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"Trust me": Patent offices in developing countries

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"Trust me": Patent offices in developing countries

Peter Drahos

Patent rules matter to the structure and evolution of pharmaceutical markets. If they did not pharmaceutical multinationals would not spend resources on their globalization and content. The role of pharmaceutical multinationals in shaping the patent provisions of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been well documented.[1] The contributions of developing country coalitions and non-governmental organizations (NGOs) in the World Trade Organization (WTO) on TRIPS and access to medicines have also been studied.[2]

One actor, the patent office, has largely escaped detailed scrutiny in the literature that has grown around intellectual property and access to medicines. There is an obvious explanation. Patent offices are administrative bodies. They administer patent standards that are decided and defined by others – the courts, legislatures or the executive acting in the context of treaty negotiation. For those interested in the structural reform of pharmaceutical markets, reforming patent office administration

[1] MICHAEL RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY (1998); PETER DRAHOS WITH JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? (2002); DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS (2002); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003).

[2] GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE ACCESS AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2002); John S. Odell & Susan K. Sell, *Reframing the issue: the WTO coalition on intellectual property and public health, 2001, in* NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85 (John S. Odell, ed., 2006).

has not been a high priority. Instead the emphasis has been on encouraging the use of TRIPS standards in ways that are consistent with protecting public health,[3] on developing counter-strategies to the use of free trade agreements to impose TRIPS plus standards,[4] as well as putting forward new structural approaches[5] or policy ideas that make more efficient use of existing patent structures.[6]

This set of priorities by those working on the patent dimensions of access to medicines is the right set. But, as this article will show, the routine operations of patent offices matter to the maintenance of pharmaceutical markets. Most patents will not be litigated and most will not be opposed where a country has a pre-grant or post-grant opposition system.[7] It follows that the vast majority of patents begin and end their life in a patent office (either because the term of grant expires or the patent is not renewed). It is the daily patent office routines of a country that determine the build-up of patents in an economy, including pharmaceutical patents. Pharmaceutical patenting has, as in other areas of technology, increased.[8] Important for present purposes is the technical assistance provided by the European Patent Office (EPO)[9],

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[3] SISULE F. MUSUNGU ET AL., UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS (2004).

[4] For an overview see FREDERICK M. ABBOTT, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*, *in* NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES, 27 (Pedro Roffe et al. eds., 2006).

[5] Such structural approaches tend to rely on treaties. See, for instance, the proposal by Hubbard and Love for a treaty on research and development. Tim Hubbard & James Love, *A new trade framework for global healthcare R&D*, 2 PLOS BIOLOGY 147 (2004).

[6] See, for example, KEVIN OUTTERSON, *Patent Buy-Outs for Global Disease Innovations for Low-and Middle-Income Countries*, 32 AM. J.L. & MED. 159 (2006).

[7] Based on US and European figures it seems that between and 1–2% of patents will be litigated. The opposition rate at the EPO for 1981–1998 was 8.3%. See STUART J. H. GRAHAM et al., *Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY, 74, 89 & 91 (Wesley M. Cohen & Stephen A. Merrill eds., 2001).

[8] Patenting in the drugs and medical area is one of the big winners in terms of numbers of patents granted. By the end of the 1990s this area accounted for 10% of all patents granted in the US. See BRONWYN HALL ET AL., THE NBER PATENT CITATION DATA FILE: LESSONS, INSIGHTS AND METHODOLOGICAL TOOLS. 13 (NBER Working Paper No. 8498, 2001).

[9] The EPO describes each year's technical assistance in its annual reports.

the Japanese Patent Office (JPO)[10] and the United States Patent and Trademark Office (USPTO)[11] to developing countries. This technical assistance enables, as we shall see, technocratic trust to grow between the office providing the assistance and the office receiving it (the trust giver). Technocratic trust influences decision-making processes of trust-giving offices. These decisions help to maintain the structure of patent-regulated pharmaceutical markets, a structure that is based on the fact that patents constitute an opportunity for the owner to pursue economic rents. It follows that maximizing patent owners will track markets in which the rents are the greatest. This leads to problems of access to medicines in developing countries.[12] For present purposes structure is being used to refer to those rules that affect the long-term incentives and strategies of interacting players in a given market. Patents rules are structural rules in this sense because they offer companies long-term incentives to invest in the development of technologies under conditions of uncertainty. It has long been recognised that patents may be central to the acquisition of dominance by a firm.[13] This is especially so in the pharmaceutical sector where there may be cases where there is global demand for a product for which there is no or little

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[10] The Japanese Patent Office website describes an extensive technical assistance program. INFORMATION FOR 2005: ASSISTANCE TO DEVELOPING COUNTRIES, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_tope.htm; INFORMATION FOR 2005: OUTLINE OF COOPERATION, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_hajimenie.htm; INFORMATION FOR 2005: HUMAN RESOURCE DEVELOPMENT, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_1e-top.htm; INFORMATION FOR 2005: INFORMATION PROCESSING, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_2e-top.htm; INFORMATION FOR 2005: EXAMINATION, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_3e.htm; INFORMATION FOR 2005: ACTIVITIES BY COUNTRY http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_4e.htm; INFORMATION FOR 2005: DISPATCH OF IP EXPERTS, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_5e-top.htm; INFORMATION FOR 2005: SYMPOSIA, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_6e.htm; INFORMATION FOR 2005: STATISTICAL DATA, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_7e-top.htm; INFORMATION FOR 2005: RELATED WEB SITES, http://www.jpo.go.jp/torikumi_e/kokusai_e/asia_ip_e/apip_8e.htm.

[11] The USPTO lists its technical assistance in its annual reports. See USPTO ANNUAL REPORTS, *available at* http://www.uspto.gov/web/offices/com/annual/index.html

[12] See Jean O. Lanjouw, *A New Global Patent Regime For Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 88–89 (2002); Hannah E. Kettler, *Using Intellectual Property Regimes to Meet Global Health R&D Needs*, 5 J. WORLD INTELL. PROP. 655, 656–59 (2002).

[13] MICHAEL A. UTTON, MARKET DOMINANCE AND ANTITRUST POLICY 29–30 (2003).

substitutability.[14] This article focuses on the role that patent offices play in the maintenance of structure, a role that has received much less attention than the impact of patent rules on the acquisition of market dominance by firms. Drawing attention to this maintenance function of patent offices in developing countries is the main purpose of this article.

A subsidiary purpose is to suggest that developing country policy makers should pay more attention to what happens in their patent offices. As will become clear, developing country patent offices have been integrated into a system of international patent administration in which the grant of low-quality patents by major patent offices is a daily occurrence.[15] Developing countries for the most part have only had modest success in influencing the evolution of standards at the international level.[16] They have little prospect of influencing the standards of patent examination in the EPO, JPO and the USPTO, even though those standards impact on the work of their own patent offices. Under these circumstances developing countries should be thinking about ways to mitigate or prevent the consequences of poor quality patents in the pharmaceutical sector.

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[14] Studies reveal a high degree of market concentration in the markets of major therapeutic categories, suggesting little or no drug substitutability. See DAVID SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY (1976). Vernon's study of 18 therapeutic markets suggests that a relatively small number of companies dominate sales in the individual therapeutic markets. See John M. Vernon *Concentration, Promotion, and Market Share Stability in the Pharmaceutical Industry, in* 19 THE JOURNAL OF INDUSTRIAL ECONOMICS 246–266 (1971).

[15] For concerns about the quality of the work of the USPTO see John L. King, *Patent Examination Procedures and Patent Quality, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 54 (Wesley M. Cohen & Stephen A. Merrill eds., 2001). Within the EPO itself there are considerable doubts about the quality of its work. See QUALITY OF EXAMINATION AT THE EPO (Staff Union of the European Patent Office, 2004). National patent offices in Europe have suggested that improving patent quality through the introduction of a European Quality Management System is a key priority. See Dutch paper on the strategy debate, EUROPEAN PATENT OFFICE, DUTCH PAPER ON THE STRATEGY DEBATE, CA/68/06, Munich 15.02.2006, http://ac.european-patent-office.org/strategy_debate/documentation/pdf/ec06068.pdf..

[16] Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 J. WORLD INTELL. PROP., 765 (2002).

The rest of this article is set out in the following way. Section 1 draws attention to the leadership of the EPO, the JPO and the USPTO in patent administration. Using the example of the EPO, section 2 shows how technical assistance causes technocratic trust to grow between offices. Section 3 draws attention to the effects of technocratic trust. Section 4 shows why strategies for the regulation of developing country patent offices have to be developed and Section 5 outlines two such strategies.

1. The Age of the Trilaterals

At the beginning of the 21st century, three patent offices receive the bulk of patent applications and issue most patents: the USPTO, the EPO and the JPO. Collectively they are referred to as the Trilateral Offices.[17] Of the 5.5 million patents in force at the end of 2004, 83% were in force in the US, Japan and the member countries of the European Patent Convention.[18]

The story of the Trilaterals is one of informal co-operation that becomes grounded in bilateral memoranda of understanding between the USPTO and the EPO in June 1982 and the USPTO and the JPO in 1983. From 1983 onwards the Trilaterals have continued to sign annual memoranda of understanding (MOUs), deepening and

[17] For example, the Trilateral Offices accounted for approximately 57% of total number of patents granted worldwide in 2004. See for USPTO and JPO statistics *Worldwide Patent Activities*, http://www.trilateral.net/tsr/tsr_2005/ and for EPO statistics see http://www.epo.org/about-us/office/annual-reports/2004/statistics.html For patents granted worldwide see http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2007.html
For the historical background of the Trilateral Offices see http://www.trilateral.net/background/.

[18] See the TRILATERAL STATISTICAL REPORT, 2005 ed., 5, *available at* http://www.trilateral.net/tsr/tsr_2005/.

broadening the co-operation amongst them.[19] The Trilateral MOUs turn the three offices into the global hub of co-operation and convergence in patent administration. The bulk of the activity by the Trilaterals in terms of international co-operation with other offices is like the bulk of an iceberg submerged, with only brief descriptions available from annual reports of the individual offices and their websites and conference summaries. The Trilateral website lists the most significant examples of Trilateral co-operation being paperless search capability, common system architecture, electronic filing, harmonization of patent practices, common patent information dissemination policies and exchange of priority documents.[20]

Trilateral Office cooperation with other offices can take a multilateral or bilateral form. So, by way of example, the EPO in 2005 under the trilateral Memorandum of Understanding between the EPO, the African Intellectual Property Organization and the French Patent Office on training in western Africa launched a regional training centre in Cameroon.[21] The EPO also has bilateral links with offices, including other large offices such as the Chinese patent office. The same pattern of multilateral and bilateral cooperation is true of the USPTO and JPO.

The model of global integration and convergence of patent office administration might be said to follow a 'hub and spoke' model. Over time the Trilateral hub has brought its technical systems for exchanging data and for search and examination of applications into greater and greater alignment. At the same time as the hub has become progressively more integrated other offices have become linked to those

[19] The Trilateral Offices held their first annual conference in 1983. See http://www.trilateral.net/background/timeline/.
[20] See http://www.trilateral.net/background/achievements/.
[21] See http://www.epo.org/about-us/office/annual-reports/2005/business-report/international-relations.html#trilat

systems via 'spokes' of bilateral or multilateral co-operation. It is the Trilateral hub that bears the financial cost of this integration.[22] Figure 1 below depicts the process.

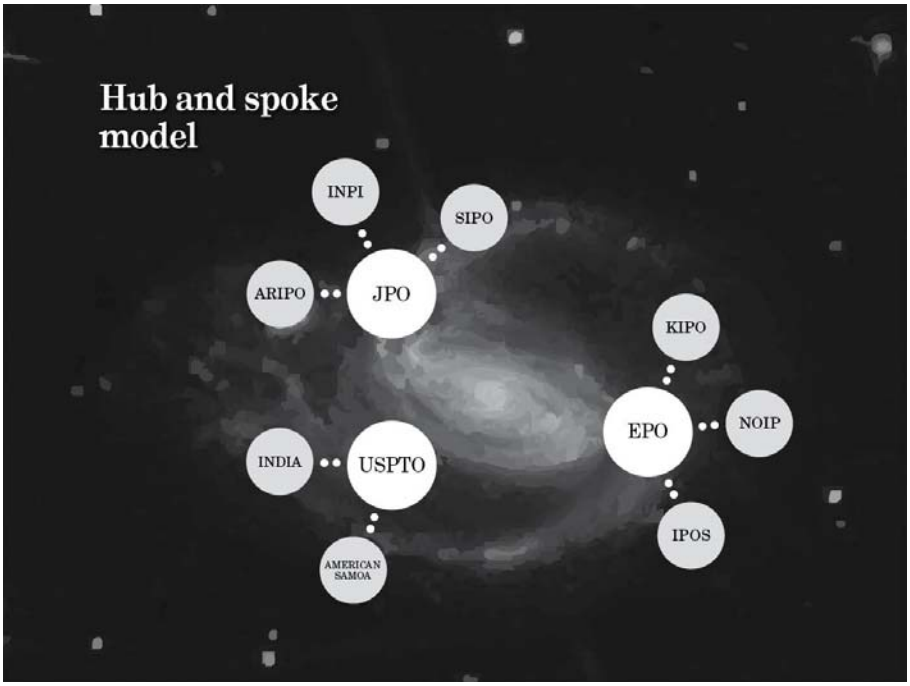

Figure 1: Hub and Spoke Model of Patent Office Integration

The Trilateral story has become one of dense cooperation that has moved well beyond technical matters such as electronic document exchange. So, by way of example, there is Trilateral Working Group[23] that is involved in the negotiation of the proposed Substantive Patent Law Treaty that is taking place at the World Intellectual Property Organization (WIPO).[24] The most likely reason for evolution of this co-operation is the workload problem facing each of these offices. The EPO's annual report for 1989

[22] The EUROPEAN PATENT OFFICE, ANNUAL REPORT(s) include information on expenditure on travel, meetings and technical co-operation. For example in 1990 it was 6 million DEM and in 1997 it was 16.6 DEM.

[23] A discussion paper that shows how the Trilaterals identify differences and work towards common ground is the paper written by the EPO as part of the Trilateral Working Group, SUBSTANTIVE HARMONIZATION OF PATENT LAW (SPLT) THE EUROPEAN PERSPECTIVE (2003), www.aipla.org/Content/ContentGroups/Meetings_and_Events1/International_Symposia1/EPOTrilateral.pdf.

[24] Work on substantive patent law harmonization is being carried out by WIPO's Standing Committee on the Law of Patents. See http://www.wipo.int/patent-law/en/harmonization.htm.

suggests that the Trilateral Offices were at first reluctant to exchange detailed information about their backlogs.[25] Following 'lengthy and difficult negotiations' at the 7th Trilateral conference in 1989, a project on 'long-term methods of coping with the increasing number of patent applications' was established.[26] Essentially the Trilaterals have concluded that they are in the same lifeboat when it comes to storms in the patent ocean.

The MOUs of 1982–3, which mark the beginning of the period of co-operation amongst the EPO, JPO and the USPTO, can be said to represent the start of an evolution of a global system of patent administration. This international system of administrative governance that is emerging for patent offices is separate from the treaty-based processes that aim to harmonize substantive patent law. Patent offices do not need treaties to create a global system of administrative governance. At the most they simply need MOUs. The politics of the post-TRIPS era has undoubtedly complicated the goal of patent law harmonization.[27] WIPO has been working on a treaty for patent law harmonization since 1983.[28] Progress has been slow. Business actors are increasingly focused on the pragmatics of speeding up the work of patent offices and reducing the costs of the application process. In 2003 an Industry Trilateral Group was formed.[29] This Industry Trilateral has made it clear that the

[25] EUROPEAN PATENT OFFICE, 1988 ANNUAL REPORT 36 (1989).
[26] *Id*.
[27] On this politics see SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 173–179 (2003).
[28] ARPAD BOGSCH, WIPO, BRIEF HISTORY OF THE FIRST 25 YEARS OF THE WORLD INTELLECTUAL PROPERTY ORGANIZATION 36 (1992).
[29] This includes representation from UNICE, Japan Intellectual Property Association, Intellectual Property Owners Association and American Intellectual Property Law Association. See the INDUSTRY TRILATERAL REPORT: GLOBAL PATENT APPLICATION (2006), *available at* www.ipo.org

Trilateral Offices should concentrate on unifying the administrative practices of patent offices:[30]

> "As a first step toward harmonization and enhanced efficiency, patent offices should adopt a common patent application format for a global patent application so that conforming applications (i) can be filed, preferably electronically, in any patent office without the need for any change in the submitted application to accommodate national/regional rules, and (ii) aid in facilitating machine translation of the applications."

In short, the Trilateral Offices have moved well beyond simple technical co-operation into a much deeper convergence of administrative systems.[31] Using the EPO as an example, the next section shows how developing countries are being integrated into the Trilateral system of governance for patent administration.

2. Technical Assistance and Technocratic Trust – the case of the EPO

The EPO's principal sources of fee income are from filing and search, examination, opposition, appeal and renewal fees.[32] Its principal source of expenditure is staff costs.[33] The strength of its financial position has been commented upon by observers.[34] Technical assistance forms a much smaller part of its expenditure. For example, in 1989 technical assistance, which is part of a category that includes travel,

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[30] *Id.*
[31] See EUROPEAN PATENT OFFICE, 2006 ANNUAL REPORT 44 (2007).
[32] In its 1997 EPO Annual Report at p.48 the figures for these categories are given in millions of DEM as 323.2, 426.4 and 282.5. In 2006 the EPO reported that its revenue from patent and procedural fees was 982,011,000 euro. See http://www.epo.org/about-us/office/annual-reports/2006/financial-report.html#2.
[33] In 1997 this was 687 million DEM of a total budget of 1173.4 million DEM. See p.48 of the Annual Report for 1997.
[34] see Hanns Ullrich, *Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?* 8 EUROPEAN L. J. 433, 443 (2002).

meetings and representation, has a figure of DEM 5.9 million next to it.[35] In that year the EPO's technical assistance activities consisted of training 66 nationals from developing countries at the EPO and sending 28 experts on technical assistance missions covering various aspects of how to build and administer a patent system.[36] This may seem a little modest, but we need to keep in mind that this was 1989, a decade after the EPO had begun operating.[37] Subsequent annual reports by the EPO show rising expenditure in real terms for technical assistance and an increase in the scale of technical assistance. So, for example, in its 1996 Annual report (the expenditure on technical assistance now being almost DEM 14 million[38]) we find reference to the Tacis programme (national assistance for Ukraine and Uzbekistan), the Regional Industrial Property Programme (covering 13 states) and the ECAP programme for ASEAN countries as well as co-operation projects with national patent offices from Argentina, China, Mexico, Malaysia and the Philippines.[39]

The fact that the EPO has a reasonably predictable income stream over which it has autonomy means that it can plan and fund long-term technical assistance programs. Its annual reports show that it has worked with developing country patent offices over many years.[40] This in turn has allowed it to build relationships of trust between itself and other offices. In fieldwork carried out by this author for a project on patent administration in developing countries a standard question asked was which other offices did the office in question trust. A number of offices would mention the EPO as

[35] EUROPEAN PATENT OFFICE, 1989 ANNUAL REPORT 21 (1990).
[36] *See id.* at 45.
[37] The EPO began accepting patent applications in 1978.
[38] EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 64 (1997).
[39] *See id.* at 55-56.
[40] By way of example the EUROPEAN PATENT OFFICE, 1997 ANNUAL REPORT (1998) at 41 describes activities with the African Regional Intellectual Property Office and the Brazilian Patent Office. The EUROPEAN PATENT OFFICE, 2006 ANNUAL REPORT (2007) at 46 also describes technical support activities with these offices.

a trusted or good office, Malaysia,[41] Vietnam[42] and Thailand[43] all being examples. In the case of patent offices organizational trust has the effect of leading the trust-giving office to depend on and use the work of other offices. So, for example, after co-operation projects with the EPO, Argentina, Mexico, Malaysia, the Philippines and Thailand decide to use the EPO's search results to speed up their granting procedures.[44]

The fieldwork data suggest that the steady drip drip of technical assistance over a period of years has led to the formation of trust between the EPO and developing country offices. Trust in institutional and organizational contexts is a difficult concept to unpack. Trust between individuals involves the person who trusts another believing that the entrusted person has an interest to act in a way that takes into account the interests of the trust-giver.[45] This account of trust works well in the context of smaller group face-to-face interactions, but seems less applicable when one is dealing with relations between large organizations and individuals or between large organizations. In large organizational contexts the sheer numbers and consequent facelessness acts against individuals outside of the organization from giving their trust to it. Trust between patent offices from different countries faces the additional hurdle that the patent institution has been and continues to be used by countries as an instrument of economic competition.[46] This would work against rather than for the evolution of trust between offices.

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[41] Interview in Malaysian Patent Office in Kuala Lumpar (Aug. 30, 2005).
[42] Interview at National Office of Industrial Property of Vietnam, Hanoi (June 3, 2004).
[43] Interview in the Thai Patent Office, Department of Intellectual Property, Ministry of Commerce, Bangkok (June 5, 2006).
[44] EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 56 (1997).
[45] For more details see Russell Hardin, *Trust in Government*, *in* TRUST AND GOVERNANCE 9, 12–13 (Valerie Braithwaite & Margaret Levi eds., 1998).
[46] The European Commission takes this view of the patent institution. See GREEN PAPER ON THE COMMUNITY PATENT AND THE PATENT SYSTEM IN EUROPE, COM(97) 314 Final, Brussels, 24.06.97

How then are we make sense of the apparent fact that trust has evolved between the EPO and some developing country offices? The trust that is being referred to here is of a limited kind that targets systems rather than individuals. Over the years the EPO has spent hundreds of millions of dollars on automating and then digitising its systems of searching and examination.[47] The EPO, JPO and USPTO have had to develop systems for managing patent documentation that is of a scale that dwarfs anything in developing country patent offices. By way of example in 1996 the EPO reported that its search files had reached 24.5 million patent documents and 2.5 million scientific or technological documents.[48] In that year it added a further 1.1 million documents bringing its total holdings to 28.1 million. Developing country examiners making the exciting journey to the patent metropoles of Europe (Munich, the Hague, Berlin, Vienna) for training during the 1980s and 1990s would have been exposed to these systems. Their own systems and offices would not have looked good by comparison. When, for example, this author visited the Philippines Patent Office in 2004 patent searching was based on a manual system. A Philippines generic company described the process as a time-consuming one in which files had to be obtained on one floor and taken for photocopying to another.[49] In Laos at the time of the author's visit the four people in the Laotian patent office were waiting for the arrival of some personal computers from WIPO so that they could get the office up and running.[50] At the time

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(1997) and PROMOTING INNOVATION THROUGH PATENTS: THE FOLLOW-UP TO THE GREEN PAPER ON THE COMMUNITY PATENT AND THE PATENT SYSTEM IN EUROPE, COM(1999) 42 Final, Brussels, 05.02.99 (1999).

[47] The importance of automating its systems is a regular item in the EPO's annual reports. See EUROPEAN PATENT OFFICE, 1989 ANNUAL REPORT 26 (1990) and EUROPEAN PATENT OFFICE, 1997 ANNUAL REPORT 25 (1998). Online filing is increasingly becoming the norm. The online filing of PCT applications at the EPO rose to 50% in 2006. See EUROPEAN PATENT OFFICE, 2006 ANNUAL REPORT 16 (2007).

[48] EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 37 (1997).

[49] Interview with the Philippine Chamber of Pharmaceutical Industry, Manila (May 6, 2004).

[50] Interview at the Department of Intellectual Property, Vientiane, Laos, (May 12, 2004).

of time of the visit to the Indonesian Patent Office in 2005 patent examiners had only just each gained their own desktop.[51] Before then it had been a question of sharing – five examiners to one machine. Probably things have improved since the author's visit to these offices. But it is interesting to compare this state of affairs in these developing countries with the EPO's systems as they stood in 1996, systems that included bibliographic data in respect of all patent documents published since 1968 and facsimile images of all documents published since 1920 in the USA, Japan and the members states of the EPO and WIPO. Access to these data and images was through various databases including 13 full-text patent databases holding some 60 million searchable records.[52] A patent examiner from a developing country visiting the Hague in 1989 might have been given a tour of the corridors that at that time held 17 kilometres of shelving used to store the patent documents needed for patent searches.[53]

The issue here is not how objectively efficient the EPO's systems were at this time, but how they would have *appeared* to outsiders coming from developing countries. The key here is the projection of technological superiority and efficiency. It is this projection of technological image that leads the visitors into the process of comparison and the generation of beliefs and impressions about the adequacy or inadequacy of their own systems and the superiority of the systems in which they are being instructed. The EPO's technical assistance programmes during the 1980s and 1990s would have created in developing country examiners a sense of confidence in the EPO's systems. The limitation of their own search and examination systems

[51] Interview in the Sub-Directorate of Patent Administration and Technical Services, Jakarta, Indonesia, (Jan. 24, 2006).
[52] EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 10 (1997).
[53] For those who believe that seeing is believing a photo of some of this shelving appears in the EUROPEAN PATENT OFFICE, 1989 ANNUAL REPORT 40–41 (1990).

would be all too apparent, systems housed in run down buildings that lacked a sufficient number of computers. Making the technocratic judgement that the EPO's systems could be trusted to generate reliable results would be a natural step for developing country examiners to take once they had been through the process of training in the EPO's systems. The trust that develops between patent offices is a narrow technocratic trust based on a confidence in the reliable performance of a system rather than individuals, a confidence that technical training builds over time. Once this confidence exists a creeping lock-in of systems begins to grow in the developing country patent office, involving access to some of the EPO's databases and new software systems and ultimately a reliance on the EPO's searches and granting decisions. Technical assistance of the long-term kind practised by the EPO creates in those receiving the assistance assumptions of reliability about the operation of systems (technocratic trust) and these in turn help to integrate the recipients of this assistance into the broader technocratic community that the EPO represents. Technical assistance of this kind is clearly integrative. It allows the EPO to build and lead a community of patent examiners that stretches around the globe.

An example of this leadership based on technocratic trust came from fieldwork in Vietnam, where over the years the EPO has been active.[54] When examiners in the Vietnamese patent office come to consider say a patent application in the pharmaceutical field they begin by looking at how the EPO has decided the application and what it has said in its search report.[55] They do not confine themselves to the EPO as the examiner's decision tree below makes clear.[56] They may also look

[54] A description of the EPO's activities in Vietnam is available in the EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 56 (1997) and EUROPEAN PATENT OFFICE, 1997 ANNUAL REPORT 41 (1998).
[55] Interview at National Office of Industrial Property of Vietnam, Hanoi (June 3, 2004).
[56] This decision tree was explained to the author during the course of the interview.

at the way in which the USPTO and JPO have treated the application. The decision tree below is the product of years of technical assistance, which includes training visits to beautiful Munich with its designed gardens and wonderful restaurants. It is the story of quiet and steady cultural integration in which examiners from patent offices of the periphery journey to the patent kingdoms of the west to be instructed in systems of apparent technological superiority to their own, systems that continue to influence them once they return home.

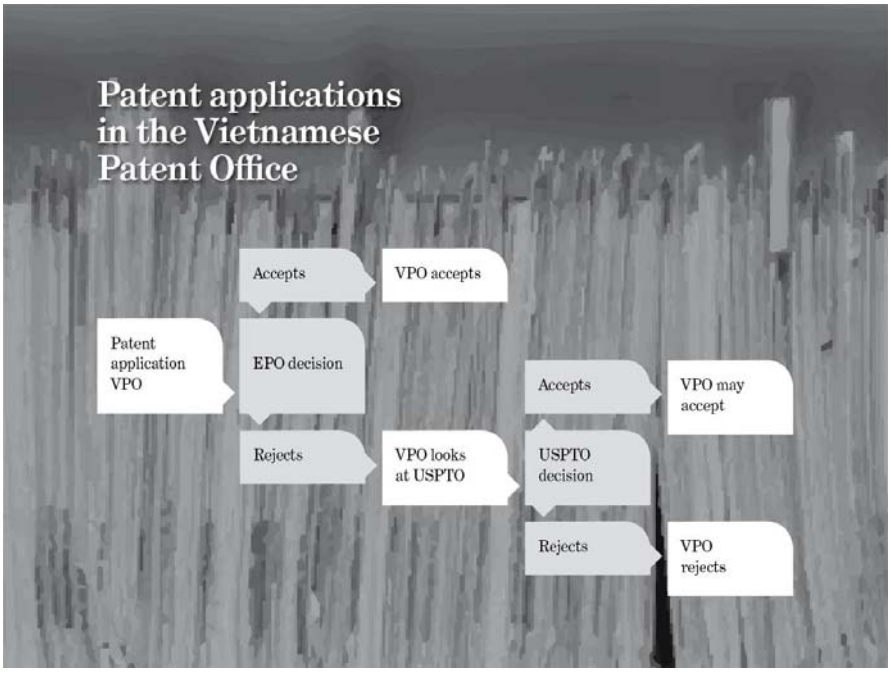

Figure 2: Patent applications in the Vietnamese Patent Office

3. The effects of technocratic trust

One crucial question is whether a leadership of developing country patent offices by the EPO based on technocratic trust ultimately serves the development interests of developing countries. This in turn raises questions about the development impact of

patent systems, answers to which are not within the scope of this article.[57] But we can make some observations about the effects of technocratic trust in systems of patent administration. In the case of personal trust, the trust-giver assumes that the trust-receiver will take proper account of the trust-giver's interest. Technocratic trust is an impersonal form of trust in which the trust-giver comes to have an expectation about the performance of the system. The system designer has an interest in ensuring the reliability of the system since otherwise there is no possibility of an expectation about its reliability. Beyond that the system designer may not necessarily have the interests of the trust-giver in mind. In the case of the EPO there is evidence to suggest that it has European economic interests in mind when it fosters technocratic trust through technical assistance. In its 1995 Annual Report it pointed out that in the case of patent filings in ASEAN countries 95% had originated outside of these countries, with 40% coming from Europe.[58] Moreover patent filings were growing at the rate of 20% per year.[59] This growing backlog in ASEAN Patent Offices resulted in a program of technical assistance that included,

> "further-training courses for employees, *incorporating search and examination results from other offices into grant procedures* and the automation of patent and trade mark administration. In addition four ASEAN patent offices were supplied with CD-ROM workstations and facilities to access the EPO's INPADOC databases."[60] (emphasis added)

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[57] For an overview of the issues see Keith E. Maskus and Jerome H. Reichman, *Globalization of private knowledge goods and the privatization of global public goods, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 3 (Keith E. Maskus & Jerome H. Reichman eds., 2005). See also COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY (2002).
[58] This figure excludes Vietnam. See EUROPEAN PATENT OFFICE, 1995 ANNUAL REPORT 62 (1996).
[59] *Id*.
[60] *Id*.

The integrative nature of this technical assistance is evident. Over the years the steady drip drip of technical assistance leads to the formation of technocratic trust in the EPO's systems. A strong belief forms that the EPO's systems produce quality results and that belief in turn forms the basis of decision-making by patent examiners in under-resourced developing country patent offices. Technocratic trust thus fosters a circle of decision-making in which the EPO trains developing country examiners to make decisions in their own countries that predominantly benefit foreign companies, including European companies.

One important effect is to transfer economic rents to European patent owners.[61] Patent examiners in developing country offices spend most of their time granting patents to foreign firms from Europe, Japan and the US. Another important effect of technical assistance is its effect on the capacity of developing country patent offices to become players in national policy networks. Policy networks have become an important variable in explaining the evolution of economic planning and performance of states.[62] The fieldwork evidence suggests that patent offices in developing countries play a role in the policy networks of a country. So, for example, when a developing country has a trade negotiation with a developed country, often it is the patent office that provides the patent negotiating expertise when it comes to the intellectual property chapter.[63] Amongst other things, these negotiations cover patent standards that deal with matters such as scope of patentable subject matter, patent

[61] One the rent transfer from developing to developed countries as a result of TRIPS see J. MICHAEL FINGER, ASIAN DEVELOPMENT BANK, THE DOHA AGENDA AND DEVELOPMENT: A VIEW FROM THE URUGUAY ROUND, ERD Working Paper Series No. 21, 13 (Sept. 2002).
[62] For an overview see Michael M. Atkinson & William D. Coleman, *Strong States and Weak States: Sectoral Policy Networks in Advanced Capitalist Economies*, 19 BRIT. J. POL. SCI. 47 (1989).
[63] This is the case for example in the free trade negotiations that Malaysia is having with the US and Australia. Information provided by the Malaysian Patent Office.

term extension, patent and drug registration linkage, protection of test data for pharmaceuticals and scope of compulsory licensing, matters that can impact in major ways on the local companies and sectors in a developing country, especially the pharmaceutical sector.[64] Similarly patent offices have an input into innovation policy because of the assumption patents are integral to innovation. Patent offices do not behave as simple land title registries. Instead they participate in processes of interpreting, advising and negotiating standards of patent protection. As players in national policy networks developing country patent offices have the following features. First, by virtue of the long-running technical assistance programs they are integrated into one or more of the Trilateral Offices. Second, they receive resources from these offices, often on a long-term basis and they have the capacity to generate income from the grant of patents. This means that in comparison to other national bureaucracies in developing countries they are often better-resourced. Third, the fee income they generate comes largely from a foreign clientele, especially multinational companies with global patenting strategies. Fourth, because of the technological and jurisprudential complexity of patent work the operation of patent offices remains opaque to other policy areas of the developing country's civil service. Developing country patent offices are thus unusual players in national policy networks because they are disposed to be pro-patent, are integrated into international patent policy networks from which they draw resources and serve a clientele that is predominantly foreign. From the perspective of innovation policy, patent offices as actors in policy networks are likely to close off or circumscribe policy initiatives that question the role of patents in innovation. Technical assistance that builds the capability of patent offices to be players in policy networks is essentially building a capability that is pro-

[64] See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L, 317, 349–354 (2005).

patent in disposition. This in short is technical assistance that tilts the policy playing field in particular direction.

4. Regulating Patent Offices

The previous sections have shown that the Trilateral Offices are leading the creation of a globally integrated approach to patent administration. Most developing country patent offices will in essence simply register patents that have been filed and examined in another jurisdiction. Despite the current talk by the major patent offices about the need for quality, quality systems, improving quality etc probably little improvement in quality of granted patents will actually take place. The basic explanation lies in the long-run reduction of the costs of patenting which has contributed to a rise in the scale of patenting that no-one expected.[65] At the time that the European Patent Convention was being negotiated it was estimated that the European Patent Office would receive about 40,000 patent applications per year.[66] In 2006 the EPO reported that it had received 208,500 applications.[67] The numbers were even higher in the JPO[68] and the USPTO.[69]

The primary concern of the Trilaterals has become productive efficiency rather than patent quality. This is not to say that patent offices are not concerned about the

[65] The direct connection between the reduction in patent fees and a rise in patenting is rarely commented upon. For an exception see KLAUS BOEHM WITH AUBREY SILBERTSON, THE BRITISH PATENT SYSTEM 37 (vol. 1 1967).
[66] Dennis Thompson, *The Draft Convention For A European Patent*, 22 INT'L & COMP. L.Q. 52, 61 (1973).
[67] EUROPEAN PATENT OFFICE, 1996 ANNUAL REPORT 15 (1997).
[68] JPO reports 408,674 for 2006. See http://www.jpo.go.jp/shiryou_e/toukei_e/report_a_r_e.htm
[69] At the USPTO, the Office of Initial Patent Examination (OIPE) received over 417,000 patent applications. See USPTO, 2006 PERFORMANCE AND ACCOUNTABILITY REPORT, *available at* http://www.uspto.gov/web/offices/com/annual/2006/3020100_patentperfrm.html

quality issue. In Europe the Administrative Council of the EPC has led a consultation and debate with a view to developing a long-term strategy for the European patent system.[70]

In a note on the patenting situation in Europe the German, Danish and Dutch delegation observed that the increase in applications had not been matched by increasing levels of R&D in Europe, something that one might have expected if a simple causal relationship between patent and R&D investment held.[71] "Mere quantity" the delegations observed "cannot be regarded as a sign of increasing innovative power".[72] One theme being discussed is a return to quality. This theme of a return to quality has been followed up by some national patent offices making specific suggestions, including raising the threshold of inventive step, reducing the costs to examiners of rejecting an application and reducing the opportunities for applicants to manipulate the application process (for example, restricting their capacity to split patent applications).[73]

That said the reality is that in the case of the EPO patent examiners have 35% less time to examine patent applications than they did in the 1990s.[74] The most likely scenario is that all the Trilateral Offices will continue their productive efficiency drive in order to deal with their respective backlog problems.[75] We noted earlier that pharmaceutical patenting has increased.[76] All other things being equal, the more pharmaceutical patents that are applied for, the more that will be granted. Developing

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[70] The documentation for the debate *available at* http://www.epo.org/about-us/epo/consultation-processes/strategy-debate.html.
[71] See NOTES ON THE PATENTING SITUATION IN EUROPE, CA/92/05, Munich, 18.05.2005.
[72] *Id*.
[73] See DUTCH PAPER ON THE STRATEGY DEBATE, CA/68/06, Munich 15.02.2006.
[74] See SUEPO POSITION PAPER, QUALITY OF EXAMINATION AT THE EPO 5 (2004).
[75] A comprehensive analysis of the EPO's workload problems is to be found in MASTERING THE WORKLOAD CA/132/02, 08.10.2002. In the USPTO, first action pendency for 2006 was 22.6 months. See http://www.uspto.gov/web/offices/com/annual/2006/3020100_patentperfrm.html.
[76] See *supra* note 8.

country patent offices acting on the basis of decision trees like the one we outlined for Vietnam (see Figure 2)will simply register patents on which one of the Trilateral Offices has taken a positive action acting in its capacity as a national office (regional in the case of the EPO) or as an International Searching Authority (ISA) under the PCT.[77] Importantly, the rise in the use of the PCT by companies means that the patent offices that are ISAs will by virtue of taking the first action on a PCT application have a considerable influence on the fate of that application in a developing country. The only two countries which could claim to be developing countries that are ISAs are China and Korea.[78] Membership of the PCT in particular by a developing country, as we will see in a moment, will make it easier for pharmaceutical companies to apply for patents in that country. The easier, cheaper and faster that developing country patent offices make their procedures, the more pharmaceutical patents will end up on their books and in their economies.

By way of example, very little patenting takes place in the Pacific Islands.[79] Yet after Papua New Guinea joined the PCT in 2003 one report pointed out that it had received about 940 designations.[80] Currently Papua New Guinea appears to be being routinely designated under the PCT by applicants.[81] Kirabati, which is one of the islands facing rising sea levels because of climate change, has approximately 20 registered pharmaceutical patents.[82] Kiribati runs a patent re-registration system under which it is possible for a UK patent-holder to re-register a patent in Kiribati. This re-

[77] The EPO, JPO and the USPTO are all International Search Authorities for the purposes of the PCT. See http://www.wipo.int/pct/en/quality/authorities.html.
[78] The list of 13 ISAs is available at http://www.wipo.int/pct/en/quality/authorities.html.
[79] See SUSAN FARQUHAR, ASIAN DEVELOPMENT BANK–COMMONWEALTH SECRETARIAT, A REGIONAL INTERNATIONAL PROPERTY RIGHTS OFFICE FOR THE SOUTH PACIFIC: COST-BENEFIT ANALYSIS, PACIFIC STUDIES SERIES, TOWARD A NEW PACIFIC REGIONALISM, (vol. 3, Working Paper 16, n.d.).
[80] See *id* at 20.
[81] A structured search of the WIPO PCT database using PG (the country code for Papua New Guinea) for designated states turned up 455, 843 records, available at http://www.wipo.int/pctdb/en/.
[82] Information provided by IP Australia.

registration system had been created during the British Empire, allowing UK patent holders to register an UK patent in a colony or protectorate of the British Empire that had adopted a law allowing for re-registration.[83] The Pacific Islands also provide an example of the way in which empire continues its institutional echo in developing countries. In a number of UK territories and Commonwealth countries (for example, Fiji, Gambia and Uganda) the owner of the UK European patent has three years within which to apply for the registration of that patent in those territories and countries.[84]

The example of Kiribati and Papua New Guinea illustrate a basic point about corporate patent behaviour. If the system of patent administration makes the option of obtaining worldwide patent protection cheaper and easier companies will use the system. Companies, as the example of Papua New Guinea shows, will use a global system of patent administration to give themselves the option of obtaining patents in developing countries. If companies exercise those options and register patents developing countries will have to have in place the regulatory infrastructure to deal with any possible problems of access to medicines that those patents raise. Papua New Guinea, for example, has a serious HIV/AIDS problem.[85] If pharmaceutical multinationals register patents on antiretroviral drugs in Papua New Guinea, then this will make it more complicated for the government to pursue the option of using generic antiretrovirals to scale up treatment. Papua New Guinea's capacity to make use of the generic option in the face of patents will depend on whether it has

[83] Report of the DEPARTMENT COMMITTEE ON THE PATENTS AND DESIGNS ACTS AND PRACTICE OF THE PATENT OFFICE, HIS MAJESTY'S STATIONERY OFFICE, 71 (1931).
[84] For the full list see EUROPEAN PATENT OFFICE, OFFICIAL JOURNAL EPO 4/2004, 179 (2004).
[85] See AUSAID, COMMONWEALTH OF AUSTRALIA, FINAL REPORT OF HIV EPIDEMIOLOGICAL MODELLING AND IMPACT STUDY, IMPACTS OF HIV/AIDS 2005–2025 IN PAPUA NEW GUINEA, INDONESIA AND EAST TIMOR (2006).

administrative systems in place to issue compulsory licences and whether it has the political will to use those systems.

The experience of Thailand with the didanosine (ddl) patent shows the demand that is put on resources in a developing country to fight one single pharmaceutical patent of doubtful validity.[86] The patent on Dideoxy Purine Nucelosides was a broad formulation patent and issued to Bristol Myer Squibb on 22 January 1998.[87] One effect of its issuance 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 BMS 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 an indigenous 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.

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[86] Didanosine (ddl) is important in second line treatment. See MEDECINS SANS FRONTIERES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES, 15 (9th ed., 2006).

[87] Thailand's experience with the ddl patent is described in ASEAN SECRETARIAT , 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, 267–71 (2005).

There is one last observation to make about the ddl case. During the litigation the Thai patent office came in for criticism because it intervened in the litigation in ways that favoured Bristol Myer Squibb.[88] This behaviour is consistent with the broader argument of the paper that developing country patent offices have over a long period of time been steadily integrated into an emerging system of global patent administration. By virtue of this integration they will be disposed to behave in ways that are likely to be pro-patent. The patent offices of developing countries will through their daily administrative practices help to maintain patent-regulated pharmaceutical markets that will make access to medicines by their citizens more rather than less difficult. This does raise the issue of how developing country governments should respond to the way in which their patent offices are functioning.

One strand of regulatory theory does provide a conceptualization of the problem that faces developing country governments when it comes to patent offices. Drawing on the work of Niklas Luhmann[89] and known as the legal theory of autopoeisis it argues that law is a closed subsystem of regulation that reproduces itself through an internal process of reference to other norms.[90] The system is said to be binary in that something is either law or not law, or in the case of patents office patentable or not patentable. This systems line of thinking in regulation conceptualizes problems of regulation in terms of failures of communication (and therefore coordination) amongst subsystems.[91] Since the patent system reproduces itself through a self-referential

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[88] See *id* at 270.
[89] NIKLAS LUHMANN, A SOCIOLOGICAL THEORY OF LAW (Elizabeth King & Martin Albrow trans., Routledge & Kegan Paul, London, 1985).
[90] For an overview see Colin Scott, *Regulation in the age of governance: the rise of the post-regulatory state*, *in* THE POLITICS OF REGULATION: INSTITUTIONS AND REGULATORY REFORMS FOR THE AGE OF GOVERNANCE 145, 151–154 (Jacint Jordana & David Levi-Faur eds., 2004).
[91] On the application of the theory to law see, for example, HUGH COLLINS, REGULATING CONTRACTS, (1999); REGULATING LAW (Christine Parker et al. eds., 2004).

process based on a narrow binary it becomes increasingly isolated from other sub-systems. The challenge then for governments is to bring patent offices in from the regulatory cold, or less metaphorically, to integrate patent office administration with the goals of public health.[92] Patent administration is one area where the processes of globalization have left states with considerable discretion.[93] How states run their patent offices is still very much up to them. The integration of developing country patent offices into a global system of patent administration is something that developing countries have let happen rather than something that was a necessary outcome of globalization. The final section of this paper suggests two ways in which patent office administration might itself be regulated in order to further the goal of public health in developing countries.

5. Knowledge is power, prevention is better than cure

A fundamental prerequisite for the regulation of patent offices is that other sectors of government take a deeper and more critical interest in the operation of patent offices. In a fieldwork project involving capacity building and intellectual property rights and public health this author interviewed numerous health officials and visited a number of patent offices.[94] On the field trip to Laos, a public health official was assigned to take the author to the patent office. The first two buildings we visited turned out not to hold the patent office, which led to some light hearted banter about a reclusive

[92] As an aside it should be said that systems thinking is not especially optimistic about regulatory interventions. For the reasons why see Gunther Teubner, *Juridification: Concepts, Aspects, Limits, Solutions, in* JURIDIFICATION OF SOCIAL SPHERES: A COMPARATIVE ANALYSIS OF THE AREAS OF LABOR, CORPORATE, ANTITRUST AND SOCIAL WELFARE LAW 3–48 (Gunther Teubner ed., 1987).
[93] States have much less discretion when it comes to choosing standards of patent protection because of international agreements. See JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION (2000).
[94] Work undertaken for the ASEAN Secretariat and reported in Regional Report: See *supra* at note 88.

patent office. On the third try we were successful. In other countries patent offices were located a little more easily, but the Laotian experience turned out to be emblematic of a broader truth. Health officials in developing countries did not know the first thing about the operations of their patent offices and how those operations might impact on access to medicines. Clearly knowledge about what patent offices do (knowledge in the old fashioned sense of knowing the truth about their operations, including their relations with pharmaceutical companies, their relations with the Trilaterals and the quality of their examination systems) is a first step if developing country governments want to integrate their patent offices into a national public health strategy on access to medicines.

Assuming such knowledge, the next question is what kind of steps can developing country governments take in order to ensure that the work of national patent offices does not undermine the goal of access to medicines. Thailand's experience with the ddl patent strongly suggests that a guiding principle for developing countries should be prevention rather than cure ie it is much better to find ways to prevent pharmaceutical patents of doubtful validity getting on to the patent register rather than trying to remove them through costly litigation. Litigation as a regulatory tool for pharmaceutical patents is not a viable option in most developing countries. It is probably a viable option in very few countries since it requires the incentive of lucrative pharmaceutical product markets worth contesting, a strong generic sector, a cultural disposition towards litigation, a profession capable of servicing that litigation and of course litigants with deep pockets. Only the US scores well on all of these factors and even then the costs of patent litigation in the US are increasingly seen as a

problem.[95] Developing countries simply do not have evolved legal markets that can act as a meaningful regulatory tool when it comes to pharmaceutical patent litigation. At the time of the author's visit to the Indonesian patent office in 2004 he was told that there were 40 registered patent attorneys with only 10 of those having a viable practice.[96] In the Philippines the generic companies interviewed complained about the problem of finding competent patent litigation expertise, pointing out that the few competent firms in the area tended to work for pharmaceutical multinationals.[97] The generic industry in Malaysia reported a similar experience.[98] As one member of a Malaysian generic firm said 'it takes a lot of guts' to take on pharmaceutical multinationals in patent litigation. Litigation as an option in least developed countries like Laos is simply not an option. None of this is especially surprising. Why, after all, would we expect developing country pharmaceutical companies operating in small economies that lack a tradition of patent law to behave like pharmaceutical companies that operate in the world's largest economy?

A model of patent office regulation in the area of pharmaceuticals that operates on the basis of prevention is the one that has been created by Brazil. In 1999 Brazil passed a measure that made the grant of patents on pharmaceutical products and processes dependent on the consent of the Brazilian Sanitary Surveillance Agency (ANVISA).[99] Patent applications concerning pharmaceuticals are processed by Brazil's intellectual property office in the normal way, but ANVISA scrutinizes them for compliance with

[95] On the complexities of patent litigation and its costs in the US see James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation, in* INTELLECTUAL PROPERTY AND INFORMATION WEALTH 199 (Peter K. Yu ed., vol 2, 2007).
[96] Interview in the Sub-Directorate of Patent Administration and Technical Services, Jakarta, (Jan. 24, 2006).
[97] Interview with the Philippine Chamber of Pharmaceutical Industry, Manila (May 6, 2004).
[98] Interview with Malaysian generic firms, Kuala Lumpur (Aug. 30, 2005).
[99] The measure was consolidated in Article 229-C of the Law 10.196/01. It reads as follows: "229-C The allowance of patents to pharmaceutical products and processes will depend upon previous consent of the Brazilian Sanitary Surveillance Agency – ANVISA".

the requirements of patentability. If ANVISA concludes that the patent application fails to meet one or more of the criteria of patentability it can withhold its consent to the grant of the patent in which case the patent cannot issue.[100] For the purpose of making judgements about patentability criteria such as the requirement of an inventive step ANVISA has established a technical group of experts.

The Brazilian model is worth close study by other developing countries.[101] It is a preventive strategy that avoids the high costs of attempting to remove patents that have been granted. It is also an integrative regulatory strategy. It links patentability criteria in the area of pharmaceuticals to the goal of welfare-enhancing innovation in the health sector. One of the real concerns with pharmaceutical patenting has been that patent offices are granting patents over essentially trivial steps in the innovation process.[102] The reasons for this are complex having to do with the incentive settings that face patent offices, the narrow training of patent examiners, the fact that patent examiners are not researchers and are not integrated into communities of public health experts that know about what constitutes real innovation in a given field. From the perspective of the patent social contract, the grant of patents over trivial or obvious steps in the pharmaceutical innovation process constitutes a welfare loss to society. Involving public health experts in the process of patent administration is one way of

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[100] Information provided to the author by Ms Ana Paula Jucá Silva of ANVISA in a paper titled 'ANVISA and pharmaceutical products and process patents', on file with author.

[101] Other countries in South America are studying the Brazilian model. Email communication from Ms Ana Paula Jucá Silva on July 11, 2007.

[102] This has led to complaints in a number of countries about the problem of evergreening. See, for example, EDWARD HORE, PATENTLY ABSURD: EVERGREENING OF PHARMACEUTICAL PATENT PROTECTION UNDER THE *PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS* OF CANADA'S *PATENT ACT* (2004), available from the Canadian Generic Pharmaceutical's Association and A. Somogyi et al. *Inside the isomers: the tale of chiral switches*, 27(2) AUSTRALIAN PRESCRIBER, 24 (2004); Aaron S. Kesselheim, *Intellectual Property policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System*, 9(3) THE AAPS JL E306 (2007).

helping to ensure that the patent social contract functions as it should in the health sector.

Another mechanism that could be used by national regulators to deal with the effects of rising numbers of patents in their jurisdictions is a transparency register. In theory, the patent system is meant to disclose invention information and create certainty for downstream innovators.[103] In practice, precisely the reverse happens. 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 often have doubts about the scope of the patents they have found. Patents, unlike blocks of land, do not come with settled boundaries. The Swedish Patent and Registration Office, in commenting on the reform of the International Patent Classification system, observed in 1999 that the problems with the IPC had grown to a point "where even experts have trouble making accurate searches".[104]

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 illustrated. 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

[103] In the words of the US Court of Appeals for the Federal Circuit, the "whole purpose of a patent specification is to disclose one's invention to the public. It is the quid pro quo for the grant of the period of exclusivity." See LizardTech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1375 (Fed. Cir. 2006).

[104] See IPC/R 1/99 Rev. 1 Annex 10, 1–2, at http://www.wipo.int/edocs/mdocs/classifications/en/ipc_ref_2/ipc_r_1_99_rev_1.pdf.

the WHO has recommended as a frontline tool for dealing with an outbreak of avian bird flu.[105]

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 to remove this complexity.[106] 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".[107] 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. 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 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 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.

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[105] Buddhima Lokuge, Peter Drahos and Warwick Neville, *Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?*, 184(1) MED. J. AUSTL. 16–20 (2006).
[106] For a philosophical defence of simple rules for dealing with complexity see Richard A. Epstein, SIMPLE RULES FOR A COMPLEX WORLD (1995).
[107] Article 27(2) of TRIPS.

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. Since companies are rational actors a deterrence mechanism could be used to overcome this potential problem. A patent (or some of its claims) put on the register 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, in the first instance, be swift and administrative in nature. 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 and the patent attorneys responsible for drafting the patent. Section 26C of the Therapeutic Goods Act 1989 (Australia), for example, imposes a penalty of $10 million on companies in order to deter companies from using patents of doubtful 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.

Transparency registers would only need to be created by regulatory agencies in areas where it was important to reduce the social costs of the uncertainty and complexity being orchestrated by patent owners. Society can live with the uncertainty generated by patents over tennis racquets. It should not have to live with uncertainty, in vital areas like pharmaceuticals, that compromises its ability to respond to serious threats like pandemics. 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 rules will simply generate rent-seeking behaviour.[108] A transparency register would require a company to disclose all the patents around a particular technology. Failure to disclose 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 and severe penalties and criminal sanctions for such gaming behaviour. After the first few prosecutions companies would think much harder about the patents they place on the register. Judgements about the quality of patents would in many cases 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.[109] Currently, however, there are incentives for companies to obtain low-quality 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.

Finally, 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.[110] Clearly, this will not be true for many local companies in developing countries. But even in the US there are

[108] See FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (2002).
[109] See *id.* at 16.
[110] For the suggestion that companies in the US do not need the notice function of the Orange Book because of private search techniques see *id.* at 54.

many other 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, gaming behaviour that is not consistent with their obligations under the patent social contract. Transparency registers are one way in which to invigorate these obligations.

Conclusion

The Trilateral Offices have since the 1980s established strong programmes of co-operation amongst themselves. Through their technical assistance programmes they have integrated developing country patent offices into an emerging global system of patent administration. The purpose of this global system is productive efficiency. It is to maximize the output of patents at minimum cost. All other things being equal, the patent offices of developing countries will end up granting more and more pharmaceutical patents. This will complicate access to medicines for citizens of developing countries. Developing country governments have to take a much more critical approach to the operation of their patent offices. Relying on patent litigation as a tool to weed out invalid patents will not work in developing countries. These offices need to be re-integrated into a national regulatory strategy that aims to deliver much better levels of access to medicines. One preventive strategy, which has been implemented by Brazil, is to force patent offices to co-ordinate with health experts who are in a much better position than patent examiners to assess the contribution of an invention to innovation and health welfare. Another strategy is to use transparency

registers to force companies to disclose those patents which they believe on reasonable grounds are valid. Both these approaches are consistent with the patent social contract and in fact invigorate what has become a hollow ideal.