REGULATORY INSTITUTIONS NETWORK (RegNet) **http://regnet.anu.edu.au**
Director: Professor Peter Drahos
Centre for Governance of Knowledge and Development
Research School of Social Sciences
Coombs Extension Building #8, Cnr Fellows & Garran Roads t: +61 2 6125 4241
The Australian National University f: +61 2 6125 1507
Canberra ACT 0200 e: Peter.drahos@anu.edu.au
AUSTRALIA

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The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Secretary,

I attach a submission for consideration by the Senate Community Affairs Committee for its Inquiry into Gene Patents. I have recently completed a study of the patent offices of 45 countries. The study looked at quality issues in patent office examination. My submission represents Chapter 11 of a book entitled, 'The Global Governance of Knowledge: Patent Offices and Their Clients' (to be published by Cambridge University Press).

Chapter 11 presents some conclusions of my study and includes a series of suggestions for improving the quality of examination in patent offices, especially in areas of high technology. These suggestions are of particular relevance to paragraph b of the Committee's terms of reference.

Essentially my study concludes that patent offices around the world have become part of a governance networked dominated by the multinational users of the patent system. As a result, patent offices are not meeting the obligations they have to their respective publics under the patent social contract.

The reform proposals being currently discussed in relation to the Patent Cooperation Treaty (PCT) in the World Intellectual Property Organization, if agreed to, may decrease Australia's capacity to do much about this problem. One proposal is that patent offices would become bound by the examination decisions of a small number of offices (two or three) operating as International Searching Authorities under the PCT system. Under this proposal it follows that the quality of Australian patents would be dependent upon the quality standards of overseas offices. One important issue for Australian policy makers to consider is whether it is better to maintain sovereignty over patent administration and look to ways to improve this administration as a matter of independent national innovation policy.

Yours sincerely

Peter Drahos

Professor in Law, RegNet, Australian National University and
Professor in Intellectual Property, Queen Mary, University of London.

SUBMISION TO THE SENATE COMMUNITY AFFAIRS COMMITTEE

GENE PATENTS INQUIRY

Peter Drahos

Professor in Law, Australian National University and Queen Mary, London University

(From Peter Drahos, The Global Governance of Knowledge: Patent Offices and Their Clients, Cambridge University Press, forthcoming)

11.

Reclaiming the Patent Social Contract

A Private Insider Governance Network

The 20th century proved to be the century of innovation in patent bureaucracy and the regulation of markets by patent owners using patenting strategies. Whether this staggering global growth in patent bureaucracy and patent regulation of markets actually caused much important scientific and technological innovation that would otherwise not have occurred, and at a cost that did not outweigh the benefits, is a question to which we will probably never have an answer. More often than not, analysis of the patent system begins with a presumption in its favour: "High levels of innovation in the United States would seem to be evidence that the intellectual property system is working well and does not require fundamental changes".[1]

[1] Stephen A. Merrill, Richard C. Levin and Mark B. Myers (eds), A Patent System for the 21st Century, National Academies Press, Washington, D.C., 2001, 19.

At the beginning of the 19th century few European states had patent law and none had recognizably modern systems of patent administration (see Chapter 3). At the beginning of the 21st century it is hard to find an example of a country that does not have a patent law of some kind on the books – Timor Leste is perhaps one example. Even in some of the poorest, smallest states such as some of the Pacific Islands, there are patent laws on the books that technically, as we saw in Chapter 10, form part of global patent filing routes. No island seems to be without a patent law. Larger patent offices such as the Australian PO trawl the region offering assistance, showing up in places like Palau much to the surprise of officials there. "We don't invent anything", one Palau official pointed out to me. In the eyes of the patent system this is true. These islands are seen as sites of raw materials where, for example, visiting marine biologists come to take samples to feed the laboratories and patent filing systems of places like the National Cancer Institute in the US.

Patent law and, much more importantly, supporting systems of patent administration now enmesh states and their systems of innovation. The growth of patent bureaucracy has become a self-sustaining enterprise. Patent offices generate fees that they keep or which are returned to them by governments for the purposes of running and spreading patent administration. As we have seen, the major offices at relatively low cost integrate developing country offices into their systems - the EPO drafts examination manuals for developing countries and trains examiners in their use, and the USPTO brings examiners from India and Brazil to its training facilities in Alexandria, Virginia and helps them understand the art of pharmaceutical examination.[2] In exchange for some manuals and

[2] For example, the EPO drafted the examination manual for the Philippines Patent Office. Information about the USPTO's training of developing country examiners was obtained from the USPTO.

hardware, developing country offices extend technocratic trust to the large players in the system. A global system of patent governance is being forged at modest cost.

The scope for institutional experimentation with the patent system is much diminished compared to the 19th century. No country today can do what the Netherlands did in 1817 and repeal its patent law. Developing countries have even less freedom to operate when it comes to the patent institution. As Thailand has learned, even a modest use of the principle of compulsory licensing in relation to medicines attracts a "shock and awe" response from the international pharmaceutical industry and its many Congressional apparatchiki. Within developed countries what passes for patent reform is a game of inches concerning, for example, the right level at which to set the standard of inventiveness. But if the patent institution is fundamentally inefficient, this will do little to improve its efficiency, any more than a percentage point drop in agricultural tariffs will help liberalize trade in agriculture.

At some point the need for radical design approaches to the patent system will be taken more seriously by states. Generally speaking, regulatory reform is crisis driven.[3] Nuclear power plants have to experience meltdown and oil tankers have to spill millions of tons of oil before there are improvements in the regulation of nuclear power and shipping. It is also clear that these disasters must affect the well-off in developed countries. Poor people dying in large numbers in developing countries gains comparatively little regulatory action amongst western policy elites when it comes to the international patent regime, although these days it does generate a lot of placatory ritualism such as the WTO's so-called

[3] For a survey see J. Braithwaite and P. Drahos, Global Business Regulation, Cambridge University Press, Cambridge, 2000.

Paragraph 6 solution in relation to the access to medicines problems of developing countries.[4]

Over time the patent system's inefficiencies in the innovation and diffusion of medicines will create greater access problems in developed countries. Climate change may also prove to be a rather big exogenous variable for those who guard the patent system with the intensity of zealots. For the purposes of managing climate change, states will want faster innovation and diffusion of alternative energy technologies, plants for food and agriculture and technologies for efficient water use. And, of course, climate change may cause changes in the geographic spread of pathogens and diseases. Colonization by Europeans from about the 16th century spread diseases to many developing countries that assisted in, for example, the conquest of the Aztec empire.[5] Climate change may enable those countries to return the favour of new disease burdens. The patent system in its present form is a risk factor, rather than a tool of risk management for handling these kinds of large scale changes and crises. The system has an appalling track record in producing medicines for tropical diseases.[6] In the case of avian bird flu the WHO recommended the stockpiling of oseltamivir, a drug that was under patent. As a result, the patent system produced an outcome where the highest risk countries had the smallest stockpiles and the lowest risk countries the biggest.[7]

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[4] For an analysis see P. Drahos, 'Four Lessons for Developing Countries from the Trade Negotiations Over Access to Medicines, 28, (2007), Liverpool Law Review, 11.
[5] R.A. Weiss and A.J. McMichael, 'Social and environmental risk factors in the emergence of infectious diseases', Nature Medicine Supplement, 10(12), (2004), 570, 572.
[6] Thirteen of the 1,223 new chemical entities between 1975 and 1997 related to tropical diseases. See Zafar Mirza, 'WTO, TRIPs, Pharmaceuticals and Health: Impacts and Strategies', Development, 42 (1999), 92, 95.
[7] Buddhima Lokuge, Peter Drahos and Warwick Neville, 'Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?', Medical Journal of Australia, 184(1) (2006), 16-20.

Today's globalized patent institution was never designed by states as a tool for the management of risk. Historically speaking, the principal players that have most influenced the evolution of the current system of governance have been the big business owners of patents, the patent attorney profession and the lead states in terms of patenting. At the end of 19th century, the lead patenting states (US, UK, Germany and France) took the decision to support the patent system not for reasons of public welfare but because of its importance to state power (see Chapter 3). Since that time patent systems have become evermore sophisticated systems of private taxation serving the interests of a few large users (see Chapter 1). At the beginning of the 21st century most states, with one or two notable exceptions, are not bent on war. They want economic development. But increasingly they realize that they must be careful that this economic development does not cause environmental systems to beginning tipping like so many dominoes. The warnings and analysis of the International Panel on Climate Change have gained the attention of most governments around the world. But predictably, as in so many negotiations before, intellectual property rights and technology transfer issues are causing divisions amongst states.[8] More than ever states need a patent system that diffuses innovation and serves global risk management goals rather than beggar-thy-neighbour trade agendas.

Patent systems in their present form represent deep concentrations of power and dominance in which networks of big business, patent attorneys and patent offices co-operate to produce an insider governance of the system. The global patent office network that has been described in the preceding chapters is not one that is devoted to benign technocratic management "enhancing the ability of States to work together to address common

[8] See Summary of views expressed during the Fourth Session of the Ad Hoc Working Group on Long-Term Cooperative Action under the Convention, FCCC/AWGLCA/2009/3, 18 March 2009.

problems".[9] As we have seen patent attorneys and patent offices have over the decades colluded in the development of patent claim drafting techniques to overcome publicly mandated restrictions on patentability (see Chapter 2). The USPTO, the EPO and the JPO formed the Trilateral Offices club in the 1980s to steer the system in ways that were responsive to the needs of the big business users (see Chapter 6). These three offices operate within international fora like WIPO to push patent treaty harmonization agendas that developing countries oppose. They circumvent this opposition by integrating developing country patent offices into their systems and training their examiners to follow their examination decisions (see Chapters 4 and 10). Through technocratic co-operation they bring about a process of invisible harmonization (see Chapters 1 and 6). In the name of capacity-building they foster simple imitation. No state, no matter how poor, is left without the benefits of this capacity assistance (see Chapter 10). The patent office network is a pervasive network that over time has come to dominate the national level of policy approaches to patents, with members of the network representing states in patent treaty negotiations as well as bilateral and multilateral trade negotiations that cover intellectual property. Its members share a common business model that has made them dependent on their big business customers. They have largely abdicated their responsibilities to their respective publics under their respective national patent social contracts.

The words of one senior insider are worth quoting at length:

> However, it is remarkable that considerations on the benefits of patent protection for the world community or individual economic areas are lacking to a large extent.

[9] Anne-Marie Slaughter, The Accountability of Government Networks, 8 (2001), Indiana Journal of Global Legal Studies, 347.

> Tons of paper are produced but the results are very poor. The concerns of the developing countries and transitional countries are not responded to seriously, particularly the formerly frequently asked question about an effective transfer of technology, or the present demands for the integration of the assets of those countries into the patent system and international trade. Rather, serious discussions are taking place about strategies on how to by-pass developing countries and transitional countries, which could lead to a closed shop of a few giants.[10]

There are, of course, public accountability mechanisms for patent offices. As we have seen in preceding chapters, they are part of public service department structures and the heads of patent offices are ultimately answerable to politicians, such as the ministers who in parliamentary systems are responsible for government departments. However, the formal mechanisms of public accountability that operate here are meaningless. Patent rules do not get decided at the ballot box. Tax, law and order, and health services are the stuff of election campaigns. Patents are not. The patent system is so densely technocratic that politicians do not take the lead on patent policy unless an industry lobby dictates a clear direction, as did the industry lobbies that led the US Congress and the Executive in the process of bringing about TRIPS.[11] The real accountability of patent offices lies with the private governance network of the large businesses that dominate patent applications. It is no surprise that the interviews showed that every patent office is in constant communication with its business users. Every patent office proposal for reform is carefully

[10] Jürgen Schade, Europe and the International Community of States on the Path Towards a Common Patent Strategy, 38 (2007), International Review of Intellectual Property and Competition Law, 517, 520. Dr Schade is the President of the German Patent and Trade Mark Office.
[11] See P. Drahos with J. Braithwaite, Information Feudalism, Earthscan, London, 2002.

scrutinized by the patent attorneys that represent the large players. The business networks that surround patent offices are amongst the most watchful and expert in the world.

The displacement of public accountability mechanisms by private networked power is, in the case of patent offices, not a new phenomenon. Business networks have been coevolving with patent offices for at least a hundred years (see Chapters 1 and 3). Public accountability mechanisms are the convenient front men of legitimacy. They help hide the fact that an organization created to represent the public under a social contract has become deeply intertwined and absorbed by a private governance network. The customer mentality that pervades patent offices makes their role in the network seem perfectly natural. The symbiotic relationship which has developed between patent offices and big business users and the depth of their networked communication with each other mean that genuinely welfare-enhancing reforms of the patent system are, for the most part, likely to fail. Ministers are too ignorant or too worried about offending the global end of the corporate world to be serious about reform. Patent offices know that if they repeat the litany that more patents equals more innovation, most politicians are simple-minded enough to believe it. The few others who are sceptical about the efficiency of patent monopolies nevertheless listen when, for example, a large pharmaceutical company screams that the right to delay and divide patent applications is a precious natural right needed for research and development purposes.

A Counter Network of Outsiders

The basic problem of the patent system can be simply stated. Standard-setting and administration of the system is dominated by a globally integrated private governance network. This network has made the patent social contract largely meaningless. More rule-based reform of the system will simply see this private governance network continue to bend the process of rule-making to its own ends. What is needed to counter the power of this network is another network made up of outsiders to the patent system. The only way to counter the power of one network is with another network. The outsider network needs to have the technocratic skill to confront the insider network. Confrontation has to be constant and detailed. Each patent rule change proposed by the insider network to serve its private interest should be tracked and fought by an outsider network serving the public interest. The thousands of patent grants that daily pour out of the major patent offices must be assessed for social harm and ways found to eliminate the most damaging patents or to contain their effects.

General accountability mechanisms such as ministerial responsibility cannot provide the kind of close oversight that is needed of patent office decision-making. Instead, there has to be a long term strategy based on building a counter network to the private governance network that has absorbed patent offices. This counter network should be guided by the separation of powers principle, something we discuss in the next section. The basic idea is to contest the power of the private network at every point where key decisions are made and where possible to create veto rights or checks over patent office decisions. An example of a veto model is the Brazilian model in relation to pharmaceutical patents where examiners in the Brazilian PO do not have the final say over the grant of a pharmaceutical

patent, a model we discuss in the next chapter. An example of a checking mechanism is the external audit mechanism for patent quality that is proposed later in this chapter.

The future of the patent social contract depends on the formation of an outsider governance network. There are many outsiders – government departments such as health departments and environment departments, competition law authorities, civil society organizations, technology movements interested in patent free innovation (for example, the free software movement), science researchers who still subscribe to public good values, university administrators who still have some sense of the public good mission of universities, companies on the receiving end of patent bullying and litigation, indigenous groups fighting biopiracy, farmer groups opposed to patent locks on seed varieties, and many others There are many more outsiders than there are insider beneficiaries of the patent system. One of the fundamental problems facing outsiders is a basic lack of information about the patent holdings of the few powerful beneficiaries of the system. Information about granted patents is public information, but it is not available in publicly useful ways that enable the forensic scrutiny of those patents by interested outsiders. Exposing and isolating those patent holdings in ways that are accessible to the many interested outsiders is a first step. The transparency register proposal discussed later in this chapter presents a model of enforceable transparency for this purpose. Revealing concentrated power in a democracy begins the process of separating that power. Exposure of power by itself is not enough. States interested in reclaiming the patent social contract have to help to create the veto and checking systems that will enable outsiders to deal with the patents that cause social harm. Many outsiders have the technical knowledge and the interest in confronting the private governance network that runs patent systems. However, few can afford the

costly battlegrounds of courts. States need to create low cost tools that will help outsiders to create a contest of networks.

Before moving on to outline some tools of engagement, it is worth asking whether there is the political leadership that is needed to take on the sophisticated private governance network that rules the patent system. Here it is worth pointing out that competitive political environments will from time to time create circumstances in which politicians will have incentives to act in the public interest and contribute to the building of an outsider network to regulate the patent system. Later in this chapter we will see that the Australian Parliament passed an amendment to its Therapeutic Goods Act that addresses the problem of patent gaming by brand pharmaceutical companies. This legislation was pushed through by an opposition that was in a position to control the Australian Senate at a time when the Australian government was seeking to implement the US-Australia Free Trade Agreement. Contained in the agreement were provisions affecting Australia's Pharmaceutical Benefits Scheme (PBS).[12] The PBS was widely regarded as the gold standard for regulating the patent monopoly prices of pharmaceuticals. But the PBS was also disliked by the US pharmaceutical industry and so it took the opportunity of the free trade negotiations to begin the process of dismantling it.[13] A small group of academics and activists pointed to the potential cost implications of this for medicines under the PBS.[14] Their warnings were picked up by the media and there followed a mass public concern about the future of the

[12] See Annex 2-C Pharmaceuticals, US-Australia Free Trade Agreement.
[13] For the details see Peter Drahos, Buddhima Lokuge, Tom Faunce, Martyn Goddard and David Henry, Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US-Australia Free Trade Agreement, 22 (2004), Prometheus, 243.
[14] See, for example, Peter Drahos, Thomas Faunce, Martyn Goddard, David Henry, 'The FTA and the PBS', A submission to the Senate Select Committee on the US-Australia Free Trade Agreement, available at http://www.aftinet.org.au/campaigns/US_FTA/henrydrahossenatesub2.htm.

PBS.[15] The opposition leader Mark Latham donned the cape of the people's health champion. Announcing that he would not let "dodgy" patents limit people's access to medicines under the PBS, he tabled amendments that aimed to deter pharmaceutical companies from patent gaming behaviour.[16] These amendments were passed.[17]

The outsider network for patent governance that needs to be built will not be built overnight. But broader political interest in the patent system has advanced much further than anyone would have predicted two or three decades ago. From time to time politicians will have incentives to act as the people's champion when it comes to fighting patent monopolies. Good ideas for the outside regulation of the system will be put in place and an outsider governance network will continue to evolve.

The separation of powers principle

The design principle that can reshape the insider governance described in the last section and that matters most to the future evolution of the patent system is the principle of the separation of powers.[18] It is an important idea in Western political tradition, perhaps the most important. Conceived of broadly, in the way that it is in *The Federalist Papers*, it

[15] Particularly important in bringing the attention of the public to the issues was the documentary "A Bitter Pill" that was broadcast by the ABC Four Corners on 2 August 2004.
[16] See http://www.abc.net.au/7.30/content/2004/s1169988.htm.
[17] See US Free Trade Agreement Implementation Act 2004, Schedule 7.
[18] On the importance of the principle to regulatory theory see John Braithwaite, On Speaking Softly And Carrying Big Sticks: Neglected Dimensions Of A Republican Separation Of Powers, 47 (1997), University of Toronto Law Journal, 305.

requires power to be divided and regulated by a system of checks and balances. Institutional designers guided by it must work towards limited and decentralized structures of power, or to borrow Madison's description of its application to public and private affairs, "the constant aim is to divide and arrange the several offices in such a manner as that each may be a check on the other – that the private interest of every individual may be a sentinel over the public rights".[19] Many principles of governance and regulation, such as the principles of transparency, accountability and audit, serve this fundamental political value.

Systems of patent administration have grown dramatically and in ways that have seen the rise of networked power. It is true that the traditional patent powers, the EU and the US have been joined by Japan first and more recently China and Korea. But as we have seen, the network remains a hierarchical network and even though its dominant core has been expanded its pro-patent values and goals have not changed. The first step in genuine patent reform is to break up these concentrations of power, to flip the system from insider governance to a networked governance that contests patent-based technocratic expertise by drawing on innovation expertise from many communities of innovators. The remainder of this chapter discusses regulatory ideas that draw on the principle of a separation of powers and are aimed at making the system more responsive to communities of innovators.

New Insiders for Insider Governance

[19] James Madison, Alexander Hamilton and John Jay, The Federalist Papers (Isaac Kramnick ed.), Penguin, Harmondsworth, 1987, 320.

Patent offices typically have policy committees or advisory committees. These committees usually have a heavy representation from business and the patent attorney profession. If there is broader representation it is usually token. Insiders have little incentive to raise critical questions or issues in the development of patent office guidelines. Rather, the focus is on productive efficiency, on making it easier, cheaper and faster to obtain patents. Questions of fundamental principle do not get raised. For example, biotech patent attorneys and patent offices have little incentive to ask whether, as a matter of legal principle, purified biological materials substantially identical to those that occur in nature actually do cross the threshold of 'invention' so as to be eligible for the grant of a patent. Both parties have a financial incentive not to do so. Biologists working in public research institutions may have different views of the invention threshold. Similarly, drugs that have been patented as a combination of left and right hand molecular structures are being re-patented by pharmaceutical companies as either left or right-handed drugs.[20] The real question that society wants an answer to is not whether this is inventive as a matter of patent law jurisprudence, a jurisprudence that has been paid for by decades of pharmaceutical company litigation, but rather whether it is innovative as judged by the community of experimental pharmacologists, a community which tends to look for genuine leaps in therapeutic benefits rather than clever marketing strategies. In a world of networked governance, power grows less out of the barrel of a gun and more from the long occupation of a seat on a key committee. It follows that one element of a strategy to dismantle the insider governance of patent systems is to look at the composition of the committees that guide the development of patent offices systems. Patent office committees need to be connected less to the patent attorney profession and more to communities of

[20] See A. Somogyi, F. Bochner and D. Foster, 'Inside the isomers: the tale of chiral switches', Australian Prescriber, 27(2), 2004, 47.

innovators or groups like economists who understand the social costs of patent intervention in the marketplace. One way in which to build this connection is to put significant numbers of members from these communities on patent office committees.

An External Audit Check

Well-resourced patent offices have internal procedures for checking the work of examiners (for example, the EPO has a Quality Audit Directorate). It is also true that the Trilateral Offices have devoted considerable resources to improving their internal procedures for checking patent quality and have developed process measures of patent quality. In many developing country patent offices I interviewed, the Thai PO being one representative example, there was no real system of checking the quality of examination work. The head of an examination section would review some of the work of the section. The story in the Thai office was the familiar one of training by the EPO with Thai examiners following the examination decisions of EPO examiners. One argument might be that Thai examiners by doing this are gaining the benefit of the EPO's quality standards and systems. But this raises the issue of whether the quality systems of developed country offices will necessarily meet Thailand's needs.

The experience of Thailand with the didanosine (ddl) patent, which is an important AIDS medicine, suggests that patent offices have to careful about the quality standards that they choose to follow. It also shows that there should be other regulatory mechanisms in place for generating information about the quality of patents. The patent on Dideoxy Purine

Nucelosides was a broad formulation patent and issued to Bristol Myer Squibb on 22 January 1998.[21] Claims over the way an active ingredient is formulated are accepted by many patent offices, including the EPO. Even old drugs such as paracetamol continue to be the subject of formulation claims in the EPO.[22] The likelihood of such a formulation claim being allowed by a patent office depends on how strictly one applies the requirement of an inventive step.[23] One effect of the issuance of the ddl patent in Thailand was that Thailand's Government Pharmaceutical Organization had to stop production of a generic version of ddl. Doubts about the validity of the patent led to a civil society campaign that included litigation to revoke the patent. The case settled in December 2003 and Bristol Myer Squibb withdrew the patent. Fighting this one patent involved a large number of government and civil actors in Thailand and dragged on for almost 6 years to produce a result in which the company simply withdrew the patent. The key issues on which civil society wanted a court ruling, issues concerning the circumstances of the patent's grant and its validity, were never ruled upon by a court. These kinds of patent litigation exercises require many civil society activists to co-ordinate and find resources to fight a case over a period of years. Thailand has historically had a vigorous NGO health movement and is one of the few developing countries in which a national civil society health movement could have mobilized in this way. Moreover, the reality is that this was a fight over just one formulation patent of doubtful validity. The example also shows the importance of having independent sources of information about the quality of patents in a country. During the

[21] Thailand's experience with the ddl patent is described in Regional Report: The ASEAN-Rockefeller Foundation Project on Intellectual Property Laws Review and Capacity Building on Intellectual Property Rights Related to Public Health in the ASEAN Region, ASEAN Secretariat, 2005, 267-71.
[22] See European Patent Application 07112327.7, Injectable liquid paracetamol formulation, filed 12 July 2007.
[23] For an argument that most formulation claims are likely to lack an inventive step see Carlos Correa, Guidelines for the examination of pharmaceutical patents: developing a public health perspective, ICTSD, WHO, UNCTAD, Geneva, 2007, 6-7.

litigation the Thai patent office came in for criticism because it intervened in the litigation in ways that favoured Bristol Myer Squibb.[24] This behaviour is consistent with the broader argument in preceding chapters that developing country patent offices have over a long period of time been steadily integrated into a private governance network. By virtue of this integration they will be disposed to behave in ways that are likely to be pro-patent and, in the case of developing country patent offices, that favour the rent-seeking practices of multinationals.

One way in which to combat the regulatory capture of patent offices is through the external audit of granted patents. Each year a committee of independent experts would target some key areas of patenting (for example, pharmaceuticals, software, biotechnology, nanotechnology) and audit the quality of a sample of patents in that area. This committee (labelled the External Patent Audit Committee (EPAC) in Diagram 11.1) would report its findings to a body independent of the patent office, such as, for example, a parliamentary committee. Legislators and ministers in many countries generally do not understand the extent of the regulatory capture of patent offices and tend to be excessively reliant on them for advice, advice that tends to be of a predictable kind. External audit mechanisms for patent offices would catalyse different information flows about patents to legislators, something needed in many, if not most, countries.

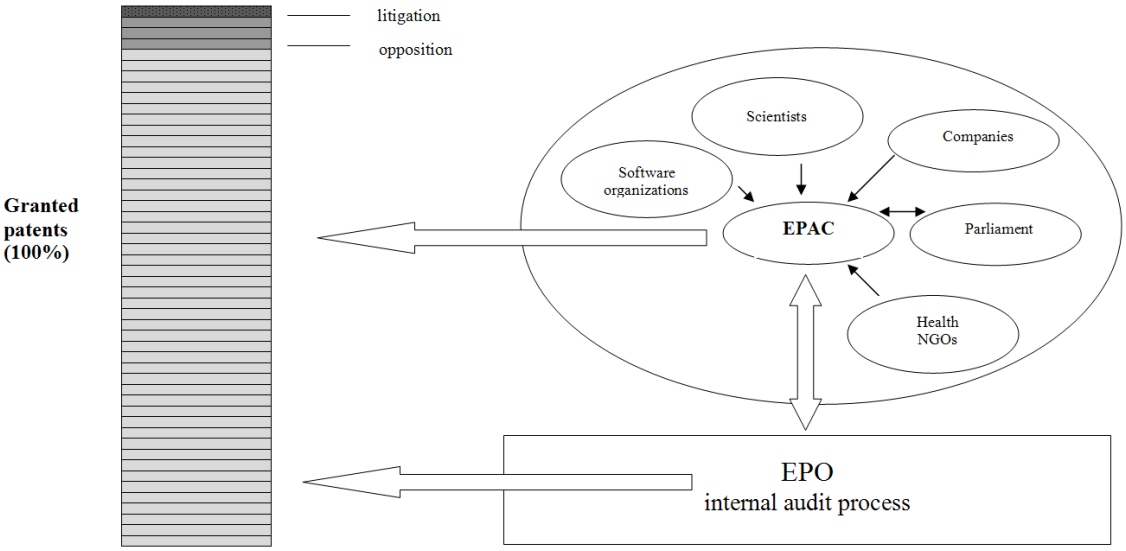
This audit mechanism could potentially be combined with other strands of governance to form a powerful tool of nodal governance. Courts and opposition procedures would

[24] See Regional Report: The ASEAN-Rockefeller Foundation Project on Intellectual Property Laws Review and Capacity Building on Intellectual Property Rights Related to Public Health in the ASEAN Region, ASEAN Secretariat, 2005, 270.

continue to act as quality filters, but as we saw in Chapters 1 and 2 these filters only reach a small number of patents. An EPAC would provide an additional filter. Companies, for example, encountering patent thickets could feed information to an EPAC so that it could focus its resources on problem areas. Patent offices would, of course, continue with their own internal audit procedures, but in the knowledge that an independent body would also be conducting audits of their work. Importantly, EPAC would also be an independent source of technical information for legislative bodies. The power of an EPAC to lead through suasion would itself be enhanced by appointing to it scientists with major international reputations who were prepared to defend the public good mission of science and who understood the dangers of low quality patents to that public good mission. So, for example, John Sulston a Nobel Prize winner in physiology has written about the dangers of patent office practice in the context of the patents on gene sequences.[25] Scientists like Sulston who understand where real innovation in molecular biology lies and the ways in which individuals in a community of innovators depend on each other's work to advance knowledge could, through an EPAC, foment a more public and rigorous scrutiny of patent office practice and its impact on innovation systems. National legislatures would be amongst the beneficiaries of the information flows about patents and innovation that could be catalysed by a high profile EPAC.

[25] See, for example, John Sulston, Intellectual Property and the Human Genome, in Peter Drahos and Ruth Mayne (eds.), Global Intellectual Property Rights: Knowledge, Access and Development, Palgrave Macmillan, Hampshire, 2002, 61.

Diagram 11.1 Patent Quality: An External Audit Check



Taking Transparency Seriously

The patent social contract justification recognizes the cumulative nature of innovation.[26] Inventor D will be better off if Inventors A, B and C have made their inventions public and Inventor E will be better off if Inventors A, B, C, and D have made their inventions public and so on. Keeping inventions secret means that inventors have less information and tools with which to solve problems. Yet, as we saw in our discussion of the patent social contract in Chapter 1, the patent system currently does a very poor job of making

[26] A cumulative model of innovation is thought to be true of many areas of high technology such as biotechnology. See Adam B. Jaffe and Josh Lerner, Innovation and Its Discontents, Princeton University Press, Princeton, 2004, 64.

information available to downstream inventors. A lot of information does not make it into patent specifications and the information that does is crafted in patent drafting language that is often of little use to scientific experts. Sometimes finding patents in the first place may be difficult. During the course of fieldwork I interviewed generic companies in Australia, Canada, Malaysia, Philippines, Vietnam and Thailand and all of them described a world of evermore elaborate patent strategies:

> "The patent issue is becoming exponentially more complex. There are patents around patents. There is less innovation from Pharma. They must extend patents around their basic products. No company can walk away from the compound." (CEO of Australian generic company)

> "There is second generation evergreening of patents with a much bigger family creation of patents taking place." (Australian generic company).

Litigation was one answer to this problem:

> "Only very aggressive litigation in Canada has been effective in dealing with linkage. Generics only get on the market after very aggressive litigation." (interview, Canadian Generic Pharmaceutical Association - linkage refers to provisions that link the registration of medicines to the patent system).

In Malaysia and the Philippines finding the patents initially was a problem, with some companies writing to the big pharmaceutical patent owner in an attempt to clarify the

position (interviews with members of the Malaysian and Philippines generic associations). Even though the medicines markets are small there is evidence of gaming behaviour. One Malaysian generic company provided me with a file on a medicine that had been patented in the US, the patent having expired in 2001. Generic companies had entered the US market. The US brand company had obtained a certificate for utility innovation under Malaysian law, giving it protection there until 2006 and the option of further protection until 2011. The Malaysian generic's application for the registration of its generic version had been rejected by the Malaysian National Pharmaceutical Control Bureau because of the certificate. Seeking advice from a Malaysian law firm it received a letter containing the usual impenetrable legal prose that concluded with "you could attempt to invalidate the Utility Innovation".

It is not only developing country companies that get the benefit of this kind of assistance from the legal profession on patents. A complementary medicines company I interviewed in Australia had dropped a vitamin product from its range in Australia because of an US formulation patent, on the basis of legal advice from its lawyers. Its General Manager said of the advice "to be frank I view it as arse covering". An Australian patent had not been applied for at the time of my interview.

From the point of view of the patent social contract, the uncertainty being generated by the patent system is not acceptable. The whole point of the patent social contract is that patents are meant to disclose invention information in order to enable competitors to enter a post-patent period of market competition. Obviously this cannot happen if relevant patents cannot be found in the first place or too many uncertainty-generating patents are found.

The patent social contract creates a very practical obligation for patent offices. They have to provide search systems and databases that will enable interested members of the public to find patents. Importantly, this is an obligation that rests with patent offices and not the market. Patent offices are, as has been stressed, society's agent. They are in the best position to know which patents have been granted and which have not because they are the granting agency.

The obligation of patent offices is not just simply to publish the patent specification. This would be to construe the obligation passively. The purpose of the patent social contract is to diffuse invention information. Simply to publish invention information in a patent office gazette is not the same as working towards actively spreading invention information. Turning patent offices from passive publishers into active diffusers of information requires patent offices to begin approaching their task much more like public libraries, finding creative ways to engage with very diverse user communities. The diffusion obligation of the patent office is not an obligation that is owed to a few high end wealthy corporate users of the patent system, but rather it is an obligation to society and to the many groups that are affected by monopolies over invention information. Patent offices obtain invention information from inventors by virtue of the operation of the law. Under the social contract they should provide it as a public good. Moreover, they should provide that information in ways that are useful to different user groups, ways that do not depend on patent searching expertise but rather more generalized skills of database searching. To date efforts in this direction have largely remained symbolic. The USPTO, for example, did make the text of

1,500 HIV/AIDS related patents available on line.[27] This is a step in the right direction but patents on many other needed medicines remain hidden in the system.

The beginnings of a much better approach to patent publishing transparency is to be found in the tables and datasets that have been developed by the US Department of Agriculture for patents in the area of agricultural biotechnology.[28] Amongst other things, these show the top 100 companies in terms of patent ownership and provide basic details of the patents that they hold. The data shows that as of 2002, 10 companies owned more than 40% of US agricultural biotechnology patents.

Why is it that patent offices are not much more active on the issue of patent transparency? Patent offices themselves have complicated relationships with commercial providers who obviously do not want patent offices investing in search systems that provide patent information as a public good and in a user friendly way.[29] These commercial providers make their living because patent offices fail to provide search systems that would allow members of the public a meaningful exercise of their rights to access invention information, rights that they hold by virtue of the patent social contract. In the past when patent offices have sought to improve patent information delivery services they have encountered criticism from private providers of those services. For example, the EPO's esp@cenet is a free search system designed for general public use. In Europe the industry association that represents private patent information providers has suggested that esp@cenet might be a

[27] See http://www.uspto.gov/web/offices/com/speeches/98-20.htm.
[28] See www.ers.usda.gov/Data/AgBiotechIP/.
[29] Richard Jefferson, 'Science as Social Enterprise: The Cambia BiOS Initiative', 1 (2006) Innovations, 13, 28.

market threat.[30] Oddly enough, the interviews showed that a number of developing country patent offices (for example, the Indian, Indonesian and Malaysian patent offices) were using it or had used it. This is one example of how such offices are not in a position to check the work of developed country patent offices which have much more sophisticated systems at their disposal.

Alarmed by the global transparency that the Internet and its search algorithms might deliver to publics around the world, the commercial providers of patent information services organized themselves into trade associations in Europe, the US and Japan, and then formed the Trilateral Alliance. The Alliance tracks and negotiates with the major patent offices the patent information that the public will be allowed to have for free.[31] Just as in the international patent standard setting game, the Trilateral Offices, when it comes to charting policies for the patent information game, find themselves being shadowed by a globally organized industry Trilateral (see Chapter 6 for a discussion of the Industry Trilateral for patent standards). In Europe the large commercial providers of patent information services, such as Derwent, are part of an industry association called the Patent Committee (PATCOM). PATCOM's website makes it clear that in PATCOM's view the EPO should limit its free offerings of patent information to the public: "Should they [patent offices] not concentrate on providing the raw data, and maybe stay with rudimentary public sites."[32] In the US, the private patent information providers have formed the Coalition for Patent and Trademark Information Dissemination and this Coalition keeps a careful eye on the USPTO's website, negotiating with the USPTO over any proposals it has for improving its

[30] See http://www.patcom.org/.
[31] On the work of the Trilateral Alliance see http://www.patcom.org/.
[32] See http://www.patcom.org/

website services to the public.[33] In Japan, patent information providers formed the Patent Information On-line Service Council. Like its European and US counterparts, this trade association has forged close links with the Japanese PO to ensure that the market position of Japan's patent information providers is protected.[34]

In theory it should be possible to have a technology platform that searched all the world's patents, allowing users to organize that information in various ways (around ownership, technologies, countries etc). The algorithms that run Google and Wikipedia would seem to suggest that we can achieve global levels of transparency for patent and invention information. As Richard Jefferson has observed, current levels of patent opacity really only serve the interests of patent law firms and patent database providers that "accumulate billable hours by providing the same information over and over for different customers, and charging full fees to update them periodically".[35] Jefferson's organization, CAMBIA (the Centre for Application of Molecular Biology in Agriculture), has shown what is possible when it comes to creating global patent transparency. Its Patent Lens system allows for simultaneous searching of USPTO, PCT, European and Australian patent information, including information about patent families in many countries. Patent Lens is a free service, available to anybody with an Internet connection.[36] If one small organization in Australia can advance the cause of global patent transparency as a public good this far, then perhaps patent offices are not trying very hard to do the same. The current level of patent

[33] For a discussion of the role of the Coalition see Joseph L. Ebersole, Patent information dissemination by patent offices: striking the balance, 25 (2003), World Patent Information, 5.
[34] For a discussion see Yutaka Wada, Recent developments in Japan's intellectual property industry, 27 (2005), World Patent Information, 31.
[35] Richard Jefferson, 'Science as Social Enterprise: The Cambia BiOS Initiative', 1 (2006), Innovations, 13, 28-29.
[36] http://www.patentlens.net/daisy/patentlens/patentlens.html

opacity does not serve innovation or goals of risk management. Those working on, for example, water technologies ought to be able to call up, in the time that it takes to do a search on Google, the patent maps and analyses that will affect their plans for such technologies. Global patent transparency is the foundation upon which other reforms of the patent system have to be built.

One reply to the argument that patent offices should become active diffusers of patent information as a public good is to say that the market provides these services through the countless commercial patent searching and advisory services that are available. But this reply misses the point. Costly market-based services only create a private transparency for their clients. Under the social contract the patent office has an obligation to work towards public transparency and diffusion. In that role it should be doing things that private agents do not. Currently patent offices offer free search tools for the purposes of searching their patent databases. Offering someone a search tool to access patented information, however, is not the same as actively promoting the transparency and diffusion of patented invention information.

We have seen that the patent system is, in effect, a system of private taxation. The details of this system of taxation, as with any system of taxation, need to be fully transparent. Patent offices should therefore track and publish the patent portfolios of patent owners, especially those with large patent holdings. The size of the patent-based fiscal empires of multinationals should be made socially transparent. This is, after all, information that belongs to the public. Patent offices are in the best position to develop this kind of transparency, which is the kind that commercial services will never deliver, any more than

tax havens will publish the tax affairs of those using their services. Putting it simply, anyone should be able to go to a patent office website and see the complete patent portfolio of a Microsoft or Pfizer in the country of that patent office, the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies. Scientists working in, for example, publicly-funded agricultural research institutes should be able to go to databases that communicate all the invention information relevant to their area and that provide a full picture of the granted patents around agricultural technologies. This is a minimum baseline of transparency that patent offices should meet. Those in the market would be forced to provide higher quality interpretive services. Patent offices should develop these kinds of databases in co-operation with user groups or other interested government agencies, but it is the patent office that has the primary responsibility under the patent social contract for diffusing patent information and so it is the patent office that bears responsibility for developing the databases. Simply offering free search tools designed for general public use or the occasional specialist database in an area like HIV/AIDS amounts to little more than organizational dissembling about a patent office's true obligations under the patent social contract.

During my interviews, a few patent offices conceded that they probably could do better in terms of diffusing invention information, but the overall impression was that the ideal of the patent social contract had assumed a rhetorical life, a flashy bit of language fit for the seminar room but not something that was relevant for the client-driven business life of a patent office. We saw in Chapter 1 that patent offices, through public sector reforms, have been increasingly turned into business agencies. As a result society now faces a classic

principal-agent problem in which the interests of the agent no longer fully match society's interests. Patent offices increasingly think in terms of business opportunities and less in terms of providing public goods. Patent offices, the UK PO and the Austrian PO being examples, set up commercial arms to their operations to run services like, for example, the express search service run by the Austrian PO in which at relatively low cost clients get rapid feedback on the novelty and inventiveness of their invention. Patent offices are more likely these days to be thinking about the commercial services that they can provide rather than the public good functions that they ought to be providing because of this business mentality. Making transparent, for example, the patent portfolios of the multinationals that are their best customers is not something that patent offices will willingly risk.

Following the argument put forward at the beginning of this chapter that what is needed is a counter network to contest the decisions of the private governance network of which patent offices have become a part, the next section outlines another possible element of that counter network.

Transparency Registers

Modern large scale patenting creates large-scale rule complexity that leads to uncertainty. Companies are often not sure that they have found all the patents relevant to a product on which they are working. They frequently have doubts about the scope of the patents they have found. Patents, unlike blocks of land, do not come with settled boundaries. These kinds of uncertainty are especially dangerous from the point of view of the public

management of risk, as the recent experience with Roche's patents and licences over oseltamivir illustrate. Roche's reluctance to disclose the patent situation in each country left public health officials confused as to what or what was not permissible in terms of the manufacture and importation of oseltamivir, the drug that the WHO has recommended as a frontline tool for dealing with an outbreak of avian bird flu.[37]

In order to deal with the complexity and uncertainty that is deliberately generated by the gaming behaviour of sophisticated players within the patent system, simple bright-line rules are needed.[38] One way to do this would be for regulatory agencies to establish patent transparency registers in areas of technology where there were serious risk management issues, and transparency concerning the patent situation was, to borrow the words of TRIPS, necessary "to protect human, animal or plant life or health or to avoid serous prejudice to the environment".[39] The scope of the transparency register's operation would be a matter for a regulator to decide as part of a risk assessment exercise. A register could target, for example, research tools in biotechnology, particular classes of drugs, specific plants or genes, or technologies of major importance in mitigating or adapting to climate change. The use of registers would not, in other words, be confined to a particular type of technology. Companies would be required to use the registers to make a full disclosure of the patents and patent applications surrounding the targeted technology. Other companies would be able to rely on the register knowing that there were no other hidden surprises for them. In addition, the registers would require the disclosure of information relating to

[37] Buddhima Lokuge, Peter Drahos and Warwick Neville, 'Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?', 184 (2006), Medical Journal of Australia, 16.
[38] For a philosophical defence of simple rules for dealing with complexity see Richard A. Epstein, Simple Rules For A Complex World, Harvard University Press, Cambridge, 1995.
[39] Article 27(2) of TRIPS.

ownership and licensing. This information is in practice difficult to track down. Private clearing house mechanisms have failed to provide this information in any systematic way.

The cost to a company of not disclosing on a transparency register a patent that it should have disclosed could be some form of estoppel that would prevent it from enforcing that patent. Some companies might respond by flooding the transparency register with patents. In the pharmaceutical sector it is clear that a transparency register would force the disclosure of a large number of patents. For example, the European Commission in a recent inquiry found that a single blockbuster medicine could have up to 1,300 patents or patent applications surrounding it and that many of these patents are applied for towards the end of the period in which the first patent expires.[40] Since companies are rational actors, a deterrence mechanism could be used to overcome this potential problem of flooding a transparency register. A patent put on the register containing claims that could not be shown to have reasonable prospects of enforcement by a court in an infringement action could be taken off the register. Procedures for removing patents from a transparency register would be swift and administrative in nature. They could be triggered by a regulator or a third party. If it were later proved that the patent owner had no reasonable basis for believing the patent or some of its claims to be enforceable, severe financial penalties could be imposed on the company. Patent attorneys would also be the target of prosecution since it would be they who had drafted the patent claims for patents on the register. Section 26C of the Therapeutic Goods Act 1989 (Australia), for example, imposes a maximum penalty of $10 million on companies in order to deter companies from using patents of doubtful

[40] European Commission, Pharmaceutical Sector Inquiry: Preliminary Report 28 November 2008, 150, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

validity as part of a strategy of preventing or delaying the registration of generic drugs. Much higher fines than these are needed, as well as criminal penalties.

In order to get the patent back on the register the patent owner would have to show that it had reasonable grounds for believing the patent to be valid. Once a patent was back on the register, its owner would be allowed to enforce it, including for acts of alleged infringement that took place between the patent's removal from the register and its restoration to it. The normal private law situation, in other words, would exist. The primary purpose of the register would be to force disclosure of a company's patents around a key technology and to deter it by means of the criminal law from using patents of doubtful validity to interfere in processes of public research or market competition in relation to that technology. Severe penalties and criminal sanctions would be used as deterrents to gaming behaviour. After the first few prosecutions, companies and their attorneys would think much harder about the patents they placed on the register.

Transparency registers would only need to be created by regulatory agencies in fields of technology where it was important to reduce the social costs of the uncertainty and complexity being orchestrated by patent owners. The key to the success of transparency registers would be to keep the rules that establish them simple and to place the onus of disclosure and judgement about patent quality on the person with the best information to make that disclosure and those judgements, namely the patent owner. The experience of the US with its Orange Book system for regulating the relationships amongst generic companies, brand-name companies, pharmaceutical patents and drug registration suggests that registers based on complex rule intensive procedures will create more opportunities for

rent-seeking behaviour.[41] A transparency register would simply require a company to disclose all the patents around a particular technology. Failure to put a patent on the register would mean that the company would not be able to enforce the patent. Placing low-quality patents on the register would have to run the gauntlet of a quick administrative procedure for their removal. The criminal law would be used to punish gaming behaviour.

Transparency registers could also be complemented by provisions that allowed governments to recover losses that they had sustained as a result of the gaming behaviour of companies. The Therapeutic Goods Act 1989 (Australia), for example, establishes the principle that a court can award the Commonwealth government compensation for any damage it has suffered as a result of an interlocutory injunction being granted to a patent owner for a patent infringement proceeding that ultimately has no reasonable prospect of success.[42] The foundational principle that crime should not pay has seen governments around the world enact criminal and civil forfeiture laws to confiscate the proceeds of crime.[43] Civil forfeiture laws operate on the basis of the balance of probabilities and a reversal of the usual onus of proof ie on the person challenging the forfeiture order. There is every reason for governments to begin thinking about legislation dealing with the proceeds of patent gaming. The sums of money involved are vast. For example, the European Commission found that in the period 2000-2007 the cost of delaying the entry of generics amounted to about €3 billion. [44] Most of the delay was due to patent gaming.

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[41] See Federal Trade Commission, Generic Drug Entry Prior To Patent Expiration, 2002.
[42] See Sections 26C and 26D.
[43] Julie Ayling and Peter Grabosky, 'Policing by Command: Enhancing Law Enforcement Capacity Through Coercion', 28 (2006), Law and Policy, 420, 430.
[44] See European Commission, Pharmaceutical Sector Inquiry: Preliminary Report 28 November 2008, 189, 8, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

A national regulator setting up a transparency register in one country might also provide a spillover benefit to a regulator in another country. Competition law authorities in the US, for example, might be interested in the use of patents granted in other jurisdictions that adversely affected competition in the US market. Information that was generated through the establishment of transparency registers in Australia or Europe might help US regulators.

Judgements about the quality of patents on the transparency register, in most cases, would not be hard to make. The fact that generic companies have prevailed 73% of the time in patent suits under the Orange Book system suggests that for a significant number of patents the judgement about their quality is relatively straightforward.[45] The European Commission in its study found, when it looked at the litigation between generic and originator companies concerning the many secondary patents surrounding the basic drug, that generic companies won 75% of the cases that went to final judgement.[46] The Commission also obtained evidence that originator companies deliberately used patents known to be of doubtful validity to slow down the entry of generic companies into the market. Currently, however, there are incentives for companies to obtain such patents (especially in many developing countries where the prospect of patent litigation is less) and no real costs in doing so. Creating transparency registers would be one way of changing the cost-benefit calculation for companies when it came to pursuing low-quality patents. Imposing criminal sanctions on the members of the patent attorney profession would be an important part of this strategy. They are crucial players in helping pharmaceutical

[45] See Federal Trade Commission, Generic Drug Entry Prior To Patent Expiration, 2002, 16.
[46] European Commission, Pharmaceutical Sector Inquiry: Preliminary Report 28 November 2008, 189, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

companies to game the system in much the same way that tax accountants and lawyers help companies to evade taxes. This line of argument is expanded in the next section.

The argument that in some jurisdictions, such as the US, transparency registers are not needed because companies have private sophisticated searching techniques for patents is not an argument against transparency registers.[47] This argument does not apply to many local companies in developing countries that do not have access to these searching techniques. But even in the US there are many more groups interested in patent transparency than just companies. Obligations of patent transparency and disclosure lie at the heart of the patent social contract. The transparency demanded is a social transparency, not private windows of transparency only available to the well-heeled. Health NGOs, citizen groups, regulators and those working in public policy should not have to bear the costs of remedying the uncertainty generated by the gaming behaviour of patent owners. Transparency registers are one way in which to reduce this uncertainty.

Finally, it is worth noting that transparency registers might gain support from politicians in charge of health departments. Politicians that oversaw the successful implementation of transparency registers to speed up legitimate generic entry into pharmaceutical markets would be making large savings to health budgets. More politically tradeable esteem might also flow to politicians who were able to preside over the successful use of transparency registers to recover money from pharmaceutical companies caught gaming the system. In

[47] For the suggestion that companies in the US do not need the notice function of the Orange Book because of private search techniques see Federal Trade Commission, Generic Drug Entry Prior To Patent Expiration, 2002, 54.

the pharmaceutical context, there is the possibility that transparency registers might help to catalyse calculations on the part of politicians that served the public interest.

'The Ticket Clippers' - Regulating the Patent Attorney Profession

It would be impossible to run the patent system without the patent attorney profession. Every examiner dreads the inventor who is convinced that he has invented something major such as the perpetual motion machine and is prosecuting his own patent application. During the interviews the word nightmare was used more than once to describe such cases. All the developed country patent offices that were interviewed agreed that a competent patent profession was critical to running a patent system. Patent officials from developing countries identified a lack of patent attorney expertise as one of the reasons that locals did not use the patent system. Patent attorneys and examiners participate in a dance in which both are highly familiar with the technical steps, and both know that if the steps are followed there is a good chance that the dance will lead to the grant of a patent.

Maintaining good relations with the profession was a priority for all the developed country patent offices that were interviewed. All had systems of regular communication in place with the profession, these systems involving joint committees or fora in which meetings between patent officials and representatives from the profession take place. Senior patent officials use the opportunity of regular meetings with the profession to float ideas and proposals for reform in order to get informal feedback and reaction from representatives of the profession. Patent offices also survey patent attorneys in order to assess customer

satisfaction. In many cases the patent office, the Canadian PO and the NZ PO being examples, is involved in the process of qualifying patent attorneys.

Even if maintaining close and co-operative relations with the profession is a high priority for all the developed country offices I interviewed, one cannot say that all the offices were enchanted by the profession. Patent offices see a profession that in many jurisdictions is a tightly controlled monopoly squeezing rents out of business, often in exchange for comparatively little service - “a real bunch of ticket clippers” as one of my interviewees put it.

Patent offices also understand better than anybody that it is patent attorneys who drive the gaming of the patent system. It is they who advise companies on patenting strategies. It is the patent agents who are the source of ‘creative’ claims drafting that slips past the restrictions in law on patentable subject-matter. And it is they who make applications longer, with more and more claims. All the developed country patent offices interviewed said that the complexity of applications had increased. This in turn makes more work for examiners. At the interview with the UK PO it emerged that the office had attempted to deal with the problem through a voluntary code of practice, but according to the senior examiners I spoke to there is little evidence that the code had changed the drafting practice of patent attorneys. The only advantage to the code was that it gave an examiner some basis for negotiating claims with the patent attorney. There was also the suggestion that this broad claiming strategy was in part being driven more by US practitioners than those based in the UK, one examiner pointing out that where the application is from a US client, the UK patent attorney is generally told to file the application as received by the attorney.

Perhaps the US is the centre of an aggressive patent drafting culture, but without a study of the patent professions of the major patenting countries it is hard to say. A more plausible hypothesis is that in a globalized economy with patent attorney firms servicing large foreign firms, there are strong incentives for those attorneys to do all that they can in order to get their clients the best monopoly weapon. In historical terms, the German pharmaceutical industry used aggressive patenting strategies to establish world-wide cartels.[48] The aggressive use of patents is a tradition not confined to the US.

In the EPO, attempts to regulate the number of claims by imposing a claim fee for claims in excess of a certain number have seen the profession counter with the single claim divided into many parts (interview EPO). Examiners, facing very large backlogs, would in interviews report these kinds of gaming strategies with a certain air of resignation and weary detachment. And yet, formally at least, some patent offices possess regulatory powers over the patent attorney profession and so are potentially in a position to develop an 'enforcement pyramid' strategy to deal with gaming behaviour by members of the profession.

In developed countries, the regulation of patent attorneys generally involves a combination of the patent office and a specialized body that represents members of the patent attorney profession and articulates rules of professional conduct (for example, a body like the UK's Chartered Institute of Patent Attorneys). A professional body that represents lawyers in general may also be part of the regulatory structure, although in a number of countries a

[48] P. Drahos with J. Braithwaite, Information Feudalism, Earthscan, London, 2002, 55-56.

patent attorney need not have qualified as a lawyer in order to be a patent attorney (for example, the Australia and the UK). Some patent offices will have, under their national law, the power to de-register a patent attorney, but in many countries the professional body that represents patent agents is involved in setting standards of conduct and disciplinary procedures.[49] Generalizing somewhat, patent agents in many countries do enjoy considerable self-regulation. In other areas of regulation, regulators armed with an ultimate sanction like deregistration have developed a regulatory approach that begins with dialogue, but ends with some sanction of incapacitation such as prison and/or deregistration if the regulatee proves resistant to all attempts to obtain compliance. The key idea behind the 'enforcement pyramid' is that punishment and persuasion should be linked in a certain sequence that begins with persuasion at the base of the pyramid and ends with the most punitive sanction at the apex of the pyramid.[50]

The cosy networked relationship between the professional bodies that represent patent agents and patent offices makes the implementation of an enforcement pyramid by a patent office not very likely. As the opening sections of this chapter suggested, what is needed in cases of network capture that has led to a structure of insider governance is an outsider governance network that shadows and contests the decisions of the insider network. The efficacy of an enforcement pyramid depends on finding a regulator other than the patent

[49] The Director of the USPTO has the power to exclude or suspend attorneys. See 35 U.S.C. 32. In the UK, the Secretary of State has the power to order the removal of a patent agent from the register under the Register of Patent Agents Rules 1990. But it is the Chartered Institute of Patent Attorneys that is the most important regulatory actor for patent agents. In Australia there is the Patent and Trade Marks Attorneys Disciplinary Tribunal established under the Patents Regulations 1991. The Director General of IP Australia is a member of the Tribunal.

[50] First put forward in John Braithwaite, To Punish or Persuade: Enforcement of Coal Mine Safety, Albany, State University of New York Press, 1985; see also I. Ayres and J. Braithwaite, Responsive Regulation: Transcending the Deregulation Debate, OUP, New York, 1992; J. Braithwaite, Restorative Justice and Responsive Regulation, OUP, NY, 2002.

office to administer the sanctions at the top of the pyramid. An independent regulator is needed to take the profession out of its comfortable zone of self-regulation.

The social cost of patent gaming by patent agents is very large. As we saw earlier, the European Commission's inquiry into the pharmaceutical sector showed that the cost of delaying generic entry into the market from 2000 to 2007, mostly by means of patent gaming, had cost about €3 billion. The social costs of patent gaming do not just occur in the pharmaceutical sector.[51] If patent gaming strategies were seen as unjustified private taxing schemes no one would doubt that the full force of the criminal law should be applied to the companies and the attorneys responsible. Fines and prison are a standard part of the tax regulator's tool kit when it comes to dealing with gaming problems in national tax systems and defending the integrity of the tax system. Famously it was the then US Bureau of Internal Revenue that put Al Capone behind bars. Every year the major tax jurisdictions send a small number of tax agents to jail for gaming behaviour that amounts to egregious tax evasion. There is no reason in principle why patent agents should not face the same kind of sanction for gaming behaviour that compromises the integrity of the patent system.

One reason that patent offices might be reluctant to develop a more robust approach to gaming by the patent profession is the absence of a broader social consensus when it comes to this kind of behaviour. Even if tax offices are not everybody's favourite regulator, in cases where the public purse has been defrauded of hundreds of millions of dollars tax authorities can count on a social consensus that the criminal law should be employed to

[51] For a discussion of the broader costs see Adam B. Jaffe and Josh Lerner, Innovation and Its Discontents, Princeton University Press, Princeton, 2004, Ch. 2.

punish the guilty. There is no reason why the use of the patent system to rob the public should not attract the same kind of moral condemnation.

The problem lies less in the absence of moral consensus about gaming behaviour that costs the public dearly in terms of access to essentials like medicines, and more in ignorance on the part of politicians, policy makers and the general public about the true costs of this gaming behaviour. Things might be different, of course, if these groups understood that the patent system has become a globally networked system of private taxation. Politicians might then be happy to take on patent reform in the way they are happy to take on tax reform. However, with little political leadership on patents, reform is left to the usual suspects – the large multinational users, the patent attorney profession and patent offices. Criminalizing gaming behaviour within the patent system would require a much greater transparency of the social costs of that behaviour, and it would also require a leadership to form some sort of social consensus around the use of the criminal law to proscribe that behaviour. This leadership is hardly likely to come from the patent attorney profession.

Some members of the profession might take refuge in professional ethics, arguing that patent gaming is a professional obligation. In the US, for example, Rule 10.83 of the Code of Federal Regulations for Patents, Trademarks and Copyrights, which is referred to as Canon 7, requires a practitioner to “represent a client zealously within the bounds of the law”. Rule 10.20(a) defines a canon as an “axiomatic norm”. Canon 7 does impose a duty to seek maximum patent coverage, but it is not an absolute duty. It is subject to the duty of

candour to the USPTO and it also requires the attorney to aim for a valid patent.[52] Attorneys can hardly argue that they have an ethical duty to undermine the patent social contract by striving for invalid patents. Ultimately, like so many legal duties, the duty to obtain maximum patent coverage must be applied by reference to a criterion of reasonableness. Patent agents must have reasonable grounds for believing that the patent claims they draft will upheld by a court. Some measure of uncertainty has to be allowed, otherwise patent attorneys will only draft the narrowest of claims. Escaping patent infringement would become too easy. But patent gaming is based on calculations in which it is known to a high degree of probability that particular patent claims will not be upheld by a court. As discussed earlier, both in the US and Europe brand name companies in the pharmaceutical sector consistently lose patent cases involving secondary patents that have been lodged just as the main product patent is about to expire. Patent gaming rests on combining probabilities in which even if there is an 8 in 10 chance of the patent being declared invalid, it makes sense to push on because there is only a 1 in 500 chance that the patent will be tested in court, or if it is, there is a good chance of obtaining a settlement or the loss of case is outweighed by the profits made in delaying generic entry. It is precisely this kind of calculation that the Australian Parliament was trying to deter when it amended its Therapeutic Goods Act requiring a patent owner alleging patent infringement to lodge a certificate (with penalties for a false or misleading certificate) stating that the owner was bringing the action in good faith and that the owner believed it had "reasonable prospects of success".[53] The legislation makes clear that the mere grant of the patent does not satisfy the requirement that the infringement proceeding has reasonable prospects of success.

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[52] For a discussion see David Hricik, 'Aerial Boundaries: The Duty of Candor as a Limitation on the Duty of Patent Practitioners to Advocate for Maximum Patent Coverage', 44 (2002), South Texas Law Review, 205.
[53] See sub-section 26C(3)(b) of the Therapeutic Goods Act 1989 (Australia).

In short, there is not in the US, and probably not anywhere else, a professional ethical obligation on patent attorneys to game the system in ways that destroy market competition in important areas such as pharmaceuticals. Patent offices could, if they wished, address this problem through a voluntary code of conduct that would have real bite if it were linked to an enforcement pyramid that was based on their powers of deregistration. This would be a much more cost effective approach to the problem of patent quality because it would be a preventive strategy aimed at changing the behaviour of patent attorneys in order to improve the quality of patent applications at the point of entry into the system. By not improving input quality and then allowing many such applications through their systems, patent offices pass on the costs of doubtful patents to other actors, actors whose costs of fighting poor patent quality are much greater than the cost of such a preventive approach by patent offices. Doubtful patents are cheap to obtain. They are expensive to fight. Faced by the threat of patent litigation many people will pay to make a problem go away rather than fight their way out of it. Those that do fight have a long battle irrespective of whether they win or not.

Patent offices equipped with powers of deregistration could do much more to change the gaming behaviour of patent attorneys. But the fact that many patent offices seek approval ratings from the profession probably makes those patent offices reluctant to move against those who, after all, obtain advances from corporations that are used to pay patent office fees.[54] It may also be that patent offices believe that they can tackle the problem of gaming by improving the quality of examination. Amongst other things, this means making it just

[54] For an example see the Canadian Intellectual Property Office's National Client Satisfaction Survey for 2008 available at http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01511.html.

as personally cost-effective for an examiner, who is subject to quotas and performance reviews, to reject a patent application if he or she believes there are real validity issues with it as to accept it. But if patent offices believe that they can lift the quality of their own processes to match the gaming behaviour of the profession, they will have to take a closer look at the way in which they treat examiners.

Examiners and Patent Quality

Improving patent quality through investing in the training of examiners and developing metrics that give examiners more autonomy is a partly travelled road for all the major patent offices. The USPTO, for example, after years of criticism has been striving to create a better work environment for its examiners (interview, USPTO). Ascertaining the actual working conditions of examiners was well outside the scope and method of this study. The interviews did suggest two linked factors that affect the quality performance of examiners. Examiners in the words of one interviewee "must be long stay" and in the words of another: "You don't get good examination quality until you have years of experience". Given that I generally interviewed senior people there is an obvious danger of selection error, but experience is certainly relevant to quality. It takes time to get to know the technological literature and to understand the significance of developments in it. One of the reasons that the quality of the USPTO's work is not seen to be as high as that of the EPO's work is the relative inexperience of the USPTO's workforce (see Chapter 5).

Developing a long stay workforce is probably not enough in itself to improve quality, as a long stay person may also be an unmotivated person, one who no longer invests in building up a knowledge of the prior art or who does not want to enter into negotiating contests with patent attorneys and so applies the test of inventive step in a way that lets too many applications make it to grant. The other factor, suggested by the interview in the German PO, is that the examination workforce as a whole must have an esprit de corps, a belief that no-one else does patent examination better. Patent offices wanting to improve patent quality have to look at how they can create a long stay workforce that takes pride in its work.

The ability of a patent office to create a long stay examination workforce will in turn be affected by the labour market variables of the country in question. We saw, for example, that in South Korea, KIPO has the advantage that there is considerable social prestige attached to government positions. This office said it does not have recruitment problems. Some offices have tended to lose patent examiners to the private sector, the US and UK offices being examples. Other developed country patent offices have done much, however, in creating a long stay examination workforce and perhaps an esprit de corps. The German PO, for example, garners a lot of recognition for the quality of its work. During the interview at the German PO it became clear that it did not have a problem with retaining examiners. Examiners, by virtue of their employment conditions, find it more or less impossible to go into private practice and if they do move out of the PO, they move to other parts of the German civil service (interview, German PO). A certain labour market inflexibility thus becomes a virtue for the German PO because it enables it to invest in the training of staff knowing that that staff are not likely to walk out the door at the first

opportunity. Labour market mobility in the UK, the US and Canada creates problems for their patent offices because in boom times many examiners are likely to shift to the private sector. The German PO recruits people with five or so years experience in industry and then gives them a further three years of training using a personal tutor approach in which a senior examiner acts as an individual tutor (interview, German PO). Outsourcing is not seen as an option by the office because of concerns about quality. In the same spirit of independence, it has designed its own electronic system for its examiners, but it has negotiated access to the EPO's EPOQUE system because of its tremendous advantages in searching the non-patent literature. The German PO's relentless drive for quality in examination also has wide stakeholder support. German companies and the patent attorney profession support the German PO's quality standards even if attorneys occasionally grumble about getting patent applications through the patent office (interview, German PO). In Austria, the PO is also confident about the quality of its work, reporting at the interview that its private studies showed that Austrian and German examiners were producing work of the same average quality (interview, Austrian PO). It was clear from the interview that the Austrian PO looked to the German PO as a standard bearer of examination quality. The EPO is another patent office that reported that its examiners tended to stay partly, it was suggested, because the EPO is an international organization and there is therefore kudos in working for it. The EPO does have some recruitment problems, but these in part are due to the fact that the EPO is seeking to find examiners capable of working in three languages in technical areas (interview, EPO).

The danger in all offices is that senior managers will become too focused on metrics and lose sight of the fact that it is examiners who determine quality. Developed country patent

offices measure, in many different ways, the performance of their examiners. At least in the beginning, those systems were biased in favour of the grant of the patent. Measures of patent quality have proven elusive. As one examiner put it, "patent quality is far more difficult to measure than things like backlog of unexamined patents, turnaround time, grant rates and so on". In the German PO there was even more scepticism about a meaningful definition of patent quality: "Nobody is able to define product quality". Offices understand the problem of incentives that undermine quality. The Canadian PO has recognized that different technologies require different examination time frames (interview Canadian PO). It is a mistake to work on the basis of the same number of hours for a disposal for all technologies. Some patent offices have tried to ensure that their quota systems do not penalize examiners for taking decisions that delay grant. The EPO's points system, for example, recognizes that a refusal action by an examiner involves much more work in terms of justification and so awards more points for a refusal action. This is an improvement from the point of view of examiners (interview, EPO). Yet as we saw in Chapter 4, the union representing EPO examiners has continued to argue that examiners are not being given enough time to do quality work. When I put this position to those at the EPO, it was conceded that "pressure [on examiners] had increased steeply, but examiners have coped somehow". The critical question this particular interviewee suggested was how much further examiners could be pushed. In the struggle between productive efficiency and examiner-led patent quality the danger is that the politics around the huge backlogs in patent offices will incline senior managers to squeeze every drop of productivity out of their examiners.