out in the otherwise gloomy picture of India's recent agrarian crisis. State governments were therefore unlikely to curb the use of the stealth Bt cotton seed by farmers. Instead, to the extent they acted on the issue, their half-hearted and sporadic attempts to enforce bio-safety laws were aimed at stealth seed distributors.

Stealth seeds in India have had complex effects on the way in which the gains of innovation have been distributed. Both MMBL and farmers have benefited from the diffusion of Bt cotton, but stealth seeds have defined the balance between the two in surprising ways. First, cheaper seeds have helped large numbers of Indian farmers gain access to a powerful new technology with undeniable benefits, while reducing MMBL profits. Second, stealth seeds may have also (paradoxically) helped MMBL by creating a farming constituency that lobbied hard for the approval of transgenic cotton. Third, their rapid diffusion may have signaled the true size of the market to both MMBL and hybrid seed companies, and consequently benefited both groups. Finally, stealth seeds may have had a dampening effect on the trait values charged by MMBL for the next generation of GM cotton.

6. CONCLUSIONS

Illicit seeds come in different forms, with different developmental consequences. The stealth seed phenomenon affects the economic consequences of modern biotechnology as well as political contests around bio-safety and international regulation. Stealth seeds give farmers advantages they cannot otherwise obtain because of restrictions in the bio-property or bio-safety regimes in which transgenic crops are uniquely embedded. Bio-property and bio-safety institutions are intertwined; conditions for effective institutions in the two spheres are similar and ultimately rest on

a stronger state vis-à-vis rural society than is typical in nations with large agricultural populations.

Transnational advocacy networks opposed to genetic engineering built their critique in part on the presumed monopoly power of multinational corporations, with a parallel critique of bio-piracy enabled by the same genomics revolution in biology. When the BBC characterized the small Indian firm Navbharat's appropriation of Monsanto's Bt cotton gene as "bio-piracy", the rhetorical tables were turned. The assumption that genetic flow can move only from South to North was suddenly rendered problematic. Moreover, the episode illustrated concretely that only a deep urban cultural bias can construct farmers as hapless victims incapable of the kind of agency that makes the illicit sector so pervasive a global phenomenon (Naim 2005). If every urban area witnesses unauthorized appropriation of the latest technology, why should farmers be cognitively condemned to passive "bio-serfdom?" Stealth seeds reflect the same kind of agency as urban appropriation of pharmaceuticals and software, films and music – the same anarchic capitalism at the grass-roots – with similar risks and rewards. The analogy of seeds to "agricultural MP3s" is, however, a limited one. Unlike MP3s, producers of seeds need access to capital, labor and know-how for production. Further, though stealth seeds have clearly benefited farmers, anarchy in seed markets increases the opportunity for counterfeit seeds to deceive and exploit them.

Stealth seeds assume importance in developmental discourse by altering the distribution of gains from technological innovation. Stealth seeds enter *politics* because they expose state incapacity to regulate biotechnology, fueling opposition on grounds of "bio-safety" from a broad coalition of global and local NGOs that assume transgenics to require special regulatory oversight. Ironically, political opposition has augmented the stealth-seed operation globally by slowing, interrupting or preventing official approval of transgenic seeds. In response, farmers in polities of quite different characteristics have created and participated in underground markets. Stealth seeds embarrass the politics of anti-GMO advocates. Claims that biotechnology enables "monopoly power" of MNCs in the products of genetic engineering, or that the technology is an agronomic failure, are rendered risible by stealth seeds. Moreover, at least some reports of technology failure widely circulated on the web may well result from counterfeits masquerading as genuine transgenic seeds: evidence from India suggests that this effect may be large.

For the state in low-income countries, illicit seeds pose developmental dilemmas, given the current formal-legal segregation of global markets along GM–non-GM–organic lines (Paarlberg 2008). Opportunity costs of bio-property and bio-safety enforcement are high. For firms, stealth

seeds increase pressure for development of gene use restriction technology (GURT) to enforce property claims biologically, precisely because of political and institutional failure to do so. Gene use restriction technology provided opponents of biotechnology with perhaps their most powerful dramaturgical tool – though Terminator Technology was only conjured, not deployed in any existing fields. Politically, development of GURT in plants would simultaneously undermine one branch of resistance to the technology (environmental concerns for horizontal gene flow) while reinstating the property claim – that monopoly and dominance vis-à-vis the farmer could characterize the industry.

Suppression of stealth seeds might be possible, but only at great economic and political cost and with dubious effects on income distribution. Moreover, if the bio-safety regime is extremely strict, only firms with deep pockets and long time horizons will pass the hurdles. If legality is enforced as a condition for sales, bio-safety approval is functionally equivalent to bio-property rights. The Mahyco-Monsanto case in India clearly demonstrates this point, though the outcome was mitigated by the underground transgenic seed market. The ethical question is then: at what level of plausible risk is regulation justified if property-like monopoly is a predictable consequence? How can the state justify handing out *de facto* property rights to firms simply because they have the capacity to deal with the state's own guesses about risk? Any legitimate ethical conclusion would set a very high threshold on demonstration of risk. To do this, the "GMO" frame requires disaggregation: what traits, in what cultivars, where? Cotton is highly unlikely to pose gene-flow risks; grasses are more promiscuous in sharing genes; rice has numerous wild and weedy relatives. The blanket framing of transgenic seeds with essentially blind risk assumptions enhances the property-like powers of the largest life science firms in ways that are extremely hard to justify normatively (Herring 2008a).

NOTES

1. GMO is a political, not biological, construct. Transgenic seeds are created through molecular plant breeding, or recombinant DNA technology. Since all modern agricultural crops are genetically modified, the term means nothing biologically but has been powerful politically. See Herring (2008a).
2. See analysis, references and Schmeiser's narrative at <http://www.law.duke.edu/journals/dltr/articles/2001dltr0015.html>; <http://www.percyschmeiser.com/>.
3. Bt denotes a crop transformed by addition of a gene from the common soil bacterium *Bacillus thuringiensis*. Use of the generic "Bt cotton" refers in this chapter to cotton that contains the Cry1Ac gene. This transgene produces an insecticidal protein lethal to many lepidopterans, including most importantly bollworms, which are the greatest insect threat to India's cotton.

4. U.S. Patent 5,723,765 entitled “Control of Plant Gene Expression”, granted 3 March 1998 on a concept termed the “Technology Protection System” (TPS). Monsanto’s initial attempt to purchase Delta and Pine Land failed, though this fact did not change the global protest focus on “Monsanto’s terminator”. Ironically, GURT offers a biological solution to the as-yet uncertain environmental risks from gene flow (Thies and Devare 2007), whereas social institutions have proved leaky (Jayaraman 2001).
5. On the optimistic scenario, see Reid (1996), Weiss and Eisner (1998). For an economic explanation of failure of bio-prospecting, see Simpson et al. (1996).
6. Joshi (2001); for a full account with sources, see Herring (2005); also Jayaraman (2001), Sahai (2002), Mehta (2005: 60–79, 130–136), Visvanathan and Parmar (2002).
7. “Cultivation of Bt Cotton Using Navbharat Seeds”, Government of India, *Rajya Sabha* Unstarred Question No. 205 to be answered on 01.03.2002 by Minister for Environment and Forests, Shri T.R. Baalu.
8. Yamaguchi (2004, Chapter 4); Herring interviews with seed producers in Gujarat (June 2005).
9. F1 is the first filial generation of seeds (such as the Navbharat 151) from parental lines. F2 is the generation of seeds made from crossing F1 parents. F2 plants in theory show greater phenotypic variation and consequently lower average yields, though some Indian farmers who grow Bt cotton dispute this conclusion (Roy et al. 2007).
10. Personal communications to Herring, October 2005.
11. Herring interview, New Delhi, 27 June 2005.
12. <http://www.scidev.net/en/features/gm-in-india-the-battle-over-bt-cotton>, retrieved 3 April 2008.
13. Pray et al. (2005) also estimated costs for meeting future regulations: \$100,000 for a variant of MMB cotton whose genetic event is already approved; \$500,000 to \$1,000,000 for cotton crops whose genetic event is not yet approved in India; \$1,500,000 to \$2,000,000 and higher for food crops whose genetic events are not approved in India or anywhere else in the world.
14. The power of the on-farm demonstration effect in overcoming regulatory resistance to novel seeds has parallels. During the early phase of the Green Revolution, Turkish agronomists were skeptical of high yielding varieties (HYVs); policymakers resisted approval of HYVs of wheat. It was only after an adventurous farmer – Mehmet Can Eliyesil – planted smuggled seeds and demonstrated large yield increases that the Turkish government changed its mind and embraced the use of HYVs (Brown 1970).
15. Sporadic raids on cotton producers occurred, but nothing like a systematic attempt to monitor and curb stealth seeds. The large gains to seed dealers and producers certainly rendered less likely any local or state attempts to invigorate enforcement mechanisms.
16. Some companies found technology partners other than Monsanto to provide the Bt gene; Nath Seeds obtained the gene from a public sector Chinese variant, while JK Seeds used a gene indigenously developed at the Indian Institute of Technology, Kharagpur. Nath Seeds and JK Seeds completed the approval process in 2006 and currently market three and four hybrid varieties respectively, though Mahyco-Monsanto variants dominate the field.
17. The politics are murky, as often. The Andhra Pradesh government was under fire from farmers’ groups protesting the high cost of seed, particularly in the politically active Warangal district, and from anti-GM NGOs that paradoxically supported the lowering of seed costs. Putting a price cap on Bt seed prices was an expedient and popular solution.
18. This requirement was waived in 2006 for the Cry1Ac gene and subsequently for all genetic events that have been approved for more than three years.
19. Ramaswami (2008) has argued that the AP government’s action reinforced Monsanto’s first-mover advantage by making it difficult for competitors to reap larger gains from their investments – an advantage that Monsanto enjoyed prior to 2006.

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5. Who speaks for the tribe? The arogyapacha case in Kerala

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Current attempts to ensure that indigenous people are given their rightful due in the intellectual property rights paradigm fail to address the actual impact of benefit sharing agreements on notions of identity, community, and the nation state. Do current narratives of intellectual property rights, by framing the question of IPR in an either/or manner, ignore the complexity of actors in the ownership of traditional knowledge and its dynamic nature? Is the idea of benefit sharing agreements itself rooted in a modern, Western-oriented approach? Can historically marginalized tribes become active players in the process of the commodification of knowledge, and adapt to a knowledge society that is marked by the owning, controlling and managing of knowledge? And finally, who speaks for indigenous people in a knowledge society?

These are the key questions that this chapter will address. Previous research has investigated the link between intellectual property policy, innovation, trade and economic policy (for example, Helpman, 1993; Andersen, 2006; Hope, 2008; Cook, 2005; Karani and Ojwang, 1996; Etro, 2005) And though the literature on IPR is large, there has been a lack of focus on specific case studies that study the impact of efforts to accommodate differing conceptions of intellectual property rights within the existing paradigm, especially on tribes, non tribals, the state, the nation and the interaction between all these.

At present, most of the literature is on the well-known case of the Hoodia cactus and Pfizer in South Africa (Dutfield, 2004: 52–5; Chennells, 2007; Moon, 2005) that gave, for the first time, an indigenous community a share in the profits emanating from a product based on their traditional knowledge (Mohai, 2007: 74–6). However, the general paucity of case studies of benefit sharing agreements, the earliest of which date to the 1990s, means that the drawing of wider lessons from the interaction between the current IPR regime and such agreements is a field that has yet to be explored. Consequently, close scrutiny of a benefit sharing agreement can highlight valuable lessons, pinpoint lacunae in the current

regime, and signpost directions towards further reform (Calestous, 1999: 2).

This chapter looks at one such agreement – the deal between the Tropical Botanic Garden and Research Institute (TBGRI), a research institute in Kerala, India, and the Kani tribe who live in the Agastya forests of Kerala state,² whose traditional knowledge of the invigorating properties of the arogyapacha plant (*Trichopus zeylanicus*, which means “evergreen strength”) was used to create an energy boosting drug, “Jeevani”. The resulting commercial benefits were shared with the tribe, and fulfilled WIPO recommendations for a just and equitable benefit sharing agreement. Hailed widely, the then director of the institute, Dr Pushpangadan, and Kani tribal Kuttimathen Kani were finalists for the United Nations Equator Initiative Prize 2002 at the Earth Summit held in Johannesburg for their role in the agreement.

Rather than focusing on the modalities of the agreement, my focus will be on how social processes affect the governance of intellectual property: how the agreement impacted the tribe, how benefit sharing agreements throw up broader questions of identity, and the implications of this for the current IPR regime. Thus, this chapter will look at an intellectual property rights dispute between actors that revolves around sovereignty, national boundaries and ownership of knowledge and how the structure, scope and boundaries of existing legal and policy frameworks on IPR are being constantly challenged. Second, it argues that current approaches to intellectual property rights, of which benefit sharing agreements are just one aspect, ignore the complexity of the intellectual property rights in favour of a simplistic “indigenous community versus exploitative, neo-colonial usually western big company” narrative. The thread that runs through the narrative on benefit sharing agreements, including the approach of the WIPO, is one of victim and exploiter – a mega narrative that ignores the complexity of ownership patterns of traditional knowledge, and the impact that benefit sharing agreements themselves have on notions of identity and ownership within indigenous communities. This chapter will try to illustrate this with reference to the benefit sharing agreement in the case of the Kani tribe.

GLOBALIZATION AND THE CHANGING PARADIGM OF KNOWLEDGE

The economic potential of biotechnology (Gaisford et al., 2001; Maskus, 2000:5), the privatization and propertization of knowledge, mergers and acquisitions driven by competitive pressures, the prohibitive expenses of

biotechnology research and development (R&D) (Byerlee and Fischer, 2002), and the denationalization of science (Horrocks, 2007: 233) have all coalesced to see a return or re-return to nature as a site for cosmetic, pharmaceutical, chemical and agricultural discovery work (Hamilton, 2006: 158). All this has made the commercialization of traditional knowledge of key importance. Finally, increasingly globalized patterns of production and strategies challenge both the scope and effectiveness of regulation and the capacity of political authorities to provide effective governance of biotechnology (Newell, 2003: 57–9).

However, in a patent based regime the increasing importance of traditional knowledge to emerging fields such as biotechnology means that imposing the current intellectual property rights paradigm in its entirety would lead to one of two outcomes, both undesirable: (a) pharmaceutical companies would have to pay a fortune to traditional communities to use their knowledge, and this could inhibit research in a wide variety of fields, such as cancer research, in a morass of patent legislation, or (b) granting pharmaceutical companies free and open access to traditional knowledge but then allowing exclusive patent rights to products created using that knowledge would result in colonial patterns of exploitation. Traditional knowledge – 80 per cent of the world's remaining biodiversity areas are also indigenous homelands (Adamson, 2006) – narrows down the research effort required by biotechnology and pharmaceutical companies, who are under considerable pressure to recoup their investment (Boyd et al., 2003), to locate beneficial species. In fact, the nature of knowledge creation in biotechnology calls for a free and fair sharing of intellectual property globally (Loypacher and Kerr, 2004: 550). Exclusive paradigms of knowledge protection under Western intellectual property rights traditions lay claim to the whole of knowledge, while the opposite “knowledge is free” paradigm argues that knowledge, by its very nature, should be in the commons. In fact, “this binary scheme forces some communities to choose between imperfect fits for their own needs” (Kansa et al., 2005: 287) but fails to address the actual difficulties of implementing such agreements. The open source nature of traditional knowledge has led to charges of “biopiracy”, referring to the fact that many patents have been granted for products deriving from genetic resources that emanate from developing countries, without the consent of the owners of the resources, or even without informing them (Martinez-Alier, 2002; Shiva, 1997a, b; also Table 5.1). Thus, activists see indigenous communities as helpless and in need of protection, romanticizing indigenous people while bio-prospectors see the rich resources of tribes as ripe for commercial exploitation. Both reflect a Western discourse about the ‘Other’ (Sarup and Raja, 1996). Thus the indigenous community is merely acted upon. It is important

Table 5.1 Patents based on indigenous knowledge of India

| COMPANY | US Patent No. | Pirated indigenous knowledge related to: |
|---|---|---|
| W.R. Grace 1750 Clint Moore Road Boca Raton, Florida USA 33487-2707 | [4556562] [4946681] [5124349] [5001146] [5405612] [5409708] [5411736] [5397571] | Neem (Hindi); Margosa Tree (Eng.); <i>Azadirachta indica</i> |
| RiceTec Inc. Schloss Vaduz FL-9490 Vaduz Liechtenstein | [5663484] | Basmati (Hindi & Eng.); <i>Oryza sativa</i> |
| Sabinsa Corporation 121 Ethel Road West, Unit 6 Piscataway, NJ 08854, USA | [5536506] | Kali Marich (Hindi); Black Pepper (Eng.); <i>Piper nigrum</i> |
| Calgene (<i>Subsidiary of Monsanto Co</i>) 800 North Lindbergh Boulevard St Louis, Missouri 63167, USA | [5510255] [547991] [5494790] [5538868] [5475099] [5576428] [5558834] | Erand (Hindi); Castor (Eng.); <i>Ricinus communis</i> |
| Calgene (<i>Subsidiary of Monsanto Co</i>) 800 North Lindbergh Boulevard St Louis, Missouri 63167, USA | [5463174] [5563058] [5512482] [5455167] [5420034] | Sarson (Hindi); Mustard (Eng.); <i>Brassica campestris</i> |
| Pioneer Hi-hred/DuPont International Inc., Des Moines, IA, USA | [5638637] [5625130] [5470359] | Sarson (Hindi); Mustard (Eng.); <i>Brassica campestris</i> |

Source: Research Foundation for Science, Technology and Ecology, A - 60 Hauz Khas, New Delhi, available online at <http://www.ratical.org/co-globalize/BPandWTO.html#BPpatents>.

that the unique qualities of traditional knowledge systems be recognized and respected; so too the privacy, dignity, culture, traditions and rights of local communities, including their right to choose not to be involved in proposed research (Laird and Wynberg, 1997: 197)

One way to approach this problem is through benefit sharing agreements. However, can a benefit sharing agreement be culturally sensitive? There are two contrasting approaches to this question. Those in favour of a free market argue that what is required is training for indigenous people so that they can exploit the immensely valuable resources that they have. Others argue that this will open the gates to the subversive influences of

materialism and consumerism that could overwhelm and destroy these societies. They call for the formulation of a rights regime which reflects the culture and value-system of these communities as a device to prevent their knowledge from being usurped, commoditized and privatized and to ward off any threats to the integrity of these societies. Where IP protection may apply, the prohibitive costs of registering and defending a patent or other intellectual property right effectively limits its availability to the vast majority of indigenous communities, primarily in developing countries, and helps corporate interests and entrepreneurs lay claim to indigenous knowledge without appropriate acknowledgement or compensation to the communities who have developed that knowledge (Simeone, 2004: 5–6). Moreover, the successful commodification of intellectual goods can only be achieved in a society which embraces individualism, which contrasts with the community centred approach of indigenous people.

Attempts to ensure that indigenous communities have a fair share of the benefits that proceed from the exploitation of their traditional knowledge have tried to find a balance between these two paradigms. There are several contrasting approaches: (i) a “*sui generis*” mode tailoring IPR paradigms to suit the unique needs of the nation, with the country emphasizing issues like biodiversity protection, community rights, and sustainable use, something that India has been active in, but again from a nation state perspective (Ragavan and O’Shields, 2007); (ii) a “some rights reserved” idea that falls between these two paradigms (Kansa et al., 2005); (iii) a market-based approach adopted by biodiversity advocates and conservationists who maintain that once the local people have a stake in the biological resources, their intellectual property rights can be translated into financial gains. This, they argue, is an incentive to encourage research and innovation. Other approaches include a “club goods” approach which calls for the treatment of knowledge that is essential to scientific progress, such as patents in biotechnology, as “club goods” that permit the participants to share access to the information and its utilization under conditions that emulate those of the public domain but allow the enforcement of the rights of the original intellectual property owners if they so choose (David, 2006). Finally there have been calls for registering the knowledge by vesting local communities with “custodianship rights of innovation”, either through local community leaders who are nominated or appointed to act as trustees of traditional knowledge for the community or where a government or local NGOs hold relevant intellectual property rights in trust for the local community (Blakeney, 1998; Anuradha, 2001: 25). Key to all this is self-motivated development and community empowerment (Gaisford et al., 2002; Shiva, 1997a), but the extremely marginalized nature of tribal populations make this a key question regarding the

governance of biotechnology and benefit sharing agreements. This chapter argues that the current literature relies on a priori definitions of the tribe, seeing them as static, while in reality they are dynamic and a systemic shock such as a benefit sharing agreement redefines notions of community, tribe, and state. Moreover, such agreements, due to the lacunae in current policy making that relies on fixed categories, often do not benefit the intended beneficiaries of benefit sharing agreements, while throwing up new challenges.

KEY QUESTIONS

It has been argued that the current IPR regime can be revised (Kansa et al., 2005), completely reconstructed (Shiva, 1997b) or preserved (Jensen and Pugatch, 2005). However, the arogyapacha agreement poses a critical question: can benefit sharing agreements mitigate some of the perceived unfairness of the current system? Or, do they, by creating new identities, complicate the complex layers of ownership that often mark traditional knowledge? Finally, in speaking for the tribe, rather than allowing the voice of the tribe to be heard independently, do well meaning NGOs, international organizations like the WIPO, and activists who defend the rights of indigenous communities impose a mega narrative of IPR upon the conception of traditional knowledge? Studying actual benefit sharing agreements can provide theoretical insights into how benefit sharing agreements redefine and reconceptualize the community. Benefit sharing agreements raise a whole set of questions that challenge the conception of the community and the tribe. These include:

1. Who represents the tribe? Is it the whole community? Or traditional authority figures like chiefs or elders? Or those who have access to traditional knowledge (traditional healers, priests and so on)? Or the researchers that use traditional knowledge to create commercially viable products and commercialize the knowledge?
2. Who defines the tribe? And what motivates the narrative? Does a benefit sharing agreement lead to a shift in the authority structure in the tribe?
3. Does increasing demand for the product lead to a commercializing of traditional knowledge?
4. Should programmes for the sharing of benefits be managed at the level of the individual, sub-clan, clan (in this case Kani), state (Kerala) or nation (India)? How does the state impact benefit sharing agreements?

5. Since a beneficial plant can be native to a host of countries, as in the case of the arogyapacha, or belong to a tribe that spills across national or provincial boundaries, is there an obligation to share benefits with other nations or groups of indigenous peoples in those countries or provinces?
6. How does a benefit sharing agreement impact a tribe? Does it lead to a reconfiguration and assertion of identity?

While questions like these have been touched upon in the extant literature (Bijoy, 2007; Chennells, 2007; Kansa et al., 2005) a rigorous political science approach to the question of intellectual property rights with reference to traditional knowledge, and especially with regard to the impact of benefit sharing agreements on target communities, is missing. There is both a theoretical and a practical need to address these questions and to incorporate them into policy making regarding IPR, and this chapter will look at these with reference to case of arogyapacha in Kerala. However, while this chapter will touch on these issues it is beyond its scope to resolve all of them. Thus, the aim of this chapter is to signpost a series of questions that can be the basis of further research. The first part of the chapter will examine how traditional knowledge interacts with the current IPR regime, the second part will look at the arogyapacha case and the Kani tribe, the third will scrutinize the benefit sharing agreement and the chapter will conclude with the lessons learnt.

THE STATE AND IPR: THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE TRIPS AGREEMENT

Governmental efforts to address the problem at the international level have been couched in a state centred approach which perceives the issue as one of striking a balance between the interests of those countries that are seeking facilitated access to genetic resources (commonly referred to as the “user” countries) and those holding the genetic resources and associated traditional knowledge (the “provider” countries) (Rojas et al., 2005). The opposition of the Southern countries towards the standardization of IPR has also been couched in national terms, ignoring the actual indigenous communities whose only role is as mere citizens of the state. For example, the Convention on Biological Diversity (CBD) allows nations and not communities that own traditional knowledge to benefit from biotechnological innovation. Some authors have argued that the way to ensure that indigenous communities are fairly compensated for the use

of their traditional knowledge is for more rigorous procedures to screen patent applications to be included in the intellectual property laws of advanced countries. This approach would need advanced nations to take explicit steps to take into account the pre-existing knowledge on which the patentable innovation might be based (Musu, 2006: 19). The state can, as the government or as a research organization, be instrumental in the interaction between traditional knowledge and its commercialization. In the arogyapacha case, the TBGRI, the research institute that commercialized the traditional knowledge of the Kani tribe, is an autonomous research organization that was established by the Kerala state government in 1979 to conserve biodiversity.³

At the multilateral level, the successful conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the World Trade Organization elevates the protection and enforcement of IPRs to the level of solemn international commitment (Maskus, 2000), making it easier for companies to profit from traditional knowledge. The two international agreements that deal with the issue of biodiversity have radically different approaches and yet both have dealt with the question of intellectual property rights in the framework of the either/or paradigm. The Convention on Biological Diversity, which India ratified in 1994, is seen as more indigenous community friendly. The CBD contradicts the TRIPS agreement at times, and this occasional discrepancy represents the conflict between two different approaches to intellectual property protection for non-formal knowledge though both are rooted in the Western paradigm of intellectual property rights. For example, the CBD requires that prior informed consent (“disclosure”) be garnered before genetic resources are used for product development, whereas the TRIPS agreement does not require such prior consent. TRIPS emphasizes the right of the IPR holder, the CBD that of the nation state; TRIPS emphasizes exclusive patent rights while the CBD does acknowledge the community oriented approach of most traditional knowledge.

However, in both it is the nation state that is at the centre and efforts to reconcile the interests of developing and developed countries in the issue have taken the form of attempts to create inter-governmental agreements concerning biodiversity conservation and intellectual property policy, which have been singularly unsuccessful (Gaisford et al., 2002). Many countries are intensely nationalistic in the protection of their biodiversity resources, but this approach does not include the exclusive right of the indigenous communities to their knowledge. Thus, even in the provisions of the CBD that oblige countries to recognize local community rights and fair benefit sharing – especially Article 15.4, 15.5. and 15.6 – the focus is on

Table 5.2 Differences between the Western and traditional knowledge paradigms

| Factor | Western science | Traditional knowledge |
|------------------|----------------------|--------------------------|
| Approach | Compartmental | Holistic |
| How communicated | Written | Oral |
| How taught | Lectures, theories | Observations, experience |
| How explained | Theory, “value free” | Spiritual, social values |

Source: IDRC, Canada.

the country and not on the community as such. The key aspect of the CBD is the recognition of the sovereign rights of states, and not local communities, over their biodiversity and knowledge. Thus, the entire approach to the IPR question focuses on how the nation state can benefit from biodiversity. On the other hand, the tribal population rarely benefit from any progress towards the recognition of the realm of traditional knowledge and intellectual property protection.

What complicates all these approaches is the nature of traditional knowledge, which does not fit easily into current knowledge paradigms. The production of knowledge cannot be divorced from its cultural context. Whether stored in the minds of indigenous peoples or set down in ethnographers' notes, museum records, or arcane research publications, traditional knowledge always was relatively inaccessible and therefore less vulnerable to exploitation (Kansa et al., 2005: 289). The key difference between traditional knowledge and modern-day science is the existence of “organized innovation”, which is a hallmark of Western science (Horrocks, 2007: 228) and this is a cultural as well as a legal issue and goes to the heart of the differences between what is traditional and what is modern – what is traditional is not new; there is no identifiable author or inventor; there is no documentation; and finally, traditional knowledge is already in the public domain (Greaves, 1995: 204; Table 5.2).

Given all this, the current IPR system, which is a cultural as well as a legal product of the West, is inherently unfriendly to traditional knowledge. For example, intellectual property must be new, original, innovative or distinctive to qualify for protection. These requirements make it difficult for traditional knowledge – generally handed down from generation to generation – to obtain IP protection. Moreover, from the perspective of the tribe, the emphasis of the existing Western intellectual property rights regime on individual proprietary rights does not address the collective nature of traditional knowledge. Because Western IP law is based on individual property ownership, its aims are often incompatible

with, if not detrimental to, those of traditional communities. For many traditional communities, intellectual property is a means of developing and maintaining group identity and survival, rather than promoting individual economic gain. On the other hand, in the context of traditional knowledge, “what has aroused current attention is not the intellectual property of individuals but the intellectual property of groups” (Greaves, 1995: 202).

Finally deep and unresolved issues centring on memories of the exploitation of religiously and culturally significant traditional knowledge by colonial powers have left a lingering suspicion of the Western paradigm of knowledge creation, which stresses exclusivity and profit garnering as opposed to the open infrastructure of traditional communities (Shiva, 1997a, b; Brush and Stabinsky, 1996). The counter-argument as to why access to traditional knowledge that is already in the public domain within the borders of a country must be denied to those outside the country’s borders has not been answered. One argument is that traditional knowledge fell into the public domain owing to abuses of human rights towards indigenous people who were denied and deprived of individual rights to their knowledge without any prior consent (Dutfield, 2004: 58), but this is questionable, especially in cases like that of arogyapacha where the knowledge was freely given.

The pursuit of modernist developmental goals by post-colonial states, which put Western knowledge at the centre of the modernization project (Klingensmith, 2007), meant that in the era immediately after independence traditional knowledge was ignored, and even looked down upon. However, in an age of biotechnology when such arcane knowledge could be the basis of incredibly profitable innovations in the pharmaceutical industry, and faced with a legal milieu that imposes a certain knowledge paradigm, both of which dramatically impact local economies and community life, tribal communities have unwittingly become “stakeholders” in the process of knowledge acquisition (Kansa et al., 2005: 296). While it is romantic to argue that all knowledge should be free and open, this neglects the fact that those most capable of exploiting traditional knowledge would be the most organized and the best qualified, which usually are private or organized government interests. Moreover, the issue is not only one of exclusive access to knowledge; it is also one of how best traditional knowledge can be protected. In fact, many traditional knowledge rights activists warn against romanticization of traditional wisdom and stress the proprietary nature of some domains of culture, especially when they are protected by patent and inaccessible to the original owners of the knowledge. The inability to predict whether a certain innovation would contribute positively or retard access to new

knowledge that exclusivist barriers produce remain issues of concern (Musu, 2006: 2).

Nevertheless, the current intellectual property paradigm remains biased in favour of the Western paradigm with the key reference point for studies of the IPR system and its limitations remaining the Uruguay Round of the TRIPs agreement, established in 1994, and its push towards harmonized intellectual property and country compliance measures including enabling persons or institutions to patent a country's biological resources (or knowledge relating to such resources) in countries outside the country of origin of the resources or knowledge (TWN, 2001).

At present the international system is in favour of the Western paradigm. Commercial companies, given the essential agreement on the sanctity of private property, have found that attempts to enforce the intellectual property rights regime have been as easy as gaining the attention of government officials and putting the issue on the policy-making agenda. Moreover, the current IPR regime allows leading sectors within the US economy, such as biotechnology and IT, to capitalize on their global dominance over intellectual property production (Bettig, 1990: 66). One area of growing concern is that the profitability of investments in biotechnology can be endangered by intellectual property piracy, particularly in developing countries (Gaisford et al., 2002). This has led to pressure on developing countries to toe the line in regard to IPR. Thus India, which had since independence followed a process based patent system, which ensured cheap drugs by manipulating the manufacturing process, had to switch to a product based patent system, which hiked the prices of essential drugs (Smith, 2000) though it did augment the fortune of Indian pharmaceutical companies (Smith, 2000: 17–19). In line with the TRIPS agreement the Indian Patent Act of 1970 has been amended twice. The 1970 Act provided a process patent for 5–7 years, while in the US and Europe product patents of 15–20 years were the norm. The first amendment in 1999 changed this to a product patent, and India changed its patent law in December 2004 to meet a January 2005 deadline to allow patents on the chemical molecules used in drugs – not only for new drugs starting in 2005 but also for many others that were patentable after 1995 (United Nations, 2003: 27).

Moreover, the fairness of distributing the commercial benefits of a patent to individuals or companies whose only role has been the using of traditional knowledge, considered common heritage of the public domain to which everybody has free access, to create a marginally different product has been questioned, sometimes successfully, as for example in the case of turmeric, when the US Patents and Trademarks Office ruled that a patent for turmeric issued to the University of Mississippi Medical

Center in December 1993 was invalid because it was not a novel invention, a victory that activists saw as the first blow in the battle against bio-piracy (for example Shiva, 1997b). These are however exceptions (see Table 5.1 above).

This chapter argues two main points. First, the issue is not simply one of piracy and protection, or of tribes being colonized and exploited yet again. The emotionally loaded term of “bio-piracy”, by making tribes appear to be mere victims, does not capture the complexity of the issue, especially the impact that benefit sharing agreements have on tribal communities. Secondly, in all this, indigenous people have been effectively sidelined, being reduced to the status of mere bystanders. In all the current approaches to the IPR/traditional knowledge quandary, what stands out is the disappearance of indigenous people as an agency. Indigenous people have been reduced to a subject to be acted upon.

Terms: Local People, Traditional Knowledge, Benefit Sharers and Bio-piracy

In this chapter, “local people” is defined as people who live in tropical forest habitats whether they are indigenous people or people of mixed descent. With reference to them the key question is how indigenous and local people can be provided with reciprocal benefits, and through what types of mechanisms (King et al., 1996: 46).

According to the World Intellectual Property Institute, traditional knowledge (TK) includes “tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields” (Gillespie-White and Garduno, 2003).

I use the definition of benefit claimers as “the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application” (King et al., 1996: 46). However, as the arogyapacha case will show, this is hardly a simple matter. Trying to identify the benefit sharer, often when it come to financial recompense, is something that challenges the definition and image of the tribe.

The loaded term “bio-piracy” automatically assumes that drug companies steal plant based indigenous knowledge from developing countries, only to sell it back to the source countries at premium prices. Businesses argue that such allegations are false, that they are

not responsible for the poverty of the countries that have indigenous knowledge at their disposal but are unable to exploit it commercially (Mgbeoji, 2006). However, my contention is that both these approaches have their roots in a narrative of IPR that comes from without, reducing the tribe to mere bystanders.

THE AROGYAPACHA CASE⁴

“Arogyapacha” is the name of a plant (*Trichopus zeylanicus ssp. Travancoricus*)⁵ from which the Ayurvedic drug “Jeevani”⁶ was synthesized using Arogyapacha and three more ingredients. Jeevani was patented by the Tropical Botanic Garden and Research Institute (TBGRI)⁷ in India. The licence for manufacture of the drug was given to one of India’s largest Ayurvedic firms, the Coimbatore based Arya Vaidya Pharmacy (AVP), with exclusive rights for the manufacture and sale of the drug in India and abroad.⁸ A plethora of drugs were patented using the leaf.⁹

However, the discovery of arogyapacha and the eventual synthesis of Jeevani is a tale that reveals the complexities and ambiguities of benefit sharing agreements as they exist. The discovery itself was accidental, and the eventual synthesis of the drug had more to do with personal connections between the scientists and the tribesmen than with official networks. In 1987, an ethno-botanical expedition to one of India’s biodiversity hotspots – the Agasthyar valley areas of Thiruvananthapuram District, in the south-western Indian state of Kerala – under the aegis of the All India Coordinated Research Project on Ethnobiology (AICRPE)¹⁰ was cataloguing the culture and bio-resource utilization of the Kani tribe. The director of the expedition, Dr P. Pushpangadan, then a senior scientist of the Regional Research Laboratory (RRL), Jammu, who would later become the director of the TBGRI in Kerala, noticed that his tribal guides munched on a fruit and never seemed to get fatigued. In a process that was similar to that of the San tribe that used the Hoodia plant in South Africa to suppress hunger pangs while trekking in the Kalahari desert, the unripe fruits of the arogyapacha plant were eaten fresh by Kanis during their long trekking trips to the forest in search of food and fodder. After initial reluctance, the Kanis imparted this closely guarded secret knowledge to Dr Pushpangadan, who promised the guides that if a commercial product was developed from the tribal knowledge on arogyapacha, the benefits arising out of the production and commercialization of this product would be shared equally with the Kanis. He was to keep his promise when he became the director of the TBGRI.

Since Dr Pushpangadan already had access to high class laboratories

under the AICRPE program, primary studies were carried out at the Ethno-pharmacology Division of the Regional Research Laboratory, Jammu, which was one of the networking institutions under the AICRPE. Investigations of the fruit confirmed its anti-fatigue properties. Moreover, the leaf of the plant contained various glycolipids and some other non-steroidal compounds with profound adaptogenic and immuno-enhancing properties. Since the fruit itself was very small and the yield very poor the scientists isolated an adaptogenic glycolipid compound from the leaves of the plant. However, as the gestation period for a modern drug from a single compound can last as long as 15 years, Ayurvedic pharmaceutical methods were used to create a poly-herbal formulation, Jeevani, with the arogyapacha leaf as one of the key ingredients. Under this brand name, Jeevani was patented as an anti-fatigue, immuno-enhancing and liver-protective drug.

Several pharmaceutical firms approached the TBGRI seeking a licence for the commercial production of Jeevani. Finally, in November 1995 the Coimbatore based AVP was given the licence to manufacture Jeevani for an initial period of seven years at a cost of US\$50,000 for the licence plus 2 per cent royalty. The TBGRI received Rs 10 lakh (around 15,000 euros) as licence fee and 2 per cent royalty on ex-factory sales. The TBGRI decided that the Kani tribes would receive 50 per cent of the licence fee, as well as 50 per cent of the royalty obtained by the TBGRI on sale of the drug. A seven-year tech-licence agreement was signed between the TGBRI, the Kani trust that was subsequently set up, and the AVP.

THE IMPACT OF THE BENEFIT SHARING AGREEMENT

In accordance with this, two of the tribal guides on the 1987 expedition – Kuttimathan and Mallan Kani – were employed as consultants to the project. Subsequently a trust known as the Kerala Kani Samudaya Khshema Trust (Kerala Kani Community Welfare Trust), was set up and registered in November 1997. The trust comprised a General Body with adult tribals elected from the 30 Kani settlements which were brought under a single organizational framework, an Executive Committee, and a 14-member Governing Council. The trust received half the licence fee (Rs 5 lakh, equivalent to 7500 euros) and a share of the royalty. The trust funds were used to build schools and hospitals, insure the tribes, pay for education and marriage, and also to buy some much desired TV sets. One of the key impacts of this process of commercializing the drug was on the Kani community. Traditionally poor and marginalized, they suddenly had

access to a nominal amount of money. At the 1996 rates one kilogram of the berries cost Rs 150 (about 2 euros) and with an annual yield of 200kg this meant about Rs 60,000 (about 900 euros). This did not convert into riches but enabled the tribe to have access to a marginally better way of life with better schools, water supply and a few television sets.

Finally, in consultation with the TBGRI, the Executive Committee of the trust decided to reward the three Kani tribesmen who provided the information about arogyapacha. Accordingly, they were congratulated by the trust and prize money of Rs 20,000 (about 310 euros) each was given to Sri Mallan Kani and Sri Kuttimathan Kani and Rs 10,000 to Eachan Kani – the two guides on the original expedition. Moreover, to meet the demand for a regular supply of the plant to the manufacturing unit, the arogyapacha plant which had traditionally grown wild, was commercially cultivated. The agreement was widely reported in magazines like *Nature*, *Science*, and *Time*, and was perfectly in line with the benefit sharing initiatives of Article 8(j) of the UN Convention on Biological Diversity. It respected, preserved and maintained the traditional lifestyle of the Kanis. It took their knowledge with their permission and shared the proceeds of the agreement with them. The tribe was financially rewarded, its contribution to the creation of the drugs was acknowledged, and the agreement was marked by the “informed consent” of tribals, sustainable harvesting, biodiversity conservation and benefit sharing.

Running into Trouble: the Aftermath

The aftermath of the agreement shows how the question of who speaks for the tribe, and who defines the tribe, bedevils the current concept of benefit sharing. In essence, the model soon ran into obstacles – a combination of archaic colonial laws, falling out over the benefits, and finally changes in the IPR milieu. Key to this was the fact that arogyapacha grows only in the Kani tribal belt (Augustya Muni forest). This meant that the invigorating plant could be sourced only from the Kanis as Indian forest laws reserve the right to cultivate within the forest exclusively to those who live there. Thus, unless the arogyapacha was supplied by the tribe itself nobody could make the drug – the lack of a patent or a trademark notwithstanding. However, under the 1927 Indian Forest Act, which made the forests state property, only minor produce could be taken out of the forest and officials of the state forest department refused to allow the Kanis to cultivate or take out the arogyapacha, saying that it was not classified as “micro-produce”. When Kanis took arogyapacha leaves out of their settlements for sale, they were stopped at the forest check-posts. Soon, non-tribals who were interested in the commercial exploitation of the plant were

involved. In return for a small amount of money or alcohol the Kanis would collect the plant and give it to these locals, who would then sell it for high prices. Thus it became difficult to distinguish between genuine forest products produced by the Kanis and those which had been smuggled out of the forest by locals who were not tribesmen.

The state's response was a blanket ban on taking the plant out of the forest. This, however, hit the tribes the hardest. In the market, it became difficult to distinguish between illegally sourced plants and those that had been sourced legally. The AVP, which manufactured the drugs, argued that they had used only legally sourced produce. However, unscrupulous middlemen had used the loopholes in the agreement to smuggle out the herb and, given its popularity, it is possible that both legal and illegally sourced leaves were used. This indicates a key gap in the current intellectual property paradigm that tries to address the basic issue of inequity in property relations by measures such as benefit sharing – the difficulty is in how to identify and define the tribe.

Another issue that the benefit sharing agreement brought to the fore was the different views that the state itself had on the right way to improve the lot of the tribal community. The official body charged with the development and improvement of the welfare of the tribes – the Kerala Institute for Research, Training and Development of Scheduled Castes and Scheduled Tribes (KIRTADS) – came into conflict with the TBGRI, which it saw as an interloper. Supported by many Kani elders who believed that the purity of the practitioner was the key element in tribal culture, they resented the agreement and argued that traditional knowledge was sacred and should remain exclusive and closed to outsiders. In September 1995, a group of nine Kani healers wrote a letter to the chief minister of Kerala opposing the sale of their knowledge. They were joined by non-tribal activists who tried to dissuade the Kanis from entering into the deal with the TBGRI and selling arogyapacha. The Kani case thus demonstrates a clash between differing paradigms on how best to look after indigenous people – a contradiction that was prominent in the contradictions inherent in the official paternalistic approach to tribal welfare.

Unlike KIRTADS, other government bodies supported the agreement. Thus, in 1995, the government's Integrated Tribal Development Project in Nedumangad initiated a scheme in collaboration with the TBGRI to help the Kanis grow medicinal plants in their settlements. Under the project, 50 selected families received Rs 1,000 (about 15 euros) each, with 20.25 hectares coming under cultivation. The TBGRI bought the leaves from the Kanis, paying Rs 30 (0.50 euro) per kg for the chemical trial and for pilot production. The model eventually benefited over 16,000 Kani people comprising over 700 families. However, non-tribals again got involved.

During the second harvest, some people uprooted the whole plant from their gardens and others took the wild herb from the forest, according to TBGRI officials. This alerted the forest department against possible large-scale “smuggling” of the herb. When Kanis tried to sell the herb, they were caught. In a widely reported operation in 1996, forest officials confiscated 10,500 arogyapacha plants from a private nursery in the forest. Thus an ideal benefit sharing agreement clashed with archaic colonial laws that saw the forest as belonging to the state rather than to the communities that belonged to it and lived in it, and unscrupulous elements that used the tribes, offering them a pittance to cultivate the herb, which was then sold on the black market. So, the state itself can be divided when it comes to benefit sharing agreements.

Further, when the TBGRI applied for the patent in 1996, India had not signed up to the WTO and still followed the process patent paradigm. Thus, at present, the patent on Jeevani’s formulation has expired and the AVP and other companies do not have to pay royalties any more. Ironically, though the drug has become popular and is sold at Rs 160 (about 3 euros) for a 75gm jar, the Kerala Kani Samudaya Khshema Trust has become dysfunctional and the tribals are cut off from the benefits. In fact, according to newspaper reports the tribal guides who were instrumental in imparting the traditional knowledge to the TBGRI have fallen into poverty (Shaji, 2008).

Identifying the Kanis

Finally there was the whole question of who were the Kanis. The “Kani” identity is nebulous. If the definition of a community focuses on a shared locale, common ties and social interaction and the community is seen as a spatial unit, an economic unit and a unit consisting of a web of kinship, social and cultural relations, then the Kanis are difficult to define in the traditional way. The Kanis are not confined to a specific geographical area, though the majority of them live in the Agastya forests near Trivandrum; they have crossed state boundaries, with some of them living in the neighbouring province of Tamil Nadu. The plant itself is found in the Malay peninsula, Sri Lanka and Thailand, in addition to India. Thus, a territorially bound definition of the tribe is challenged. Social boundaries have also been crossed as a result of affirmative action by the state government and the national government. All this means that there cannot be a monolithic definition of the notion of the Kani community, and the Kani community which is frequently cited in the case carries a high degree of uncertainty in the way it is defined.

The benefit sharing agreement redefined the tribe. Though the traditional

knowledge of the plant's invigorating properties was known to the entire Kani tribe, including some tribesmen who had shifted into an urban setting, the TBGRI benefit sharing arrangement was made with only one Kani tribal group – the one to which the two guides who had given the information about the plant belonged. The TBGRI was criticized for favouring a section of the tribe and for treating the tribe as mere subjects. Other Kani groups protested against this and the money could not be distributed for a few years. This brings into the debate on intellectual property rights the question of who defines the tribe and the extent to which colonial attitudes towards tribes, as seen in the Indian Forest Act of 1927, and the general attitude of the TBGRI and other agencies like KIRTADS impact definitions of the tribe. Moreover, neighbouring communities interact within the same ecological system and have some degree of knowledge and the one who gets the rights is the one who claims them. This then raises the question of who the actual owners of the knowledge are. This was one of the key problems of the arogyapacha agreement. Again, it is a case of believing that the tribals cannot speak for themselves and that they should be spoken for.

From the perspective of the tribe, the benefit sharing agreement can be seen as an attempt to come to terms with an entirely different concept of intellectual property rights and to engage modernity. In fact, one of the key objections of KIRTADS to the agreement was that the Kanis themselves had not been involved in the negotiating process. However, the impetus behind the impulse to share the knowledge was not altruistic but essentially a way of making money. It was this that the tribal elders who were more puritan and more traditional resented.

In addition, the agreement marked a key shift in the cultural ethos of the tribe. For the first time instead of freely giving away their knowledge they were able to profit from it. However, the earlier willingness to give was circumscribed by notions of exclusivity – the secret of the plant would be given only to those who belonged to the tribe or those who were trusted. Moreover, had it not been for the personal relationship that scientists at the TBGRI had with the Kani, especially the relationship that the director had, the agreement would not have been reached. This reflects the broader conception of knowledge in traditional societies. In keeping the secret, the tribe was following the practices of indigenous people worldwide, and the quest for esoteric knowledge possessed by tribes reflects a key aspect of modernity – the fascination of the West with traditional wisdom, a fascination that now has tangible commercial rewards.

The agreement also showed the extreme vulnerability that tribes who are poor face when it comes to their traditional knowledge. This is one reason why, despite the opposition of the elders of the tribe, the Kani were

willing to negotiate with the TBGRI. The implication of this is that, for tribes who are marginalized and poor, what is really important is not the debate over cultural commodification or the exploitation of indigenous resources that activists generally focus on but bread and butter issues like buying a new television set, building a new school or having access to clean water. It is extremely significant that it is not ideological differences over the nature of poverty and property that NGOs and activists see as the core issues that were at the centre of negotiations between tribes and pharmaceutical companies. Therefore, by trying to reform the intellectual property paradigm without addressing the basic issues that create incentives for the commodification of indigenous knowledge, activists may be putting the cart before the horse.

It also brings to the fore the broader question of the place that tribes have in emerging economies like India. It is significant that both in the arogyapacha case and in a similar case, that of Hoodia in South Africa (Moon and Aneesh 2005), the benefit sharing agreement was brought to the tribes by external agencies – in the first case by the TBGRI and in the second by an NGO. Depending on one's perspective, this can be seen as aid for traditional communities to claim their rights, or an external intervention in their affairs that then breaks up the community and disturbs the harmony of the tribe.

On the other hand, the arogyapacha case can be seen as an example where an indigenous tribe was made aware of the value of their traditional knowledge. Surely it can be argued that marginalized tribes like the Kanis and the San tribe in South Africa that share their knowledge are profiting from the demands that emanate from the West – the desire to go on a diet in the case of the Hoodia plant, the desire to have reinvigorating drugs in the case of arogyapacha. In this respect, the development can be seen as positive, enabling hitherto marginalized tribes to profit without having to join the mainstream, and on the basis of traditional goods that are suddenly valuable. The case also points to the emerging role of external actors such as research institutes in the recognition and acknowledgement of the traditional knowledge that various indigenous people have.

However, whether the enormous profits that emanate from commercialized products that use traditional knowledge actually trickles down to the indigenous communities is a matter of debate. The difference between the costs of the final product that was produced using the knowledge of the Kanis and what the tribe actually got out of the benefit sharing agreement points to this. The retail cost of a small bottle of Jeevani is roughly 60 times more than what was originally paid and now, with the original patent having lapsed, the Kanis no longer benefit – victims of changing paradigms of intellectual property rights (Shaji, 2008).

At the core of all these issues is how previously communal knowledge can be reconciled into a privatized system. When this is done, a whole plethora of issues emerge. If the benefit sharing agreement is reached, who should benefit? The whole tribe? Those who represent the tribe? And if so how should such representation be acknowledged? Should it be on the basis of traditional positions of authority such as the chief of the tribe, in the case of the Kani the “mottu kani”, who is priest, chief and leader combined but who usually only has a ceremonial role? Or should it be on the basis of those who know? In the Kani case, the knowledge was transferred by two guides on the basis of a personal relationship and they, by later being hired as consultants, benefited.

Another key issue that benefit sharing agreements raise is that many people outside the tribe have this knowledge in a cultural and collective sense. Should only those who can prove that they have historically utilized the plant be allowed to benefit? Should anyone who has been defined as belonging to the Kani community benefit? Should those who know about tribal secrets second hand or those who know them because they are aware of knowledge in the commons benefit? Moreover, there is the question of the modalities of the benefit sharing agreement – should the benefits accrue only after the commercial potential of the drug has been utilized, or should agreements be drawn up even before the research begins? Or, going further, should the research potential of traditional knowledge be accessed before bio-prospecting even begins?

In all this, the question is “Who defines the tribe?” Unquestioning acceptance of state defined or government defined categories suddenly becomes extremely important when it comes to the question of delineating beneficiaries. Simplified notions of the community can be useful when it comes to benefit sharing agreements but then, as the arogyapacha case shows, simple definitions of the tribe can break down in the face of economic and social pressure. The challenge is to convert simplified notions of “community” into more specific policy recommendations without causing damage to the tribe and the community. More specifically, one of the major complications arising from the case at hand is the problem of determining beneficiaries and how to distribute rewards.

While the case of arogyapacha is confined to Kerala, it raises the broader question of how one defines within geographical limits a tribal community. And how does one define relations between tribes and non-tribes? Should these relationships be defined by history or by society or by the ownership of land, or by outsiders? Moreover, should the agreement for benefit sharing be confined to those who are within the specific boundaries of the nation state? Or should one go beyond the paradigm of the nation state to provide benefits? The introduction of incentives

for being classified or defined in a certain way can engender conflict in previously benign attempts to determine community. Suddenly, those that believe they belong have an incentive to exclude those that they think should not.

LESSONS LEARNT

The arogyapacha case shows that benefit sharing need not be confined to potentially conflict inducing financial incentives but can refer to other benefits such as infrastructure and capacity building or the augmentation of on-going community efforts. The arogyapacha case also shows the sudden influx of financial wealth into a traditional community can have a destabilizing effect. If indigenous communities choose to adapt to the new paradigm, such adaptation obviously means a paradigm shift in the culture, society, and economy of these marginalized tribes. On the other hand, as the arogyapacha case shows, this rise of the knowledge society could also mean the emergence of new forms of exploitation of historically underprivileged communities.

Several studies address the question of the importance of including mechanisms to facilitate technology transfer in partnership agreements. Moreover, agreements to rights to intellectual property are usually made between national governments and foreign firms but this raises the question of how the communities that actually possess the knowledge can benefit. Moreover, even if the government decides to share the benefit, the exact modalities of the transfer, including the amount of money transferred, the benefits that go to the community, who represents the community and so on, remain contentious issues. Of greater significance than “official” determinations of trust funds, benefit sharing, and research guidelines, the debate as to whether policy means practice is foundational, in the realm of bio-prospecting, and yet has been only lightly addressed in the literature. The lessons of the arogyapacha case bring into question the actual extent to which “marginalized communities” benefit from bio-prospecting deals and point to the need for a concerted and coordinated effort to address conservation and development problems. There is a need for such efforts to be accompanied by a set of comprehensive and innovative approaches to consumptive and non-consumptive use of biodiversity. Moreover, tribes do not exist in a vacuum. They interact with non-tribals, the state, and authorities on a daily basis and often close links exist between tribes and non-tribes – commercially, personally, and socially. The conflict between the state law and tribal traditions goes into deeper issues of who defines the citizen and what role indigenous people have in the modern state.

CONCLUSION

Current approaches to intellectual property and benefit sharing agreements have a “good guy–bad guy” concept, seeing traditional communities as victims, and pharmaceutical companies, or any entity that is based on a modern propertization approach to IPR, as being exploiters of traditional knowledge. The nation state centred approach of most international agreements on IPR also means that, as the Kani case demonstrates, the state always has the power to cut out the community. At the heart of the issue is the close relation between innovation and research – and the larger question of whether innovation is tied up with the power of exclusion in knowledge. Benefit sharing agreements are rarely straightforward and the sheer poverty of tribal areas in India and the lack of trained personnel such as lawyers who understand the intricacy of the current IPR regime, or activists who can stand up for tribal rights, tend to make the tribes especially vulnerable to commercial exploitation. Given the illiteracy and unawareness of rights that is a mark of tribal and indigenous people, it is quite difficult for tribals to profit from the current IPR regime. All these features are evident in the arogyapacha case and underscore the need to compensate indigenous people for the use of their traditional knowledge.

However, as the Kani case shows, intellectual property disputes are nuanced, and the benefit sharing agreements themselves throw up new paradigms of identity. In the case of the Kani, only one section of the tribe, based on personal networks, benefited. Thus, an inherent problem with the benefit sharing approach is that it is difficult to decide who profits from the commercialization of traditional knowledge. Moreover, the state remains the reference point for traditional IPR theorizing on the environment and in the current IPR paradigm it is the state that puts itself forward as the representative of the tribe. In the same way, NGOs who “speak for” the tribe also buy into a mega narrative that is superimposed on the actual debate. The current approach to benefit sharing agreements assumes that the tribes are victims, and that they need to be protected by knights in shining armour – whether NGOs as in the case of the San in South Africa or a research organization as in the case of the Kani tribe.

Moreover, organizations like the UNDP and WIPO see an external agency – the state, or the NGO – as representing indigenous communities. This precludes the fact that even within the state there can be disputes on the best way to help indigenous societies – arguments that are thrown into sharp relief when an external factor like a benefit sharing agreement intrudes on the tribe. In all this, the tribe is spoken for, but its voice is silent. The arogyapacha case shows that, in all disputes that revolve

around traditional knowledge, what needs to be scrutinized is the role of the agency – who speaks for the tribe? To deny this is to romanticize the question of intellectual property rights.

NOTES

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2. The Kani tribals belong to a traditionally nomadic community, who now lead a primarily settled life in the forests of the Agast-Himalai hills of the Western Ghats, a mountain range in south-western India, in the Thiruvananthapuram district of Kerala. The Kanis, numbering around 16,000, live in several tribal hamlets, each consisting of 10 to 20 families dispersed in and around the forest areas of Thiruvananthapuram district. The Kanis are the traditional collectors of non-timber forest products from the forest.
3. <http://www.tbgrl.in/>
4. For the technical details of the agreement I heavily draw upon Anuradha (2003), Chaturvedi (2007), Agrawal (n.d.), Bijoy (2007) and the official form submitted to the Equator Initiative Prize 2002 at the Earth Summit held in Johannesburg that nominated this benefit sharing agreement for the prize.
5. Belonging to the family Trichopodaceae the plant was a herbaceous, perennial, rhizomatous plant and was also known as “varahi” – one of the 18 divine herbs mentioned in the ancient Ayurvedic treatises, *Charaka Samhita* and *Susruta Samhita*.
6. Jeevani is claimed to have anti-fatigue, anti-tumour, antioxidant, anti-allergic, aphrodisiac, immuno-modulatory and hepato-protective actions. Details of the product can be seen at <http://www.jeevani.com/>.
7. TBGRI is an autonomous research centre established by the Government of Kerala in 1979. It has been accorded the status of a Centre of Excellence in Conservation and Sustainable Utilization of Tropical Plant Diversity by the Ministry of Environment and Forests, Government of India. The key aim of the Institute is the conservation and sustainable utilization of plant diversity in tropical India and the arogyapacha case has made it famous.
8. Response of Smt. Panabaka Lakshmi, Minister of State for Health & Family Welfare, in a written reply to a question by Shri Raghuvver Singh Koshal in the Lok Sabha (Indian Parliament), Press Information Bureau, Government of India, “Patenting of Traditional Medicine by USA”, 8 March 2006.
9. In total, 12 active compounds were isolated from arogyapacha, and five process patent applications have been filed since 1994, the most important being the process of preparing an immune system enhancing, anti-fatigue, anti-stress and hepato-protective herbal drug, Jeevani (P. Pushpangadan, S. Rajasekharan and George V., Patent application number 959/MAS/96, 4 June 1996) and a process for the Isolation of a Glycolipid Fraction from *Trichopus Zelyanicus* Possessing Adpatogenic Activity (K.K. Butani, D.K. Gupta, B.S. Taggi, K.K. Anand, R.S. Kapil, P. Pushpangadan and S. Rajasekharan, Patent application number 8/Del/94 (1994). The others refer to a diabetes medicine (957/MAS/96, June 4, 1996), a sport medicine, Vaji (958/MAS/96, 4 June 1996) and a herbal preparation for cancer (MAS/650/2001).
10. The AICRPE, a multidisciplinary and multi-institutional project initiated in 1982 under the Man and Biosphere Programme (MAB), was initially under the Dept of Science & Technology, but later transferred to the Ministry of Environment & Forests (MoEF), of the Indian government. Dr Pushpangadan was the Chief Co-ordinator of

this ambitious programme, which operated at 27 centres in India and lasted for 16 years (1982–98). The AICRPE project documented the use of over 10,000 wild plants used by tribals on a day to day basis. The MoEF played a pivotal role in the TBGRI Benefit Sharing Experiment by providing administrative and financial support through the AICRPE.

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6. Lobbying or politics? Political claims making in IP conflicts

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1. INTRODUCTION

In the official declaration of the 2007 G8 summit in Heiligendamm, Germany, the heads of government of the eight most powerful industrialized countries gave the “protection of intellectual property rights” top priority. In fact, IP protection was mentioned in their final statement even ahead of climate change, as a political issue of crucial importance, preceded only by global economic growth, the stability of financial markets, and the freedom of investment. The statement stressed that “Innovation is one of the crucial drivers of economic growth in our countries. . . . The protection of IPRs is of core interest for consumers in all countries, particularly in developing countries” (G8 2007, 2). This prominent placement reflects the growing importance of the politics of intellectual property, which has changed over the last 15 years from a field of technical expertise to an increasingly contentious global political issue.

How did the protection of intellectual property (IP) become such a high-level issue? And how has the idea that strong intellectual property regimes should be a central component of any global trade regime become the dominant view?

Susan Sell (2003) shows in her study of the history of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) how, during the Uruguay round of global trade talks, a small group of transnational corporations successfully got IP protection on the agenda and subsequently managed to codify their vision of a strong IP protection regime, in the form of the TRIPS agreement, with relatively little contestation (Sell 2003; Drahos and Braithwaite 2003). The political process that yielded TRIPS is an excellent example of a power game in which resource-rich private actors are able to get their way, with support from the powerful governments of industrialized countries. In this case, they managed to successfully install a global IP regime that requires all WTO member countries to adopt strong national systems of IP protection. Developing

countries that initially tried to resist the tightened IP regime were silenced through the US initiating “Section 301 actions”, that is, bilateral trade sanctions (Meier 2005, 506).

Sell’s study also shows that the success of the lobbying that led to the TRIPS agreement cannot be explained merely in terms of power dynamics. Many of the same resourceful and powerful actors were not that successful a few years later during the negotiations of the new WIPO copyright treaties, which consequently, in their current version, exhibit a much more balanced approach between authors’ rights and the public’s interest in having access to information (Sell 2003, 26). As Sell shows, in this second set of negotiations a well-organized group of opponents successfully framed IP as an issue of “fair use” to counter the dominant frame of IP as a trade issue. These findings suggest that a strategy focused on achieving discursive hegemony was at least partially able to compensate for weakness in terms of economic power.

The TRIPS story was not just a story of financial resources and economic power. As Sell argues, it “is difficult to overestimate” the influence of Jacques Gorlin, advisor to the US Advisory Committee for Trade Negotiations (ACTN) and the private Intellectual Property Committee (IPC) (Sell 2003, 49). Gorlin’s achievement was to develop a coherent argumentation framing intellectual property rights as a (free) trade issue – an inherently contradictory task, since intellectual property rights are by definition monopolies granted by the State for a designated period of time, and therefore intrinsically contradict the idea of free market competition (Gorlin 1985). Obviously, constructing the right frame is important not only for weak actors but also for the powerful players in the field. Indeed, the above cited G8 policy statement can be read as an attempt to re-frame IP as an issue of consumer interests in the Global South – a quite surprising interpretation that clearly reflects the growing number of challenges to the TRIPS framing of IP as a trade issue.

The importance of framing processes as discursive interventions that influence policy outcomes has been overlooked in much of the interest groups literature, which focuses mainly on the resources actors have at their disposal (Bouwen 2002; Greenwood 1997; Richardson 2000). On the other hand, research on social movements has long acknowledged that, aside from resources and political opportunities, the construction of collective action frames is an important factor in its own right for explaining movement success or failure (Snow and Benford 1992; Snow et al. 1986; Gamson et al. 1982).

Granting the importance of framing processes, then, the question remains: which frames can successfully influence IP policies and under what conditions? Sell’s example of the WIPO copyright treaties suggests

that actors need to construct a convincing counter-frame that offers an alternative interpretative frame. The conflict about IP issues and global health policies also follows this pattern. Here the construction of a counter-frame that pitted IP protection for pharmaceuticals against public health was a successful strategy for those actors that wanted to prioritize the fight against HIV/Aids (Hein 2007; Hein and Kohlmorgen 2008).

However, the literature on framing is only partially helpful here. An impressive number of case studies (see Benford and Snow 2000; Snow 2004 for an overview) have detailed framing processes in different social movements and have identified the complex discursive strategies necessary to construct potent collective action frames. Most notably several studies have pointed out that, to be successful, collective actors need to construct a coherent master frame that has the potential to ideologically integrate a heterogeneous set of actors (Gerhards and Rucht 1992, 573; Snow and Benford 1992, 138). A number of frame typologies have been developed, but so far none of them has been able to explain which framing strategies might be more successful than others.

This chapter starts from the general assumption that framing processes do indeed matter, and examines their role in two recent conflicts in the European Union over two EU directives in the field of IP policies. Based on our analysis of these cases, we argue that the construction of a coherent master frame was a precondition for successful mobilization, especially for resource-poor actors. Our findings challenge the notion that the success of oppositional actors always depends on their ability to construct a strong counter-frame. Instead, we argue that displacement strategies, which attempt to re-frame an already existing hegemonic frame and give it a new meaning, may often be just as fruitful, especially where IP protection cannot easily be portrayed as a threat to some common normative value.

2. CONFLICTS ABOUT THE EU DIRECTIVES ON SOFTWARE PATENTS AND IP ENFORCEMENT

The two directives we will analyze have played a central role in shaping the regulatory framework for intellectual property rights in the EU over the last decade. Both directives were introduced and decided upon between 1997 and 2005. Both were carried out under the “co-decision” procedure, in which the European Parliament and the European Council must reach agreement on the issue. They were drafted in the same Directorate General in the Commission (DG Internal Market), and in both cases they faced

opposition from stakeholders, who tried to influence the decision-making process in their favor.²

The “Directive on the Enforcement of Intellectual Property Rights” (IPRED 1, or the IP Enforcement Directive) was intended to strengthen and harmonize the enforcement of intellectual property rights, including copyrights, trademarks, and patents, in the EU member states. It requires all member states to apply “penalties which must be effective, proportionate and deterrent” (COM 2003, 19) against counterfeiting and piracy. The directive gives rights holders more possibilities to bring civil suit against counterfeiters and other violators. Rights holders, for example, may call on judicial authorities to issue an interlocutory injunction preventing further infringement of intellectual property rights or to demand destruction of counterfeited goods.

The second directive, the “Directive on the Patentability of Computer Implemented Inventions” was drafted by the Commission to introduce patents on inventions “implemented on a computer or similar apparatus which is realised by a computer program” (COM 2002, 13). Whether this definition would include “software as such”, which is explicitly exempted from patentability under the European Patent Convention, was a highly contested question in the conflict around this directive. In any case, the opponents of the directive successfully framed it as the “Software Patents Directive” (SWPat), while only the core supporters referred to it as the CII Directive.³

In both cases the Commission received strong support from industry lobbying groups and business associations, which represented a number of powerful key players in the respective fields. However, business interests did not unanimously support the Commission’s proposals in either case. Major firms from the European telecommunications industry opposed the Enforcement Directive, and a large number of mostly small and medium enterprises (SMEs) opposed the Software Patents Directive. Civil society and consumer interest groups mobilized against the directives in both cases. Members of the European Parliament (MEPs), national politicians, and scientific experts can be found in both the proponents’ and opponents’ camps in both conflicts.

Despite the similarities in the two decision-making processes, there were significant differences in the trajectories and intensity of the conflicts. While there was heated debate over the pros and cons of software patents⁴ – an issue that initially seemed much less controversial – the legislative process in the case of the IP Enforcement Directive went relatively smoothly and the directive was adopted without much disturbance, even though one would expect *more* conflict here, since the directive touches on issues like file-sharing that have received substantially more public attention than the

arcane subject of software patents. We argue that the contrasting trajectories and outcomes in these two conflicts can be explained by examining their framing processes.

3. METHODOLOGY

To collect data about the actors involved in the two IP conflicts and about their positions and frames, we used the methodological framework of *political claims analysis* developed by Koopmans and his collaborators (Koopmans and Statham 1999). The principal idea in this approach is to analyze the claims of all of the actors involved in a political conflict – as opposed to just the challengers – expressed in their forms of action and interaction and in their collective action frames. The idea here is that, since collective action that goes beyond lobbying depends heavily on establishing a presence in the public sphere, only claims that are reported in the media are of interest, because they are the only claims that have a chance of influencing the decision-making process. Political claims analysis combines the empirical power of traditional protest event analysis with the analytical power of a frame analysis at the discursive level, and tries to map the claims of all actors, not just those of the challengers, within a given policy field. Drawing on Koopmans and Statham's (1999) definition, we conceptualize claims as demands, proposals, criticisms, decisions, and so on made by actors active in the respective field of conflict in the form of statements or collective mobilizations. A frame is understood as an "interpretive schemata that simplifies and condenses the 'world out there' by selectively punctuating and encoding objects, situations, events, experiences, and sequences of actions within one's present or past environment" (Snow and Benford 1992, 137).

For our two cases we analyzed data from quality newspapers in four countries: Germany, France, the UK and Poland. In general, we included France, Germany, and the UK because of their political and economic importance in Europe. Another reason for including the UK is that it has the most liberal patent practices with respect to software patents. It was also important to include France, because in both conflicts the rapporteurs of the EP were French nationals, and because France was one of the most vocal critics of software patents. Germany was an essential candidate because the most important oppositional actor in the software patents conflict, the Foundation for a Free Information Structure (FFII), had its origins in Germany, and because it represents a country with a comparatively strict practice with regard to the granting of software patents. Finally, Poland was selected because of its important role in the software

patents conflict, where it was the most vocal of the newly acceded East European countries in criticizing the Software Patents Directive.

For all the countries we analyzed all newspaper articles, published between January 1997 and July 2005 in selected national quality newspapers, that mentioned either or both of the conflicts or centrally dealt with the subject of software patents or the general issue of IP enforcement, *and* that were available in the full text collection of LexisNexis for the whole period. Lastly, articles were only coded if they contained a claim. They were not included in the database if they only contained some information about the respective issues or if no attributions to specific actors were made. Overall a total of 188 articles (G: 75, UK: 37, F: 45, PL: 31) were coded according to a previously developed code book (Haunss and Kohlmorgen 2008a), which had been adapted from the code book used in the EUROPUB project (Koopmans 2002). A total of 324 claims were reported in the articles; 277 related to the Software Patents Directive and 47 to the IP Enforcement Directive.

4. RESULTS

The claims making in the two conflicts differed significantly, both in content and in scope. Figure 6.1 shows that in both cases the overall pattern of claims making expressed in the newspaper articles closely reflects important steps in the decision-making process, with peaks in the number of claims reported corresponding to the publication of the directive proposals, their readings in the parliament, and the meetings of the Council.

A comparison of the timelines also immediately reveals a number of important differences. The most striking, as already mentioned, is the contrasting levels of intensity in the two conflicts, with 277 claims in the software patents conflict but only 47 in the conflict over the Enforcement Directive. A second set of differences relates to the timing and developmental patterns of public claims making. There were several waves of intense claims making in the software patents conflict, peaking at the time of the second reading of the directive in the European Parliament, whereas in the other conflict only one wave of claims making made it into the news, at the very end of the conflict. With few exceptions, the contention was publicly visible in the Enforcement Directive conflict only between September 2003 and March 2004, in the six months before the first and only reading in the EP. Moreover, it is only in this last stage that there was relatively balanced reporting of the claims of both supporters and opponents of the directive. The first claims were made exclusively by the

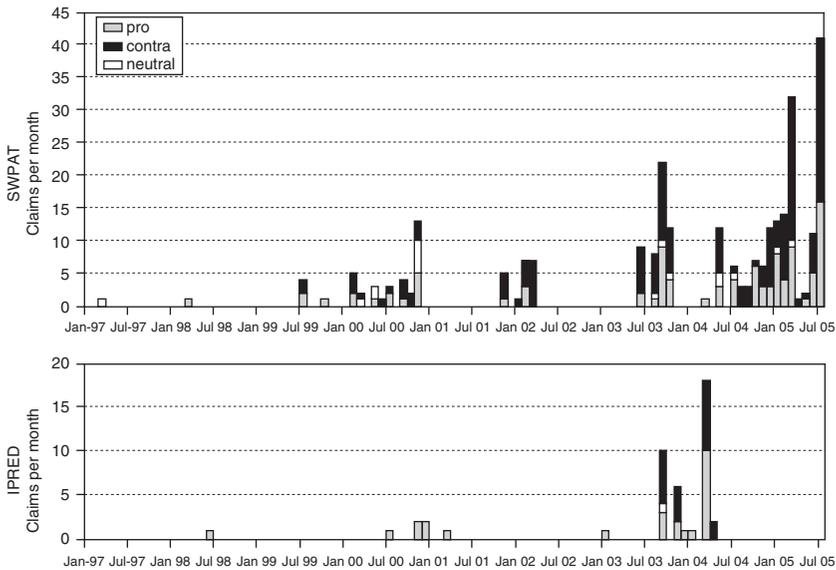


Figure 6.1 Timeline of claims making in both conflicts

European Commission, who announced the publication of the proposal for the directive several times. It is also significant that during the whole conflict the proponents' claims were reported significantly more often than those of the directive's opponents (51.1 per cent of the total claims versus 42.6 per cent, with the remaining 6.3 per cent being neutral).

On the other hand, in the software patents conflict, opponents of the directive entered the stage much earlier. The first claims against the proposed directive were reported in the newspapers as early as July 1999, and throughout the conflict the directive's opponents remained highly visible, with 58.1 per cent of the total reported claims being made by opponents and only 35.4 per cent by supporters of the directive. The remaining 6.5 per cent of the claims were either neutral or ambivalent.

Regardless of timing, the successful group of actors in both cases were those whose claims received greater exposure in the media. The opponents of software patents successfully defeated the directive, while the proponents of the Enforcement Directive succeeded in getting it adopted. As the timelines clearly show, the software patents conflict took place to a large degree in the public sphere and therefore was a public political conflict, whereas the conflict over the Enforcement Directive could be better characterized as a struggle between lobbyists, which only at the very end became a publicly visible political conflict.

To get a more detailed picture of the conflicts beyond these structural characteristics we analyzed three additional aspects of the claims-making process, to which we now turn: which actors were present in the conflict; which forms of action the opposing parties chose to utilize; and how they framed their claims.

4.1 Actors and Actions

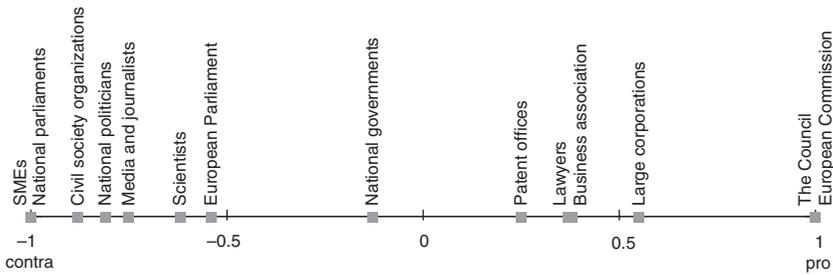
The most visible actors in both IP conflicts, in terms of newspaper coverage, were parliamentarians and political parties from the European Parliament. They were responsible for 18.8 per cent of the claims in the software patent conflict and for almost one-third (29.2 per cent) of the claims in the conflict about the Enforcement Directive. In contrast, the Commission played a much smaller role, garnering only 5.6 per cent and 8.3 per cent of the coverage, respectively.

As expected, the greater intensity of the software patents conflict brought more actors into the conflict. Two groups are especially noteworthy here: small and medium-sized enterprises (SMEs) and lawyers. The significant number of lawyers involved in the conflict is an expression of

Table 6.1 Actors present in the software patents conflict

| Actor | Reported Claims | | Pro | Con | Neutral |
|---|-----------------|--------|-----|-----|---------|
| | Percentage | Number | | | |
| European Parliament | 18.8 | 54 | 12 | 41 | 1 |
| Civil society organizations | 11.8 | 34 | 2 | 32 | 0 |
| Small and medium-sized enterprises (SMEs) | 11.8 | 34 | 0 | 34 | 0 |
| Large corporations | 10.1 | 29 | 21 | 5 | 3 |
| Business associations | 10.1 | 29 | 19 | 8 | 2 |
| National governments | 8.0 | 23 | 8 | 11 | 4 |
| Lawyers | 6.6 | 19 | 11 | 4 | 4 |
| National politicians | 5.6 | 16 | 1 | 14 | 1 |
| European Commission | 5.6 | 16 | 16 | 0 | 0 |
| Scientists | 4.5 | 13 | 1 | 9 | 3 |
| Media and journalists | 2.8 | 8 | 1 | 7 | 0 |
| European Council | 1.7 | 5 | 5 | 0 | 0 |
| Patent offices | 1.4 | 4 | 1 | 0 | 3 |
| National parliaments | 1.0 | 3 | 0 | 3 | 0 |
| Sum | 100* | 287 | 98 | 168 | 21 |

Note: * Error due to rounding.



Note: Positions in this chart represent the mean positions of actors of the respective type. Scientists for example were in 1 instance reported to support the directive and 9 times reported to be against the directive and in 3 instances their position was neutral or ambivalent, resulting in an overall score of -0.62 ($(1 \cdot 1 + 9 \cdot -1) / 13$).

Figure 6.2 Mean actor positions in the software patents conflict

their status as experts in the field. Before this conflict, software patents were generally regarded as a highly specialized subfield of patent law. The fact that this became a politically contested issue is in itself a remarkable development.

The strong participation of SMEs is an important characteristic of the software patents conflict. The directive's opposition was mainly organized by computer programmers working self-employed or in SMEs. They successfully lobbied the European and national SME business associations, who in turn positioned themselves against the directive. The attempts of the European Information & Communications Technology Industry Association (EICTA) and the Business Software Association (BSA) to mobilize SMEs in favor of the directive did not attract much press coverage.⁵ As we can see in Table 6.1, SMEs were the only relevant category of actors for which no claims were reported in favor of the directive. The only other actor groups that were unanimously either for or against the directive were a small number of national parliaments, who opposed it, and the Council, which supported it. Neither of these, however, was highlighted in reporting on the conflict. Of those actors who played a relevant role in the public discourse, not surprisingly, only the European Commission unequivocally supported the directive.

Figure 6.2, which plots the actor groups according to their overall position on the Software Patents Directive, shows that all of the other actor groups were split, although some were clearly more in favor of the directive than others. One large cluster of opponents scored between -1 and -0.5 on the positional scale, together representing a little over half (56 per cent) of the actors mentioned in the press. At the other end of the spectrum, the

Table 6.2 Actors present in the enforcement conflict

| Actors | Reported Claims | | Pro | Con | Neutral |
|----------------------------|-----------------|--------|-----|-----|---------|
| | Percentage | Number | | | |
| European Parliament | 29.2 | 14 | 9 | 5 | 0 |
| Civil society organization | 27.1 | 13 | 0 | 13 | 0 |
| Business association | 14.6 | 7 | 7 | 0 | 0 |
| European Commission | 8.3 | 4 | 4 | 0 | 0 |
| Big companies | 6.3 | 3 | 0 | 3 | 0 |
| Patent offices | 4.2 | 2 | 1 | 0 | 1 |
| National governments | 4.2 | 2 | 2 | 0 | 0 |
| Scientists | 4.2 | 2 | 0 | 2 | 0 |
| National politicians | 2.1 | 1 | 1 | 0 | 0 |
| Sum | 100* | 48 | 24 | 23 | 1 |

Note: * Error due to rounding.

Council, the Commission, lawyers, business associations, and a number of large individual firms supported the directive, but even the large firms were not unanimously in favor of it.

Looking only at single actors, rather than groups, the most important actor in the software patents conflict was clearly the FFII, which accounted for 5.8 per cent of all published claims. EICTA (4.0 per cent), Michel Rocard (3.6 per cent), Florian Müller (2.5 per cent), and Frits Bolkestein (2.5 per cent) were also noteworthy single actors who together were responsible for a little under one-fifth (18 per cent) of the claims. Interestingly, this constellation varied greatly from one country to the next. FFII was not mentioned at all in the French press but constituted 10 per cent of the claims in the German newspapers. Michel Rocard, on the other hand, was mentioned only once in Germany but accounted for 10 per cent of the claims in France. EICTA had an insignificant presence in both France and Germany, but was important in Poland and the UK, where it was responsible for 6.4 per cent and 10 per cent of the claims, respectively.

In the case of the IP Enforcement Directive the picture is more clear cut (see Table 6.2). Five actor groups dominated in the reporting: MEPs and political groups from the European Parliament, civil society organizations, business associations, the European Commission and three large corporations (British Telecom, Telecom Italia, and Nokia). Interestingly, in this case the large individual firms, all from the telecommunications sector, spoke out against the directive, whereas the business associations – in this case mainly from the music and information technologies industries – strongly supported the directive. However, ETNO, the business

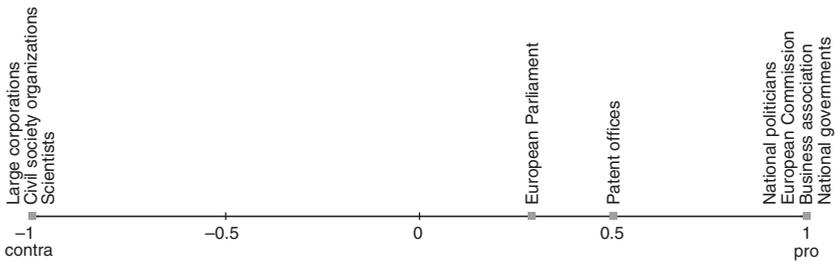


Figure 6.3 Mean actor positions in the IP enforcement conflict

association representing the telecommunications industry on the European level, was never mentioned in the newspapers, even though they actively tried to prevent the directive from being passed.

More so than in the software patents conflict, the actors were clustered largely at the extreme ends of the spectrum, with most actors – with the notable exception of the MEPs – either clearly for or clearly against the directive (see Figure 6.3).⁶

More than simply a measure of their respective influence in the debate, the relative frequency of each actor's appearance in the press also reflects their different strategies. The business associations and large corporations focused mainly on traditional lobbying channels. They tried to exert influence during the drafting and consultation phases of the process and later lobbied important MEPs. The civil society organizations, who were not able to use these avenues, concentrated their efforts much more on a public media strategy. Here again the media focused on the MEPs, who were as central to the decision-making process as the Council, but much more accessible.

Due to the lower number of claims in this conflict, a comparison between the four countries is less reliable than in the software patents case. In Poland the conflict was simply not covered in the press. We found only one article in which a claim concerning the Enforcement Directive was reported. This is not surprising, since the conflict ended before the EU enlargement, and therefore before Poland's entry into the EU. There was slightly more coverage of this conflict in the UK and French press than in Germany (18, 17 and 11 claims, respectively), a sharp contrast to the situation in the software patents conflict, where the German press accounted for 123 of the total 277 claims, as compared with 56 in the UK, 55 in France, and 42 in Poland.

Based on this limited set of data, the most important actors in the IP enforcement conflict were the French MEP and rapporteur for the parliament Janelly Fourtou, commissioner Frits Bolkestein, the German MEP Angelika Niebler, the Foundation for Information Policy Research

(FIPR), and IP Justice, who were each mentioned three times in the news. Again national differences were significant. Fourtou and Niebler were present only in their respective home countries. Bolkestein's claims were only reported in France, and the claims of the two non-governmental organizations (NGOs), FIPR and IP Justice, were only reported in the UK and Germany, respectively.

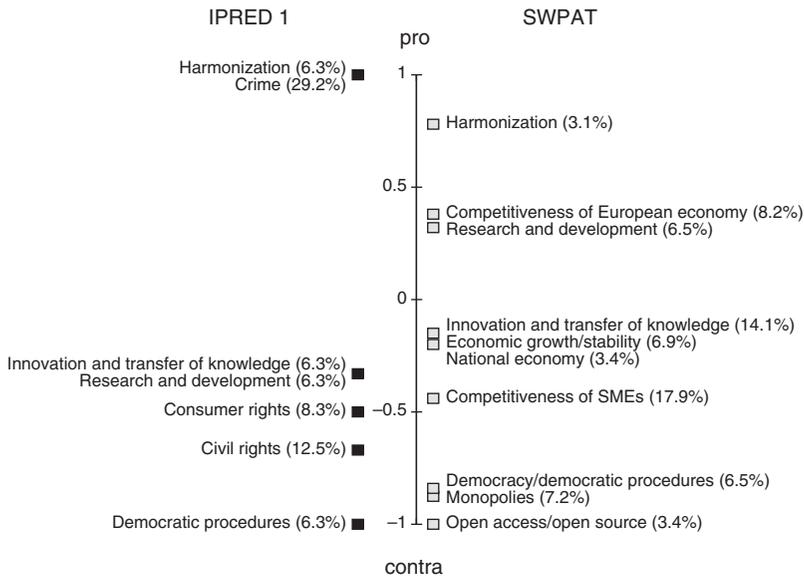
In both conflicts the actor constellation clearly reflected the degree to which the IP issue had been politicized. The actors involved in the conflicts represented not only business interests and legal experts but diverse stake-holders in civil society as well. FFII is an interesting case in itself. Its members are mainly individual software developers or CEOs of SMEs in the fields of software development and information technology. FFII claims to represent the business interests of its members and of IT SMEs in general, but it is not a business association in the traditional sense. In its internal structure and forms of action FFII more closely resembles an NGO. It is actually a hybrid between a business association and an NGO, which is also true for the LinuxPetition and the Economic Majority Campaign.

In the case of the IP Enforcement Directive, MEPs, commissioner Frits Bolkestein, and a few civil society organizations were the most important claims makers. Here one aspect is particularly interesting. The most important organizational actors on the proponents' side, IFPI (the International Federation of the Phonographic Industry) and the Anti-Piracy Coalition, each appeared only once in the media discourse. Yet we know from interviews with key actors and from a network analysis of the two conflicts (Haunss and Kohlmorgen 2008b) that IFPI played an important role in drafting the Enforcement Directive proposal and had close ties with MEPs and members of the Commission.⁷ Its work was quite effective, but obviously IFPI relied on traditional forms of lobbying and more direct non-public avenues of interest representation to influence the decision-making process.

On the opponents' side, one important actor, ETNO (the European Telecommunications Network Operators Association), did not appear in the media, and from the European Digital Rights Initiative (EDRi), which our network analysis and expert interviews showed to be the central actor in the network of civil society organizations opposing the Enforcement Directive, only two claims were reported in the newspapers. This shows that EDRi was not very effective in placing claims in the media or in mobilizing actors.

4.2 Framing

Thus far we have concentrated on the characteristics of the actors involved in the two conflicts. We now take a closer look at the frames the actors



Note: Positions in this chart represent the mean positions of the frames. The research and development frame for example was used 6 times in a claim against the directive, 12 times in support and 1 time in a neutral or ambivalent form resulting in an overall score of 0.32 $((6 \cdot -1 + 12 \cdot 1) / 19)$.

Figure 6.4 Mean positions of frames in the two conflicts

used to justify their claims. First it is important to note that in both conflicts roughly a third of the reported claims (SWPAT: 31.4 per cent, IPRED 1: 29.8 per cent) contained no articulated frame, and in about 40 per cent of the claims more than one frame was reported. Overall we therefore have 291 reported claims containing articulated frames in the software patent conflict and 50 in the IP enforcement conflict. Again the picture is rather different in each case.

As Figure 6.4 shows, in the conflict around the IP Enforcement Directive, the dominant frame was the crime frame. It was used to justify 29.2 per cent of the claims and was the only frame used exclusively by the proponents of the directive. The criminality issue functions as a master frame that unites the diverse interests of the music and film industries, large software firms (especially Microsoft), and luxury goods manufacturers. In this frame the directive was about fighting product piracy and was necessary to protect consumers from counterfeit goods.

The opponents were not able to use this master frame in their own argumentation. Some of them tried to put forward the argument that

IPRED 1 would criminalize ordinary citizens who only wanted to share their music with their friends. This can be interpreted as a kind of reversion of the crime frame. However, this criminalization frame did not appear as such in the public discourse. It was mostly subsumed under the frame of civil rights. And, to be precise, it is not a true re-framing, as it only objects to the severe penalties that would be attached to the prosecution of copyright and patent infringement. The foundation of the proponents' argument, that counterfeiting and product piracy entail high costs for companies and for entire economies, is a matter of empirical fact and therefore could not itself be refuted. One way to answer it would have been to argue that money spent prosecuting copyright infringers would make fewer resources available for prosecuting truly dangerous criminals. Instead of starting with the proponents' interpretation and re-framing it, however, the directive's opponents concentrated on constructing their own counter-frame, which focused on consumer and civil rights (used in 20.8 per cent of the claims). Unfortunately for them, these rights-based arguments were less successful than the piracy and counterfeiting frame used by the directive's proponents. As mentioned before, ETNO, the business association representing the telecommunication industry, did not appear as a public claims maker, preventing their main argument – that IPRED 1 would impose high costs on internet providers – from entering the public discourse about the directive. Nor did the arguments made by the automotive parts and generic medicines manufacturers play any role in the debate. The only frame that was exclusively used by opponents of the directive was the democratic procedures frame, which was mainly used by MEPs criticizing the selection of the rapporteur.⁸

It is striking that in the IP enforcement conflict the frame “culture” does not show up in the reporting, especially since IFPI, the interest group representing the music industry, was the main actor in the conflict. A number of participants we interviewed told us that, in their perception, the argument that the directive would protect (European) culture and artists played a significant role in shaping the conflict. Be that as it may, this framing obviously did not resonate in the public discourse.

Overall the opponents did not succeed in creating a common interpretive frame, and consequently were not able to agree on a common political strategy. Without a master frame that resonated with the public, the opponents were unable to construct a collective actor with a more or less consistent identity. The frames of the two relevant opponent networks (CSOs and telcos) remained disconnected and neither frame on its own was able to convince the general public or the majority of the decision makers. This is one reason for the opponents' failure to defeat the Enforcement Directive.

The positional distribution of frames in the software patents conflict gives a rather different picture from that in the IP enforcement conflict. Figure 6.4 shows that the frames various actors used were generally much more contested than in the other conflict, indicating a much more vibrant public debate. Unlike in the IP enforcement conflict, where arguments basically coexisted independently, in the software patents conflict opponents engaged directly with the other side's arguments and tried to re-frame them according to their aims. Looking at the seven most frequently used frames, which together comprise almost two-thirds of the frames, one can see that the conflict was primarily cast as an economic issue. In Figure 6.4 the democratic procedures frame is the only one that does not refer to the economy.

Competitiveness of SMEs was used in 17.9 per cent of the claims. Both opponents and supporters of the directive used this frame (contra: 36; neutral: 3, pro: 13), with opponents (software developers, SMEs, and some MEPs) claiming that the directive would endanger European SMEs, who would lack the knowledge and resources to use the patent system to their advantage, and supporters (large firms, European and national business associations, and again some MEPs) arguing that SMEs would profit from the directive, as patented "computer implemented inventions" would attract venture capital. The importance of the SME argument over the course of the conflict is well illustrated by the mobilization in the last phase of the conflict in which EICTA mobilized 56 SMEs to speak out in support of the directive. Our interviews confirm that until that point, neither the Commission nor the directive's other supporters had taken the SMEs seriously.

The second most frequently used frame in the software patents conflict depicts it as an issue of innovation and the transfer of knowledge (14.1 per cent). Again this was a highly disputed frame, used by both sides (contra: 23, neutral: 1, pro: 17) to support their claims. The opponents of the directive usually combined this frame with the SME frame, arguing that SMEs are the cornerstone of innovation in Europe, and that by putting SMEs at a disadvantage software patents would have a negative impact on European innovation. The other side generally followed the conventional wisdom of the economic and legal mainstream, which saw strong IP protection and especially patent protection as necessary for the protection of investments in innovation. According to this argument, not being able to file patents for computer implemented inventions would keep large corporations from investing in Europe, which would negatively affect not only individual firms but the whole European economy and result in the loss of many jobs. Thus, the competitiveness of SMEs and innovation frames were clarified and invigorated by both camps, though they were

interpreted differently. This is a special case of “frame amplification” (Snow et al. 1986).

The only relevant⁹ frame that was used exclusively by one side only in the software patents conflict was the open access/open source frame, which was an attempt by some of the directive’s opponents to construct a counter-frame similar to those used in the IP enforcement conflict. This open source frame – the argument that open source software should generally be preferred to closed source proprietary software – was relevant to some degree in the internal discussions among opponent organizations,¹⁰ but in the conflict as a whole the argument too closely mirrored the interests of those opposing the directive to incorporate the interests of the other side. It also played only a minimal role in the public discourse.¹¹

Two other frames, the monopolies and the democracy frames, were also almost exclusively used by the opponents. MEPs made use of the democracy frame when, after the Parliament’s first reading of the directive, the Commission and later on the Council completely ignored the Parliament’s amendments, and when subsequently several presidencies in the Council, specifically Ireland, the Netherlands, and finally Luxembourg, tried to pass the directive without discussion. The relative strength of the democracy frame (6.5 per cent) illustrates the fact that one level of the conflict was an institutional power struggle between Council, Commission, and Parliament, in which the Parliament tried to defend its newly augmented decision-making rights in the co-decision procedure. The democracy frame, which was powerful primarily in the final phase of the conflict between March and July of 2005, helps to explain the reluctance of some MEPs to let the common position of the Council pass in the second reading – even if some of them did not object to the patentability of computer implemented inventions. The democracy frame was not related to the issue of software patents initially. It developed as a legitimacy frame in response to the decision-making process and was then combined with frames that were originally derived from the software patent issue. This is an example of “frame bridging”, a process that describes the linkage of two structurally disconnected frames (Snow et al. 1986).

The research and development frame, on the other hand, was used primarily by supporters of the directive, who argued that patents would be necessary to recover the research and development costs involved in inventing the product. The directive’s opponents picked up on this frame, however, and claimed that software patents would in fact inhibit research, because they would make sequential innovation, a dominant practice in the field of software engineering, more difficult and more costly.

The opponents were successful in re-framing the issue of software

patents, which was originally framed by the European Commission as a harmonization, European competitiveness, and innovation issue. Over the course of the conflict, these initial frames were overtaken by the frames competitiveness of SMEs and innovation and transfer of knowledge. Specifically, the innovation frame, which was originally used by the Commission and large corporations, was re-interpreted by FFII and others to make the case that innovation is in fact largely promoted by SMEs and individual software developers, and would therefore be jeopardized rather than enhanced if the Software Patents Directive were adopted.

5. CONCLUSION

This analysis has revealed the publicly visible claims-making processes surrounding two recent European conflicts over intellectual property rights. One striking difference between these conflicts is that the software patents conflict took place mainly in the public sphere, whereas the one about the Enforcement Directive was largely a lobbying conflict. This publicity was an important factor for the actors opposing the Software Patent Directive – who were the weaker side of the conflict in terms of their access to resources – allowing them to influence the decision-making process and pursue their interests successfully.

Moreover, our analysis illustrates on two levels the importance of how an issue is framed:

1. At the level of interaction within the network of actors mobilizing on the same side of an issue, collective action frames are necessary to develop a coherent interpretation and a coordinated action strategy – to create a collective actor with a coherent collective identity.
2. In the public sphere the resonance of a frame determines its potential to become hegemonic and influence those decision-makers that depend on public opinion – in the two cases presented here, this was mainly the MEPs.

In the case of the Enforcement Directive the proponents managed to construct a hegemonic master frame. They claimed that the directive was about “fighting against criminality and product piracy”, and this master frame was accepted by the majority of the actors involved as an appropriate interpretation. Consequently, the directive was seen as the proper tool to solve the problem of product piracy. Even some of the left-wing MEPs accepted this frame and the problem solving strategy it implied.

On the other hand, the opponents of the Enforcement Directive were

unable to reconcile the frames of the two primary groups of actors into a coherent oppositional master frame that could accommodate the various interests opposing the directive. Instead each group advanced its own counter-frame, interpreting the conflict as a consumer issue, a civil rights issue, an issue of access to information, and so on. But none of these frames on its own was able to counter the hegemonic frame from the other side of the discursive field. While the argument made by civil society organizations – that the Enforcement Directive would threaten civil rights and adversely affect innocent citizens – had at least some traction with a number of MEPs, the critique leveled by the telecommunications firms and generics manufacturers was not taken up by other actors and never played more than a minor role in the public debate. IPRED 1 was a clear case of a failed counter-framing strategy. The directive's opponents were not able to re-frame the dominant crime frame, nor did any of the opponents' attempts to establish a counter-frame succeed.

In contrast, the conflict over the Software Patents Directive is a good example of a successful re-framing strategy. Rather than concentrating their efforts on constructing a consistent counter-frame, the opponents of this directive successfully shifted the original frames used by the Commission (innovation, harmonization, and European competitiveness), effectively turning them on their head. To do this, the opponents reaffirmed the necessity of innovation and a competitive European economy, but claimed that the principal agents of innovation in the European IT sector are SMEs and that only a directive that effectively prevents software patenting would safeguard innovation. The trajectory of this conflict was a discursive struggle in which both sides continuously tried to re-frame this innovation frame to include their respective core interests. Both actor groups engaged in attempts with frame bridging and frame amplification, but attempts to construct genuine counter-frames remained marginal.

In the software patents conflict, rather than a struggle to establish a hegemonic frame, we see attempts to knit various frames together to shift the frame's overall meaning. We suggest calling this strategy *frame bundling*. It tries to alter the meaning of an original frame by bundling it with other frames that change the content of the whole package. In this case the opponents tied a bundle that contained the frames innovation and transfer of knowledge, economic growth and stability, growth of national economies, and competitiveness of SMEs. The result was that the innovation and transfer of knowledge frame that was originally used to argue in favor of the directive now became an argument against software patents and, subsequently, against the directive. The opponents' master frame – that innovation depended on the competitiveness of SMEs, which could only be secured *without* software patents – provided a unified collective action

perspective, which allowed them to mobilize a diverse constituency. Along with the democracy frame, it resonated in the broader SME sector, and more importantly, with many MEPs, who finally stopped the directive.

The political claims analysis of the two IP conflicts supports our argument that the framing of the issue profoundly affects the outcomes of the decision-making process. It adds to the literature on framing by showing that under certain conditions re-framing strategies may be more successful than counter-framing strategies. With only two cases we are not able to fully specify these conditions. Nonetheless, our findings suggest that a number of key factors are important:

1. *Embeddability* Re-framing is likely to be more effective if the issue being framed can be linked up with some larger conflict over normative values. The dominant frame can then be recast in a way that taps into popular moral sentiments around the larger conflict, for example, the provision of health services versus property rights.
2. *Ease of redefinition* A re-framing strategy is more likely to succeed if the dominant frame lends itself to reformulation; that is, if it can be easily reappropriated and does not automatically lock one into a static set of associations. For example, innovation is generally considered a good thing and crime a bad thing, but there are more “sellable” notions about how to foster innovation than there are about how to deal with crime. Once something is framed as a crime, it is very difficult to dislodge that idea (whether by saying “no, it’s not a crime” or by saying “this isn’t about crime”), and opposing the directive becomes associated with being “soft on crime” or pro-criminal.
3. *Actor diversity* The more diverse the interests are within a coalition, the more difficult it is to establish a counter-frame as a unifying master frame. A gradual re-framing strategy may be more successful in such a situation.

While further research is needed before we can conclusively determine the conditions under which different framing strategies allow weak actors to successfully influence public discourse, the above propositions may offer a good place to start.

Last but not least, our research also demonstrates the limits of the political claims approach. A network analysis of the two conflicts (see Haunss and Kohlmorgen 2008b) reveals that the complete network of participating actors is much larger than the group we were able to identify by analyzing newspaper reports. Some actors who obviously have played important roles in the two conflicts were completely absent in the press. While a political claims analysis based on newspaper data can reveal the

public part of a political conflict, it also obscures other routes actors use to influence decision-making processes. We have demonstrated the importance of framing for shaping public discourse and influencing political processes. Only by combining this approach with other methods will we be able to generate an accurate picture of the conflicts and more complete understanding of the determinants of political influence.

NOTES

1. The research for this article was made possible through a research grant from the Fritz-Thyssen Foundation.
2. However, there is one significant difference in the de facto decision-making process: in the case of IPRED 1, the decision-making process was considerably accelerated through the introduction of a so-called “trialogue”, that is, informal negotiations between the European Parliament, the European Commission, and the Council of the European Union. The main actors involved in this legislative procedure wanted an adoption at the first reading of the directive, before the EU enlargement in May 2004. There were concerns that the new EU member states (some of which were facing widespread IPR infringement) might complicate and delay the deliberations.
3. According to a former Commission employee, even the Commission circulated its preparatory documents with filenames containing “swpat”.
4. According to some European parliamentarians, this controversy generated one of the most intensive political conflicts the European institutions have seen in the recent past (Michel Rocard, interviewed by Sebastian Haunss, 17 January 2007, interview 9, transcript).
5. In June 2005, 56 SMEs published an “SME Manifesto on Patents for Computer-implemented Inventions” (http://w3.cantos.com/05/eicta-504-0arfg/documents/SME_manifesto_0106.pdf). The Manifesto does not mention EICTA, but the website where it is available to be signed is run by EICTA and its member firms, all of whom are large IT firms (<http://w3.cantos.com/05/eicta-504-0arfg/cii.php?page=aboutus>).
6. The UK patent office is not shown among the supporters only because one of the two articles in which it appeared reported a rather ambivalent claim.
7. Yolanda Smits, interviewed by Sebastian Haunss and Lars Kohlmorgen, 12 December 2006, interview 2, transcript.
8. Their main point of criticism was that French MEP Janelly Fourtoul’s private interests as the wife of Jean-René Fourtoul, the then CEO of Vivendi-Universal, would interfere with her role as rapporteur for the directive.
9. We classified as “relevant” all frames that were used in at least 3 per cent of the claims.
10. Thomas Eimer (2007) distinguishes two different conceptual approaches within the opponents’ camp on how to treat software: where the FFII favors a “club good” or “open source” approach, which guarantees some rights for the developer, other relevant organizations, such as the Free Software Foundation (FSF), champion the idea of free software as a public or common good. This latter approach extends the largely economic perspective of the club good approach and takes a political position that is more fundamentally critical of capitalism and neoliberalism. This difference, however, did not play an important role in the campaign.
11. It is quite interesting that the European Commission chose not to use the open source/open access frame, as it would have fitted nicely with the argumentation it made in the March 2004 anti-competition case in which the Commission ordered Microsoft to pay €497 million for failing to disclose the interface information necessary for other firms to integrate their media player software into the Windows desktop environment – a classic open access case.

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7. Can patent legislation make a difference? Bringing parliaments and civil society into patent governance

Ingrid Schneider

Traditionally, patent governance has been confined to a closed, self-regulated community of patent lawyers and technicians in patent offices and courts. Biotechnology patents, however, brought a highly complex and seemingly distant issue area into the public sphere. The patenting of “biological material”, such as cells, genes, plants and animals, has become a contentious issue and induced political mobilization. While these controversies arose in many countries, it was only the European Union which dealt with them by technology specific patent legislation (European Union 1995). This happened due to some special, incomplete features of the supranational European patent system, particularly the lack of a European Patent Court, and the institutional split between the European Patent Organisation and the European Union. However, this *legislative* governance provided a public arena for deliberation on these issues which both responded to and went beyond the contestation of biopatents in civil society. The treatment of biotechnology patents as addressed in the legislative arena differed from their treatment in the traditional legal and administrative arenas. Parliaments played a vital role in introducing new perspectives, and in reframing patent law as regulatory law.

My proposition is that legislative action in this case actually made a difference, as it provided an important catalyst for the European patent system, opened up the arena of decision-making for other stakeholders, and reconceptualized patents as a *political* issue. As I will argue, the politicization of biopatents has impacted upon the evolution of the patent system and its historical confinement to patent attorneys, civil servants, and judges. The conflicts leading to protracted processes of political decision-making can be regarded as resources for cracking the hermetic seal of the technico-legal patent community. What was achieved in the course of these conflicts was a new, “European mode” of patent governance, which takes regulatory concerns into account. I will prove this hypothesis by

providing an empirical case study on the EU Directive “on the legal protection of biotechnological inventions” (98/44/EC) (1988 to 1998) and its national implementation in Germany and other EU member states (1999 to 2006).

To make my case, I first introduce frame analysis as a methodological tool for elucidating stubborn policy controversies, and for shedding light on conflict resolution by reframing, which in this case also entailed some legal transformations. I secondly provide some theoretical underpinnings and rationales of patents as devices to tame the uncertainties of innovation. In the third and fourth parts I analyse the frame constellations and frame dynamics of the legislative processes at the EU level and in Germany respectively. In the conclusion, political achievements gained in these legislative processes, in which civil society and parliaments came to play a preeminent role, are evaluated. I also spell out some dimensions of this “regulatory turn” of European patent governance. The chapter is based on extensive fieldwork, expert interviews with politicians and other stakeholders, participatory observation, and the analysis of policy documents.

1. THEORETICAL BACKGROUND – FRAME ANALYSIS

My empirical study on the biopatent controversy is theoretically located in argumentative and discursive approaches within the field of policy analysis (Fischer and Forester 1993; Fischer 2003). Methodologically, I make use of frame analysis, as developed by the seminal work of Schön and Rein (1994) to examine stubborn and seemingly intractable political controversies. Frame analysis provides analytical tools to reconstruct what is seen as being “at stake” in contentious political conflicts. I combine frame analysis with some contributions from democracy and governance theory, with particular reference to the input dimension of governance. I will hence emphasize the participation of “weak actors”, and the relationship between input and output legitimacy, as well as between horizontal and vertical governance arrangements (see Mayntz 1998).

Another conjunct focus is the transmission of problem articulations from the public sphere and civil society towards parliaments and government (Habermas 1996; Dryzek 1990). I will highlight the role of parliaments in mediating frame conflicts and in providing policy resolutions which resonate with extra-parliamentarian frame articulations to achieve compromises or even consensual agreements. Thus, my analysis puts some emphasis on how problem articulations manifested in the public sphere and in civil society are transmitted, translated, processed and transformed

by political institutions, from the legislative towards the executive branch of government, and linked to other functional systems (patent practice and the patent profession/discipline) and their internal, self-referential logics.

My central thesis is that controversies should not be regarded as barriers to and procrastination of effective political decision making, but as resources for governance, by providing opportunities for a reframing of IPRs (Schön and Rein 1994). Controversies thus trigger shifts in perceptions, institutional frameworks, as well as power structures in dealing with new technological developments and their governance through (patent) law. To anticipate the result of my study, through these legislatively treated conflicts, a redefinition of patent law has gained momentum. Patent law is shifting from a narrow definition of private law attending interests of inventors and economic competitors by legal entitlements towards regulatory law mediating between different rights and entitlements, taking several “third” parties, stakeholders and public interests into account, as well as providing foresight on the socio-economic impact and political dimensions of patent granting.

2. THE BIOPATENT CONTROVERSY – PATENTS AS INTELLECTUAL PROPERTY RIGHTS (IPRS)

The dominant perspective on patent law is that it is value-free, but technology and innovation-friendly, that there is no need for technological specification, and that stronger patents lead to more innovation. Patents are tools of market societies for dealing with the uncertainties of R&D and innovation. While uncertainties prevail about the practical functioning, economic success, and social acceptance of new technologies, patents have come to be seen as devices to tame at least some of these uncertainties.

For many decades, the patent system remained a “dry and dusty corner of the law” (Emmott 2001: 374), largely self-regulated by interaction between patent applicants and patent granting offices (practice), by lawyers as a profession and specified discipline, and by courts. Even within the law as a discipline, patent law has occupied a fringe area of private law, a hermetic science with its own doctrines, largely inapprehensible to outsiders, and left to technicians and engineers with a specialized legal training. Legislation only occurred rarely, to fix immediate problems; patents seemed to be uninteresting for political parties and governments (Artelsmair 2004).

Starting in the 1980s and 1990s, there was a shift towards stronger intellectual property rights (IPRs), largely influenced by the rise of the Japanese semiconductor industry and the emerging biotechnology. A

landmark case for biotechnology was the US Supreme Court's decision in *Diamond v Chakrabarty* (1980), which ruled that genetically engineered oil-eating bacteria were patentable and claimed that "anything under the sun made by man" could be patented.

In the European Union, political willingness to regulate IPRs at the European level arose from 1985 with the thrust of the single market project and was translated into initiatives for harmonizing IPRs in the EU (Borrás 2003). Concerning patents, however, the stillborn Community Patent Convention meant that a double structure had come into existence: patents were regulated by the 1973 European Patent Convention (EPC) as an international treaty, which was governed by the European Patent Organisation and executed by the European Patent Office (EPO). Therefore, the EU has so far no direct legislative powers to regulate patent law on the supranational level, and the EPO is not subject to EU jurisdiction (Artelsmair 2004; Schneider 2006b). Nonetheless, the European Commission (EUC) aimed at legislation for biotechnology and software (so-called computer-implemented inventions), to provide legal clarity in these new technological areas, where traditional patent language had not yet been translated. Hence, the EPO practice of granting patents on biotechnological inventions should be (indirectly) secured by clear statutory norms at the EU level.

Both the biotech and the software Directive drafts initiated by the Commission aimed to speed up innovation, to allow catching up with the US and Japanese industries and to provide the same degree of patent protection for European companies as the US competitors enjoyed. The EUC's problem-setting story for the Directive and its objective also was to provide for "preventive harmonization", because it was assumed that diverging national court decisions on biotech patents in the EU member states could lead to legal fragmentation and unfavourable split-up of the European patent framework.

Thus, the biotech Directive first introduced by the EUC in 1988 pursued two goals: both the harmonizing and the strengthening of biotech patent law, to provide legal security for private actors and to achieve economic ends. These IPR initiatives operated in the context of globalization, increased competition, and later the knowledge-based society.

Article 52 EPC stipulates that patents "shall be granted for any inventions which are susceptible for industrial application, which are new and which involve an inventive step", thus naming the most important criteria for patentability. Traditionally, exemptions from patent eligibility – among them "discoveries, scientific theories and mathematical methods" (Art. 52(2)(a) EPC) and methods for treatment on the human body (Art. 52(4) EPC) – were interpreted very narrowly. The same came to be applied to exceptions to patent eligibility, as codified in Article 53 EPC, namely

“inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality” (Art. 53(1) EPC) and “plant or animal varieties” (Art. 53(2) EPC). In the course of time, patent examination, jurisdiction and interpretation by legal scholars rendered these boundaries to patent eligibility largely irrelevant (Nack 2002).

The first patent Directive proposal “on the legal protection of biotechnological inventions” (98/44/EC), introduced to the European Parliament in 1988, should provide legislative guidance for a new field of innovation. Whereas patent law historically primarily concerned machines and chemical substances, a new subject matter of human in(ter)vention, termed “biological material” and “living matter”, comprising cells, gene sequences, and other biological compounds, as well as plants and animals as organisms, and biotechnical processes were to be made to fit with traditional categories of patent law. While the proponents of this Directive presented the patentability of this subject matter as mere application of the formerly known universal patent criteria and conform to traditional case law, opponents from civil society regarded it as an illegitimate expansion of patenting into the “field of the living”. The application of patent law to biotechnology followed the pattern of rules already developed for chemical substances, thus treating them in analogy with “products of nature”, which in an isolated and purified form could be made patentable (“composition of matter” doctrine) and were provided a broad scope of protection (“absolute” protection of *all* possible industrial applications) (Kreff 2003; Schneider 2003).

3. FRAME CONSTELLATIONS AND FRAME DYNAMICS OF THE LEGISLATIVE PROCESSES

In the following case study of the EU’s biopatent Directive I focus on the two dominant frames, termed “economy” and “ethics”, which structured the controversies. I first outline the static constellation of these dual frames, and then describe the frame dynamics.

3.1 Biopatent Directive’s Introduction – as Embedded and Expressed in the Frame “Economy”

The introduction of the biopatent Directive in 1988 was embedded in a politically supported rise of the patent system, which expanded quantitatively (around 10 per cent increase of patents filed per year in Europe and in the US), as well as qualitatively, comprising new technological fields. This tendency acted together with attributing more importance to intangible assets in firm strategies and in the knowledge-based economy.

Patents thus provided an important legal entitlement for new actors in the biotech industry, particularly for start-ups: patent portfolios came to be seen as essential to attract venture capital from the financial markets in the “new economy”. Patents also came to be seen as playing a predominant role in protecting the innovation powers of the “old” industrial giants from “cheap” copying efforts by emerging economies. Growing trilateral competition also was a rationale given for requiring a strong patent regime within the EU. And patents came to be seen as vehicles for stronger cooperation between university-based science and industry.

Thus, strengthening of the patent regime as a means to control the uncertainties of the future, to provide for economic prosperity, to speed up technological innovation, and to enhance therapeutic outcomes of the medical industry characterizes basic assumptions of the frame “economy”. This hegemonic frame, which reflects the Directive proponents’ perspective, was strongly entrenched in the traditional regulatory patterns of the patent field. Harmonizing IPRs was seen as paramount for the thriving single market project. In terms of research policy, patents provided a just reward for inventors and investors. The privatization of inventions by property rights was necessary for securing a return on investment, for technology transfer and for the allocation of resources. Technological optimism prevailed. Generally, a maximalist approach to patents was pursued. These story lines can be summed up in a single equation: patents equal innovation, equals economic development, equals therapeutic improvement, equals beneficence for general wealth, and thus benefit for the common good. As a negative equation this implied that no or weak patent protection meant stagnation, economic decline, hazards to the national economic situation and under-use of technological potentials.

The actor coalition behind the frame “economy” was led by the pharmaceutical and biotechnical industry (European firms, but also US-based TNCs), comprising the “Big Players” as well as small and medium enterprises (SMEs). Start-up companies regarded patents as an essential asset to draw in venture capital and as a key bargaining chip to negotiate with big companies. The European Commission and the Council tended to lean towards this position.

3.2 Contestation of the EU Directive – the Emergence of the Frame “Ethics”

Contrary to expectations, it took more than a decade from the first proposal in 1988 until the EU Directive on the Legal Protection of Biotechnological Inventions was passed in 1998. Surprisingly, the EUC’s legislative efforts encountered fierce opposition in the public sphere, and its

legitimacy became fundamentally contested. This encompassed the strong politicization of a technocratic field formerly outside public attention.

Paradoxically, it was the very legislative effort by the EUC which enabled politicization and provided a public arena for deliberation on the formerly hermetic patent field. One of the starting points was the iconic patent on the “Harvard oncomouse”, granted to Leder by the EPO in 1992, which was opposed at the EPO’s boards of appeal by several public interest groups (Dutfield 2009).

The draft patent Directive triggered a wide array of very different concerns: agricultural concerns about the patenting of seed supplies at the expense of small farmers, environmental concerns on biodiversity and genetic resources, concerns on risks associated with genetic engineering, concerns about a widening North/South divide and unequal distribution of resources and technological benefits, concerns on animal welfare, and religious or ethical concerns on the private ownership of life forms.

Thus, a wide diversity of actors and concerns were bound together through the emergence of a new frame “ethics”, which challenged the hegemonic frame “economy” and enabled a new discourse coalition of relatively weak actors, primarily from civil society organizations. The problem setting story for this frame was set up as an expansion of patent law beyond codified legal norms, as enshrined by the European Patent Convention, and beyond significant moral norms. Strong morality claims aimed at the delegitimization of both the EPO’s patent granting practice and the proposed Directive.

The frame “ethics” gathered together in one discourse coalition several rather distinct story lines and rationales: it rejected patents on “living matter” and on DNA sequences, claiming that this would be implying a commodification of the human body and of living organisms in general, indeed “life itself”. This frame regarded gene sequences and biological material as discoveries, not as inventions. Some of the story lines were motivated by what might be called conservative or religious values emphasizing the “sanctity of life” and its inalienability for private property; others defended the principle that the human body should not be commodified; others claimed that nature should not be genetically re-engineered and commercialized. Another story line focused primarily on limits to the market in capitalist societies, while still another relied on the relationship between the public and the private domain, placing emphasis on unrestricted access to knowledge as a universal public good. Another story line claimed genes to be “the common heritage of humankind”. The central motto for this frame was “no patents on life”. The ensemble of story lines which formed the frame “ethics” was primarily based on deontological normative claims and declarations. These remained to a

great extent abstract, were not necessarily consistent and coherent with each other, and were not very much elaborated. What made them persuasive was very much based on their intuitive plausibility. In particular, the claim that gene sequences, material derived from the human body, plants and animals were “discoveries”, not inventions, was very convincing to outsiders of patent law, thus demonstrating that the use of those terms in the patent discipline had far departed from everyday speech. Patents became a symbol for the “commodification of life”, which was expressed and underlined by several of the story lines.

The frame “ethics” actor coalition encompassed medical associations, churches, public interest and advocacy groups, and (some sections of) the European Parliament. The frame “ethics” critique fundamentally opposed the rationality of patent doctrines, the legal structure of the EPC treaty, and the biotech Directive proposal. At the same time, there was a need to stick to some elements of the EPC to “inscribe” another rationality, to persuade politicians and the public that something had “gone fundamentally wrong” with biopatenting.

It was most notably two gates which provided entrance to the seemingly closed and hermetic body of patent law:

1. the *ordre public* and morality exemption clause (Art. 53(a) EPC)
2. the distinction between discovery and invention as the boundary line for patent eligibility (Art. 52(2) (a) EPC).

In particular the *ordre public* clause provided both enablement and restriction for the new discourse coalition. As patent law does not include any technology assessment of impact on the environment, social distribution or technical risks, the central point of reference for this actor coalition needed to be “ethics”, and not “culture” or “socio-economy”. Therefore these clauses from the existing European Patent Convention were drawn as the entry points for a critique *within* patent law itself, to give evidence for the “wrongness” and “illegitimacy” of patent practice and of the Directive’s content. This reasoning was uniformly and monotonously countered by the epistemic community of patent practitioners (EPO) and scholars (discipline) as a “fundamental misunderstanding” of patent law (“as it really is”), thus defending their established monopoly of interpretation of the legal statutes.

3.3 Frame Constellation Phase 1: Agonal Constellation and Principalism (1988–95)

Thus, characteristic of the initial structure of the frame constellation and its interaction for the first years of the dispute was that “the morality

arguments are ultimately countered by technical ones in what often appears to be a dialogue of the deaf” (Black 1998: 649). The frame “economy” and the frame “ethics” were antagonistically opposed and incompatible. Communication to reach some agreement could never be achieved, because problem setting stories, core assumptions and conceptions about the Directive’s content and objectives differed absolutely. Until the mid-1990s, the frame constellation was agonal and adversarial; the frames frontally collided. There was no common base for approximation, let alone for any agreement.

3.4 The Role of the European Parliament

Parliaments are neglected players in policy analysis and governance studies. Either governments are seen as predominant state actors, or other players such as multinational enterprises or NGOs are favoured subjects of studies. However, both in the European Parliament and in national parliaments remarkable “changes of text” of a legal Directive between “entrance and exit” from the legislative arena occurred. The pressure for legislative decision-making enabled mediation between seemingly incompatible policy frames, and effectuated considerable frame dynamics. In the parliamentary proceedings on the draft legislation as proposed by the EUC, processes of argumentation and negotiation took place which succeeded in – at least partially – overcoming the antagonistic and irreconcilable frame constellation by producing deferrals and reframing processes.

This took place because of and despite severe restraints, which distinguish parliamentary deliberation from action in the public sphere. In the public sphere, fundamental contestation of policies is possible, but there is no empowerment for (legal) decision-making, whereas parliaments have statutory decision-making power, but encounter several restrictions in their potential for action. To recapitulate some of the institutional features and mechanisms in the EU multi-level system:

- Agenda setting is bound to the European Commission, as it possesses the monopoly of initiative power for legislative Directives.
- Parliament thus is forced to propose amendments to a pre-given text – it cannot write its own Directive’s text, but needs to reshape a text as given.
- Parliament also needs to currently adjust given statutory texts, and thus is bound to continue “old” patent law.
- Parliaments need to comply with given legal norms and statutes, and with international agreements underwritten by governments (such as TRIPS).

- The European Parliament (as the whole EU as polity) lacks legislative competence in bioethical fields and questions framed as “ethical”, those are predominantly left to national sovereignty and subsidiarity.
- Parliaments are bound to majority votes.

The European Parliament (EP) resonated with the contestation of the legitimacy (compare Dryzek 1990) of central parts of the Directive which were voiced in the public sphere. A special focus was whether the human body and its parts – genes thereby considered as body parts – deserved a special status and should be exempted from patent eligibility.

The agonal frame constellation was reproduced in the relationship between the European Commission, the Council, and the European Parliament. The EP presented over 40 amendments to the Directive. As some points could not be resolved, a conciliation procedure went on for several months at the end of 1994 until the beginning of 1995 and was closed with the adoption of an “agreed” text, on which, however, interpretation was contentious.

What became the central point of disagreement was the meaning of the two words “as such”. The agreed text stated that the human body, its elements and products should not, “as such”, form the subject matter of patents. While Parliament assumed that this meant non-patentability of human cells and genes, the Council assumed that *isolated* parts of the human body, including gene sequences, could form the subject matter of patents. This fundamental difference led – among other factors – to the failure of the Directive. The final vote on the Directive, in its third reading on 1 March 1995, was accompanied by a strong presence of NGO lobbying efforts and direct, visible action, which employed pathos and ethos: a huge banner from Greenpeace proclaimed “Vote ‘No’ to Patents on Life” in front of the Parliament’s building in Strasbourg (Emmott 2001: 376).

Surprisingly, and unprecedentedly, the European Parliament voted against a Directive, with a simple majority of 240 votes against, 188 votes in favour, and 23 abstentions. It was not only the Green faction, which always had opposed the Directive, but also the majority of the Socialist group who voted against, thereby abandoning the Directive’s Rapporteur, who was a Social Democrat; a number of Conservatives and Christian Democrats abstained or voted against as well. The reaction to this astonishing event of European Parliament flexing its muscle, however, was mixed. While some Parliamentarians stated this to be “a sidereal hour of Parliament”, and NGOs proclaimed it to be “a vote of Conscience over Capital”, industry representatives and some media blamed the Parliament for its “emotional” and “irresponsible” decision (Emmott

2001: 377). Thus, the frame constellation had clashed, which produced a negative output – because the resulting failure of the Directive also meant non-decision on biopatents at the EU legislative level.

3.5 Frame Constellation Phase 2 (1995–98): the Consequentialist Turn: Intra-frame Differentiation and Inter-frame Dynamics

The next round started only nine months after the vote with the Commission's proposal of a "new" biotech patent Directive, which very much resembled the old one. This time, Parliament felt the pressure to "act responsibly" and also signalled the political will to get a new Directive passed. The Commission and the Council, on the other hand, were ready to admit some concessions to the EP. Nonetheless, amending the Directive was a power play.

What happened on the arguing side, and concerning both intra- and inter-frame interaction? Concerning the intra-frame development, an internal differentiation took place: both frames, "economics" and "ethics", established "maximalist" and "minimalist" subdivisions. Concerning inter-frame interaction, a remarkable consequentialist turn occurred. This does not mean a dissolution of the frames and their corresponding discourse coalitions and actor "camps". But the strong agonist constellation receded and provided space to a new constellation. This happened – at least partly – because both discourse coalitions aimed to persuade the audience.

The focus shifted from the (essentialist) question, what patents "are", towards what patents "do". Formerly, frame "economy" members responded, "a purely technical and legal device", whereas the frame "ethics" made strong statements on the illegitimacy of converting "living" objects into intellectual property. This contention produced unsatisfying and irresolvable results. In shifting from principalism to consequentialism, a common focus and subsequently some common language could be found: both discourse coalitions now issued statements on the implications and effects of patent protection.

Nonetheless, a new "black and white" division appeared: the frame "economy" postulated almost exclusively positive consequences of biotech patent protection, while the frame "ethics" claimed permanent negative consequences on research and innovation. Actors from both frames alluded to empirical facts and examples, to give evidence for their claims – which subsequently were rejected by the other side as singular, anecdotal, exceptional and thus not generalizable. Argumentative resources for this inter-frame constellation were provided by scientific experts, presented as "objective empiric knowledge and facts", and on the other hand by "critical events".

Two “events” gained specific prominence:

- Patents on BRCA1 and BRCA2, two breast cancer genes, were granted both by the USPTO and by the EPO to the US-based company Myriad Genetics. These patents were embedded in general controversies on gene patents for predictive diagnostic tests and their effects concerning research, access and public health problems (van den Belt 2004, Parthasarathy 2007). This “case” lent credibility to the claim of negative consequences of gene sequence patenting.
- ESTs (expressed sequence tags) and their patent eligibility were one major focus of attention after, in the early 1990s, the US NIH applied for patents on several thousand cDNA sequences (provoking James Watson’s outrage and departure as leader of the Human Genome Project). The applications were later partly withdrawn by the NIH. This controversy contributed to the “minimalization” of the frame “economy”, through the demand that DNA sequences without known function, which were only used as markers, should not be patentable subject matter in Europe (Kreffft 2003).

As a result, the maximalist claim by the frame “ethics” for categoric exclusion of “all living matter” from patent eligibility, in particular “biological substances” and gene sequences from the human body, was mitigated and finally resolved through a rhetorical compromise, which I will explore below.

Concerns of the frame “ethics” were also minimized by selectively focusing on special reprogenetic issues. In the Directive’s legislation, this resulted finally in Article 6(2) providing a non-extensive list of exclusions from patent eligibility.

These legislative results were achieved not only through processes of arguing and bargaining (primarily in the EP’s committees) and through majority votes on amendments (in the plenary), but also through strong invocation of morality and emotions. This time, pathos and ethos appeared more pronounced in the field of the frame “economy”, giving rise to a crosswise-reversal phenomenon.

The frame “economy”’s actor coalition was expanded by a new actor: representatives of organizations for people with rare genetic diseases. On the occasion of the decisive vote (first reading) of the new Directive’s text in 1997, the European Alliance of Genetic Support Groups (EAGS) gained special prominence. Its claim to represent 18.6 million Europeans suffering from rare and severe genetic diseases was later questioned, however, both in terms of internal democratic structures for decision-making and in terms of representation of the wide range of heterogeneous

patient-groups (compare Schweiger and Then 1997). The emergence of this actor was supported – both financially and by means of professional consultancy agencies – to the British pharmaceutical company SmithKline Beecham. Patient-group members started strong lobbying efforts on Parliamentarians, sailing under the banner “No patents – No cure”. Thus they were mobilizing ethos – by speaking on behalf of those suffering from hitherto incurable diseases – and pathos – by appealing for compassion, solidarity and care (Compare Gottweis 2005). Argumentatively, morality was invoked by alluding to and alluring the “therapeutic imperative”.

Interestingly, this campaign very much resembled, and indeed in a certain way just copied, the “ethics” frame-coalitions campaign in 1995, by using fax, e-mail and other lobbying efforts, as well as visible action on the day of the Parliament’s vote. At the EP’s plenary vote on 16 July 1997, a dozen members of the Danish Cystic Fibrosis Association, many of them in wheelchairs, were present in the EPs’ lobby, wearing T-shirts and posters proclaiming “Patents *for* Life”.

In terms of frame interaction in front of the audience, this time the frame “ethics” abstract moral claims for “non-commodification of humans bodies” were thus countered by direct and very personally transmitted moral claims to support those in need, innocently suffering from unfortunate conditions due to “genetic causes”. In terms of persuasion, the “therapeutic imperative” story line was very influential and sheerly impossible to counter, because hope cannot be rebutted. There is no doubt that finding cures for severe diseases is a laudable goal. Whether and how much genetics and biotechnology can contribute to this goal, and whether and how much patents contribute to or hamper this end, remains contentious. But this line of reasoning was shut off from exposure by the strong moral and emotional message “no patents – no cure”, which asserted a direct and causal relationship.

This time, morality pointed to the personal conscience of Parliamentarians, who claim to be “the political conscience of the EU”. For EP members who were at unease with their voting decision, or did not know to which side to lend credibility, the patients present in the Parliament provided an instance for authentication. This time, they could vote *for* the Directive and “feel morally good” in the face of those suffering from diseases, exhibiting themselves in wheelchairs.

In terms of frame constellation, a “consequentialist turn” enabled arguing on common terrain and language, thus overcoming the agonal constellation. Hence, deontological claims by the frame “ethics” receded in favour of consequentialist reasoning. Contradictory effects of patenting began to become visible, which affected political decision-making and

also to some extent relativized the maximalist frame “economy”’s core assumptions about the unequivocal positive effects of biopatents.

Concerning intra-frame dynamics, both frames subdivided into maximalist and minimalist structures. This intra-frame differentiation enabled new inter-frame dynamics. In the end, this facilitated at the discursive level a selective integration of parts of the rival frame: the frame “economy” integrated some minimalist “ethics” positions and the frame “ethics” integrated some minimalist “economy” positions, particularly on genetic research and innovation.

3.6 Evaluation of the 1998 Directive’s Outcome: the Prevailing Frame “Economy” Selectively Integrates the Minimalist Frame “Ethics”

I now proceed to a summing-up of the situation in 1998 in terms of voting majorities and to a first evaluation of the results of the EU decision-making process.

In the first EP reading on 16 July 1997, 66 of 250 amendments which were brought in by the deputies were passed (388 votes in favour, 110 against, 15 abstentions). The EUC and the Council accepted all of these 66 amendments, except one. In the second reading by the EP on 12 May 1998, the Directive was passed with grand majority (388 votes in favour, 110 against, 15 abstentions). In the EU’s Council the Directive was passed with qualified majority on 28 November 1997, against the vote of the Netherlands, with abstentions by Belgium and Italy.

The somewhat asymmetric corpus of the Directive’s text – 56 (non-binding) recitals giving “interpretative guidance” to the 16 legally binding articles – is a manifestation of the intense discursive struggles that had taken place. In its “core”, the Directive remained very similar to the first draft, by calling the member states in Article 1(1) to “protect biotechnological inventions under national patent law” and by stating in Article 3(2) that “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 codifications allow for the general patent eligibility of biological material, including DNA sequences, and thus reflect the prevailing frame “economy”. They also comply with traditional codifications, particularly the “isolation and purification” doctrine for products derived from nature. The phrase “may be the subject of an invention” however makes clear that patentability requires fulfilment of the regular criteria for patent granting.

Nonetheless, parliamentary amendments allowed for a number of concessions and introduced human rights wording, which hitherto was

alien to patent law and its self-characterization as “purely technical” and “value-neutral”. In this respect, the most important parts concerning the biomedical focus of my analysis are Articles 5 and 6 of the Directive passed, which I will briefly analyse.

Article 5 states:

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.
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.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6 states:

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
 - (a) processes for cloning human beings;
 - (b) processes for modifying the germ line genetic identity of human beings;
 - (c) uses of human embryos for industrial or commercial purposes;(. . .)

Article 5(1) endorses the validity of European basic norms and human rights and anchors them within patent law. Thus, a central request of the frame “ethics” entered the Directive. The traditional dichotomy between “discovery” and “invention” which had become obsolete for the practice of patent law, was also rearticulated in the Directive’s wording. However, controversy has been reinstalled with the concretization of these norms and principles. Article 5(2) distinguishes between the human body and its – isolated – elements, making the latter patentable. Thus, the “exception” (Article 5(2)) from the rule verbalized in Article 5(1) makes underhandedly the exception to the norm: isolated body parts, including gene sequences, can be the subject matter of patents; it is not only their *use* which can constitute a patentable invention.

Such settlement notwithstanding, Article 5(3) requires disclosure of the industrial application of a gene sequence in the patent application. This requirement can be read as specification of the patentability requirements concerning enablement, inventive step and sufficiency of disclosure. They also later – in the process of the Directive’s national implementation in the

EU member states – have allowed for a window of opportunity to address the *scope* of patents on gene sequences.

Thus, while the Directive's text seemed on the one hand to be providing unequivocal legal clarity, on the other hand some terms and expressions left substantial space for interpretation – and thus extensions and shifts in meaning later on.

Article 6 provides another distinction between rule and exception, if related to Article 5. While Article 5(2) acknowledges the general patent eligibility of isolated human bodily materials, Article 6(2) provides for exemptions to this rule in giving a non-exhaustive enumeration of exceptions from patent eligibility, which at the same time specifies for the first time the general *ordre public* clause (Art. 53(a) EPC). Thus, Article 6 has integrated concerns of the “minimalist” frame “ethics” into the Directive.

These specifications were the product of long arguing and bargaining processes between the European Parliament, the Council, and the EUC, this time with the EP prevailing, and hence the minimalist frame “ethics” concerns. Broader deontological story lines of the (maximalist) frame “ethics” were narrowed down and channelled to specific subject areas, such as industrial and commercial use of human embryos, human germ line intervention, and human cloning efforts. This implied an encapsulation and containment of “ethics”. Article 6(2) has left substantial space for new arguing and negotiation practices, because no legal definitions of the terms “cloning”, “human being”, and “embryos” were given in the Directive's text. This allowed for consideration as to whether SCNT (somatic cell nuclear transfer or “research cloning”) should be validated as “cloning”, whether embryos were to be classified as “human beings”, and whether the early product of egg and sperm fusion (at conception *in vitro*) should be deemed an embryo (compare van Overwalle 2002; Schneider 2002, 2004).

Regarded from May 1998 – the point in the timeline when the Directive was finally passed – it can be argued that the concessions made by the EUC were primarily “symbolic politics”, whereas in terms of “substantial politics” the Directive codified “strong biopatents”, hence protecting patentability of biological substances and genetic information with a broad patent scope.

Yet “symbolic politics” can be transformed into “substantial politics”, if and when changes in context take place. Any legislative act is firstly only a written text, created by the authoritative power of state government. Whether legal acts and norms are executed, and in which way, remains a matter of practice, and thus of translation from government to the functional systems of society. It is an ensemble of different effects (power relations, interests, interpretation by professionals, administrative

and institutional execution) which determines the concrete meaning and implementation of a legislative act.

It must be stressed that the practical significance of statutory acts can be achieved through the actions of multiple actors. Hence the “symbolic” dimension of statutory acts can potentially become as important as the “substantive”.

3.7 Symbolic Politics Becoming Substantial: the Patenting of Human Embryonic Stem Cells

What in May 1998 seemed to be a minor concession of biopatent law in a tiny and negligible field of reprognetics has, in the further course of affairs, carried much more weight. As a result of new technical achievements, the primarily symbolic legislation gained currency as material politics.

It may be attributed to the ironies of history that the seemingly strictly confined field of the use of human embryos, which was exempted from patent eligibility, gained much more importance only a few months later, in November 1998, with the first human embryonic stem cells produced by James Thomson in the US, which were patented at the USPTO by the Wisconsin Alumni Research Foundation (WARF). This field was paramount in keeping the broader controversies alive.

The famous “Edinburgh case” concerned a controversial patent (EP 695351) on a technical process for selectively identifying stem cells, including human embryonic stem cells. It was granted by the EPO in December 1999 and exposed in February 2000 by Greenpeace, who in a spectacular action walled up the entrance doors of the EPO offices in Munich. In reaction to the NGO’s “name and shame” strategy, the EPO spokesperson publicly declared that some patent claims were granted erroneously. The granting was then opposed at the EPO’s opposition division. Among the opponents were not only Greenpeace but also the governments of Italy, Germany and the Netherlands. The 2002 decision of the EPO’s opposition procedure can be regarded as a landmark decision insofar as it provided for a broad interpretation of the non-patentability requirement of Article 6(2)(c), thus rendering – as case law – procedures as well as products of human embryonic stem cell research unpatentable at the EPO. A most significant case law decision by the EPO’s Enlarged Board of Appeal (G 02/06), issued in November 2008, reconfirmed that inventions which can only be obtained through the destruction of human embryos are non-eligible for patent grant at the EPO, thus following the EU legislator’s intent (EBA 2008).

Hence, it is remarkable that, in contrast to the USPTO, the EPO has imposed very strict requirements for human embryonic stem cell patents

and the basic patent for human embryonic stem cell research which was granted in the US to James Thomson and the WARF, and held up in re-examination procedures in the US jurisdiction (Vrtovec and Scott 2008), has been rejected by the EPO. However, it remains up to the interpretation of the examination boards whether all products and processes involving human embryonic stem cells (hESCs) become unpatentable, or whether those based on hESC cultures or cell lines will be granted by the EPO. As in the US the strong patent position of WARF and the granting of exclusive licences to the pharmaceutical company Geron is regarded as less beneficial for R&D within the stem cell field, the EPO's non-granting of bottleneck patent rights may allow more flexibility and leeway for researchers in Europe (compare Schneider 2002, 2004; Rai and Eisenberg 2003).

To sum up, these and other cases raised new controversies about a narrow or broad interpretation of the novel legislatively codified exclusions from patent eligibility. They also brought to light some problematic aspects of the EPO's governance structure, competences and mandate, for instance the fact that the EPO cannot revoke or even appeal by itself patent claims granted erroneously (Schneider 2006b, 2007). Patents on embryo research have also kept the ethical legitimacy of biopatents publicly alive.

Another contentious field was gene patenting. While the Directive seemed to provide legal certainty and legislative support for the granting of broad patents on DNA sequences, in the practical realm uncertainty about the scope of gene patents granted has grown (Hopkins et al. 2007).

Article 5(1) and Article 6 imply recognition for concerns voiced by the frame "ethics", and thus reinforced common European and universal norms concerning the inalienable status and non-commercialization imperative of the human body. Article 5(1) and (3) and Article 6 have provided gates for other frame perspectives and novel potentials for anchoring those within patent law.

In terms of the Directive's formal legitimacy and its contestation, another important step was taken by the Netherlands, supported by Italy and Norway, at the end of 1998 in challenging the validity of the Directive at the European Court of Justice. The ECJ (C-377/98) dismissed the challenge, however, stating that the Directive was concerned only with the patentability of biotechnological inventions, not their use, and that it provided for adequate moral safeguards, thus protecting human dignity.

In formal terms, the EU legislation did not affect the EPO. However, to ensure a coherent European approach, the EU biopatent Directive's articles were adopted by amendment to the Implementation Regulation

for the European Patent Convention (EPC) by resolution of the EPO's Administrative Council on 16 June 1999, to become effective as rule 23(d)–(e) of the EPC's Implementation Regulation on 1 September 1999.

4. NATIONAL IMPLEMENTATION PROCESSES (1998–2006) – THE CASE OF GERMANY AND OTHER EU MEMBER STATES

The EU Directive's national implementation processes provided another opportunity for creative engagement of the parliaments with both civil society's concerns and the national patent community. In some cases this resulted in amendments to the biopatent Directive's text. The political controversies surrounding biopatents did not settle down but continued in many EU member states, producing significant delays in the implementation. Only four countries (Denmark, Finland, the UK, Ireland) transposed within the two-year time frame (July 2000). Spain, Greece, Sweden, and Portugal implemented between 2002 and 2003. France, the Netherlands, Germany, Austria, and Belgium passed national legislation to give it effect between 2004 and 2005, and only after legal proceedings for failure to transmit transposition measures initiated before the ECJ. The ECJ pressed for implementation by threatening the imposition of high fines (up to €850,000 per day, according to the economic power of EU member states). Italy and Luxembourg finally passed implementation laws in 2006. The new EU member states had to accept the Directive as entry ticket for their admission to the EU (see Schneider 2009).

The resurgence of the “old” frame controversies in the public sphere resonated with national parliamentary proceedings and allowed for new alignments and twists in the frame constellations. Thus, the need for legislative implementation again provided governance opportunities beyond the former self-regulation of the field. Public critique was translated into the language of legal doctrines – with considerable deferrals. In the following, I will concentrate on these processes in Germany.

Since patents on biological material as “products” came to be considered a *fait accomplis* and were legitimized by the European legislator, there has been a displacement and relocation of the debate. Special attention moved towards the patenting of DNA sequences. In the 1990s, the central controversy revolved around the question of whether patents on DNA sequences should be granted at all. Since 1998 the focus shifted towards the “how” of DNA patents, primarily directed at the scope of gene patents. The major controversy now addressed the issue of whether an “absolute” protection of “composition of matter” should remain or whether the scope of patents

should be restricted according to the specific biological function of the DNA sequence, its utility or its commercial application.

The focus of the debate thus switched from ethical (primarily deontological) principles towards questions of efficiency. These concerns were voiced both by the frame “economy”, which resulted in a further “minimalization” of the frame’s internal composition, and as questions of “just reward”, fairness and equity, as termed by the (former) frame “ethics”. Instead of insisting on the “sanctity of life” and on non-commodification, a more pragmatic tendency developed, demanding a just and fair balance between inventor and society, and adequate access to knowledge as part of the public domain. An “issue-relabelling” has thus taken place, concerning patent protection as a regulatory and redistributive policy arena.

4.1 Frame Constellation 3 (1998–2003): Crosswise Reversal – “Ethicization” of the Frame “Economy” and “Economization” of the Frame “Ethics”

Ironically, on the discursive level, what could be observed was a crosswise reversal – at least in the German context. The actor coalition of the frame “economy” was now arguing “ethically”. Both the pharmaceutical industry and the German government were emphasizing what they called major progress in the Directive. They pointed to the Directive’s prohibitions of patentability (Article 6(2) of the Directive) as arguments for its “one-to-one” implementation, which means in exact accordance with the wording of the Directive. On the other hand, the actors behind the initial frame “ethics” now argued “economically”: they raised objections to the broad scope of patents on the grounds that they would hinder research, raise transaction costs, be inefficient for innovation, jeopardize scientific freedom and restrict knowledge on genes as a “public good” (compare Heller and Eisenberg 1998).

This shift seems to be partly the result of a change in strategic and rhetorical arguments, and partly the result of real policy learning. New categorical distinctions were discursively constructed and portrayed as “essential traits” and “properties” of DNA, backed by scientific knowledge and expertise. In particular, DNA came to be characterized as “information” and contrasted with the materiality of chemical substances. This was aligned to the call for a distinct mode of patent protection for DNA sequences as compared with chemical material, and particularly for a reduction in the scope of (human) DNA patents (REM 2000).

These strands of argumentation drew upon new insights and paradigm shifts within genetics as a scientific discipline. Some of these important shifts were

- the break with the old central dogma, which is “DNA makes RNA makes protein”, and with *deterministic* assumptions about the *causal* effects of DNA, which allowed for *systemic* gene concepts and the articulations of gene–environment *interaction*;
- the focus on the *multifunctionality* of DNA sequences, as effected by “splicing” and different “reading frames” which delete or rearrange coding sections of a gene sequence and allow for several proteins being produced by one and the same gene sequence;
- the substantial reduction in the number of genes of the human genome from previously estimated 100,000 to 20–30,000 “human genes”, published as a result of the Human Genome Sequencing Project in 2002, which gave evidence for the multitude of functions of “one gene”.

These novel scientific facts – or better, paradigm shifts – were adduced to justify a modification of the “composition of matter” doctrine in patent law and calls for a readjustment to the “needs” and “characteristics” of genetic inventions.

It may be asked whether the fact that actors of the frame “economy” found it necessary to prominently relate to “ethics” has something to say about a possible cultural hegemony of the frame “ethics”, at least for a certain period of time (2000 to 2004). It may at least point to the power of the discourse formation, and to the need to relate to the opposite frame. Again, it must be stressed that the “ethicization” of the (former) frame “economy” and vice versa the “economization” of the frame “ethics” should not easily be dismissed as cooptation or as purely tactical and rhetorical moves. A change of argumentative strategy – even if it were only for strategic and persuasive reasons – impacts on the frame itself, on discursive dynamics, and on the outcome. The phenomenon which I have coined “crosswise reversal” may thus be seen as an indicator for reframing processes being at work.

4.2 Frame Constellation 4 (2004): Reframing

The strong morality claims which were previously predominant now receded. This may suggest that the persuasive power of morality claims fades over time and must be replaced or at least complemented by more “rationalized” reasoning and arguing.

As a result, a reframing was achieved which concerted the former agonal and dichotomized frame structure into a bipolar structure allowing for many overlaps and positions “in-between”. This allowed for much more flexibility and for the conversion of a principled approach of

“whether” patents with DNA as subject matter should be granted towards a modulating “how” approach, centrally focusing on the scope of patents. This in turn allowed for questioning the adequate tailoring of patents and evoked the negotiation of interests. However, not only interests of competing economic rivals got into the picture but also a plurality of definitions of “common interests” and the “common good” – as represented for instance by patients’ needs for affordable advanced therapies and by the researchers’ need for access to general knowledge – in short, the democratic governance of innovation in the public interest. This resulted in a shift in the biopatient controversy from a fundamental conflict of values towards a more interest-based reframing, allowing for trade-offs between competing norms, preferences, and interests.

4.3 Legislative Outcomes: Amendments to the Directive’s Text

It must be seen as a substantial achievement of parliaments to translate the general public critique and to thread it into the small eye of the needle of patent doctrine. This happened by maintaining the strict wording of the Directive’s text and at the same time extending and subverting its content.

In Germany, this was made possible through an engagement of parliamentarians with the patent discipline. The expression of a strong political will to convert the formerly “absolute” protection of DNA sequences into a “function-bound protection” or “purpose-bound protection”, together with articles written in professional journals (Renesse et al. 2001), was responded to with a quite intensive debate within patent law as a discipline. In Germany, more than 40 scholarly articles on the subject were published between 2002 and 2004, discussing the pros and cons of this new mode of patent protection (compare Schneider 2003). Finally, this debate resulted in a turnaround of the prevailing opinion, and entered canonical textbooks (Krasser 2004).

The adoption of a purpose-bound reduction in patent scope – which in the beginning was fiercely rejected by the patent profession – implied a 180 degree reversal of patent doctrine and rendered the “absolute” protection of compositions of matter for DNA-related inventions obsolete. This step subverted “unity” as one of the core assumptions of patent law: it admitted technological specificity within patent law, thus differentiating between chemistry and biotechnology.

Both France (Art. L. 613-2-1) and Germany (§1(a)4 PatG) in their 2004 implementation acts passed amendments to Article 5(3) of the EU Directive, limiting the scope of (human) gene patents to the function and purpose disclosed (Schneider 2006a). These amendments try to strike a

new balance, as they counter biopatents that are too broad and granted at too early a stage upstream in the R&D process; they thus seek to rebalance what has been regarded as an “over-compensation” of the inventor, and allow for new downstream inventions of a certain gene sequence non-dependent patents to be granted.

Italy copied the wording of the German amendment, Luxembourg the French version of amended legal text; thus, four countries introduced a purpose-bound protection of (human) DNA sequences. In Belgium, a new bill provides for a widening of the research exemption and for compulsory licences for reasons of public health. Questions remain, however, about the implementation of these new amendments in the practice of patent examination and grant. At the EPO, at least some sensitivity to reorientation can be observed (compare Schneider 2007). A scenario project provided challenging views on the future of the patent system (EPO 2007), and the EPO’s new president Alison Brimelow has announced an intention to “raise the bar” in examining and granting patents.

5. CONCLUSION

5.1 Political Achievements

To recapitulate, policies to tame the uncertainties of the technological future with stronger IPR protection and the expansion of the patent system in the field of biotechnology gave rise to the introduction of the draft biopatent Directive in 1988. This legislative initiative was backed by hegemonic assumptions, characterized as the frame “economy”, on the affirmatively coupled strengthening of patents and innovation.

As an effect, the need for legislative government of patent law has been acknowledged, resulting in the insight that patent governance should not be left solely to the patent profession (as a discipline), to patent offices (practice) and to courts (jurisdiction). This is an important outcome which needs to be underscored in terms of vertical governance (compare Mayntz 1998). Legislative intentions to provide both incentives and legal certainty for investors and inventors, and to use strong patents as a mode for steering technological development, were backed by metanarratives such as the neoliberal call for withdrawal of the state from directly intervening in macroeconomic R&D decisions and from policing technological innovation. However, these intentions and objectives resulted in a wide range of unintentional effects, and in some aspects rendered opposite results.

Uncertainty for industrial and research stakeholders has only partly diminished, insofar as biological material now forms expressly a legal

subject matter for patents. However, the “inventive step” threshold and requirements for utility and industrial application remain to be clarified. Uncertainty about the interpretation of the biopatent Directive’s Article 5(3) allowed for new modes of interpretation and altered legislative codifications. The national implementation processes may thus be considered corrective mechanisms to the maximalist harmonization drive in patent politics.

Agenda setting for the biopatent Directive in 1988 was received with high public attention, and triggered protracted processes of argumentation and negotiation, until in 1998 the final EU Directive was passed. Resurgent controversies at the national level (1998–2006) led to another procrastination in the Directive’s transposition to national law. These delays should not be regarded as stemming the tide of effective political decision making but, on the contrary, enabled important learning processes and opportunities for a reframing of patent law as regulatory law.

As the analysis of the frame dynamics has shown, fundamental contestation of the legitimacy of the Directive, framed by “ethical” opposition in civil society, resulted in cracking the tough nut of a hermetically closed patent system. In the course of parliamentary debates and procedures, which resonated with oppositional voices in the public sphere, an agonal frame constellation could be overcome. Internal frame differentiation leading to maximalist and minimalist subcompartments, and inter-frame interaction, triggered by a “consequential turn”, resulted in the selective integration of elements of the opposing frame. As an interim result and preliminary closure process, the EU Directive passed in 1998 included some recognition of human rights norms and values as inherent in European patent governance. The Directive codified exemptions from patent eligibility, thus concretizing the abstract *ordre public* clause in European patent law.

Ongoing controversies at the national level of several EU member states resulted in a further frame dynamics. As exemplified by the German debate, a “crosswise reversal” of frame positions took place, resulting in a reframing of the topic at issue. The scope of patents concerning DNA sequences was regarded as too broad, and new requirements were introduced which restrict the scope, thus enabling modulation and remedies to excessive patenting.

These amendments as performed in some national patent acts took both “ethical” and “economic” concerns into consideration and allowed for practical concordance. DNA sequences derived from humans were regarded as deserving special status, because of sharing in the dignity of human persons. Adverse economic and research consequences of excessively broad DNA patents were addressed.

While many questions remain open, a preliminary evaluation suggests that output legitimacy was increased by taking input legitimacy into account. Parliaments transmitted problem articulations voiced in the public sphere, and processed them in line with their institutional capabilities and restrictions, by mediating between controversial frames and by translating reframings into the language of patent law, thus connecting them to the patent discipline and profession.

5.2 Reframing of Patent Law as Regulatory Law

In the end, the controversies rocked the foundation of patent law by challenging long-established beliefs, contesting dominant paradigms, and identifying new strategies of analysis and politics. Core assumptions forming the bedrock of the patent system were dismantled, and severe doubts were cast on politically subscribed presumptions of patents' unequivocally beneficial effects on innovation. Contradictory effects of patents became apparent, deeply undermining the hegemonic assumption that more and stronger patents mean better innovation. These concerns in terms of the efficacy and effectiveness of patents, in terms of their relationship with the public good, and in terms of policing technological innovation remain stimulating questions both for the future governance of biotechnological inventions and for the governance of the patent system as such. Some concerns raised in Europe at the time of the biopatent Directive's legislative efforts are being articulated in the US and in other countries as well.

The formerly closed patent system with its monoculture of technicians and lawyers has become porous. Ironically, with regard to the field of the frame "economy", which was predominantly populated by lawyers, it is particularly since economists have re-entered the field of patent expertise that the tension between patent-based monopoly and competition and anti-trust law is being emphasized (Ullrich 2001), and the more traditional reservations of the economic discipline about the "added value" of patents are rearticulated (Guellec and van Pottelsberghe 2007).

This novel focus on empirical evidence for the impact of patenting has challenged in a fundamental way previously taken-for-granted assumptions, institutional self-perceptions, and routines. Through the controversies it became apparent that patents have manifold and contradictory implications. They are neither inherently beneficial nor a natural-born evil, but require careful tailoring and application suited to the needs and characteristics of a new technological field and to the sources and users involved. This means that the "one size fits all" approach is being increasingly rejected (Burk and Lemley 2003). By the same token, the "value-neutral, but innovation-friendly" self-description has come under fire.

The biopatent controversy has elicited a critical reappraisal of patent law: while it formerly was presumed to be a merely “technical” field, there is now a shift towards a “regulatory” patent law perspective. A regulatory concept means that conflicts inherent in patents must be treated within patent law and practice itself, both pre- and post-grant, and cannot solely be delegated to other social spheres and legal institutions. Among those conflicts are tensions between the generation and the diffusion of knowledge, between exclusivity, licencing and broad access, thus touching both on distributive issues and the social regulation of research (Boyle 2003; Godt 2007; Schneider 2008). This calls for a reconceptualization of patent offices as regulatory agencies. Patent examination and grant is not an “objective” and “neutral” act, not merely an execution of law, but a (tacit) policy-making process, significantly contributing to the shaping of technological trajectories (compare Schneider 2007, 2009).

Thus, the controversies have shed some light on the need for institutional reforms, entailing

- a democratization of national patent offices and the EPO;
- the participation of other disciplines – additionally to lawyers and technicians – in the patent field, particularly economists, social and political scientists and ethicists;
- myopic patent law getting far-sighted lenses in order to expand its horizon, taking the implications of patent granting into account;
- the inclusion of other actors, such as sources and users, in patent policy.

For setting these reforms into motion, more reflexivity and new institutional venues for public participation and deliberation are very much needed. This shift towards regulatory patent law marks a potential which as yet is in its embryonic state, but which was launched in the wake of the biopatent and software controversies. The involvement of new actors, particularly “sources” and end-users of technology, not least patients as sources of human biological materials for research purposes and as consumers of drugs, and advocacy groups from civil society, has challenged the hitherto relatively hermetically closed legal patent system. Patent offices are in the process of redefinition from (inter)governmental branches executing law towards regulatory agencies for the governance of technology and innovation (compare Schneider 2008).

The responsiveness of parliaments to contestations of legitimacy and new problem definitions articulated by civil society has led to reframing processes and to compromises in the policy outcomes, which – albeit bound to legal constraints – may contribute to transformations of patent

law and institutions. Thus, patent legislation in this particular case *has* made a difference, as parliaments prompted the self-regulated system of patent governance to change course. However, patent legislation is neither a magic bullet nor a panacea. Successful “altering” legislative intervention was dependent on high levels of public mobilization on the one hand, and creative inventions of compromises in the wording of the legislative acts by parliaments on the other hand. The new “European mode” of patent governance consists in reintroducing boundaries and constraints within patent law to restrict its expansion, and to integrate socio-economic, regulatory, and distributive concerns into the body of patent law (Godt 2007; Schneider 2006b, 2008). The uncertainties of the future of technological innovation may thus be tamed within new discursive and institutional arrangements in the governance structure of knowledge-based societies.

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8. Intellectual property rights in the digital movie industry: contemporary political conflicts in Germany

Lars Bretthauer

INTRODUCTION

With the market introduction of digital technologies of reproduction and consumption (DVD, DVD- and CD-burners, peer-to-peer technology) during the late 1990s in Germany, political conflicts emerged among artists, companies and consumers in the movie industry, state actors, hardware-producers and German civil society actors. As in many other countries, the German movie industry started a campaign with the slogan ‘Copythieves are criminals’, criticising consumers for the non-licensed appropriation, exchange and consumption of digital movies. At the same time, disputes evolved between companies and movie artists about the limits of the German *Urheberrecht* (copyright law) in the digital age. These conflicts were concerned with the different shares companies and artists should earn out of the production and distribution of movies and the economic potentials of the industry’s transformation in the digital age. Simultaneously the revision of the German *Filmförderungsgesetz* (film funding law) fostered the strategic reorientation of state subsidies for movie production from an artistically oriented form to a mode of industrial policy.

In this chapter, I will discuss these three different lines of political conflict in the processes of copyright and film funding law-making in the period from 1998 until 2008 in Germany. These laws have undergone a process of revision since the digitalisation of the industry. Drawing on contributions from materialist state theories (Gramsci 1971; Jessop 1990; Poulantzas 1999 [1978]), I will discuss how different social forces engaged in the processes of law-making and how they benefited from the re-regulation of movie politics. The focus of the analysis will thus be to present the different political positions regarding intellectual property rights in the digital

movie industry, and the different political alliances that revolved around these positions. As I will argue, these alliances were not solid in all fields of action but differed according to the three lines of political conflict.

Concerning the relations of distribution and consumption, movie company groups supported by movie artists succeeded in re-establishing private intellectual property rights on digital movies against weak protests from civil society groups, thus excluding non-licensed and non-capitalist movie sharing from a legal status. However, non-licensed movie sharing was only sanctioned with relatively weak fines and still prevails in German civil society. This points to the fact that social practices located in the private sphere of German civil society entail a relative autonomy from contemporary state regulation concerning intellectual property rights.

In contrast to this, movie production companies accomplished partial successes in the legislative procedure with regard to the relations of production *against* the trade unions of movie creators. Whilst the benefits of movie creators from the transfer of commercial rights on movies to movie companies were strengthened, movie companies gained the commercial rights on movies distributed in technologies unknown during the production process. With regard to the new German film funding law, political conflicts *between* different capital factions in the movie industry emerged. Thus the revised German film law increasingly privileged commercially oriented movie enterprises over smaller art production companies. Based on these empirical findings, I will finally draw conclusions for future academic discussions on intellectual property (IP) law, taking into account that the dominant discourses on IP do not question the commodification of culture through private intellectual property rights and are increasingly oriented towards the competitiveness of national movie industries, nation-states and supra-national competitive zones like the European Union for flows of foreign direct investment. Academic discussions that aim to influence political discussions about intellectual property relations should critically engage with these discourses.

PRELIMINARY STATE-THEORETICAL REMARKS

From a materialist perspective on capitalist societies, historic-specific developments of new technologies transform the internal organisation and power relations of production, distribution and consumption in specific economic sectors (Marx 1974 [1867]). Thus technologies alter the conditions of competition between different single capitals on capitalist markets, as well as the power relations between companies and wage-labourers in the relations of production, and between companies and consumers in

the relations of distribution and consumption. In the context of IP, this is particularly related to the potential transformation of private property relations (Nuss 2006). Private property relations form a core element in capitalist economies, since they constitute the legal appropriation of labour and work products through companies in the relations of production and the property-protected distribution and consumption of goods on capitalist markets (Heinrich 2004; Marx 1974 [1867], 1977 [1844]). Concerning this, the implementation of new technologies might develop new models of economic production, distribution and consumption and thus alter the social conditions for state-given private property rights.

Subsequent to that, materialist state theories are concerned with the analysis of the political regulation and embedding of these technological and economic processes in and through state politics (Jessop 1982; Sayer 1995). In this chapter, two particular concepts developed in materialist state theories will be applied: first Bob Jessop's notion of the strategic selectivities of the capitalist state, and secondly Antonio Gramsci's category of hegemony.

Bob Jessop argues for a strategic-relational understanding of the state in order to give weight to the political struggles, resistances and projects in relation to the state apparatus. Thus, he follows the state-theoretical work of Nicos Poulantzas who conceptualises the capitalist state as the material condensation of the relation of social forces (Bretthauer 2006; Bretthauer et al. 2006; Poulantzas 1999 [1978]). In this concept, the state is understood as a social terrain with inscribed material practices that functions as an important point of condensation for different social relations of forces. However, the terrain of capitalist statehood is not accessible to all social forces in the same way, therefore Poulantzas – following the German sociologist Claus Offe (Offe 1972) – identifies *structural selectivities* on the terrain of the state that embody and privilege certain political projects and struggles over others. Hence, continuing Poulantzas' theory in his strategic-theoretical approach, Bob Jessop argues that *strategic selectivities* like juridical and bureaucratic procedures, formal and informal networks and political projects can be identified in the specific modes of representation and intervention of the state (Jessop 2003).

Related to IP, this mainly implies the legal form of state politics, the concept of private property relations and the political accentuation of intellectual labour. With respect to the movie industry, this is primarily concerned with the appreciation of 'creative work'. However, following Bob Jessop's theoretical frame, social actors are not directly committed to these state strategies and their inherent strategic selectivities. Instead they are able to calculate on the political frame of their field of actions and develop trial-and-error-strategies to realize their strategic goals (Jessop

2002). Thus, Jessop stresses the fact that state politics in its strategic orientation can only be identified *ex post* as potentially (de-)stabilising capitalist economic relations, since the reproduction of capitalist social relations through state power relies on the historic-specific outcome of the social relations of forces and their strategies (Jessop 1990).

In a similar way, the Italian Marxist Antonio Gramsci was occupied with the relation between state politics and civil society (Gramsci 1971). Gramsci argued for an organic link between the state and civil society in liberal societies that secures the power positions of the ruling social classes: *hegemony*. For Gramsci, hegemony consists of common world-views and social practices that create consent between the ruling and subaltern forces in a society (Gramsci 1971; Morera 2002). Thus, Gramsci emphasised the ‘constructive’ aspect of a cultural hegemony: a hegemonic force has to pursue an ‘intellectual and moral reform’ (Morera 1990) in order to establish a common understanding of the world that is applicable in everyday life. These world-views have to be able to attract and link other forces to the new emerging ‘hegemonic bloc’ in which the dominant hegemonic forces lead the subaltern forces morally and intellectually whilst opposing subaltern forces are excluded and repulsed from the hegemonic political project.

Concerning the implementation of digital technologies in the German movie industry, the scientific perspective of materialist state theories provides us with questions about the transformation of the movie industry as well as movie politics. This comprehends on the one hand the digital mode of production, distribution and consumption in the movie industry. On the other hand, the transformation of movie politics comprises the political conditions of access for social actors to the state regulation of technological processes and – conversely – the positioning of social actors through state regulation processes. This is related to the development, access and appropriation of new technologies, and concerns the politically and legally formed conditions of access to new technologies, the acceptable purposes and projects for which new technologies are adopted and finally the sanctions against their illegal use.

THE GERMAN MOVIE MARKET

In order to give a picture of the German movie industry, it is worthwhile to identify the relations of dominance in the German movie market. In 2007, the German movie market was worth 2.35 billion euros: 1.6 billion euros in the DVD and video market and 755 million euros in cinema tickets (Bundesverband Audiovisueller Medien 2008). As in many other cinema markets of the world, the US movie industry, based mainly in Hollywood,

holds the largest shares in cinema tickets and DVD rents in the German movie market. In the cinema sector, movies produced by the US Majors account for 50–70 per cent of all sold cinema tickets during the last five years (Deutsch-Französisches Filmtreffen 2007). This economic success results from a long-term strategy from the 1950s in which the US movie industry developed specific advertising strategies, worked on the internationalisation of movie distribution and consumption and primarily defined movies as economic goods (Wasko 1994). This included the invention of the Blockbuster model as the economic dominant movie format at the end of the 1970s, the implementation of cross-integrated merchandising concepts especially since the 1980s and the package-booking model for movie distribution in the distribution companies of the US Majors (combining demanded and less demanded movies) (Maltby and Craven 1995).

In contrast to that, the German movie industry is heavily fragmented into small companies that include movie production and distribution companies like small cinema owners (Thiermeyer 1994). German movie productions account for between 9.5 and 21.5 per cent of all sold cinema tickets in the German movie market (Spitzenorganisation der Filmwirtschaft 2008). In general the German movie sectors lack the internationalisation of their products and the vertical and horizontal integration processes which secure the investments of US Majors in movies by multiple advertisement strategies, cross-marketing and the control of distribution chains. As a result the German film production companies are mainly oriented towards the production of movies for the national TV market, since the German TV stations give secure investment structures to smaller production companies (Schröder 2008). That said, those German movie companies that still produce for the cinema market are not identified as credit-worthy by the private bank system and are therefore heavily subsidised by the German state. Founded in 1968, the German film funding board (Filmförderungsanstalt) gives credits and subsidies to film production and distribution companies as well as cinema companies. Until 1993, public film funding was structured dominantly by nationalistic criteria that aimed to support the production and distribution of 'German movies'. Following the revision of the German film funding law (*Filmförderungsgesetz* (FFG)), movies gained their support as 'German movies' through (a) a German dependence of the movie company, (b) directors, cutters, cinematographers and actors with German citizenship and (c) German movie studios as partial production sites of the movies. In 1993, the German film funding system was partially opened to European companies as long as they mainly used German sites for their movie productions and organised the world release of the movie in Germany (Deutscher Bundestag 1998).

Speaking in state-theoretical terms, these nationalistic ('German') and supra-nationalistic ('European') criteria in the German film funding law constitute strategic selectivities for social forces such as German, European and US companies that aim to receive public film funding. Yet, international movie companies were historically able to circumvent these regulations, as the approaches of movie companies to different national film funding systems show. As early as the 1960s the US Majors started co-productions with different European movie companies from Italy and Spain in order to lower the production costs of their movies through public film funding (Jarothé 1998). Concerning the German movie market, the US Majors as well as European movie production companies apply for film funding. With regard to movie production processes, their application is justified through co-productions with German movie companies, the production of movies in German film studios, most prominently the Babelsberg film studios (Berlin), and the incorporation of German actors, directors and cutters in their productions. As a recent result, international co-productions made 36.1 per cent of the newly presented German cinema movies in German cinemas in 2007 (44 of 144) (Spitzenorganisation der Filmwirtschaft 2008).¹ Besides the field of co-productions, the financially strong distribution companies of the US Majors include particular German productions into their distribution portfolio in Germany and so are able to apply for public film funding for their movie distribution. Thus, distribution companies like Buena Vista, Warner Bros., Paramount and United International Pictures receive public film funding for the distribution of German movies (Spitzenorganisation der Filmwirtschaft 2008).

NON-LICENSED MOVIE COPYING AND THE RE-REGULATION OF IP LAW

Over the last ten years, an informal movie economy has emerged in Germany in which the reproduction, distribution and consumption of digital movies is organised outside the movie industry's commercialised channels of distribution.² Prompted by the movie industry's decision to digitalise its channels of distribution and consumption with the market introduction of the DVD in 1996, many movie consumers transformed their economic position into a mixture of private digital reproducers, distributors and consumers. The reproductive role of consumers is related to the fact that the majority of private movie sharing in Germany depends on established movie productions from Hollywood and their global advertisement strategies (P4M and RTWH Aachen 2005).

The digitalisation of the capitalist relations of distribution and

consumption in the movie industry was thus accompanied by the emergence of non-capitalist relations of reproduction, distribution and consumption. These resulted from the normalisation of highspeed Internet connections and CD- and DVD-burners in private households. These informal and non-capitalist relations mainly consist of file-sharing networks (online-sharing) and private exchange circles in which copied physical data carriers (CD, DVD; offline-sharing) are exchanged without the constraints of private property relations and payment. While offline-sharing is mainly limited to the local scale, online-sharing partly crosses national boundaries, especially in international file-sharing networks.

Technologically, this informal movie-sharing economy relies on the one hand on market-mediated opportunities of digital movie reproduction like personal computers, CD-/DVD-burning technologies and software solutions offered on the Internet or in computer magazines which allow infinite digital copies of movies without any loss of quality. On the other hand the free provision of computer software through the open source community – especially the development of peer-to-peer file-sharing services and compressed video formats like the divx-Format – allowed private consumers to establish and use their own digital channels of movie distribution.

Since the implementation of digital technologies altered the social conditions for the economic success of the established movie industry, as well as for state-given intellectual property rights, the lobby groups of the movie industry in Germany pressured for a re-regulation of intellectual property law from the end of the 1990s. Representatives of the movie industry – including representatives of the US Majors – justified their cause with a series of political reproaches based on the comparison of non-licensed movie copying with the ordinary theft of material goods. These reproaches included claims that the developing non-capitalist practices of consumers destroyed the economic base of the movie industry and movie artists, prevented the movie industry and international investors from securing the profits from their investments in movie production, and apparently damaged the German cinema as an important expression of ‘national culture’. Furthermore the allowing of non-licensed movie copying through state law and politics would undermine the whole system of private property ownership in general (Spitzenorganisation der Filmwirtschaft and film 20 2002a).

According to these multiple lines of reasoning, the private digital exchange of movies should be completely abandoned in favour of private intellectual property rights in the movie industry, and non-licensed movie copying should be identified as a serious crime. This position was partly supported by the lobby groups of the movie artists that also demanded a ban on non-licensed movie copying. In contrast to the movie industry,

however, the lobby groups of movie artists acknowledged the difference between state laws and their prospects of enforcement. Thus movie artists only called for restrictions on private movie copying where they were technologically realisable in the Internet and on the electronic hardware market (Vereinte Dienstleistungsgewerkschaft (ver.di) 2008).

These positions of the movie companies and movie artists were countered by consumers' lobby groups, mainly the 'private copy initiative'. According to existing copyright law in Germany, they demanded the consumers' free right to copy digital movies for private non-commercial use in an alternative hearing to the legislative process. This included on the one hand that private consumers should not be criminalised for their movie sharing activities and instead gain unrestricted offline access and copyrights to the cultural goods acquired from the commercial entertainment industries. With regard to the question of online-sharing, the initiative proposed to introduce a new market-oriented levy system called the 'file-sharing flat-rate'. Thus Internet users ordering an Internet flat-rate should pay a higher price for their Internet connection in order to let state agencies distribute the extra money to copyright holders. In return, non-licensed movie copying should be allowed through the German copyright law (Initiative Privatkopie 2003).

In its central parts, the copyright law-making process in Germany included the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (World Trade Organization 1994) and the WIPO Copyright Treaty (WIPO 1996).³ Yet, these international law norms were superimposed with political strategies on the national scale that legitimised both the implementation of supra- and international law and the concrete design of national copyright law in Germany. Related to that, the law-making process was dominated by the competitive strategies of the 'information economy'. These strategies seek to strengthen the existence of the German movie industry in the digital age as well as foreign direct investments from foreign movie companies into the German movie infrastructure (Deutscher Bundestag 2002). For both reasons, the establishment of private intellectual property rights on movies, it was argued, was a political necessity according to the demands of the movie industry (Spitzenorganisation der Filmwirtschaft and film 20 2002b). These strategies of economic competitiveness were countered by political strategies concerned with the technological enforcement of new copyright law and potential damages to the German law system that might evolve out of failing law-enforcement processes. On the other hand, the legal ban on non-licensed movie copying could imply extensive consumer surveillance technologies and criminalisation efforts, which were criticised by liberal actors in the German parliament (Deutscher Bundestag 2002).

In the process of state re-regulation of consumers' rights on digital movies, these different political positions of social forces became – as Poulantzas would term it – condensed in the revised German *Urheberrecht*. As a result, the relations of distribution and consumption in Germany were re-regulated in three important aspects. First, following the WIPO Copyright Treaty (WCT) and the European Directive on the harmonisation of certain aspects of copyright and related rights in the information society (European Parliament and European Council 2001), the right of distribution to the public was exclusively adjudicated to the movie industry. By this, the non-licensed online-sharing of movies was banned, since offering movies in file-sharing networks was now identified as a distribution to the public (Deutscher Bundestag 2003b). Moreover, movie downloading from an unoriginal source was also banned in order to abolish the whole process of online-sharing (Deutscher Bundestag 2007). Secondly, consumers were legally not allowed to circumvent technical copy protection measures on data carriers, so offline-sharing was also put under compliance to the movie industry (Deutscher Bundestag 2003b). Additionally the law abolished the distribution of techniques to circumvent the protection measures of the media industry through the Internet and computer magazines. This means that producers of burning technologies are entitled to pay lower levies if their machines effectively disallow the circumvention of protection measures.⁴

To summarise, the re-regulation of copyright law suspended central consumers' rights to copy media products for private use. Taking both re-regulations together from a materialist perspective on property relations, consumers were legally separated from the non-capitalist use of digital technologies for movie reproduction, distribution and consumption (Bretthauer 2008). Instead, the private use of digital technologies for the reproduction, distribution and consumption of movies was legally directed towards the capitalist distribution and consumption channels of movie companies thus establishing new strategic selectivities in the use of digital technologies.

Compared with this strict legal ban on non-licensed copying, the new German copyright law is much more ambivalent towards the criminalisation and sanction of contraventions. The movie industry indeed gained the right to ask Internet providers for the personal data and IP addresses of persons offering movies through file-sharing networks (Deutscher Bundestag 2008). At the same time, the lobby groups of the movie industry failed to establish non-licensed movie copying as a legal crime in the new copyright law. This defines non-licensed movie copying as only a petty offence. In accordance with that, the reform of the German copyright law in 2008 also abolished the appeal practices of law firms specialised in

copyright infringement cases (Deutscher Bundestag 2008). Over previous years, these firms continuously sent appeals with fines of several thousand euros to consumers involved in non-licensed movie copying practices. Following the last revision of German copyright law, first appeals from these law firms to non-commercial file-sharers must not exceed an amount of 50 euros, which effectively ended the threatening of private consumers through disproportionately high fines.

Thus the contemporary picture of German copyright law making is ambiguous. As a result of linking non-licensed movie copying with the private property system and state strategies oriented towards economic competitiveness, the property interests of the movie companies and movie artists are represented in the abolition of offline- and online-sharing. Or, speaking from the perspective of civil society groups, the abolition of offline- and online-copies symbolises the failure of their counter-hegemonic efforts during the legislative procedure. Despite their creative suggestions for a reformulation of German copyright law and sharp critiques of the movie industries' demands for re-regulation of digital movies as scarce goods protected by private property rights, the political demands of civil society groups did not gain wide public support. However, at the same time, the movie companies' intent to criminalise private file-sharers on a legal level failed due to the anti-criminalisation efforts of civil society groups that referred to – what Bob Jessop would call – the pre-existing strategic selectivities in the German law system related to concerns about data protection and civil rights. Therefore, from a legal standpoint, non-licensed movie sharing could effectively continue if sharers accept the possibility of receiving minor fines for their actions.

HEGEMONIC STRUGGLES ABOUT THE ACCEPTANCE OF IP LAW IN GERMAN CIVIL SOCIETY

This legal re-regulation process for a new German copyright law was accompanied by massive public attacks by the movie industry's lobby groups on private consumers. Adopting Antonio Gramsci's theory on hegemony in contemporary Western societies (Gramsci 1971), these attacks can be understood as the industry's continuous attempt to establish a new hegemonic world-view in German civil society. This new world-view should exclusively accept the private property rights of the movie industry on digital movies and – as a consequence – use solely the developing commercialised channels of digital movie distribution.⁵ These hegemonic efforts of the movie industry attempted to counter and criminalise

the sharing practices of consumers. Most prominently, this applied to the public campaign ‘Copythieves are criminals’, in which the industry threatened non-licensed movie copiers with imprisonment, associating this with rape, social exclusion and the disintegration of family ties. Although private consumers can only be punished with fines for private copying of movies according to the contemporary German copyright law (Deutscher Bundestag 2003b), the industry’s lobby groups continuously created the picture of imprisoned private file-sharers. This was most notably symbolised in a public campaign in which people were asked to sit in an artificial prison cell on public spaces in order to ‘anticipate their personal consequences’ of private file-sharing (Zylla 2004).

Besides this, the industry’s attempts to report illegal file-sharing to the local police had developed new markets and practices for the surveillance of consumers’ behaviours. Here, the industry could rely on its own private surveillance group, the *Gesellschaft zur Verhinderung von Urheberrechtsverletzungen* (GVU) (Society for the Prevention of Copyright Infringement). The GVU selectively monitors the grey market for offline-copies and observes flea-markets and Internet sites like Ebay. At the same time private online detective agencies, lawyers and IT companies specialise in the online surveillance of file-sharing networks and the storing of consumers’ IP addresses. Similarly, cinema owners order light-sensing equipment in order to monitor movie audiences for the unauthorised filming of movies (Koesch et al. 2007).

Despite these threatening campaigns from the movie industry, the global non-capitalist and informal movie economy prevails and has taken new technological forms over the years. According to recent approximations, there is a steady total of over seven million consumers that are privately sharing movies in Germany every day (Gesellschaft für Konsumforschung 2005; Krempf 2005).⁶ Nonetheless, the industry’s campaigns had remarkable effects on the copying practices of consumers, reducing the number of people active in copying networks and establishing an atmosphere of fear among non-licensed consumers (Gesellschaft für Konsumforschung 2005). Therefore the main protests against the political strategy of the movie industry were articulated against the fear-creating and criminalising campaigns of the industry, which were criticised as intentional disinformation and violation of human rights. Nevertheless, the movie industry continues with its – in its own word – ‘provoking’ public campaign for their private intellectual property rights on digital movies.

This strategic situation points to the fact that file-sharing as a non-money-mediated practice has not gained wide hegemonic effects in the established German public so far. Despite the fact that a critical mass of users in Germany participate in file-sharing practices, users as well as

lobby groups have not succeeded so far in establishing an alternative – what Gramsci would term – hegemonic world-view that is directed openly against the private property oriented discourses of movie companies and artists. However, this does not mean that movie sharers act secretly; they communicate openly in community forums and file-sharing platforms on the Internet.

Reinterpreting this situation from a state-theoretical perspective, it is worthwhile to concretise three interrelated areas of political conflict and social practices in these struggles about digital movies. First, there was the legislative conflict about the re-regulation of IP law in Germany which was primarily dominated by movie companies who succeeded in refreshing their private property claims. However, at the same time, they failed regarding the implementation of strong measures of law enforcement and consumers' control in law enforcement through the protests from civil society groups and data protection forces. Secondly, there are struggles in public civil society, particularly the mass media, which is targeted by various PR campaigns of the movie companies but also – in a remarkably weaker sense – by civil society groups like the 'Private Copy Initiative'. And thirdly, there is the private part of civil society in which the social practices of movie sharing exist at a relative distance from state law, law enforcement procedures and PR campaigns in the public part of civil society. This implies private exchange circles as well as Internet relations between file-sharers. Here, selective interventions from the movie companies can be observed. These include surveillance operations by online detective agencies as well as house searches by local police prompted by complaints from movie companies.

Given this, the contemporary strategic situation refers to the political contradictions between the German parliament with its procedures of law making through the integration of organised interest groups and the public part of civil society (especially the media sector⁷) on the one side, and the Internet and private exchange circles as a new developing semi-public on the other side. As the example of private file-sharing shows, movie-sharing communities developed specific common practices and a strong representation, attractiveness and therefore limited hegemony in the Internet and among private circles whilst at the same time lacking representation in state politics and the mass media. This contradictory situation can be explained by the prevailing legal stability and discursive hegemony of notions of private property with regard to the distribution and consumption of cultural goods. What is at stake here is the naturalised commodification of culture that is still dominant in the materiality of the state apparatus and the public part of civil society.

Speaking in state-theoretical terms, this prevailing notion of private

property can be identified, with Bob Jessop, as the strategic selectivity which forms the central political frame of the contemporary debates on IP law in Germany. As a result, the most progressive public demands from free-copy forces like the file-sharing flat-rate refer to a market-oriented levy system secured by state agencies. However, these demands effectively fall behind the present everyday practices of non-capitalist file-sharing that reproduce, distribute and consume movies without property relations and money-mediated exchange relations. These social practices thus prevail in the private part of civil society without effective public and legal representation.

THE RELATIONS OF MOVIE PRODUCTION AND THE RE-REGULATION OF IP LAW

Although the focus of recent public discussions about intellectual property rights in the German movie market was on the question of consumers' rights, there was a parallel re-regulation of industrial relations in the movie industry. At first view, intellectual property rights in the continental tradition produce an empirical anomaly for materialist understandings of capitalist property relations in industrial relations. Marx argued that private property rights on the means of production lead to the appropriation of labour while the wage labourers have no entitled property rights on the work product (Marx 1974 [1867]). In contrast to that, the German *Urheberrechtsgesetz* (UrhG) (Intellectual Property Law) does not entitle the whole movie industry but only a certain group of *Urheber* (movie creators) with intellectual property rights for their 'creative work'. These intellectual property rights are divided into moral rights on the art product and commercial rights related to the commercial utilisation of the movie. They are given to those directors, cinematographers, sound engineers, lighting technicians and constructors of the film sets that are in charge and determine the creative outcome of the movie production process (§7 UrhG). In contrast to that, those movie artists that mainly execute instructions, including movie actors, are excluded from these rights.

Thus, following Marx' theory on the division of labour in capitalist relations of production (Marx 1974 [1867]), the German copyright law contains a hierarchical division that legally privileges mental labour (the intellectual organisation of the movie production process and of labour power) over manual labour (the manual production of the movie). However, this prior entitlement of the 'movie creators' is overthrown by a special Annex in the copyright law text. According to that, all employed movie creators have

to transfer their commercial rights and the central parts of their moral rights to movie companies (§§88–94 UrhG). Hence, like wage labourers in other industrial sectors, movie creators have to accept their permanent dispossession by capitalist movie companies.

Nevertheless the accentuated position of movie creators in German IP law is reflected in the German copyright law in two important ways. First, they inspired the establishment of collecting societies (*Verwertungsgesellschaften*; compare §§27, 54 UrhG). By making contracts with them, artists can earn a share out of the reproduction of their works since companies that produce data carriers and copying machines have to pay a levy to collecting societies which redistribute the money to artists. Secondly, the strategic orientation of German copyright law shapes the social perception of movie production in Germany in an important way. Although almost all popular movies are made in industrialised capitalist relations of production, ‘creative artists’ mostly constructed as ‘free-floating creative individuals’ form the centre of popular discussions about movies. This also pertains to the debates about consumers’ rights on digital movies where parts of the public debate focused on individual movie creators as the primary victims of file-sharing practices. Thus movie artists tend to be displaced from their industrial conditions of cultural production.

Based on this institutional setting, the digitalisation of movie distribution led to a two-part re-regulation of intellectual property rights in the work relations of the movie industry. First, there was a political attempt by copyright law makers to strengthen the position of movie creators towards movie companies concerning the transfer of commercial rights. This was particularly related to the common practice in the work contracts of the German movie industry whereby movie creators had to transfer their commercial rights on movies to movie companies without an extra benefit beside their wages. However, according to the dominant interpretation of German copyright law, movie creators were qualified to receive an extra benefit for their commercial rights. Thus, following the new copyright law from 2002, movie creators have the explicit right to an extra benefit for the transfer of commercial rights (§11.2, Deutscher Bundestag 2002). This re-regulation of copyright law generally strengthened movie creators in relation to movie companies. Yet, there were on-going conflicts about the structure of these new benefits during the law-making process. While movie creators demanded an individual share related to the commercial success of their movies, movie companies pressed successfully for a sweeping benefit. Thus, the amount of benefits has to be negotiated in collective proceedings between trade unions and lobby groups of movie production companies.

Subsequently, conflicts between employers and trade unions focused on the legal model for transferring commercial and moral rights for movies in unknown technologies. Here the conflict was centred on the question of if and how artists profit from new technological forms their products can take after the initial publication, particularly in relation to digital distribution technologies. In the process of law making, artists and movie companies voted for two different legal models. The first one (and legal standard at that time) favoured a legal procedure in which artists own all rights on their movies until they explicitly transfer them to movie companies. Thus artists were provided with the chance to negotiate their shares at every single introduction of new technologies (§31.4, Deutscher Bundestag 2003b). The second and finally successful one entitles movie companies with all distribution rights on movies. This includes the IPRs on movies distributed through technologies unknown during the production of the movie as long as the companies simply inform the movie creators about the re-release of their works in new technologies (§31a, Deutscher Bundestag 2007). As with the extra benefit for the transfer of commercial rights, the movie companies have to pay an extra sweeping benefit to the movie creators for the appropriated distribution rights.

This legal appropriation of distribution rights was remarkably justified with the problems of the movie industry to legally stop consumers from sharing movies in new technological forms. According to the movie industry's lobby groups, the industries' legal complaints against private consumers were complicated since only movie artists held all intellectual property rights for movies in unknown technologies. Thus a legal vacuum had developed in which the movie companies' lobby groups defended the distribution rights of movie creators on digital movies against the social practices of private movie consumers. The political success of the movie industry's lobby groups thus consisted in the political coupling of the question of the legalised appropriation of rights in industrial relations to the question of 'movie piracy' and the apparent financial damage of the movie sector. In this argumentation, the movie companies presented themselves as the core of the movie sector that has to be protected by all legal means. That way, the adopted re-regulation of industrial relations according to digital standards strengthened the position of movie companies towards artists in the relations of production and towards consumers in the relations of consumption. As a result the prospective appropriation of movies in unknown technologies by consumers is already hindered as a violation of the movie companies' distribution rights, and opens new opportunities for legal complaints and surveillance politics throughout the movie industry.

THE RE-REGULATION OF PUBLIC FILM FUNDING LAW

As already discussed, the production of domestic movies in Germany is mainly financed through the German Federal Film Board (Filmförderungsanstalt). Although under constant critique from international movie companies and especially the US administration for the distortion of competition, the German government (like other European governments) refused to open the subsidy system to single non-German movie companies.⁸ With the increasing appreciation of the movie industry as one of the leading competitive sectors in information societies, the system of state subsidies has yet been re-regulated with the German film funding law of 2003.

First, the application procedures for German public film funding were further opened to single non-German but European companies. These can now also apply for public film funding when they produce movies primarily in European film locations with European movie artists – as long as the movie is primarily shot in German (Deutscher Bundestag 2003c). This formal shift in the German film funding law was justified by the German government through the policy of European economic integration. This includes the construction of a common European market and the opening of national state subsidy systems for European companies (Ziltener 2000). With regard to the movie industry, the Lisbon strategy of the European Union with the promotion of economic competitiveness in the ‘information society’ is the central political strategy (European Council 2000). It targets the economic success of European cultural goods on the domestic market whilst aiming to decrease the success of US blockbuster movies from Hollywood. Thus the formerly nationalistically inscribed German film funding law was redirected further towards supra-nationalistic strategic selectivities referring to European political projects like the unified domestic market. However, since the commercially successful international movie language is English, and single international movie production companies have not produced movies in the German language so far, the nationalistic inscription in the German film funding law prevails as a central strategic selectivity of German film funding law.

Secondly, the application procedures for state subsidies that were originally also invented for the support of smaller movies have been increasingly directed towards the economic success of movies. According to the procedures in the German film funding law until 2003, movie producers had to prove that one of their previous movies had a movie audience of at least 100 000 people.⁹ With the re-regulation of film funding law in 2003, this institutional requirement was increased to a minimum of 150 000

cinema visitors (Deutscher Bundestag 2003c). During the law-making process, smaller movie companies protested against this re-regulation of film funding law. However, the German government insisted on the tightening of the allocation principles. In their view, the German movie industry should be able to compete economically with the US movie industry for shares in the domestic German and the international movie market. In the renewed definition of the German government, 'quality movies' should be successful according to artistic *and* economic criteria at the same time (Deutscher Bundestag 2003a). Thus, German film funding – which has been situated in the area of conflict between economic and art subsidies since its inception in 1968 – is increasingly interpreted as a form of industrial policy for economic competitiveness. Speaking in materialist terms, smaller and economically unsuccessful movie capital factions tend to be excluded from state subsidies for movie production and distribution compared with big budget production companies.¹⁰

CONCLUSION – FOR A CRITICAL ACADEMIC DISCUSSION ON THE POLITICS OF IP

In a nutshell, various political conflicts emerged on the terrain of the German state during the digitalisation of movie distribution and consumption. As a result, these conflicts strengthened different legal positions. The re-regulated public film funding system increasingly privileges bigger and economically successful movie companies over smaller production companies. This re-orientation of public film funding law results from dominant strategies of economic competitiveness that are linked to competitive strategies on the European level. As an effect, German film funding has also been increasingly opened to European movie companies. In the relations of digital distribution and consumption, consumers lost the legal possibility of online- and offline-sharing of digital movies in favour of movie companies which appropriate the reproduction and distribution rights from movie artists in the relations of production. However, movie sharing is not considered a serious crime but an administrative offence. In the relations of production itself, movie creators were strengthened in their demands for benefits related to the transfer of commercial rights to movie companies, whilst at the same time losing their distribution rights on works in technologies unknown at the time of the movie production. In the last two cases, the movie industry succeeded in establishing a political world-view which links the digitalisation of the movie industry to a destabilisation of private property relations and – as central effects – to the potential decrease of macro-economic wealth in the information economy,¹¹ the loss of jobs

and the downfall of German cinema culture.¹² As a result, the intellectual property rights of movie companies were increased and stabilised.

Summing up, differences and analogies can be observed between the three law-making processes and their social consequences. First, the re-regulation of IP law was driven in all three cases by the neoliberal policy of national and supra-national competitiveness (Jessop 2002). This refers to the competitive advantages of economically successful movie companies supported through the film funding system, and the threat to competitiveness through private file-sharing and the 'inappropriate' distribution rights of movie creators in the relations of production.

Secondly, however, this competitive policy was in two cases opposed by counter-policies that specifically limited the scope of political change through competitive IP law. In the relations of production, this included the welfare-oriented protection of creative workers from over-exploitation by movie companies. In the relations of distribution and consumption, the protection of consumers from companies' surveillance techniques and legal threats was justified by civil rights related to data protection and privacy issues. Only in the field of public film funding did opposing social forces not manage to effectively articulate their demands.

Thirdly, the implementation of new IP law in everyday life differs according to the different social relations in which the new IP law intervenes. Hence, opposing actors situated close either to state transfers or to the strongly regulated social relations sphere developed less capabilities to question the rule of competitive IP law. Whilst movie creators have to accept the new legal model of transferring copyrights to movie companies even for unknown technologies in the established relations of production and smaller movie companies have to survive with less support from state-funded bodies, many consumers refuse to accept the new illegal status of private movie copying. Instead, they continuously share and copy movies for their private use in the private part of civil society, in particular the relatively less regulated Internet, effectively not accepting their legal exclusion from the digital technologies of movie reproduction, distribution and consumption.

Thus, these three lines of conflict highlight the fact that nowadays goods governed by IP law, such as movies, play an increasing role in the competitive strategies of Western states and their national economies. As I have shown, these dynamics become more important as alternative social organisation and political regulation models for goods governed today by IP law are strongly downplayed by the hegemonic international capitalist competition among Western TNCs and the closely related competitive state programs for the flows of foreign direct investments. In this process, strong private intellectual property rights in favour of media

conglomerates and state-funded bodies seem to be the 'natural way' for achieving these goals. Given these strong institutional preconditions, those engaged in alternative discussions aiming to strengthen critical perspectives in the politics of IP should not discuss their models in spheres outside the dominant IPR discourses. Instead, they should critically intervene in political conflicts about the effects of global capitalism and Western state dominance, for example on the production, distribution and consumption of cultural goods like digital movies (Bettig 1996; May 2000; Segrave 2003).

Speaking in state-theoretical terms, academic discussions like other social forces could therefore engage with the strategic selectivities of state and civil society that shape the institutional terrains of contemporary political conflicts about goods governed by IP law. With regard to the question of digital movies, these strategies include, from my point of view, (a) the excessive notion of private property relations that is transferred to the field of digital movie distribution and consumption despite the developing non-capitalist digital models and opportunities, (b) the strong position of transnational companies for macroeconomic wealth in political growth strategies, (c) the prominent position of transnational companies for cultural production processes on a global scale, (d) the competitive political coupling of the regulation of production, distribution and consumption of IP-related goods according to the conception of private property relations, (e) the reorientation of state subsidies for cultural production to a form of industrial policy and (f) product qualities and consumers' standards in relation to their political organisation. The last point refers to the fact that contemporary movie-sharing practices still rely primarily on established movie productions from Hollywood. Thus, economic and political alternatives of digital movie distribution and consumption models might involve discussions about contemporary consumers' standards oriented towards big-budget productions.

In this context, a critical analysis of the informal movie economy could start from the assumption that the digitalisation of movies has developed non-capitalist social practices of digital sharing and exchange which deserve to be supported by academic discussion on IP. These practices reflect a distinctive understanding of culture as a socially oriented practice without competitiveness, money-mediated exchange, market barriers and artificial scarcity of cultural goods through private intellectual property rights. Instead of criminalising private movie exchange, these initial impulses should be taken as a positive starting point for further academic reflections on the social organisation of the production of cultural goods and artefacts.

This leads to the difficult question of how the economic organisation

and political regulation of digital movies could be accomplished, bearing in mind the fact that cultural production based solely on state subsidies always entails the danger of a possibly state-controlled and censored art production scene. At the same time, the capitalist production of cultural goods threatens the contemporary work of cultural workers and creators itself. Besides the exclusion of the movie format through the market-mediated and advertisement-oriented production models, the literature on IP on movies is very outspoken that movie artists – except for the ‘star elites’ – are subordinated strongly in the contemporary capitalist relations of production in the international movie industry (Reber 1998). Thus, if movie artists and their works as well as the public should form the centre of future academic discussions, further reflections need to begin about more self-organised modes of movie production beside the commodification and state control of cultural production. This also entails the question of whether only economically successful movie productions are worth keeping on the market or whether a culturally diverse as well as politically and economically independent movie sector might be a political value in democratic societies. With the digitalisation of the movie sector, these political questions can be posed on new technological grounds.

NOTES

1. Of these co-productions, 20 were produced with a major share and 24 with a minor share from German movie production companies. German movie companies cooperated most prominently with companies from France (14 movies), Austria (11), Great Britain (9) and Italy (6) whilst only 3 co-productions with the US Majors appeared on the German movie market (Spitzenorganisation der Filmwirtschaft 2008).
2. Over the last century, those included cinemas, television (terrestrial and satellite), VCRs and DVD players.
3. The movie-related aspects of the TRIPS agreement were mainly induced by lobby groups of the US American movie industry. Accordingly, representatives of the Motion Picture Association of America were part of the US delegation during the TRIPS negotiations (Drahos and Braithwaite 2002; Wang 2003).
4. These levies are related to the financial shareholding of movie creators on the reproduction of their works through collecting societies which will be described later (see ‘The relations of movie production and the re-regulation of IP law’).
5. These include – besides the DVD as the digital offline distribution medium – online distribution channels like video-on-demand, online videostores and streaming services. In contrast to the music industry, the movie industry still lacks a widely accepted online distribution model like the iTunes store from Apple (Kremp 2007).
6. The main problem with empirical data in the field of IP on digital movies is related to the fact that no valid data exist about the number of private consumers that are involved in non-licensed movie-sharing practices. Instead, the movie industry produces empirical approximations of loss amounts and private consumers that rely on estimates of copied files, for example in file-sharing networks. Moreover, qualitative social science research methods are used to identify the practices of private consumers in order to politically close these private channels of movie distribution. Thus, I join

those critical social sciences approaches to the question of 'movie piracy' that solely research the empirical data in this field as the social construction of a 'crime wave' (Yar 2005), without producing my own empirical data about consumers involved in sharing practices.

7. Without being able to qualify this empirically, it is still noteworthy that the private German media sector is owned by transnational media conglomerates like the Bertelsmann group that also produce movies in other company sectors. Thus, with regard to public debates about IP on cultural products, the private media sector is at the same time a central place for the formation of public opinion and an interest group.
8. The last remarkable critique on the film subsidy system was articulated during the GATS negotiations at the beginning of the 1990s where the European delegation refused to open its public film funding systems to single companies from other contracting states in the WTO (Jarothe 1998).
9. This number is reduced under certain conditions, such as when previous movies won awards at international movie festivals (like the Oscars, Cannes, Venice and so on) or if a movie is evaluated by the German Film Evaluation Board as a 'valuable movie' (Deutscher Bundestag 2003c).
10. It is still worth mentioning that German 'big budget' productions differ remarkably from Hollywood's big budget productions. While the average Hollywood movie costs 100 million dollars including the global advertisement campaigns (Motion Picture Association of America 2007), the average German movie productions costs 5 million euros (Kurp 2004).
11. However, statistically, the digitalisation of the movie industry has not led to any significant economic losses in the movie industry so far. On the contrary, the German movie market expanded between 2000 and 2005 from 1.76 billion to 2.35 billion euros. This increase resulted from a major boom in home cinema entertainment products, especially DVDs (Bundesverband Audiovisueller Medien 2007).
12. In the conflicts between consumers and companies, the movie industry even attempted to link the banning of private copying with the 'war on terror'. According to publications from the international lobby groups of the movie industry, terror groups finance their political actions increasingly through illegal movie copies, so the 'war against illegal movie copies' is congruent with the 'war on terror' (Govil 2004).

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9. Who benefits? An empirical analysis of Australian and US patent ownership

Hazel V.J. Moir

1. INTRODUCTION

The story of the role a small handful of major companies played in the inclusion of regulatory patent laws into free trade negotiations is well told elsewhere (Drahos 1995, 2002; Ryan 1998; Sell 2003). During the Uruguay Round negotiations there was little public discussion of the proposed agreement on Trade-Related Aspects of Intellectual Property (TRIPS), and there was little organised opposition until towards the end of the process, when the implications for public health budgets became more apparent. Commenting on why lower-income countries agreed to a measure which was clearly welfare-reducing,¹ Scherer notes:

Third-world nations . . . accepted the bargain in the hope of better export prospects in agriculture and textiles and to ward off punitive measures under U.S. Trade Act Section 301. Because the textile and especially agricultural changes have at best been slow in coming, it would not be improper to suggest that the third-world nations were led into a Faustian bargain. (Scherer 2006: 42)

The story of the TRIPS negotiations is a prime example of Olsen's explanation of the impact of interest groups on public policy – a small well-organised group which will gain significant benefits from an initiative may well prevail in obtaining artificial rents where those who lose are dispersed and individually suffer small losses (Olson 1971).

Shadlen shows in Chapter 2 of this book how in Argentina, Brazil and Mexico the coalitions of interest groups have shifted, following the introduction of TRIPS. The outcome of these changes has been to strengthen support for the new TRIPS regime and to reduce the activities and 'voice' of those opposing this policy change. This demonstrates a second important aspect of interest-group politics: those benefiting from artificial rents (such as patent monopolies) will strongly resist efforts for change (Tollison 1997: 524).

Although the patent system may be almost an ideal example of Olsen's application of public choice analysis to the study of interest groups, there has been little empirical investigation of this. This study is an initial attempt to investigate whether the conditions set out by Olsen apply with respect to patents, and to identify the parties most likely to resist reform of patent systems. This is of interest in both the academic and real worlds.

Most patents are granted to corporations, and fully one-third of patents granted to corporations are owned by just 100 companies in both the USA and Australia. Many companies owning a high proportion of patents in one country also own a high proportion in another – 46 companies feature in the top 100 patenters lists in both the USA and Australia. This suggests that globally a very small number of companies may own a very large share of all granted patents. Twelve of the thirteen companies which promoted the TRIPS treaty are frequent patenters. An analysis of the top ten patenters in the USA shows that over the past four decades US-based companies have been displaced by overseas companies.

The remainder of this introduction summarises briefly the evidence on the welfare impact of the patent system and whether patent reform is an important policy issue. Attention is then turned to the available information on the losers (Section 2) and the winners (Section 3) from the patent system. This brief review of the evidence shows the dearth of solid data on patent winners and losers. Given the available data, it is simply not possible to investigate losers in more detail. However datasets for the USA and Australia provide some insight into possible winners. An overview of patenting patterns and a discussion of problems in analysing patent ownership data is presented in Section 4. The data on the most frequent corporate patenters in the USA and Australia are analysed in Section 5. The chapter concludes with some suggestions for further research (Section 6).

Is Patent Reform an Important Issue?

The US patent system has been substantially strengthened since the early 1980s, and this stronger patent regime has spread to other countries, both through borrowings in case law and through trade diplomacy. This has occurred despite a general trend towards de-regulation (Landes and Posner 2004). Recently a number of respected experts on patents and innovation have argued that the current patent system, as it operates in 'Western' countries, has become welfare-reducing and is in urgent need of reform (Jaffe and Lerner 2004; Bessen and Meurer 2008; Boldrin and Levine 2008).

One of the most startling aspects of the academic literature on patents

is the general lack of empirical evidence. There is a vast literature analysing patent doctrines, but only a small sub-set of this looks at any data. The much smaller economic literature on patents is largely theoretical, using models to analyse such issues as duration/breadth trade-offs or the appropriate monopoly rents for 'initial' and subsequent innovators. This work provides no insights into whether actual patent policy enhances or reduces economic welfare. Many 'conclusions' on the welfare impact issue are simply statements of assumptions, often without supporting evidence. This is particularly true of the frequently repeated assertion that patents are essential to induce a more optimal level of industrial innovation. This assertion derives from the theoretical proposition in economics that copying is costless. The assertion is strongly maintained despite the evidence that in general copying is expensive (Mansfield et al. 1981; Levin et al. 1987; Cohen and Levinthal 1989).

A decade ago Mazzoleni and Nelson expressed surprise at the continuing strong support for the 'conventional' view that patents were needed to induce innovation. They reviewed the empirical studies on the role of patents, and commented that 'those studies have been interpreted by knowledgeable economists as an indication that in most industries patents were not an important part of the incentives firms have for investing in R&D' (Mazzoleni and Nelson 1998: 274). Almost ten years later, Scherer also reviewed this evidence, noting first the finding that 'alternative barriers to rapid imitation . . . leave a substantial class of cases in which would-be innovators can anticipate revenue gains exceeding their innovation and production costs even when patent protection is totally absent' (Scherer 2006: 8–9). Overall the empirical evidence shows that, except for pharmaceuticals and fine chemicals, patents are entirely unnecessary to obtain a good return on investments in research and development.² This evidence has been repeatedly presented, including by leading researchers such as Richard Nelson and F.M. Scherer, but is repeatedly ignored. Macdonald concludes that this repeated ignoring of the evidence suggests that beliefs about innovation, and the role of patents in that process, are a matter of faith (religion) rather than rational thought (Macdonald 2004: 138).

The recent trend towards evidence-based policy is importantly influenced by the desire to ensure that policies are designed in the public interest, rather than for their benefits to narrow sectional interests. As yet patent policy has not been assessed on the basis of evidence. Anecdote and rhetoric are often used to bolster the positions of interest groups (Bessen and Meurer 2008: 3). The work cited above strongly suggests that evidence-based patent policy would differ radically in its design from existing patent policy. The material presented in the remainder of this

chapter confirms that the patent system conforms to a situation where beneficiaries are likely to be highly concentrated and losers dispersed and not well organised. This creates fertile ground for propaganda and regular repetition of propositions that are not supported by any sound evidence.

2. PATENT SYSTEM LOSERS

This section reviews the evidence about who loses because of patent systems. This question goes beyond the costs of the patent system to identifying who bears these costs. The ‘conventional’ view is that costs are largely borne by final consumers, and that, because of substitute goods, no one need pay a higher price for a patented product – they can simply purchase the unpatented alternative. This view is not supported by any empirical evidence. There are, however, well-known instances of the opposite impact. For example, although pharmaceutical companies develop alternative complementary products, all are patented, and such products have generally high prices. This has major implications for access to medicines, with consequent costs in terms of morbidity and mortality, as well as health outlays. Krikorian (Chapter 3) discusses one of the rare examples of compulsory licensing of patented pharmaceuticals to deliver affordable medicines, in Thailand. Despite such case studies the empirical literature on the costs of patent systems is small to non-existent (Cole 2001; Macdonald 2002; Moir 2009).

Bessen and Meurer suggest that a major unrecognised cost of patent systems is establishing clear boundaries to the granted monopolies. They argue that in the USA this cost has become so high that it is not rational to even attempt to determine where the boundaries are. So the likelihood of inadvertent infringement has soared, and the risk of litigation increased. They estimate that, excluding pharmaceutical firms, the private cost of the patent system now exceeds the private benefit for publicly listed US firms (Bessen and Meurer 2008). They emphasise that these high costs are paid by innovating firms.

It has always been recognised that a likely cost of patent systems is technological hold-up, where patents are used to prevent independent development of a technology. Boldrin and Levine (2008) document a number of major cases where patents have been used to prevent or delay the development of new technologies and to extract significant monopoly rents.³ The earliest documented case is James Watt’s steam engine; more recent examples include airplane manufacture in the USA, radio development in Europe, and electricity. These examples are well known and are also discussed by Cohen, who suggests that although such events may be

rare, they can have a significant social cost (Cohen 2005). In cases such as these, the losers are again other innovators.

The rent-seeking literature identifies that where artificial monopoly rents exist, it is rational to spend up to the value of the rent to obtain it (Tollison 1997). While there have been a number of empirical studies of rent-seeking in respect of tariffs, there are no such analyses of patents. Like tariffs, patent policy attracts a profession of experts to assist in ensuring that boundaries are managed to provide benefits to certain firms. In the patent field these experts are known as patent attorneys. The ratio of intellectual property lawyers to \$US billions spent on research and development has increased from under 45 in 1970 to about 75 in the late 1990s (Barton 2000). These costs are paid by firms and individuals applying for patents, while patent attorneys are major beneficiaries. As these expenditures could be directed to productive activity, rather than to seeking access to monopoly rents, they may constitute net social losses. Again those paying are innovating firms, this time those using the patent system.

Despite the National Innovation Surveys that are now regularly undertaken in many OECD countries, there are as yet no data on the impact on innovating firms of patents held by other parties. Until such data are collected evidence about losers from the patent system will remain sparse. There have been calls for the collection of systematic data on the benefits and costs of granted patents (IPAC 1984; Bakels and Hugenholtz 2002), but there has not yet been any positive response. In the narrower field of patents for software and business methods, there is evidence that those benefiting from the patent system have actively intervened to prevent the collection of systematic data. With regard to the extension of patents to software and business methods, a White House Office of Science and Technology Policy study into the quality of such patents was suspended due to the intervention of an (unnamed) large global company (Kahin 2003). Kahin also notes the role of the patent bar in overturning a proposed US General Accounting Office study of business method patents. Bessen and Meurer comment that the Federal Trade Commission (US FTC 2003) recommendation which was most prominently rejected by the Intellectual Property Owners Association was Recommendation 10, to 'expand consideration of economic learning and competition policy concerns in patent law decisionmaking' (Bessen and Meurer 2008: 293–4).

The extreme dearth of useful patent data makes it impossible to estimate patent system losers in any systematic way. The limited discussion above shows that known losers include innovating firms as well as final consumers, especially of pharmaceutical products. Any innovating firm, whether or not it uses the patent system, can potentially lose because of the patent system. Firms may incur higher costs in 'inventing around' a patent; or

may be sued by patent holders whose technology is allegedly infringed. It appears likely that innovating firms are bearing a large part of the cost of patent systems.

3. PATENT SYSTEM WINNERS

It is not widely known that patent policy delivers benefits to only a very narrow segment of the business community, though this has been documented for a considerable period of time (Edwards 1949). National Innovation Surveys confirm that only a minority of innovating firms use the patent system.⁴ Patent renewal data demonstrate that only a tiny proportion of patents generate substantial private returns.

This section briefly discusses the empirical studies on private returns to patenting. The two main approaches are the analysis of patent renewal data, and estimates of the contribution of patents to stock market valuations.⁵ These studies demonstrate that only a small minority of patented innovations generate the bulk of the private returns, but they do not identify who owns the most valuable patents, or whether such ownership is concentrated. They thus do not provide data on whether or not there are likely to be relatively small numbers of winners who might organise to maintain or enlarge the flow of rents from legislatively backed monopolies.

Most of the renewals analysis is based on European data as the US patent system does not require payment of annual renewal fees. These studies systematically show that the distribution of patent values is extremely skewed, with low average returns and a very small percentage of patents holding most of the private value from the patent system.

Pakes estimates average gross private returns to French and UK patents as \$6000 to \$7000.⁶ Germany has a very much lower grant rate (less than half the proportion granted in France and the UK), so German patents are likely to be considerably more inventive. This is reflected in the higher estimated average value of \$16200. Only 1 per cent of patents had values over \$65000 in France or the UK or over \$118000 in Germany. Overall half the total private value lay with 5 to 10 per cent of the granted patents (Pakes 1986: 777–8). Schankerman and Pakes (1986) find that about half of granted patents were renewed to year ten, and about half were not.⁷ They suggest that patents with low private value expire quickly, and those renewed to the end of the patent term – about 10 per cent – have greatest value. Drawing on this work, Griliches (1990) suggests ‘that though the aggregate value of patent rights is quite large, it is only on the order of 10 to 15 per cent of the total national expenditures on R&D’ (Griliches 1990: 1682).

In an interesting study of 222 patents selected as being of most value, Harhoff and colleagues find that fully 76 per cent of the total gross private value of this set of valuable patents rests in just 19 (Harhoff et al. 1997). If these results are generalisable this means that the bulk of the value that lies with the top 10 per cent of patents actually lies with the top 10 per cent of that – that is, with just 1 per cent of patents.

These empirical studies demonstrate that a very small proportion of patents contribute most of the private value. The long tail of granted patents is extremely skewed – even among the most valuable patents, a small proportion dominate. The patent system has been likened to a lottery, and it seems that, as in a lottery, most participants get a very low return on their investment. Perhaps traditional economic analysis, focused as it is on decisions at the margin, is not the appropriate basis for analysing such a winner-takes-all market.

It must be emphasised that these estimates are not of the total value of the innovation; rather they attempt to estimate the additional value contributed by holding a patent. Indeed Pakes and colleagues conclude that ‘patent protection per se is not the chief means by which firms appropriate the returns from their R&D investments’ (Pakes et al. 1989: 362).

The other strand in research on the private value of patents also attempts to measure the value of patents, abstracting from the value of the underlying innovations. This approach uses multivariate statistical techniques to determine the impact of patent holdings on a company’s stock market value. Using Australian data Griffiths and Webster (2004) find the value of patents has been falling over the period 1989 to 2002, but are able only to speculate on possible reasons for this. Bessen calculates the private value of patents for publicly listed US companies, to generate upper-bound estimates and confirm the reliability of valuations derived from renewal data. He estimates that a very high proportion of the global gross value of patents – over 80 per cent – is owned by chemical and pharmaceutical companies, with a large share of this being owned by ‘two dozen or so large pharmaceutical companies’ (Bessen 2006: 19).

Overall, these studies provide a weight of evidence that the gross private return to the average patentee is low. They also show that for a very small minority of patents private values can be extremely high. None of these studies goes on to identify or analyse the firms owning the high-value patents, or whether ownership of high-value patents is concentrated. Given the lack of evidence that patent policy is welfare-enhancing, the question arises as to whether a small proportion of winners exist and whether these are able to exert substantial influence on the direction of patent policy.⁸ The remainder of this chapter addresses the first part of this question – are the benefits of patent ownership concentrated among a small number of

actors? The analysis is limited to patent owners and does not address the role of patent system intermediaries, particularly patent attorneys, though these clearly benefit considerably from the patent system.

4. PATENTING IN THE USA AND AUSTRALIA

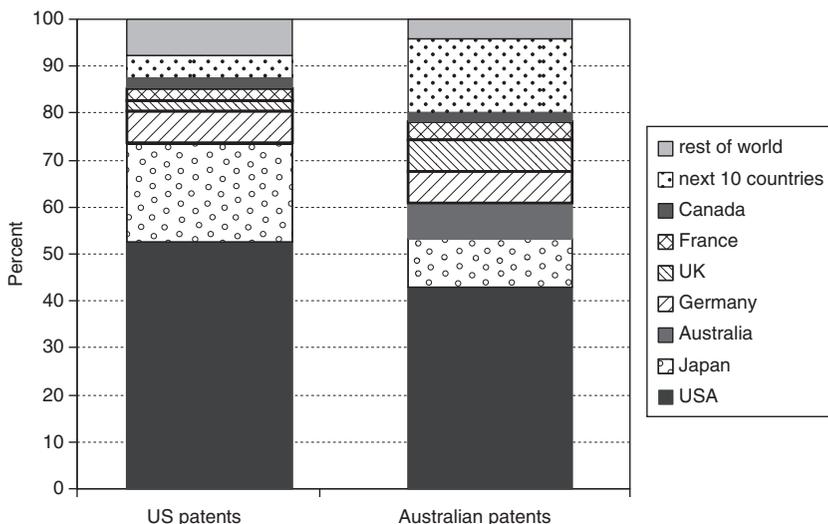
This section provides data on overall patterns of patent ownership, and includes a short discussion of some of the methodological issues involved in analysing such data. The discussion is limited to the USA and Australia, as it is possible to obtain at least some data on corporate patent ownership for both countries.⁹ The two economies are quite different in size: the Australian economy is only 6 per cent the size of the US economy.¹⁰ Because of this larger market, the US has a much deeper industrial structure, especially in manufacturing. This is despite the recent shifts in production to lower-cost overseas countries. On the other hand, both countries have high levels of education and urbanisation and strong traditions of innovation.

Patenting Patterns in the USA and Australia

By the end of 2007, 7313828 US patents had been issued, 4222954 of these (58 per cent) in the period from 1963.¹¹ That is, over half the patents ever granted in the USA have been granted within the last 50 years. This astonishing number of 'inventions' raises queries about just how inventive an invention has to be to be patented.¹²

Over the 38-year period 1964 to 2001, the volume of US patent grants increased by 483 per cent. The increase was substantially greater for grants to foreigners (by a factor of more than three) than for grants to domestic inventors. So the foreign share of granted patents increased from around 20 per cent in the early 1960s to nearly 50 per cent by the end of the period. The proportion foreign-owned has been quite stable since the mid 1980s.

Foreign ownership of US patents is highly concentrated. Only a small number of countries account for the bulk of foreign-held US patents (Figure 9.1). Until 1972, Germany accounted for most overseas-held US patents. In 1973 Japanese inventors became the most prolific foreign patenters in the US. Germany, France, the UK and Canada each hold small but respectable shares of US patents. Overall, 73 per cent of US patents held by foreigners are held by inventors in five countries, with a further ten countries holding another 10 per cent. Despite being included in this list, Australia (and Israel, Belgium and Austria) each account for less than



Notes: Total patents granted from 1990–2001 applications as at end 2007 were 1 811 967 for the USA and 161, 404 for Australia. The ‘next 10 countries’ for US patents are Taiwan, Korea, Italy, Switzerland, Sweden, the Netherlands, Israel, Finland, Belgium and Austria. The ‘next 10 countries’ for Australian patents are Switzerland, Sweden, the Netherlands, Finland, Israel, Denmark, Korea, New Zealand, Italy and Belgium.

Source: US data calculated from http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_at.htm (accessed 4 March 2008); Australian data calculated from data provided by IPAustralia.

Figure 9.1 Residence of inventor/owner of patents granted from applications in 1990–2001: USA and Australia

0.6 per cent of US patents. So many countries that rank quite highly in ownership have in fact only a tiny share of the market. This is one sense in which patent ownership is highly concentrated. On a volume basis the bulk of potential winners are inventors resident in the US, Japan, Germany, the UK, France and Canada.

Most patents are owned by companies. Of US grants in the period 1964 to 2003, 82 per cent are held by companies, less than 2 per cent by governments, and 17 per cent by individuals. The share of individuals is steadily declining – from well over 20 per cent in the 1960s to around 12 per cent in the 2000s. This is largely offset by an increase in corporate patent ownership – from 74 per cent in the 1960s to 88 per cent in the 2000s.

So the US patent scene is one where the volume of patenting has ‘exploded’, particularly since the mid-1980s. Patent ownership is dominated

by companies, and foreign companies, particularly from Japan, now own a very large share of US patents.

Although the Australian market is substantially smaller than that of the USA, there are some surprising parallels in the patenting experience of the two countries. But first, the differences. The overall volume of patenting is much less – 161 404 patents were granted from applications between 1990 and 2001, only 9 per cent of the 1 811 967 equivalent US grants. This is unsurprising given that Australia's GDP is only 6 per cent of that of the USA. The proportion of patents owned by foreigners is much higher in Australia than in the USA – it has long been the case that ownership of patents in small economies is dominated by foreigners (Bates 2003; Lamberton and Mandeville 1980; Penrose 1951).¹³ Overall 92 per cent of Australian patents are owned by foreigners, compared with 47 per cent in the USA.

But the share of patents granted to organisations is similar – 92 per cent in Australia compared with 88 per cent in the USA. In both countries the largest single patent owner group is US-based inventors: their share of patents was 53 per cent in the USA and 43 per cent in Australia. While US-based inventors hold the largest share of US patents, Australian applicants only rank third in Australian patent ownership. With a mere 8 per cent of granted patents, Australia is a long way behind the US, with its 43 per cent share.

The degree of concentration in foreign patent ownership is similar to that in the USA – applicants from the top five countries own 76 per cent of Australian patents granted to overseas residents. As in the USA, applicants from a small number of countries hold almost all Australian patents. The USA dominates, followed by Japan, Germany, the UK and France (Figure 9.1).

Using Patent Ownership Data

From an economic perspective patent grants are of substantially more interest than patent applications. The sole economic impact of an as-yet-ungranted application is to add to the cost of patent search. Very high proportions of applications are granted in some countries,¹⁴ but some applications do not proceed to grant, usually because of withdrawal by the applicant. This chapter uses only data on granted patents. These data are presented by year of application, as it is then that the underlying business decision is made.¹⁵

The US data used in this chapter are from a table on organisations owning 1000+ patents available on the United States Patent and Trademark Office (USPTO) website. There are several caveats to using these data (Moir 2008b: Appendix). The major disadvantage is that if a

company patents through subsidiaries and none of these individually owns 1000+ patents, the company is not included in the table. Several large chemical, pharmaceutical and related companies are identified as major patenters in Australia but do not show up in the top US patenters list.¹⁶ Where companies are included their total patent count may be underestimated if major patenting subsidiaries do not reach the 1000 threshold.¹⁷

Australian data are for standard patents filed from 1990 onwards and granted by the end of 2007. A considerable period of time can elapse between the patent application and the patent grant. It currently takes six to seven years for a cohort of patent applications to move completely through the Australian patent system. A decision was therefore made to base the analysis on the 12-year period 1990 to 2001.

The ownership details in the dataset required considerable cleaning. Because of the focus on corporate ownership, the first step was to separate out individual (8 per cent) and non-profit (4 per cent) owners. The remaining 141 584 patents included at least one corporate owner. Patents owned by multiple companies are excluded from the analysis (5214 patents or 4 per cent of corporate grants). The final dataset of 136 399 corporately owned patents covers 84 per cent of granted patents, 92 per cent of patents granted to organisations and 96 per cent of patents with at least one corporate owner.

Initially the data were split into two periods: 1990–95 and 1996–2001. Within each of these six-year periods companies were sorted by name, then grouped into counts for the same company. Substantial effort has been put into tracking down common ownership for the more frequent patenters, especially those that are among the top 100 US or Australian patenters. A more complete exercise would require access to business name registers, which lie in the private domain and are not cheap to access.

Because of the initial intent to compare the patenting patterns between the two six year time periods, frequent patenters were initially defined on the arbitrary basis of those with ten or more patents in any one six-year period. Using this decision rule 1344 frequent patenters were identified. However companies with nine patents in each period could be excluded, although they would have more patents than some identified in the listing. A non-ambiguous cut-off in the identification of frequent patenters occurs at 19 patents in the 12-year period – 908 such companies have been identified.

5. CORPORATE PATENTING IN THE USA AND AUSTRALIA

The patent renewal literature shows that a tiny percentage of patents hold most of the private value. The discussion in Section 4 showed that the

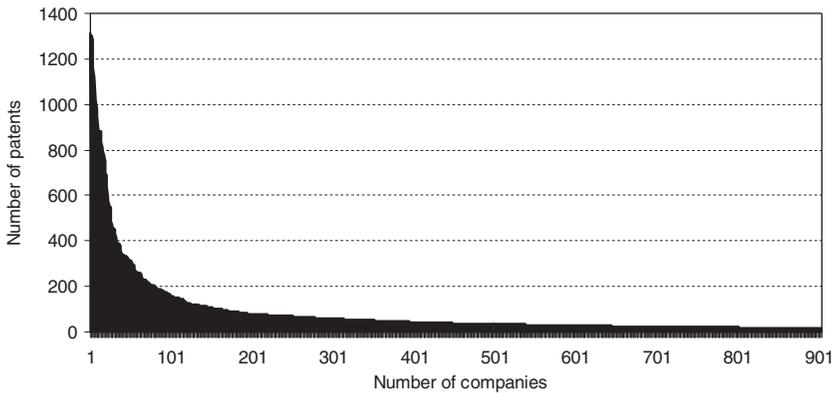
large majority of patents are owned by companies, and that residents of only a few countries own the bulk of granted patents in both the USA and Australia. The World Intellectual Property Organization (WIPO) provides an annual summary of Patent Cooperation Treaty (PCT) statistics, and their latest report indicates that the four top global patenting countries are Japan, the USA, Germany and Korea, sharing 73 per cent of PCT grants in 2006 (WIPO 2008: 22).

Newspaper and magazine articles on specific frequent patenters – for example, IBM – suggest that a few companies may dominate patent ownership. But there has been little recent academic interest in the concentration of patent ownership. The sole article located on this topic was published in 1970, and has never been cited. Using US data for three time periods (1921–38, 1939–55 and 1946–62), that study found little increase in concentration for the top 4, 8 and 20 companies but a marked increase in concentration for the top 40 companies between 1938 and 1955 (Watson and Holman 1970: 115). Because of this lack of interest in patent ownership, there is no published material on major patent owners.

US patent data on organisations which have been granted 1000 or more patents ('frequent patenters') can be obtained for the period 1969 to 2006. Frequent patenters hold a stable but gradually increasing share of patents (35 per cent in 1970, 40 per cent in 2001). Most of the patents held by frequent patenters are held by the top 100 companies, whose share has increased from 27 to 33 per cent. This growth in the share of the top 100 patent owners drove the increase in overall share held by frequent patenters. Frequent patenters own 45 per cent of US patents granted to organisations and 38 per cent of all patent grants.

The concentration of patent ownership in Australia is surprisingly similar. The 100 companies holding most patents have 34 per cent of all patents granted to organisations in this 12-year period. The Australian data allow some insight into the wider distribution of corporate patents. The visual representation of the highly skewed ownership distribution (Figure 9.2) tells the story starkly. This graph excludes the three companies with most patents, because extending the scale to include them made the long tail harder to see. The tail also extends only to the 908 companies with 19 or more patents. If the unknown number of companies with fewer patents were included the skewness would increase considerably.¹⁸

Ideally this skewed distribution should be considered in the context of patent ownership among all innovating companies. But it is hard to relate the distribution of Australian patent ownership to the universe of innovating Australian companies because 92 per cent of Australian patents are foreign-owned. Data from the National Innovation Survey found 35 per cent of Australian-based firms to be innovators (Australian Bureau



Notes: Based on applications between 1990 and 2001. Excludes three companies with most patents (Ericsson 1858, Hoechst (Sanofi-Aventis) 1818 and Procter & Gamble 1526). Also excludes all companies with less than 19 patents granted in the period.

Figure 9.2 Ownership distribution of Australian patents, 1990–2001

of Statistics 2005). Among these innovating firms only 4 per cent held patents. This suggests that the distribution might be even more skewed if all innovating companies were included.

A major difference between the two countries is in the representation of domestic companies among major users of the patent system. In the USA, 43 of the top 100 patenters are US-based. In Australia, only one of the top 100 patenters is Australian-based. Thus in Australia, in respect of this very large share of granted patents, almost all benefits flow overseas: royalty payments and knowledge spillovers. These are funded by Australian consumers through higher prices paid for products with monopoly powers.

The Top 100 Patenting Companies

The list of companies with the most patents exhibits both stability and change over time. Seventeen companies that were in the top 100 patenters in the USA in the 1970 to 2001 period were no longer in that list in the period 1990 to 2001. More US-based companies left the list than joined it. Over 80 per cent of the companies in the top 100 list held this leading position in both periods, and the majority of these (66) are US or Japanese. They are a diverse group in terms of industries, though chemicals, pharmaceuticals, electrics/ electronics and computers/software dominate.

Because the Australian data available are only for the 1990–2001 period, the focus in the remainder of this discussion is on this more recent period.

While there are 43 US companies among recent top US patenters,¹⁹ there are 41 East Asian companies, dominated by Japan, with 35 companies. Nortel Networks is Canada-based, and the other 15 are European, mainly German, French or Swiss. Indeed the US has more companies among top Australian patenters (47) than at home. There are 38 European companies among top patenters in Australia, dominated by companies from Germany, Switzerland and the UK. Only 12 Japanese companies are found among Australia's top 100 patenters, despite Japan ranking second in the overall share of Australian patents.

Among top US patenters the electronics and information technology industries dominate (Moir 2008b: Table 3). This contrasts with Australia, where less than 7 per cent of top patenters' patents are in these sectors. On the other hand chemicals and pharmaceuticals contribute 20 per cent of all patents owned by the top 100 patenters in Australia, compared with just 4 per cent in the USA.

If the lists of the top 100 companies owning patents in the USA and Australia are combined, a total of 154 companies are identified. Of these, 46 are among the top 100 patenters in both countries. These 46 companies are all based in the US, Japan, Korea or Europe. Nearly half (18) are chemical (including oil but not oil services) or pharmaceutical companies, and a further 16 operate in the information technology/electronics/telecoms sectors. Many of these companies are household names (Table 9.1). This group of 46 companies owns 60 per cent of the Australian patents owned by the top 100 Australian patenters, and 51 per cent of patents held by the top 100 US patenters. A further perspective is that these 46 companies own 18 per cent of all Australian patents and 16 per cent of all US patents (from applications in the years 1990–2001).

These companies are clearly quite selective in what they patent in Australia compared with the USA. But where a company patents in both countries, the number of patents taken out in Australia is usually much less. Within the chemical and pharmaceutical industries the ratio varies from 69 per cent (Hoechst)²⁰ to 14 per cent (Sumitomo Chemicals) around an average of 28 per cent. On average the number of Australian patents acquired is less than 6 per cent of those acquired in the US in electronics, information technology and telecoms. However the two mobile telecoms companies in the list (Ericsson and Nokia) both acquire about a third as many patents in Australia as in the US. Another company that has a high Australian patenting ratio is Kimberly-Clark (37 per cent). Possible explanations are that only genuinely significant innovations are patented on a global basis or that where Australia lacks industrial depth it is seen as unnecessary to take out patents.

Table 9.1 Companies in both top 100 US and top 100 Australian patenters

| Company name | HQ | US rank | AU rank | AU Main field of activity | No. of AU grants from filings in: | | | No. of US grants from filings in: | | |
|--|-------|---------|---------|-------------------------------|-----------------------------------|-----------|-----------|-----------------------------------|-----------|-----------|
| | | | | | 1990-95 | 1996-2001 | 1990-2001 | 1990-1995 | 1996-2001 | 1990-2001 |
| <i>Chemicals, pharmaceuticals and related</i> | | | | | | | | | | |
| SanofiAventis (Hoechst) | FR | 55 | 2 | pharmaceuticals | 1058 | 760 | 1818 | 2144 | 490 | 2634 |
| Procter & Gamble | US | 32 | 3 | mixed chemicals | 665 | 861 | 1526 | 1705 | 3268 | 4973 |
| Exxon-Mobil | US | 41 | 7 | chemicals/oil | 553 | 608 | 1161 | 2863 | 1019 | 3882 |
| Du Pont | US | 26 | 11 | chemicals/plastic, rubber | 520 | 458 | 978 | 3170 | 2832 | 6002 |
| Bayer AG | DE | 36 | 12 | pharmaceuticals | 341 | 608 | 949 | 2396 | 2207 | 4603 |
| Merck Sharp & Dohme (MSD) | US | 76 | 13 | pharmaceuticals | 332 | 559 | 891 | 1051 | 1081 | 2132 |
| BASF AG | DE | 28 | 14 | chemicals/synthetics | 395 | 495 | 890 | 2585 | 3288 | 5873 |
| Pfizer | US | 57 | 16 | pharmaceuticals | 382 | 501 | 883 | 1117 | 1391 | 2508 |
| Shell Oil Company | NL/UK | 75 | 17 | chemicals/oil | 424 | 412 | 836 | 1274 | 859 | 2133 |
| Dow Chemicals | US | 66 | 19 | mixed chemicals | 509 | 287 | 796 | 1596 | 764 | 2360 |
| Novartis AG | CH | 71 | 21 | pharmaceuticals | 475 | 276 | 751 | 2178 | 70 | 2248 |
| Hoffmann La Roche | CH | 85 | 23 | mixed chemicals | 260 | 427 | 687 | 972 | 894 | 1866 |
| Wyeth | US | 70 | 28 | pharmaceuticals | 305 | 242 | 547 | 1660 | 622 | 2282 |
| Eli Lilly | US | 93 | 32 | mixed chemicals | 241 | 218 | 459 | 930 | 782 | 1712 |
| Abbott Laboratories | US | 92 | 35 | pharmaceuticals | 194 | 222 | 416 | 936 | 781 | 1717 |
| L'Oréal | FR | 77 | 46 | cosmetics | 110 | 224 | 334 | 651 | 1478 | 2129 |
| Corning Incorporated | US | 98 | 52 | glass, ceramics, fibre optics | 139 | 175 | 314 | 566 | 1067 | 1633 |
| Sumitomo Chemicals | JP | 84 | 58 | chemicals | 133 | 135 | 268 | 909 | 973 | 1882 |
| Sector sub-total | | | | | 7036 | 7468 | 14504 | 28703 | 23866 | 52569 |
| % of top 100 Australian or top 100 US companies' patents | | | | | 14.6 | 15.5 | 30.1 | 5.2 | 4.4 | 9.6 |

Electronics, computing, telecommunications and related

| | | | | | | | | | | |
|--|---------|----|----|-----------------------------|------|------|------|-------|--------|--------|
| Eriksen | SE | 30 | 1 | telecoms | 475 | 1383 | 1858 | 767 | 4879 | 5646 |
| NEC | JP | 3 | 5 | IT | 586 | 719 | 1305 | 5319 | 11463 | 16782 |
| Alcatel-Lucent | FR (US) | 17 | 8 | telecoms | 668 | 454 | 1122 | 1380 | 8036 | 9416 |
| Nokia | FI | 60 | 18 | telecoms | 315 | 494 | 809 | 265 | 2199 | 2464 |
| Sony | JP | 5 | 25 | electronics/IT | 276 | 312 | 588 | 4530 | 9636 | 14166 |
| Motorola | US | 10 | 29 | telecoms | 308 | 182 | 490 | 5887 | 6069 | 11956 |
| Samsung Electronics | KR | 11 | 30 | diversified | 31 | 439 | 470 | 2590 | 9249 | 11839 |
| Panasonic | JP | 4 | 45 | electronics, semiconductors | 114 | 221 | 335 | 5105 | 9701 | 14806 |
| Sumitomo Electric | JP | 69 | 47 | electronics | 193 | 138 | 331 | 1339 | 965 | 2304 |
| AT&T | US | 34 | 57 | telecoms | 231 | 42 | 273 | 2891 | 1871 | 4762 |
| Mitsubishi Denki | JP | 8 | 61 | electronics | 131 | 131 | 262 | 6055 | 7058 | 13113 |
| Fujitsu Limited | JP | 9 | 64 | computers | 179 | 77 | 256 | 4516 | 8174 | 12690 |
| General Electric | US | 12 | 67 | diversified | 127 | 105 | 232 | 5333 | 6259 | 11592 |
| Philips Electronics | NL | 15 | 70 | electronics, lighting | 130 | 100 | 230 | 3505 | 6418 | 9923 |
| Hitachi | JP | 6 | 93 | electronics, healthcare | 76 | 105 | 181 | 5984 | 8051 | 14035 |
| LG Electronics | KR | 68 | 94 | electronics, healthcare | 19 | 160 | 179 | 168 | 2142 | 2310 |
| Sector sub-total | | | | | 3859 | 5062 | 8921 | 55634 | 102170 | 157804 |
| % of top 100 Australian or top 100 US companies' patents | | | | | 8.0 | 10.5 | 18.5 | 10.2 | 18.7 | 28.8 |

Table 9.1 (continued)

| Company name | HQ | US rank | AU rank | Main field of activity | No. of AU grants from filings in: | | | No. of US grants from filings in: | | |
|--|----|---------|---------|---------------------------------|-----------------------------------|-----------|-----------|-----------------------------------|-----------|-----------|
| | | | | | 1990-95 | 1996-2001 | 1990-1995 | 1996-2001 | 1990-1995 | 1996-2001 |
| <i>Instruments; light machinery</i> | | | | | | | | | | |
| Canon. | JP | 2 | 10 | cameras, copiers, printers | 330 | 686 | 1016 | 9101 | 11774 | 20875 |
| Medtronic | US | 81 | 81 | medical devices | 126 | 78 | 204 | 530 | 1402 | 1932 |
| Eastman Kodak | US | 13 | 84 | photographic & optical | 125 | 69 | 194 | 5200 | 5725 | 10925 |
| Sector sub-total | | | | | 581 | 833 | 1414 | 14831 | 18901 | 33732 |
| % of top 100 Australian or top 100 US companies' patents | | | | | 1.2 | 1.7 | 2.9 | 2.7 | 3.5 | 6.3 |
| <i>Diversified, and engineering</i> | | | | | | | | | | |
| 3M | US | 24 | 6 | mixed | 673 | 613 | 1286 | 3196 | 3304 | 6500 |
| Siemens | DE | 22 | 33 | diversified | 168 | 283 | 451 | 2630 | 5016 | 7646 |
| Robert Bosch | DE | 29 | 56 | automotive products, appliances | 70 | 225 | 295 | 1944 | 3802 | 5746 |
| Eaton | US | 79 | 62 | diversified (components) | 151 | 109 | 260 | 938 | 1049 | 1987 |
| Honeywell | US | 27 | 87 | diversified (defence/aerospace) | 64 | 126 | 190 | 2918 | 2983 | 5901 |
| Caterpillar | US | 59 | 89 | heavy equipment | 80 | 106 | 186 | 856 | 1615 | 2471 |
| Hughes Aircraft | US | 83 | 96 | defence/aerospace | 161 | 17 | 178 | 1834 | 51 | 1885 |
| Sector sub-total | | | | | 1367 | 1479 | 2846 | 14316 | 17820 | 32136 |
| % of top 100 Australian or top 100 US companies' patents | | | | | 2.8 | 3.1 | 5.9 | 2.6 | 3.3 | 5.9 |

There are 56 companies in the top Australian patenters list which are not among the top 100 US patenters (though 36 are found among the 300 companies in the US frequent patenters table). Similarly there are 56 companies in the top 100 US patenters list which are not among the top 100 Australian patenters. Only nine of these are among the top 300 Australian patenters, though another 16 have at least 19 Australian patents (that is, they are among Australia's top 900 patenters).

As noted earlier there is only one Australian company among the top 100 Australian patenters. Silverbrook Research operates in the high-speed printing business, and its technology involves a high-speed printer, a scanning device, coded forms and invisible ink (Moir 2008a). This is an industry rife with patent thickets. Silverbrook's website notes with pride the number of patents it is acquiring. Many are clearly designed to hide the underlying technology, with titles such as 'network refrigerator and printer' (a combined fridge and printer), 'method for searching information using coded data' (a rather cumbersome web searching method) and 'method and system for route planning' (this prints a map with coded data, then a scanner and computer are needed to determine the route).

The data analysed here show that a very large proportion of patents granted in both countries are acquired by a very small number of companies. Ownership of such large numbers of patents does not guarantee that any of these patents fall in the very small set of high-value patents. But it does suggest that their owners see an important value in patenting. The chemical industries, as noted above, involve highly codified technologies and have always been seen as particularly suited to the patent intervention, given the high costs of Phase III trials. The electronics and semiconductor industries are well known for requiring large volumes of patents which are cross-traded to acquire access to the patented technology owned by other parties. But in other sectors, such as computer software, major global companies vary considerably in their patenting strategies. Some patent very selectively, in contrast to IBM with over 49 000 granted US patents.

These data on concentration in patent ownership suggest that a small number of companies are positioned to benefit very considerably from patent monopolies. Some data are available on the role played by some of these companies in the development of patent policy. Thirteen US companies played a major role in the development of the TRIPS agenda (Drahos 2002: 118). Two of these – Rockwell International and FMC – were among the top 100 US patenters in the period 1970–2001,²¹ and ten are major patenters in the 1990–2001 period.²² Four of these ten companies are among the 46 companies which patent heavily in both the USA and

Australia: Merck Sharp & Dohme, Pfizer, Du Pont and General Electric. Another three – IBM, Hewlett-Packard and General Motors – are among the top 100 patenters in the USA, and are frequent patenters in Australia, but not among the top 100. The final three companies – Bristol-Myers Squibb, Monsanto and Johnson & Johnson – are among the top 100 patenters in Australia, but not among the US top 100.

It is noticeable that seven of these 12 companies are from the pharmaceutical/chemicals sector, where knowledge is more highly codified. Two other companies are from the information technology sector, one of which, IBM, is very well known for its enormous patent portfolio. As at the end of December 2006 it had been granted 49 171 US patents. During the period from 1969 to 2001 IBM was consistently among the ten most prolific patenters in the USA. General Electric is the next most prolific US patenter, having been among the top ten US patenters for 26 of these 33 years. It ranked top from 1969 until 1985 (Table 9.2). The marginally shifting pattern among the top ten US patenters illustrates a number of points. Despite a number of new entrants to this exclusive group, there are only 33 companies that have ever been in the top ten group in this 33-year period, and six of these have only been in the group for three years or less. So, in general, 25 companies dominate US patenting. But the most striking thing about the top ten patenters is the shift to a predominance of Japanese and Korean companies.

The story of the US–Japan patent wars has been told elsewhere (Warshofsky 1994). Another story that has been told elsewhere is the rising concern in the USA during the 1970s and 1980s about declining productivity (Scherer 2006). It was against this background that the argument to extend the reach of US patent legislation, initially through Special 301 and subsequently through the GATT framework, gained ground. It is therefore particularly ironic that as US patent laws have broadened their reach, in response to US corporate lobbying, the major companies now taking advantage of these government-backed monopolies in the USA are foreign companies.²³

In 1969 the top ten patenters in the USA were all US companies. This number gradually fell during the 1970s to three out of ten in the late 1980s. By 1995, the year TRIPS became mandatory as a qualification for membership of the WTO, only two out of the top ten US patenters were US companies. These outcomes would not actually have been known until the early 2000s, because of long processing delays. There has been some recovery since then, with Hewlett-Packard, Intel and Micron Technologies entering, but foreign companies still dominate the top ten US patenter ranks. There appears to be very little comment about this in the various debates about the US patent system.

Table 9.2 Top ten patenters in USA: 1969 to 2001

| 1969 | 1970 | 1971 | 1972 | 1973 |
|------------------|-------------------|------------------|-----------------|------------------|
| GEC | GEC | GEC | GEC | GEC |
| Honeywell | Honeywell | Honeywell | Honeywell | Westinghouse |
| AT&T | AT&T | AT&T | General Motors | Honeywell |
| Dow Chemical | General Motors # | General Motors | IBM | Dow Chemical |
| IBM | Dow Chemical | Dow Chemical | Dow Chemical | General Motors |
| Du Pont | IBM | Westinghouse | AT&T | Du Pont |
| Westinghouse | Westinghouse | IBM | Westinghouse | IBM |
| Wyeth | Eastman Kodak | Du Pont | Du Pont | Novartis |
| Eastman Kodak | Du Pont | Eastman Kodak | Novartis | Xerox # |
| ConocoPhillips | Novartis # | Novartis | Eastman Kodak | Siemens # |
| US: 10 | US: 9 | US: 9 | US: 9 | US: 7 |
| 1974 | 1975 | 1976 | 1977 | 1978 |
| GEC | GEC | GEC | GEC | GEC |
| Honeywell | Honeywell | Honeywell | Honeywell | Honeywell |
| Westinghouse | Novartis | Dow Chemical | Dow Chemical | Dow Chemical |
| Dow Chemical | IBM | Westinghouse | Wyeth | Exxon-Mobil |
| Xerox | Westinghouse | IBM | IBM | Novartis |
| Bayer # | Philips | Novartis | RCA | Hitachi |
| Novartis | Xerox | Hitachi # | Exxon-Mobil # | Westinghouse |
| Siemens | Bayer | AT&T | Bayer | Bayer |
| Philips # | Dow Chemical | RCA # | Westinghouse | AT&T |
| AT&T | Wyeth | Bayer | Siemens | IBM |
| US: 5 | US: 6 | US: 7 | US: 8 | US: 7 |
| 1979 | 1980 | 1981 | 1982 | 1983 |
| GEC | GEC | GEC | GEC | GEC |
| IBM | Honeywell | IBM | Hitachi | Toshiba |
| Honeywell | Hitachi | Honeywell | Toshiba | Hitachi |
| Hitachi | IBM | Hitachi | Exxon-Mobil | IBM |
| RCA | Dow Chemical | RCA | Honeywell | Exxon-Mobil |
| Bayer | RCA | AT&T | IBM | Dow Chemical |
| Siemens | Philips | Exxon-Mobil | AT&T | Honeywell |
| AT&T | Exxon-Mobil | Dow Chemical | Dow Chemical | AT&T |
| Dow Chemical | AT&T | Toshiba # | Philips | Philips |
| Exxon-Mobil | Siemens | Siemens | Canon # | RCA |
| US: 7 | US: 7 | US: 7 | US: 6 | US: 7 |

Table 9.2 (continued)

| 1984 | 1985 | 1986 | 1987 | 1988 |
|---|--|--|---|---|
| GEC Hitachi Toshiba Exxon-Mobil Canon Dow Chemical Honeywell Philips IBM Fuji Photo # | Hitachi GEC Dow Chemical Toshiba Canon Philips Fuji Photo Exxon-Mobil IBM Honeywell | Hitachi Canon Toshiba GEC Philips Dow Chemical Fuji Photo IBM Siemens Mitsubishi Denki # | Hitachi Toshiba Fuji Photo Canon GEC Philips Mitsubishi # IBM Siemens Exxon-Mobil | Hitachi Toshiba Mitsubishi Denki Canon Fuji Photo GEC Philips Eastman Kodak IBM Honeywell |
| US: 5 | US: 5 | US: 3 | US: 3 | US: 4 |
| 1989 | 1990 | 1991 | 1992 | 1993 |
| Hitachi Toshiba Canon Mitsubishi Eastman Kodak GEC Philips Fuji Photo IBM Du Pont US: 4 | Toshiba Hitachi Canon Mitsubishi Eastman Kodak GEC IBM Motorola # Fuji Photo Du Pont US: 5 | IBM Toshiba Canon Mitsubishi Hitachi Eastman Kodak GEC Panasonic # Motorola Fuji Photo US: 4 | IBM Canon Eastman Kodak Mitsubishi GEC Toshiba Hitachi NEC # Motorola Panasonic US: 4 | Canon IBM Motorola Mitsubishi Hitachi Panasonic Toshiba GEC Eastman Kodak NEC US: 4 |
| 1994 | 1995 | 1996 | 1997 | 1998 |
| Canon IBM NEC Motorola Toshiba Fujitsu # Hitachi Mitsubishi Panasonic Sony # US: 2 | IBM Canon Motorola NEC Fujitsu Sony Hitachi Mitsubishi Toshiba Panasonic US: 2 | IBM Canon NEC Samsung # Sony Motorola Fujitsu Toshiba Eastman Kodak Panasonic US: 3 | IBM Canon NEC Sony Samsung Fujitsu Motorola Lucent* # Panasonic Toshiba US: 3 | IBM NEC Lucent* Samsung Canon Sony Micron Technology # Fujitsu Panasonic Toshiba US: 3 |

Table 9.2 (continued)

| 1999 | 2000 | 2001 |
|---------------------|-------------------|-------------------|
| IBM | IBM | IBM |
| NEC | Panasonic | Hewlett-Packard |
| Canon | Micron Technology | Panasonic |
| Lucent* | NEC | Hitachi |
| Sony | Canon | Canon |
| Panasonic | Hitachi | Micron Technology |
| Micron Technology # | Hewlett-Packard # | Philips |
| Samsung | Intel | Intel |
| Intel # | Sony | Sony |
| Hitachi | GEC | Samsung |
| US: 4 | US: 5 | US: 4 |

Notes:

Companies shown in bold are headquartered outside the USA.

first entry into top ten in 1971–2001.

* Lucent is now merged with Alcatel, but achieved top ten entry on its own account so is counted here as a US company.

6. NEXT STEPS: PRIORITIES FOR FURTHER RESEARCH

In both Australia and the USA a mere hundred companies own over a third of patents granted to organisations. This distribution has a very long tail, with very many companies owning just a few patents. Data from National Innovation Surveys show that the proportion of firms holding any patents is a tiny fraction of innovating firms. Frequent patenters may not receive the greatest gross private value from their patents, because of the very skewed distribution of patent values. But it is likely they receive substantial value from their patents or patent volumes would be lower. Their very high patent volumes increase costs for other innovators. Bessen and Meurer (2008) have pointed out how the costs of establishing the boundaries of patented technology increase with the volume of patents.

These data support the view that patent policy is likely to be determined by interest group politics. This could explain why there are deeply held beliefs about innovation which are not supported by any empirical evidence. It is also likely to explain the strong political support for increasing patent ‘protection’ despite the lack of evidence that patents are needed to induce innovation. The most parsimonious explanation of this conundrum

is the rent-seeking activities of a small number of major beneficiaries, and this has recently been noted (Landes and Posner 2004; Scherer 2006; Bessen and Meurer 2008). Because data on frequent patenters are not readily available, the specific companies concerned are rarely named. The exception is a small number of studies investigating the new subject matter area of business methods (Hall 2003; Lerner 2002; Wagner 2008).²⁴

Organisations representing large global companies have suggested it is inappropriate for non-profit non-government organisations to participate in global policy negotiations. However it has been the practice for some decades for profit-making non-government organisations (companies) to have an inside seat at the negotiating table. This has particularly been the case in negotiations on 'intellectual property' policy (Drahos 2002; Sell 2003).

Given this, it seems at first sight surprising that there is so little analysis of whether the major beneficiaries are involved in determining patent policy. It is also surprising that the patent case is not frequently used as an example in case studies of rent-seeking and regulatory capture.²⁵ There are some real research opportunities here. A major reason for the dearth of empirical studies is, however, the difficulty of obtaining data that can be analysed from this perspective. Where such data are obtained, they require long and tedious cleaning before they can be used.

The data presented here are a small first step in addressing this gap. The source data for the US is not the preferred source, but is the sole reasonably available public source. Both data series used here also suffer from gaps in identifying wholly or majority owned subsidiaries. Nor has it been possible to extend the analysis to Europe and Japan. Given the global reach of the patent system, a global analysis would be appropriate. Another interesting area for research would be how the ownership structure and distribution has changed for those countries forced to radically change their patent legislation or introduce patent systems as part of their World Trade Organization membership.

Finally the role of another beneficiary group – patent attorneys – needs to be mentioned. The patent attorney industry has grown rapidly in the past two to three decades. Incomes are high, and patent attorneys have formed associations which are very actively involved in lobbying on patent policy issues. Companies often turn to their in-house patent attorneys to represent their views on intellectual property matters. The role of this intermediary group in patent policy development would bear some in-depth investigation.

The data placed on the table here will hopefully encourage innovation and competition policy makers to ask more demanding questions in regard to the impact of the patent system, and to insist on evidence-based

answers to these questions where submissions are from parties who stand to benefit directly from the existence of patent monopolies.

NOTES

1. For non-industrialised countries the welfare-reducing impact of the patent monopoly protection included in TRIPS was well known (see, for example, Penrose 1951; Deardorff 1992). An International Finance Corporation paper circulated during TRIPS negotiations was widely cited as arguing, contrary to the broader analyses of Penrose and Deardorff, that TRIPS would increase foreign direct investment and through this route would more than offset the welfare losses of patent monopolies (Mansfield 1994). Heald (2003) has shown this view to be a substantial over-statement of Mansfield's findings.
2. Full documentation of this point – that there is no general failure in the market for innovation – would take a book in itself. The interested reader could consult Mazzoleni and Nelson (1998) and (Scherer 2006: 5–15) for brief summaries of the empirical evidence, or Boldrin and Levine (2008) for an exposition of the role of competition in driving innovation. The large empirical literature demonstrating that patents are generally the least important mechanisms for obtaining a return to research and development (R&D) expenditure is summarised in Moir (2008a). Major references are Taylor and Silberston (1973); Levin et al. (1987); and Cohen et al. (2000). Data from National Innovation Surveys confirm that patents are generally reported by business to be the *least* effective means of ensuring a return to innovation (Australian Bureau of Statistics 2005; Eurostat 2004).
3. They also note that the patent holder was often not the most significant inventor, and in some cases contributed only marginal modifications.
4. For example only 17 per cent of innovating European firms use the patent system (Eurostat 2004), and only 4.4 percent of innovating Australian firms hold any patents (Australian Bureau of Statistics 2005).
5. There is also at least one survey-based study (Gambardella et al. 2008). This approach is strongly criticised by Bessen and Meurer (2008) as providing inflated estimates and failing to separate the value of the underlying invention from the value of the patent. Given the strong evidence that most inventions would occur without patents, separating the value of the invention from the value of any associated patent is critical.
6. These figures are in 1980 US dollars, using official exchange rates for conversion (Pakes 1986: 768).
7. In one of the few US renewal studies Thomas, using data on applications from the early 1980s, found that 40 per cent had a life of eight years or less, and a further 20 per cent had a life of 12 years. Just under 40 per cent were renewed for the then full term of 17 years (Thomas 1999).
8. Bessen and Meurer argue that in the USA 'patent policy has long been the domain of those entrenched interests who have the most to gain from patents' (Bessen and Meurer 2008: 257).
9. The other major patent offices (Europe and Japan) do not seem to allow ready access to comparable data.
10. GDP data (expenditure approach, in constant US\$ using constant purchasing power parities) show estimated 2006 GDP as US\$11 265 200 million in the USA and US\$638 227 million in Australia. (http://stats.oecd.org/wbos/Index.aspx?datasetcode=SNA_TABLE1, accessed 25 August 2008).
11. All references to US patents are references to utility patents (patents of invention) only.
12. There is a voluminous literature on the quantum of inventiveness required for patentability. See, for example, Lunney (2001); Bagley (2001); Lunney (2004); and Lemley et al. (2005–06).

13. Bates cites 2003 WIPO data for selected countries, showing that the percentage of grants to residents (by grant year) is 12.4 in the UK, 15.1 in Sweden, 22.4 in Israel, 40.6 in Germany and 89.2 in Japan. While WIPO provides an interesting series on applications by country of grant and residence of owner/inventor (from 1883 to 2006), there are some difficulties with these data (<http://www.wipo.int/ipstats/en/statistics/patents/index.html>, accessed 15 March 2008). For example, they give the resident share of applications in Australia in 2006 as 30 per cent. IPAustralia data indicate that the relevant figure is 11 per cent (calculated from <http://www.ipaustralia.gov.au/pdfs/statistics>, Table P30(Feb08), accessed 15 March 2008).
14. In the USA some 95 per cent of applications are granted (Quillen and Webster 2001). Grant rates were 93 per cent in France, 83 per cent in the UK and 35 per cent in Germany for the period 1950 to 1979 (Schankerman and Pakes (1986: Table 1). For Australia recent grant rates have varied from 88 to 94 per cent.
15. Moreover as Griliches has clearly shown, grants by grant year can vary significantly depending on patent office resources, not underlying economic factors (Griliches 1990: 1690–93).
16. For example, Unilever is not in the list, but a name search identified 1156 patents granted to Unilever companies for applications from 1969 to 2006. Rhodia is not listed under any name, but a search for Rhone and Poulenc identified 3185 patents granted during the period.
17. For example, Johnson & Johnson is among the top ten Australian patenters but only 249th in the USA, where it is listed as its subsidiary Ethicon, with a patent total of 1194 for the 1969 to 2006 period. A search for patents granted to any Johnson & Johnson company identified a total of 3954 patents for the whole period, increasing the US rank to 81st.
18. 51 387 corporately owned patents at the right-hand end of the scale are excluded. Assuming a (rather high) average of ten patents per company, this would mean over 5000 extra companies beyond the 905 shown in Figure 9.2.
19. If Alcatel and Lucent had not merged this would have been 44, as Lucent ranked among the top 100 US patenters. But the new merged company is based in France, so no longer shows up as a US company.
20. This high percentage may be due to undercounting of Hoechst patents in the USPTO major patenters table. That table shows a 45 per cent undercount for Hoechst for the 1969 to 2006 period, compared with a basic USPTO search for the Hoechst constituent companies. If the 1990–2001 data are inflated by 45 per cent then the ratio of Australian to US patents falls to 48 per cent, which is still well above the sector average.
21. In 1979 Rockwell International began to spin-off its various business segments, and it finally separated into Rockwell Collins and Rockwell Automation in 2001 (http://en.wikipedia.org/wiki/Rockwell_International and http://en.wikipedia.org/wiki/Rockwell_Automation, accessed 25 August 2008). FMC ranked 91st among US patenters in the period 1970 to 2001, but was only 182nd in the 1990 to 2001 period.
22. The 13th company closely involved in TRIPS was Warner Communications. During the lead-up to the TRIPS negotiations Warner Communications is likely to have had a greater interest in copyright than patents. In the early 1980s, when the Uruguay Round of negotiations commenced, software was generally seen as unpatentable. Indeed copyright protection for software was written into the TRIPS Agreement (Article 10).
23. It is also ironic in the context of patent policy that empirical studies of rent-seeking suggest this decline in productivity may be due to the increased proportion of lawyers in an economy or to the nature of legal processes (Tollison 1997: 512–13).
24. Each of these studies finds quite concentrated patent ownership. For US business method patents granted to 2000, Hall found that 36 per cent were held by just 44 companies. Lerner found that 25 per cent of US finance patents were held by 19 companies. Wagner found that over 40 per cent of business method applications at the EPO (where patents had already been granted in the USA) were held by just 14 firms.
25. The likelihood of the regulatory capture of patent offices was noted in a paper presented to the 1984 Australian review of the patent system (Beggs 1981).

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10. Timing, continuity, and change in the patent system

Sivaramjani Thambisetty

It is common, and increasingly so, to encounter absurd patent law doctrine in European and US law. Seemingly simple language in statutes can give rise to convoluted and exceptional interpretations. Thus in Europe ‘animal varieties’ are excluded from patentability, but this does not mean that animals cannot be patented. Computer programs ‘as such’ are not inventions, but there are at least four interpretations of the phrase in UK and European case law. Discoveries are not patentable, but biological material as the basis of biotechnological inventions is commonly patentable.

Each of these interpretations is supported by a functionalist explanation – Y is patentable because of X. However, for a long-term observer of the patent system, the quotidian occurrence of such interpretations suggests that functional explanations are not the only possible ones. Given the possibility of alternate legitimate and viable interpretations, it is no longer valid to assume the relative efficiency of patent law doctrine. If we went back and took a look at the emergence and sequential development of some of these doctrines, what would we see?

The patent system presents many unusual features that impact on the interpretation and stability of law. This chapter argues that interpretive processes in the patent system are subject to increasing returns, self-reinforcing or positive feedback processes which can distort substantive outcomes, and this explains many of the absurd interpretations seen in this field of law. Consensual goals and criteria are scant in patent law and this, along with the institutional complexity of decision-making, makes this area of the law prone to the contorting effects of increasing returns. The focus here is on legal doctrine – where and how it emerges in the patent system – and on the actors who, through formal and informal processes, either facilitate or constrain its evolution.

WHY INCREASING RETURNS?

For some theorists increasing returns are one kind of path dependence, for others they are a source of path dependence (David 2001). 'Increasing returns' captures the central element of path dependence, namely timing and sequence and simply defined means that 'the probability of further steps along the same path increases with each move down that path' (Pierson 2000b). Therefore 'issues of temporality are at the heart of the analysis' (Pierson 2000a). The explicatory value of analysts' use of increasing returns processes is based on the idea that it is not only *what* happens that is important but also *when* it happens.

Patentability in the US and European patent systems lends itself to a study of timing and sequences due to the large number of institutions involved in formal and informal law making. In the early stages when a new or immature technology is introduced there is often a period of openness unlike the usual closed style of interpretation that is common in law aided in part by the level of generality in most patent legislations (Sherman 1990). During this period of openness more than one viable standard of patentability may be suggested. In processes subject to increasing returns, these relevant standards of patentability have differing chances of being accepted, based not on their optimality, which is difficult to gauge given the opacity of technological projections, but rather on when new interpretational ideas emerge. Depending on contingencies or events, one or another standard may be propelled forward.

Once random events select a particular path, the choice may become (relatively) locked in regardless of the advantages of the alternatives. There is no guarantee that the outcome selected from among the many alternatives will be the 'best' one. Therefore, the possibility of increasing returns provides an acute challenge to explanations or justifications of patentability standards expressed in functionalist or efficiency terms. The analysis here specifically shows that the growing costs of policy reversal in the patent system go beyond the law's preoccupation with precedent and legal certainty.

The configuration of complementary institutions in the patent system in which the behaviour of each is affected by the performance of the others, is poorly captured by the legislative and policy framework. The following analysis focuses on specific characteristics of the patent system that make this aspect of social life prone to increasing returns processes. These are inter-institutional linkages, legal authority exercised by prominent institutions and the intrinsic and extrinsic uncertainty associated with patents. A fourth 'source' is not so much a source as a feature of the patent system that intensifies increasing returns, namely the inadequacy

of corrective mechanisms (such as litigation) to function as ‘efficiency filters’ (Pierson 2000a). These generic sources in the patent system make the emergence and development of legal doctrine in this field subject to increasing returns.

INCREASING RETURNS: SOURCES AND FEATURES

Increasing returns mechanisms are generated in complex knowledge-intensive circumstances and according to Arthur (1994) many of these are variants of, or derive from, four generic sources. First, *large set-up or fixed costs* create a high pay-off for further investments in a technology, giving individuals and organisations a strong incentive to stick with a single option. Secondly, *learning effects* refer to the knowledge gained in the operation of a complex system that leads to higher returns from continuing use. Thirdly, *coordination effects* appear when the benefits an individual receives from a particular activity increase as others adopt the same option. Fourthly, *adaptive expectation* is related to coordination effects and derives from the self-fulfilling character of certain kinds of expectations.

The above description of technology characterises many aspects of social relationships. It takes time and resources to learn new things, and we often learn by trial and error. People are more likely to do something that many others are also doing and may adapt their own behaviour according to what they expect other people to do. North’s work is based on an application of these features to institutions. Thus:

in contexts of complex social interdependence, new institutions often entail high fixed or start-up costs, and they involve considerable learning effects, coordination effects and adaptive expectations. Established institutions generate powerful inducements that reinforce their own stability and further development. (North 1990)

It is not just single institutions that generate increasing returns; institutional arrangements that induce complementary configurations of institutions and organisations are a powerful source of positive feedback or self-reinforcing feedback (North 1983; Hall and Soskice 2001).

Pierson builds on Arthur’s and North’s work (Pierson 2000a, 2000b) to identify four prominent and interconnected features of politics that make it conducive to increasing returns processes. First, *the central role of collective action*. In politics the consequences of one’s actions are highly dependent upon the actions of others because most of the goods produced in political markets are public goods, most goals pursued by political

actors have a 'winner-take-all' quality and there is no linear relationship between effort and effect. Secondly, *the high density of institutions*. The pursuit of public goods requires the construction of formal institutions and public policies that place extensive, legally binding constraints on behaviour. New institutions and policies are costly to create and often generate learning effects, coordination effects and adaptive expectations. As social actors make commitments based on existing institutions and policies their cost of exit from established arrangements generally rises dramatically. Thirdly, *the possibilities for using political authority to enhance asymmetries of power*. When certain actors are in a position to impose rules on others, the employment of power may be self-reinforcing as actors use their authority to generate changes in both formal institutions and public policies to enhance their power. Fourthly, *the intrinsic complexity and opacity of politics*. It is very hard to measure or observe important aspects of political performance due to the complexity and multiplicity of the goals of politics, as well as loose and diffuse links between actions and outcomes. The prevalence of 'mental maps' (Denzau and North 1994) can make understandings of the political world themselves susceptible to path dependence.

Pierson's interconnected features form the closest point of departure to gain analytical specificity by identifying actors and sources of increasing returns specific to the patent system. The sources of increasing returns in the patent system identified here will equip an analyst to correctly identify and explore specific empirical case studies. However, two further aspects of the patent system must be addressed – the first is the relevance of 'timing' in the patent system, and the second is the application of the notion of 'inefficient or sub-optimal' to patent law doctrine.

The Value of Timing in the Patent System

One of the key arguments running through this chapter is the effect of the complexity of patent law on the content of the decision-making process itself – constraining learning processes are to be expected. As Pierson notes, on the basis of cognitive psychology and organisational theory researchers have argued that actors who operate in a context of high complexity and opacity are heavily biased in the way they filter information into existing 'mental maps'. 'Confirming information tends to be incorporated and disconfirming information is filtered out' (Pierson 2000a). This in turn puts disproportionate importance on early events which may go on to have a decisive impact on the substantive content of doctrine, not because they are the best or most appropriate standard, but because they came first.

Patent law represents one of the most knowledge-intense aspects of legal interpretation. Novelty, inventive step and industrial applicability or utility and disclosure requirements tie legal concepts to technical know-how manifested frequently by the notional person skilled in the art. Often judges attempt to untangle what the person skilled in art, with attributes unique to any particular technology sector, would have understood the inventor's actions or words to mean. When new or immature technologies arise, this process can get even more complicated as the meanings and scope of scientific terms take time to settle resulting in doctrinal fluidity (Thambisetty 2007b). The process creates multiple layers of ambiguity that must be balanced with the requirement of legal certainty.

It is possible to argue that judges in the highest appellate courts, the Supreme Court in the US and the House of Lords in the UK, are not susceptible to 'mental maps' as their remit specifically extends to considering all relevant information and even changing the status quo if required. However, even if this were true, the highest appellate courts in most jurisdictions rarely take up patent law decisions and much of patent law is run and managed by patent offices¹ and lower courts. The evolution of patent doctrine is facilitated by a mixture of patent offices, lower courts, and specialised appellate courts – the Court of Appeals for the Federal Circuit (CAFC) in the US and the European Patent Office (EPO) in Europe, which functions as a quasi-judicial authority (Leith 2001). Patent offices in particular function under little oversight, sending signals to industry that can quickly build up expectations of value around specific patentability standards. Specifically, the patent office in recent years has emerged as a powerful agenda-setter that often frames issues and is in a position to guide litigation strategies. Specialist courts are prone to aggrandisement of their subject matter and pre-formulated 'mental maps' are to be expected here (Landes and Posner 2004).

Increasing Returns and Sub-optimal Outcomes in the Patent System

The possibility of inefficient outcomes is a key feature of the unorthodoxy of path dependence but enjoys different degrees of appeal in economics and politics. Political actors pursue a range of goals making for a murky environment, and consensual outcomes are much harder to come by than in economics where price acts as the ultimate measuring rod (Pierson 2000a). The trade-offs in intellectual property law in general not just in patents, are rooted in the need to induce scarcity in public goods (information) in order to increase the availability of information. The complexity of the goals and complementarities between trade-offs make it very difficult, or indeed impossible, to identify 'inefficiency' or 'sub-optimal' outcomes.

Having noted this however, understanding sub-optimal outcomes is necessary in order to empirically evaluate increasing returns sequences.

The very nature of the patent right as monopoly is a carefully crafted anachronism in free markets. The desire to grant incentives for present innovation is matched by the need to facilitate future innovation, a balance that is often struck in infringement actions through a notoriously difficult process. In a process akin to the interpretation of statutes or contracts – the meaning of terms used in patents is *constructed* on the basis of settled convention in the field, prosecution history and the patentee's own intent. In Europe the construction of patent claims must balance 'fairness to the inventor with certainty for third parties' – a broad guideline which may be interpreted differently in different European jurisdictions according to judicial processes and cultures, at times leading to different outcomes in the same set of facts (*European Central Bank v DSS* 2008).

Many other questions central to patents can have more than one legitimate and internally consistent answer. For example, the inventive step standard referred to as the 'gate-keeping' criterion attempts to capture the incentive effect of patents by answering this question: 'Would a particular invention have been invented even in the absence of the patent system?' If yes, it is an obvious improvement on what existed before, and therefore not patentable. If not, it is inventive and rightfully deserves a patent. Most jurisdictions apply 'objective' tests often populated with subjective assessments and discretionary standards. The level of the inventive step standard should be neither too high nor too low – and levels are often technology specific.

In the context of the study of legal processes in the patent system, I propose *doctrinal incoherence* as a sub-optimal outcome. Doctrinal incoherence as understood and defined here, results when there is no legal certainty as to how a particular fact situation will be decided, when legal reasoning can support an assessment either way. This is often the case when there are a number of interpretational variations to be found in the case law – these multiple variations may be explicit or implicit. Doctrinal incoherence may also result when the law relies on technological mistakes when construing the attributes and knowledge of the notional person skilled in the art; it may also result when lateral or neighbouring legal doctrines are affected by the confusion in one particular area of the law. Doctrinal incoherence may be accompanied by abbreviated decision-making on the viability or legitimacy of particular legal standards, or the reasoning may be overly 'operationalised' without reference to broader questions on the framework or purpose behind the law. This working definition of doctrinal incoherence as a sub-optimal outcome is different to, and must be distinguished from, the discretionary spaces in

law that are necessary in order to deal with technology or fact-specific circumstances.

One such sub-optimal outcome is presented by the transplantation of the specific, substantial and credible standard (SSCS) of utility from US patent law into European law, where it is currently used as a standard of industrial applicability. This standard is not supported by the wording of the European Patent Convention 1973 or 2000 and was adopted with no discussion on its viability or legitimacy via an ‘operational’ process whose remarkable success suggests that positive feedback processes are at play. It has been argued that the SSCS as it is applied in Europe has unintended consequences for lateral doctrines such as inventive step and sufficiency of disclosure, and creates actual and potential doctrinal incoherence (Thambisetty 2009).

GENERIC SOURCES OF INCREASING RETURNS IN THE PATENT SYSTEM

Inter-institutional Linkages

Inter-institutional linkages as a source of increasing returns arises principally from the insight that not just single institutions but also groups of institutions function as a source of positive feedback. Overlapping authority, complementarities and the struggle to share responsibility and legitimacy perpetuate or aggravate initially created advantages or disadvantages. Large set-up costs of coordinating between institutions provide strong incentives to stick with the early initiatives. This section details the formal institutional set-up of European and US patent systems and the nature of the expansion in roles of some of the actors in order to elaborate on the set-up and coordination costs within inter-institutional linkages in the patent system.

Over the last three decades organisations involved in the grant, exploitation and enforcement of patents have emerged from obscurity to play a highly influential role in the political economy (Doern 1999): an expansion in role that has brought an inevitable complexity to the institutional structure of the patent system. Patent offices in particular, are no longer confined to basic operations focused on examination functions. Patent offices (including the EPO and the Trilateral Office) and courts (general appellate courts, and specialist courts, including the EPO) are usually regarded as key formal elements of the institutional cluster that make up the ‘patent system’.

Central research funding bodies such as the US National Institutes

of Health (NIH) should be added to this cluster because of the considerable impact they can have on the post-grant exploitation of patents (Thambisetty 2007a). International bodies such as the WIPO (World Intellectual Property Organization) and ARIPO (African Regional Intellectual Property Organization) and institutional networks within such bodies are an interesting and significant extension of the patent system (Drahos 2004). The international dimensions of the patent system are best signified by the extraordinary Trilateral Office, comprising the US, European and Japanese patent offices. This is an informal, transgovernmental, regulatory network that often takes common and influential positions in international negotiations.

Under the European Patent Convention (EPC) (2000) a single application to the European Patent Office (EPO) results in a patent valid in designated European countries. Each European country also retains its own national patent office where patents are domestically valid and whose procedures are harmonised with the procedures of the EPO. In the case of a patent granted by the EPO, infringement and questions of validity post-grant (and post-opposition, if any) fall within the jurisdiction of national courts. Since enforcement and post-grant exploitation of patents are left to national bodies and do not directly involve as many institutions as patentability, the problem of inter-institutional linkages and competencies in the European patent system is intensified in the case of patentability.

Effectively, the EPO is not concerned with the manner in which patentability rules impact on infringement. This may lead to divergent validity in different European countries based on differing outcomes in infringement litigation, a possibility described by a leading UK Court of Appeal judge as 'deeply regrettable' (MIP 2008). It can also lead to oddities – for example when EPO rules on patentability directly contradict established rules of infringement. When the EPO decided to accept novelty of purpose patents it allowed patents on the new use of a substance used in the same way but for a different purpose. Only the intention of the user would indicate which of the two purposes was being deployed. Infringement however takes place irrespective of the intention of the alleged infringer. This has created an as yet unresolved problem (*Merrell Dow Pharmaceuticals v HN Norton* 1996).

Additionally, the EPC and consequently the EPO, is not formally part of the European Union. Thus the Biotechnology Directive is a EU document that has no direct legal basis under the EPC although some of the patentability standards were clearly based on EPO practice and Board of Appeal decisions. The EPO currently uses the Biotech Directive as a supplement to the interpretation of the EPC. This apparent symbiosis is not uncontroversial as demonstrated by the failed Directive on computer-

implemented inventions initiated by the EC (European Union 2002). The provisions of this Directive were little more than the consolidation of some of the most tortuous legal interpretation ever to be developed by the EPO – an interpretation that was widely seen to allow patents on computer programs in certain circumstances despite the exclusion of ‘computer programs’ as such from the EPC. As noted by the Economics and Social Committee of the EC, it would have been preferable for the EC to take the initiative away from the EPO, which is only competent in one area of intellectual property and was ‘naturally attempting to extend its own area of competence and sources of revenue’ (ESC Opinion 2002).

In the UK, in the face of divergences between legal standards of the EPO established via examination and Board of Appeal decisions, and the Court of Appeal, the UKIPO feels compelled to follow the Court of Appeal although it is mandated to harmonise patentability standards between the UK Patents Act and the EPC. The most sustained of these divergences has developed in the case of computer-implemented inventions. A recent Court of Appeal decision worked out at least four different strands of interpretation emanating from the EPO and the UK courts. The situation is intractable with the EPO criticising a recent UK decision as being ‘against the spirit of the EPC’ and the UK High Court adding that ‘computer programs are not excluded in all cases’ (*Astron Clinica Ltd and Others* 2008).

As a result European patent law continues to explicitly exclude computer programs while adopting interpretations that blow a hole through it. The density of institutions involved diffuses responsibility and is illustrative of learning effects within groups of institutions. Adopting a poor legal standard has led over time to returns from continued use. The juxtaposition and overlap of competencies and the confounding of legislative and interpretive function is a running theme in the European patent system that makes early institutional or legal initiatives inordinately important – institutions can be expected to adapt, making it more difficult to exit specific policies.

The US patent system presents a not dissimilar situation although the direct complexity of the European system is avoided. US legal doctrine is dominated by the Court of Appeals for the Federal Circuit (CAFC), a specialist court that occupies a unique role as an appellate body jurisdictionally demarcated by subject matter rather than by geography. The basic premise behind establishing the CAFC distinct from the 12 regional circuits, was the belief that centralisation of authority would lead to clearer, more predictable patent law. However, studies have suggested that the mere establishment of a specialist court has not led to consistency and predictability of outcome (Wagner and Petherbridge 2004; Atkinson et al. 2008).

The creation of the CAFC seems to have had a positive impact on the number of patent applications, the number of patents issued, the success rate of patent applications and the amount of patent litigation (Landes and Posner 2003; Turner 2005; Henry and Turner 2006) but all of these have not necessarily had a positive effect on technological progress. While interest group politics seem to have led to the creation of the court with its 'mission' orientation and specialised character it must be regarded as an informal institution that impacts on the direction and content of legal doctrine. Studies have predicted and identified a 'pro-patent' attitude that favours more and stronger patent rights. According to Landes and Posner this is to be expected as

A patent court is more likely to take the pro-patent side . . . simply because a court that is focused on a particular government program, like an administrative agency (invariably specialised), is more likely than a generalist court to identify with the statutory scheme that it is charged with administering. (Landes and Posner 2004)

Higher appellate courts that are generalist in nature have recourse to a greater variety of approaches to a legal problem. They are more likely to adopt a 'purposive' approach to interpretation where the appropriateness of a prohibition on exclusion from patentability is explored, and they may identify issues that are better dealt with by legislatures. In contrast, specialist courts often take the 'purpose' of a statute as given and proceed to address questions of interpretation at least partly as an exercise in semantics. A unique contrast in approaches can be seen in the case of the patentability of the genetically modified onco-mouse at the European Patent Office, a body with specialist quasi-judicial functions, and the Canadian Supreme Court, a generalist appellate body (Thambisetty 2007a).

In contrast the status of the EPO is a curious one. It is a specialised administrative body with quasi-judicial functions and a corporate structure geared to service consumers. These consumers are often actual or potential patent holders and only infrequently are they public domain stake-holders. In this context, it is to be expected that the EPO will function with a pro-patent attitude we can expect within specialist courts. This in itself is not surprising, but what is remarkable is the apparent complacency with which the conflicting institutional roles patent offices are set up to play is received.

To illustrate, there is an existing rule in UK law that allows infringement actions to be brought to the comptroller of the patent office, if the alleged infringer agrees. In 2002 the Department of Trade and Industry together with the UK patent office proposed to relax the rules, allowing for infringement action even without the alleged infringer's permission – a

proposal described as the ‘least thought through, most ill considered proposal to emerge for many years’ (MIP 2003). There is an obvious public choice theory argument to make against allowing the same entity that grants patents to sit in on the legally valid scope of the patent, but it indicates an unwarranted trust in the role of the patent office. This may be due in part at least to the present context of a knowledge-intense and technically opaque area and the *de jure* and *de facto* role epistemic communities (Haas 1992) such as patent offices play here.

The above proposal may have been driven in part by a perception that UK patent litigation is excessively costly because of the number of procedural tools such as disclosure, experiments and cross-examination. In 2003 the Patents Court introduced a new streamlined court procedure geared towards a one-day trial six months after the order for such a procedure is given. It eliminates a number of steps within standard trial directions that fail a cost–benefit analysis and was set up amidst concern that patent litigation would drift towards more ‘efficient’ courts like those in Germany. The rapid procedure could become an important strategic tool in multi-jurisdictional patent litigation (Hitchcock 2005) as an early judgment in the UK may be used persuasively in other European jurisdictions, increasing the profiles of UK judges and generating coordination effects.

The European Patent Litigation Agreement is an effort to set up a Europe-wide litigation agreement as a solution to the current fragmented framework. A number of EU countries promote a rival proposal to litigate patents under the European Court of Justice (ECJ), a European Union judicial body that would give the initiative in the important aspect of the single market back to the EU rather than to the EPO, which administers the EPC. Organisational persistence here is remarkable and its causes and consequences are worth exploring further (Impact Study of the European Patents Court in UK 2009).

The European system seems tied to an institutional design that relies on collective action between the EPO, national patent offices and national courts in over 20 countries to bring about a harmonised working system. Collective action in particular includes many of the features conducive to positive feedback (Marwell and Oliver 1993), because institutions within the system have adaptive expectations and constantly adjust behaviour with respect to how other institutions may act.

Examination procedures are the key to substantive patentability standards. What can or cannot be patented is a signal that is sent out initially from the patent office and can build up expectations in capital markets that can be hard to reverse, even for courts. Courts are often keen to cooperate with patent offices in establishing examination methodologies that are conducive to predictability and consistency. The Trilateral Office is a

framework for coordination that ostensibly ‘collaborates’ on examination procedures at each of the patent offices, namely Japanese, European and US, in a bid to reduce legal uncertainty for transnational corporations looking for intellectual property protection in multiple jurisdictions. Even within developed countries, explicit harmonisation of substantive standards raises a number of ideological issues – within this context the work of the Trilateral Office has the outward marking of an ‘epistemic community’ and coordinates patentability standards on controversial issues such as biotechnological inventions, business methods and computer-implemented inventions. The Office negotiates as a single body at WIPO negotiations on the SPLT – the Substantive Patent Law Treaty.

The Trilateral Office is essentially a closed community of regulators that raises important questions of accountability (Davies 2002) and perpetuates the view that international coordination and harmonization of patent law is a technical debate to be resolved solely by technical cooperation. This collective dynamic has the potential to generate learning and coordination effects in the emergence and evolution of patentability standards.

Legal Role and Authority of Patent Offices and the Force of ‘Expansion’

Asymmetry in power as a source of increasing returns is based on the reasoning that powerful entities will work at increasing their own power, generating self-reinforcing processes. Patent law emerges from three distinct but related spheres of authority – judiciary, legislature and examination by the patent office. Judicial and legislative authority is capable of being scrutinised in well-defined ways; by contrast the patent office as an institution is subject to little oversight and works to poor principles of accountability. In addition the expanded roles of patent offices in UK, US and European jurisdictions have created an asymmetry between those who advocate more property rights and those who would like to constrain this expansion using fast-receding normative boundaries.

The legally backed authority of the patent office is first and foremost a formal constitutive ‘examination function’ that it fulfils under patent statutes. This technical function uses scientific-legal terminology that makes this a closed book even to non-patent intellectual property lawyers. Theoretically the examining function is supposed to occupy a different space from legislative interpretation carried out by judicial bodies. In effect however patent offices often function like courts, exercising quasi-judicial authority – a juxtaposition of roles that is deeply problematic because of the apparent sanctity it gives decisions of an administrative body.

Courts work with established rules of legal interpretation and actively

justify and reason outcomes – a characteristic of the judicial process that enables methodological and substantive scrutiny. The patent office is an administrative agency whose internal structure and processes are difficult to scrutinise. European patent office ‘judges’ are produced by a system directed towards one goal – ‘examining patents’, a function based overwhelmingly on documentary evidence (Leith 2001). Procedural expertise such as ‘evidence sifting’ or weighing of arguments that may be routinely expected from judges of national courts is not common in this context.

Examining guidelines derive content from litigated rules and doctrines, but also impact on legal doctrine directly and indirectly, in a feedback loop. One of the most dynamic interpretive tools in patent law is the ‘person skilled in the art’. This notional person has the aptitude, knowledge and know-how of an average person of skill in any particular art and provides a technology-specific link to the internal cognitive processes of scientific and technical researchers (Eisenberg 2004). Broad questions such as inventive step or sufficiency of disclosure with direct impact on the social value of innovation boil down to what the person skilled in the art knows or does. And since patent offices have considerable say in specifying how much the person skilled in the art can be assumed to know through examination procedures, they set key doctrinal standards. Substantive patent law doctrine is thus routinely broken down to incremental ‘operational’ measures that are often fully controlled by patent offices. Due to the self-reinforcing nature of the patent system, an ‘operational’ measure once set up can be very difficult to modify or overrule. Swiss medical claims are an oddity that illustrates the operationalisation of substantive patent law.

Prior to EPC 2000, European and therefore UK patent law excluded methods of medical treatment on grounds of them being incapable of industrial applicability. The reasoning behind this is the idea that some fields of endeavour should not be subject to commercial or industrial connotations. The EPC explicitly allows for the patenting of the first medical use of substances that are already known. Additionally, and as a response to pressure from the pharmaceutical industry, the EPO extended patent protection to second medical use of known products. Second medical uses of known chemical entities are often commercially significant because expensive safety or toxicology profiling for the substances or compositions is already completed.

However second medical use of a known substance is a ‘method’ of medical treatment and falls foul of the exclusion on grounds of lack of industrial applicability. Swiss-type claims, so called as they were first allowed by the Swiss patent office, get over this hurdle by wording claims in the form ‘use of X to manufacture medicament Y’. In *EISA/Second Medical Use* (1985) the EPO disallowed a claim in the form.

‘The use of a (certain substance or composition) for the treatment of the human or animal body by therapy’ because it is the same as ‘a method of treatment of the human or animal body by therapy with a (certain substance or composition)’, which falls foul of Article 52(4). However they allowed. ‘The use of a (certain substance or composition) for the manufacture of a medicament for a specified new and inventive therapeutic application’.

Note here that the process of manufacture itself in all three cases does not differ from the known processes for the same substance or composition. There is no difference in the substance of what is protected under all three of these claims; however only the third one ostensibly fulfils competing legislative requirements while extending pharmaceutical protection to second and subsequent medical uses of a substance. Such claims, known as ‘manufacturing use’ claims, are therefore new only in terms of the new therapeutic use of a known chemical entity.

The combination of technical language and operationalisation of patent law and the fact that patent offices are the first agency to engage with new technologies makes them powerful agenda-setters. A recent example of ‘agenda-setting’ with implications for European patent law is provided by the treatment of the ‘technological arts’ test at the US Patent Office and the Board of Patent Appeals and Interferences (BPAI). Carl Lundgren’s application for a method of calculation was initially found unpatentable by the USPTO as being ‘outside the technological arts, . . . without the disclosure, or suggestion of a computer, automated means or apparatus of any kind’ (*Ex parte Lundgren* 2005). On appeal however, the rejection was reversed on a divided opinion at the BPAI which found no basis for the ‘technological arts’ test, specifically rejecting judicial precedent stating that there could be no ‘technological arts’ test separate from the enumerated classes in §101. The move recasts substantive changes in ‘operational’ terms – in this case as a matter of removal of one of the steps in the examining procedure (Thambisetty 2009).

As is amply clear from the European context, reliance on ‘technology’ or ‘technical aspect’ is not without problems, since mere association with banal computer equipment should not make otherwise unpatentable subject matter patentable. Removing the ‘technological arts’ test from the USPTO’s examining process is however a radical signal that it intends to steer away from the limiting notion of ‘technology’. The USPTO often presents itself as a global agenda-setter in undermining the ‘technical’ aspect of patent eligibility. Specifically, the interim guidelines put in place after the *Lundgren* decision strengthen the negotiating position of the US in international fora such as the WIPO and aid the case for going beyond the TRIPS Agreement’s limiting use of the term ‘technology’:

The United States is a leader in the protection of intellectual property and strongly supports patent protection for all subject matter regardless of whether there is a 'technical aspect' or the invention is in the 'technological arts'. The application of a 'technological art' requirement could be used to preclude the patenting of certain inventions, not only in the United States but also in other jurisdictions. (USPTO 2005)

Admittedly, an agenda-setting power in itself may not be problematic for a knowledge-intense field such as patent law where 'mental maps' are bound to develop. However, this power often comes coupled with an explicit programme of extension of the reach of intellectual property – again behaviour that is not surprising for a specialist agency, but one that may contradict conditions conducive to capturing the social value of innovation.

A related and explicit source of increasing returns is specific policy paradigms that perpetuate the power of patent offices. Recent research has shown, albeit implicitly, how policies that are grounded in law are prone to increasing returns. Such policies establish many of the rewards and penalties associated with particular activities and are a strong reinforcing feature of existing institutional arrangements (Pierson 2000a). Rather than relegating policy ideas to the back of theoretical constructions (Beland 2005), it is important to recognise that the force of ideas is an independent variable in the patent system that must be understood in the context of specific institutions. Patent offices are able to set policy and legal arrangements so as to constantly strengthen intellectual property rights in ways that are often not warranted or justified by original legislative mandates.

An example of a 'policy paradigm' or 'directional idea' that has emerged recently in intellectual property law in general and patent law in particular is 'expansion' – expansion in the types of subject matter that can be protected by intellectual property and expansion in the scope and strength of such rights. The US and European patent systems are both subject to this paradigm; even in jurisdictions averse to 'expansion', law and policy may be tailored as an opposition to this idea, emphasising its force. This aspect transforms a plausible balance in the power and responsibility of the patent office to one where ideological manipulation increases power asymmetries. Key to understanding this is to consider some of the ways in which the role and function of this body has changed in recent times.

A decision of the EPO is widely regarded as having made it easier to get patents on diagnostic methods despite the exclusion of 'diagnostic methods' from patentability in Article 52(4) of the EPC (*Diagnostic Methods* 2006). The EPO *inter alia* justifies restricting the meaning of this exclusion to a small number of methods where every aspect is directly practised on a human or animal body on the grounds of Article 4(3) of the

EPC. This article is an introductory provision that states that it is the task of the EPO to grant patents – a provision that must be read in the context of the rest of the Convention. However, according to the EPO any exceptions to this mandate such as those in Article 52(4) are therefore to be construed narrowly. This is a ‘political’ reading of Article 4(3) that furthers the legal and political agenda-setting power of the EPO.

The pressures of revenue-raising for patent offices can also lead to changes in the social benefits of intellectual property. Formally in most countries patent offices are ‘statutory persons’, a constitutive rule that seeks to maintain the integrity of the office. Since the late 1980s and 1990s, patent offices’ status has been changed in a number of countries bringing with it greater powers over its finances, personnel and other operations. A number of patent offices are now self-funded, including those of the UK and the US. Lemley for example, argues that converting a patent office into a nimble customer-oriented body creates an indefensible position for a quasi-judicial administrative agency entrusted with issuing patents in the public interest (Lemley 2001; Merges 1999).

Patent renewal fee structures are an integral part of patent offices as revenue generators. In an environment where it is not possible to analyse whether the value of an innovation justifies the R&D costs, increasing patent renewal fees leads to reduced length for inventions of lesser social value (Scotchmer 1999; Cornelli and Schankerman 1999). However self-funded patent offices can distort fee structures when the maximisation of revenue conflicts with the imperative to optimise the social value of innovation. Gans et al. predict that a financially constrained, self-funded patent office can be expected in course of time to reduce renewal fees and increase initial application fees in a bid to increase revenue. Reducing renewal fees increases the inventor’s expectation of profits, which can then be appropriated through initial high application fees. Over a period of time it can distort social welfare by discouraging the filing of some useful patents while encouraging the effective life of others (Gans et al. 2004).

Explicit policy-making roles and opportunities have also recently been added to patent office functions. For example, the USPTO Corporate Plan undertakes to ‘help protect, promote and *expand* [emphasis added] intellectual property rights systems throughout the United States and abroad’ (USPTO 2000 p. 17, 2001a, p. 71). The UKIPO has recently launched a programme to promote the value of intellectual property among school children, enrolling Wallace and Gromit. The material includes measures to tackle ‘IP crime’, an ideologically contested notion. In the UK the Gowers Review recommended measures to help the patent office take a strategic view of IP. This involved setting up the Strategic Advisory Board for Intellectual Property (SABIP) as an advisory body to the government

with a broad mandate to commission external research (Gowers Review 2006). Although there is direct exhortation to involve all stakeholders, it remains funded by the patent office.

When patent offices avow the expansion of intellectual property rights they function as an interest group that drives up the demand for greater and stronger intellectual property rights. This self-reinforcement is further intensified by the inherent asymmetry between the value that creators of intellectual property place on having property rights and the value that would-be users place on the freedom to use intellectual property without obtaining a licence from the patent holder. It is easier to organise interest groups demanding an expansion of intellectual property rights than it is to get would-be users to oppose such an expansion. Landes and Posner offer the absence of serious opposition to the bill that became the Sony Bono Copyright Term Extension Act of 1998 in the US as evidence of this persistent asymmetry (Landes and Posner 2004). Informal policies and actors that promote them are a key source of self-reinforcing behaviour that impacts on the emergence and development of legal doctrine.

Incrementalism and Uncertainty Associated with Patents

A direct consequence of the imprecise nature of patents as property rights, the inherent opacity of value and the resulting uncertainty is the incremental nature of doctrinal development here. Given the risks of formulating law under new circumstances, learning behaviour and adaptive expectations are prominent in the patent system. Satisficing and incremental changes to legal doctrine are the norm. Reform takes place in small, operational chunks and reasoning is often by analogy rather than through the mooting of radical ideas. Furthermore, there is no central organising principle (like price in economic markets) to evaluate performance in the patent system except perhaps for 'legal certainty', which functions as a status quo bias. Herein lies the possibility that incrementalism could lead through a series of sequences that are difficult to reverse to path dependence in the patent system. Radical ideas that might reverse the direction are difficult to formulate given the reasoning process in law, which is inherently skewed in favour of past sequences.

The opacity of patents as property rights leading to considerable uncertainty (Thambisetty 2007b; Bessen and Muerer 2008), is one of the key reasons why incremental changes are more likely than radical ones. Patents carry considerable intrinsic and extrinsic opacity. Extrinsic uncertainty in patents is a result of an attribute of knowledge that makes it 'lumpy' (Long 2002). Some patents are very valuable, while some are worth almost nothing – this makes firm patent totals a very noisy indicator

of the underlying economic value of the innovations (Hall et al. 2001). The principal problem that makes the intrinsic uncertainty qualitatively different from extrinsic uncertainty is the persistent inability to *quantify* the effect of novelty, inventive step, disclosure and breadth on a patent's economic value. The literature centres on parameters such as the number of times a patent is cited, the length of its renewal, or the number of countries where it is taken. Patent lawyers may often rely on their own judgment or experience to gauge or 'get a feel for' the overall quality of a patent based on various clues revealed by the patent and its file history (in fact, all methods of patent valuation involve some element of forecasting and speculation). This can be seen for example in the patent renewal process where even owners who make quick, unreasoned judgments make implicit valuation decisions in addition to the more explicit valuations necessary when considering licensing, litigation or sale.

To give two examples of incremental change, when biotechnology brought the prospect of gene sequence patentability most patent offices responded as though gene sequences were variations of chemical products, of which most patent offices had considerable experience by the early 1990s. This turn of events is credited with a number of oddities in the way in which genes are now treated in the patent system, including the reliance on structural elements rather than the 'information' nature of gene sequences (Eisenberg 2005). Similarly with the first cases of genetically modified animals, the EPO was inclined to grant expansive protection – a legal position developed from the fact that plant varieties had their own form of intellectual property rights whereas inventors of 'animals' could only rely on the patent system. This was used to justify patentability in spite of the exclusion of animal *and* plant varieties.

Patent law is often interpreted in a 'technologically specific' way (in spite of a monolithic legislative framework), some of which is common to the European and US systems. Illustratively, in both the US and at the EPO, high-level functional descriptions are sufficient to disclose a computer-implemented invention – disclosure of source or object code, flow charts or detailed descriptions of the patent programme are not required. By contrast, gene sequences have to be fully described even where such level of detail is unnecessary given what the notional person skilled in the field knows. Technological specificity originates in the patent office in examination guidelines although patent offices have no recourse to the judgement of contemporaneously active technological practitioners (Eisenberg 2004). Patent offices can also be expected to mimic the practice of other offices in comparable jurisdictions. Such 'borrowing' is an inevitable consequence of risk-averse patent examiners, who abandon a resource-intensive root and branch investigation of new legal standards in favour of an 'it-will-do'

solution (Thambisetty 2007b). Once established, basic understandings or orientations can become tenacious and the exit option far too costly (Pierson 2000a).

Interpretation of patent law in technologically specific ways also reinforces the agenda-setting power of the patent office and enables the operationalisation of substantive standards, leading to the possibility of what one commentator terms ‘the whitewashing of the formal criteria of eligibility in order to secure the patenting of potentially ineligible and otherwise unpatentable subject matter’ (Pila 2003). Technology-specific rules of interpretation in the UK and Europe for computer programs have led incrementally to a weakened subject-matter eligibility enquiry. Conversely, incrementalism in the patent system may also create opportunities for reform in favour of interests currently not well represented in the patent system.

Additionally, if the pattern of change is largely ‘operational’ and ‘incremental’ there is very little scope for alternate conceptual frameworks to take root and gain ground except in exceptional and revolutionary terms. Incrementalism in the patent system may thus also have the significant result of limiting the effect of ‘framing’ as a form of public dialogue in ‘which actors wishing to change political processes offer an alternative conceptual scheme through which to interpret those political processes’ (Drahos 2008).

The Skewed Nature of Patent Litigation

The fourth source of increasing returns is an aspect of the patent system that intensifies positive feedback. Conventionally, the ‘evolution to efficiency’ paradigm seems to describe a linear process where

(common) law evolves towards efficient rules because, *inter alia*, judges favour efficient rules, inefficient rules are litigated more often than efficient ones, litigants advocating efficient rules have greater incentives than those advocating inefficient rules to incur legal expenses that increase the likelihood of a favourable decision, and resorting to court settlement is more likely in cases in which legal rules governing the dispute are inefficient. (Hathaway 2001)

The above view of litigation as ‘efficiency facilitator’ is not supported empirically in the patent system (Lanjouw and Lerner 1997). The economics of patents often create a grave imbalance of incentives between a patentee and a potential challenger to the validity of the patent, with obvious repercussions not just for patent enforceability but also for the creation and continuance of appropriate doctrine. The rules and processes that survive and get entrenched are often the ones that survive the system of litigation itself, with its imperfect selection process.

The cost of litigation varies dramatically with the amount of money at stake. The fact that participants in high-stakes cases choose to spend more strongly indicates that by spending more a party can increase its chances of winning. Money and skewed incentives are the main reason why patent litigation is unable to weed out inefficiency (Farrell and Merges 2004). Patent litigation is different from a purely private dispute over a sum of money, where the stakes are alike for both parties. A patentee's incentive to defend his patent grossly exceeds an alleged infringer's incentive to challenge it. The asymmetry of stakes results from endemic aspects.

First, in the case of multiple infringers, patent invalidity judgments result in patents being turned into public goods. A patent attacker does not have the ability to exclude others from appropriating the benefits of a successful attack.

Secondly, there is the 'pass through problem'. When multiple infringers compete in a product market, royalties are often passed through at least in part, to consumers downstream. Therefore there is no economic reason to expect direct infringers to have appropriate incentives to challenge a patent even if they act collectively. Clearly, if one party's stakes in winning are far greater than the other's, that party is more likely to pull out all stops while irrespective of the merits of the case, the other party may be inclined to cut corners (Farrell and Merges 2004).

Thirdly, the incentive to challenge in the first place can be quite skewed. Losing a challenge can be a very different outcome from uncomplainingly paying non-discriminatory royalties, as challengers often find themselves subject to injunctions or less favourable licensing terms. Patentees can also charge differential royalties to penalise firms that do not settle early, all of which weakens the infringer's incentive to challenge in the first place (Farrell and Merges 2004).

Recent litigation in the UK demonstrates how a simple legal arrangement can further skew incentives to litigate. Following a decision to overturn a patent that was previously found to be valid, a defendant had to pay damages on a patent that was later held to be invalid and revoked (*Coflexip v Stolt Comex* 2004). Understandably, the defendants in the original action contended that it would be 'monstrous' if they were ordered to pay an enormous sum in respect of a wholly non-existent right.

Under UK law the decision on validity and liability for infringement had already become final and only the inquiry into the damages payable remained to be considered. Although such an inquiry in fact takes time, for all legal consequences it may be supposed to be instantaneous and to take place when the judgment is pronounced. The principal reason for such an obtuse outcome is to discourage defendants who having lost a patent action, seek to dig up better prior art and motivate another party

to attack the patent with a view to ‘get him off the hook of damages’. This kind of problem is an inherent feature of patent litigation because a patent is good against the world and therefore revocation is *in rem* and ‘any person’ can challenge a patent.

Given that invalid patents are a deadweight loss on society, it is desirable to keep the door open for further invalidity actions. Abuse of process would be rare because of the nature of patent litigation and the ‘uniquely life sapping horror’ (Cornish 2004) that it often represents. A defendant is unlikely to reserve his best piece of prior art for the next set of litigation when he stands to gain by revoking and being able to use the invention as soon as possible. The strength of patents as property rights depends on the efficacy of the litigation process and on maintaining the correct balance of incentives to litigate. *Coflexip* seems to have further tampered with this balance. As the dissenting opinion notes,

anyone not possessed of a strictly legalistic turn of mind would think it most unjust that Coflexip should be entitled to receive, and Stolt required to pay, tens of millions of pounds for infringements of a revoked patent, simply because Stolt, through misfortune, poor judgement or ineptitude failed to find the crucial prior art which has now been established as justifying the revocation of the patent. (*Coflexip v Stolt Comex* 2004 CA)

In the US litigation involving that ubiquitous technology product the Blackberry, highlights the shortcomings of patent litigation in weeding out property rights on invalid patents even where large sums of money are involved. A number of patents of US licensing company NTP Inc relating to radio frequency wireless text communication was held infringed by Canada-based RIM (Research in Motion), which runs the Blackberry service (*NTP, Inc v Research in Motion* 2005). A final injunction in favour of NTP would have forced RIM to shut down the Blackberry email service, affecting millions of customers in the US.

Following a director-initiated inter partes re-examination by the USPTO, several of NTP’s disputed claims were rejected. Nonetheless a settlement was reached in March 2006 where RIM paid 6.12 million US dollars to NTP in an out-of-court settlement, an outcome which the judge in this case seemed to encourage (Bodoni 2006). The invalidity of some of NTP’s claims did not prevent the early settlement because the patents remained valid until a final decision could be taken on NTP’s patents – a process that could take years (RIM 2006). Clearly, any ‘evolution to efficiency’ argument needs to be made within the context of institutional efficacy and competency, particularly as in the case of patent litigation, institutions often function under a patchwork of circumstantial constraints.

Litigation in the patent system ensures that the preservation of

irrational patent doctrine is a real possibility. One key example is the survival of the non-obviousness doctrine in *In re Deuel* (1995) in the US patent system (Ducor 1998). According to this case a novel chemical is inventive if there are no structurally similar compounds in the prior art. Proteins are not structurally similar to the DNA molecules. The fact that a person skilled in the art could have used known methods to isolate the DNA sequence from the amino acid sequence was according to the court, irrelevant to the enquiry as to whether the DNA sequences themselves were inventive.

Remarkably, this interpretation is sustained in the USPTO Utility Examination Guidelines (USPTO 2001b) despite the well-recognised rift in scientific and legal perception (Varma and Abraham 1996). The US Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation makes a telling observation on the institutional nature of this outcome:

[b]ecause it makes it easy for patent applicants to get past the nonobviousness hurdle, they have no incentive to challenge the rule, and after being repeatedly reversed on this point, the USPTO seems to have little interest in raising it again, even though advances in the art may culminate in a different result. (National Research Council 2006)

Clearly, in the patent system it is difficult to reverse 'sub-optimal' outcomes through litigation. When coupled with the desire for legal certainty, this results in a status quo bias for legal doctrines – once they emerge they are likely to be tenacious.

CONCLUSION

Increasing returns processes may impact on patent law in a number of ways. When a question is first raised in litigation, or new legislative measures are put in place, or unprecedented technology is presented to the patent office in patent applications, a number of legal interpretations of a particular provision are often possible. In such early contexts relatively small events, if they occur at the right time, can have large and enduring consequences on legal doctrine. 'Because earlier parts of a sequence matter much more than later parts, an event that happens "too late" may have no effect. Although it might have been of great consequence if the timing had been different' (Pierson 2000a, p. 263). Once an increasing returns process is established positive feedback will lead it to a single point that is resistant to change. As a positive agenda, increasing returns and path dependence allows us to identify the sources of stability and change. In particular it

highlights the meshing of interests and authority in the institutional cluster that makes up the patent system, the centre-piece of which is the powerful agenda-setting role of patent offices.

In using the framework presented here to choose and analyse legal doctrines, several points of caution apply. Conditions conducive to positive feedback are of differential importance throughout the life of legal doctrine. Thus increasing returns may be more prominent during the formulation of a policy than when it is operationalised and institutionalised. And not all sub-optimal outcomes will be the result of increasing returns processes. Further, analysis must be able to distinguish between the positive feedback driven by institutional factors and the impact of legal precedent. Often legal precedent only becomes an issue when the law is settled and there are clear and consistent decisions that can be followed. Increasing returns are likely to be important in the time before such precedents are set.

Nearly all of the literature on patent law doctrine is rational-actor based; however, prominent and interconnected sources of increasing returns in the patent system show the fallacy of assuming information about goals or criteria when it comes to formulating legal doctrine. Normative generalisations about what should happen are undercut by the dynamics of stability and change. Generally if we leave the unwieldy patent system to water-like 'find its own level', it is more likely than not to result in unintended, unforeseen and at times bizarre doctrinal outcomes.

This chapter explains continuity in the patent system while acknowledging implicitly that sometimes policies do change course and direction. Thus, although the costs of policy change in the patent system grow and grow and become prohibitive, the possibility of policy reversal suggests the presence of political actors, institutions and policies that alter incentives and thus push for policy reversal. Autonomous institutions that can trigger change have to be designed to be less subject to reinforcing processes, for example the NIH (Thambisetty 2007b). On occasion the US Supreme Court and the House of Lords do change course, and European Commission led Directives fail. Further, actors who get little for their efforts may, over a period of time, become available to reinforce coalitions that push for change – a phenomenon described exceptionally by Shadlen (2007 and Chapter 2 in this volume). The actors, features and critical timing of such policy reversal promises to be a fruitful avenue for future research and has to follow from a theoretical study of the relationship between path dependence and conditions of change. What this chapter has tried to do is to analyse continuity and the scarcity of change in the patent system in the face of widespread increasing returns.

NOTE

1. Here the term patent office is used generically. The operational term for the UK patent office is now the UK Intellectual Property Office.

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