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Regulating Patent Offices: Countering Pharmaceutical Hegemony

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Abstract

The grant of a patent is not a reward. Rather it is an opportunity for the patent owner to pursue profits using the patent monopoly to exclude competition. Profit-maximising patent owners focus their monopoly powers on markets in which profits are the greatest. In the case of patents over medical products this leads to well known problems of access to medicines for poor people. The costs and abuses of the patent system in the pharmaceutical sector have been persistent and known for a long time, as John Braithwaite's magisterial 1984 study, Corporate Crime in the Pharmaceutical Industry vividly illustrates. The failure to do anything substantial about these costs and abuses is a function of the power of pharmaceutical transnational corporations (TNCs) and US and EU hegemony over standard-setting in the international patent framework.

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1. Introduction

The grant of a patent is not a reward. Rather it is an opportunity for the patent owner to pursue profits using the patent monopoly to exclude competition. Profit-maximising patent owners focus their monopoly powers on markets in which profits are the greatest. In the case of patents over medical products this leads to well known problems of access to medicines for poor people.[1] The costs and abuses of the patent system in the pharmaceutical sector have been persistent and known for a long time, as John Braithwaite's magisterial 1984 study, *Corporate Crime in the Pharmaceutical Industry* vividly illustrates. The failure to do anything substantial about these costs and abuses is a function of the power of pharmaceutical transnational corporations (TNCs) and US and EU hegemony over standard-setting in the international patent framework.

The purpose of this article is to draw attention to another aspect of this hegemony – the development of a global system of patent office administration in which the aim is to grant patents in as many countries as the applicant wants as cheaply as possible. Amongst other things, this will see an increase in pharmaceutical patenting, including in developing countries. The signs are that the leading developing countries, Brazil, China and India are embracing the patent system in the belief that they will be eventual winners from the system. It follows that if states are not prepared to address the structure of the patent system in order to deal with access to medicines problems, they will have to develop alternative regulatory strategies for dealing with the effects of large scale pharmaceutical patenting on access rights.

2. The Rise and Rise of Patenting

In 2005 about 1.6 million patent applications were filed in patent offices around the world.[2] Five patent offices accounted for 77% of the patents filed – the Japanese Patent Office (JPO) and the United States Patent and Trademark Office (USPTO) (the two largest in terms of filings), followed by the Chinese Patent Office (CPO), the Korean Intellectual Property Office (KIPO) and the European Patent Office (EPO).[3] According to the World Intellectual Property Organization's (WIPO) patent databases, which stretch back to the 19th century, the big picture for patenting is an acceleration in the use of patents that begins in the 1960s. Since 1995 the average annual increase in total patent filings has been a little less than 5%. Pharmaceutical patenting continues to form a significant part of patenting activity. For example, pharmaceuticals and cosmetics was the third fastest growing field in 2006 in terms of international patent applications that were published under the Patent Cooperation Treaty (PCT).[4]

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[1] See J O Lanjouw, "A New Global Patent Regime For Diseases: U.S. and International Legal Issues" (2002) 16 *Harvard Journal of Law and Technology* 85-124, at 88-89.

[2] WIPO Patent Report: Statistics on Worldwide Patent Activities, 2007, 10.

[3] *Ibid*, at 11.

[4] *Ibid*, at 30.

Companies can use a number of different patenting routes to obtain a national patent in a country. The PCT route has become the single most important route for most companies, and it is a very important route for pharmaceutical companies. The annual reports of developing country Patent Offices (PO) also confirm the importance of the PCT route. For example, foreigners could designate India in an international application under the PCT as from 7 December 1998. In financial year 2005-2006 there were 15,467 PCT foreign filings in which a PCT application had entered the national phase (meaning it was being processed by the Indian PO) as opposed to 4,571 applications by foreigners using other routes.[5] Applicants from the US, Germany, and Japan are the biggest users of the PCT route to India.[6] Of the 24,505 patent applications that the Indian PO received in 2005-2006, 33% were for chemicals, drug and food.[7] If one adds biotechnology applications to this group the percentage climbs to 39%.[8] Foreigners are responsible for most of the patent applications in these sectors.

3. What Big Business Wants From Patent Offices

Transnational companies, the biggest users of the patent system, want a world in which, at a moment of their choosing, they can obtain high quality patents at low cost. The diversity of patent law and administration stands in the way of this kind of world. Diversity means drafting different patent applications for different jurisdictions, going through different procedures, meeting the costs of translation, using the services of local patent attorneys, etc. TNCs acting either individually or through business organisations have become important forces for change in the international patent regime.[9] One such business organisation, the Industry Trilateral Group, has a clear goal of deep harmonisation of patent administration and ultimately patent law as one of its recent resolutions shows:

> *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.*[10]

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[5] Appendix B in Indian Patent Office, Annual Report, 2005-2006, 18.

[6] See Indian Patent Office, Annual Report, 2005-2006, 10.

[7] For 2005-2006 the number of patent applications were as follows: chemical – 5,810; drug – 2,211; food – 101. See Indian Patent Office, Annual Report, 2005-2006, 19.

[8] The number of biotechnology applications was 1,525. See Indian Patent Office, Annual Report, 2005-2006, 19.

[9] On their role in shaping TRIPS see P Drahos & J Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan, 2002).

[10] See Industry Trilateral Report: Global Patent Application, 14 November 2006, available at www.ipo.org

4. What Big Business Wants, Big Business Gets

4.1 Co-operation Amongst Patent Offices

The EPO, JPO and the USPTO are collectively referred to as the Trilaterals. Starting with a June 1982 Memorandum Of Understanding (MOU) between the USPTO and the EPO, and following their first annual conference in 1983, the Trilaterals have continued to sign annual MOUs, deepening and broadening the co-operation amongst them.[11] These three offices have become a global hub of cooperation and convergence in patent administration. Cooperation amongst them spans a range of areas including information exchange through information technology, developing common practices to new areas of patenting and policy cooperation on international patent issues.

The MOUs of 1982–3 can be said to represent the start of an evolution of a global system of patent administration. This emerging international system of administrative governance is separate from the treaty-based processes that aim to harmonise substantive patent law. POs 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 harmonisation.[12] WIPO has been working on a treaty for patent law harmonisation since 1983.[13] 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. As noted in the previous section, the Industry Trilateral Group has made it clear that the Trilateral Offices should concentrate on unifying the administrative practices of POs.[14]

The model of global integration and convergence that PO administration might be said to follow is 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, patent offices from developing countries have become linked to those systems via 'spokes' of bilateral or multilateral cooperation.

The POs of three countries, China, Japan and Korea, have formed the Asian Trilateral. The first meeting of these offices took place in Tokyo in September of 2001.[15] Both collectively and individually, these three offices have become a force for the spread and harmonisation of patent law in the Asia Pacific region. All three offices are International Searching and Examining Authorities (ISEA) in the PCT system. Co-

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[11] The Trilateral Offices held their first annual conference in 1983. See http://www.trilateral.net/background/timeline/.

[12] On this politics see S K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: CUP, 2003), at 173–179.

[13] A Bogsch, "Brief History of the First 25 Years of the World Intellectual Property Organization" WIPO 36 (1992).

[14] 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

[15] KIPO, Annual Report, 2001, 38.

operation with POs from ASEAN countries is a priority and in some cases has gone as far as recognition of an Asian Trilateral office's examination results. So, for example, a patent registered in Korea will be accepted without examination in Singapore and Malaysia.[16] Amongst themselves, the Asian Trilaterals have agreed to examiner exchanges and the electronic exchange of priority documents. All three offices engage in missionary style work that consists of spreading intellectual property consciousness and awareness to as many segments of society as possible.

4.2 Superhighways of Cooperation

The patent prosecution highway (PPH) was an initiative started in July 2006 in the form of a pilot program between the JPO (as initiator) and the USPTO. For the JPO, the potential benefit of the PPH lies in helping Japanese companies overcome the long queues of applications in the USPTO. The large backlog in the USPTO disproportionately affects Japanese companies which patent heavily in the US market. Typically, a Japanese company will lodge an application in JPO first and a corresponding application in the USPTO. The JPO is the office of first filing (OFF) and the USPTO the office of second filing (OSF). Under the PPH, if the JPO allows at least one claim of the application the Japanese company can then request that the USPTO examine the corresponding US application under the PPH procedure. The USPTO can embark on an accelerated examination of the application in which it gets access to the JPO's search and examination work for the purposes of carrying out its own search and examination. The second office is able to come to decision about issuance faster than if it carried out a search and examination that did not utilise the work of the first office. The arrangement is reciprocal. If the USPTO is the office of first filing then the patent applicant can trigger the accelerated examination procedure in the JPO (assuming the USPTO has allowed the claims). In each case the office of first filing provides a benefit to the office of second filing in terms of work savings, and to the applicant in the form of a faster process in the office of second filing.

Since the implementation of the patent superhighway between the JPO and the USPTO both offices have moved to build superhighway connections with other offices. The USPTO has pilot programs in place with the UK, Canadian, Korean and Australian POs. The JPO has a superhighway program with KIPO and pilot programs with the UK and German POs. It is clear that superhighway arrangements will only be put into place with "trusted offices". Trust depends on one office coming to understand the examination process of another office through joint projects and examination exchange. In the case of the superhighway arrangement, the search and examination of the first office has to be easily traceable and transparent to the second office. One can see from the list of offices that, with the exception of the UK and German POs, all are International Searching and Examining Authorities (ISEAs) under the PCT, with those two offices being in any case capable of meeting PCT standards for qualification as ISEAs.

If the current pattern is followed, patent superhighway arrangements will only emerge between ISEAs or POs capable of meeting those standards (where that PO is also a high patenting destination, Germany and the UK both being high patenting destinations). This 'superhighway elite' will collectively be responsible for most of

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[16] KIPO, Annual Report, 2004, 39.

the world's search and examination work. Within the elite group competition will take place for the patenting work of TNCs, those TNCs going to that office that can process a PCT application faster, cheaper and be seen to be producing a 'quality' product. It is already the case, for example, that Microsoft, Intel and 3M go to the KIPO in preference to the USPTO to start the PCT process.[17]

4.3 Truckloads of Patents

The PCT is essentially a procedural treaty. It allows an applicant to make one international application that can be used to designate countries that are members of treaty for a national application in that country. As from January 2004 the designation of all states under the PCT in an application became automatic.[18] The applicant has the option of withdrawing states from designation. The PCT process leads to national patents in the designated countries (not one international patent). Membership of the PCT stands at 138 countries, so one international application can reach many national offices and all the world's most important economies.

One way in which smaller countries are being integrated into the PCT system is through free trade agreements. A standard provision of a free trade agreement with the US, for example, is an obligation for both parties to ratify the PCT. The Central America-Dominican Republic-United States Free Trade Agreement, which was signed on 5 August 2004, for example, contained an obligation that the parties ratify the PCT by 1 January 2006.[19] The US was already a member of the PCT, as were Costa Rica and Nicaragua, but El Salvador, Guatemala and Honduras became members in 2006 and the Dominican Republic in 2007.

Under the PCT, an international application has to be the subject of an international search.[20] The applicant is provided with an international search report along with a written report that analyses the search report. The international search report lists prior art relevant to the patentability of the applicant's invention. Carried out by a PO that has been appointed as an International Searching Authority (ISA) under the PCT, the quality of the search is likely to be as good and probably better than searches carried out by POs that are not ISAs.[21] Along with the search report the ISA also provides a preliminary written opinion on the patentability of the invention.[22]

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[17] Since 1 January 2006, US citizens and residents can elect to use KIPO as an International Searching Authority for PCT applications filed in the USPTO. The information about the activity of these companies was obtained from KIPO.

[18] See Rule 4.9(a) of the Regulations Under the Patent Cooperation Treaty.

[19] See Article 15.1.3 of the agreement.

[20] Article 15.1 of the PCT.

[21] ISAs have to meet certain standards in order to become ISAs and report to WIPO on steps they take to maintain and improve quality. These reports to WIPO are available at http://www.wipo.int/pct/en/quality/authorities.html. For the purpose of carrying out a search an ISA has to search a prescribed minimum of documentation. See Rule 34 of the Regulations Under the Patent Cooperation Treaty.

[22] See Rule 43bis.1 of the Regulations Under the Patent Cooperation Treaty. The written opinion relates to novelty, inventiveness and industrial applicability.

Most applicants with global patenting strategies will begin the process by establishing a priority date in a major national office (e.g., the USPTO, JPO, EPO, German PO) and then move to the PCT. The national filing will give them a period of 12 months under the Paris Convention for the Protection of Industrial Property in which to file a PCT application, and from that filing applicants have about 18 months before the international application turns into a bundle of national applications.[23] Essentially, applicants can defer national entry for 30 months or so. Deferral of national entry is a common goal of PCT applicants.[24] Companies from some industries like the pharmaceutical industry find advantage in delay while those in the information technology field may prefer to move quickly to grant. Both options are possible under the PCT.[25] A company can maximise the time under the PCT and minimise its disclosure obligation by starting at the national level with a provisional patent application. Alternatively, if it wants to speed up matters it can bypass the national phase and start with a PCT application. The opportunity to delay the timing of the application process allows companies to gather more information about the commercial desirability of moving to the national phase of the patent process. From a cost point of view the ability to delay the national application process means that the costs of that process can also be delayed (for example, costs of filing, translating, and using local attorneys).

Broadly speaking, the PCT is evolving in the direction favoured by TNC users, but complete contentment is a ways off. The US reform proposals of 2000 signalled a much more radical agenda in which, for example, there would be fewer PCT searching and examining authorities doing the work and their examination results would be binding on the contracting states of the PCT.[26] The US proposal accurately describes this more radical revision of the PCT as a "longer-term undertaking". Within the PCT Reform Committee process the US, Japan and the EPO have made it clear that the reforms made to the international search and preliminary examination system of the PCT, which began operating in 2004, are simply the first stage.[27] The longer term US agenda of reform for the PCT is a much simpler system in which patenting costs "played little or no role" in business decisions.

Most national POs are part of the PCT system in that they function as receiving offices for PCT applications. However, only a few offices perform the functions of being an International Searching and Examining Authority in the PCT system. Essentially, such offices have to meet certain manpower and documentation standards.[28] In a reformed PCT world where usage of the PCT was even higher than it is now, those offices that were ISEAs would be in an even greater position of dominance than they are today. This dominance would be stronger if, for example, the examination decisions of these offices were binding on the POs of other countries. A small group of offices would therefore be responsible for granting monopolies over

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[23] On the use of Paris Convention priority under the PCT see Article 8(1).

[24] The US made this point to the PCT Assembly in 2000 on the topic of PCT Reform. See WIPO document PCT/R/1/2, 23 March 2001, 5.

[25] On faster entry into the national phase see Article 23(2) of the Patent Cooperation Treaty.

[26] See WIPO document PCT/R/1/2, 23 March 2001.

[27] Committee on Reform of the PCT, PCT/R/2/9 July 5 2002, 3.

[28] See Articles 16(3)(c) and 32(3) of the PCT.

the world's most important technologies. Becoming an ISEA is thus one way in which the national PO of a country can ensure that it remains part of the lead pack of POs in terms of attracting work and having influence in the patent regime. For most developing country POs there is little prospect of gaining ISEA status. They will act as mailboxes in the PCT system and rely on the work of ISEAs. The Chinese PO was admitted as an ISEA in 1994 and the POs of India and Brazil have recently been recommended for ISEA status.[29]

5. And What About Patent Quality?

One issue that is discussed both within and outside POs is the quality of issued patents. In a study of POs conducted by the author, POs repeatedly selected the EPO as having the best quality. If indeed the EPO is the standard bearer of quality, there is reason to worry. In Europe, the Administrative Council of the European Patent Convention has led a consultation and debate with a view to developing a long-term strategy for the European patent system.[30] 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. "Mere quantity," the delegations observed, "cannot be regarded as a sign of increasing innovative power."[31] The basic solution was a return to quality in the grant of patents.

This theme of a return to quality has been followed up by some national POs with 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 (e.g., restricting their capacity to split patent applications).[32] Without going into details, most of what the EPO has done has been aimed at improving productive efficiency, where productive efficiency means gaining more from existing resources. The drive for productive efficiency along with the cost reduction drive does raise questions about the final quality of the product. In fact, a paper by the Staff Union of the EPO pointed out that EPO examiners were not able to meet the EPO's quality standards because the time allowed for examination had been reduced by some 35% since the early 1990s, and this had led to the grant of low standard patents.[33]

Quality issues confront every office. A 2005 report by US National Academy of Public Administration concluded that the USPTO did not have enough experienced examiners.[34] It pointed out that for ten of the years between 1992 and 2004 for every

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[29] See PCT Committee for Technical Cooperation PCT/CTC/23/5 12 November 2007.

[30] European Patent Office, Strategy Debate Documentation, http://www.epo.org/about-us/epo/consultation-processes/strategy-debate.html (last visited 29 April 2008).

[31] See "Notes on the patenting situation in Europe", CA/92/05, Munich, 18 May 2005.

[32] See "Dutch paper on the strategy debate", CA/68/06, Munich 15 February 2006.

[33] See SUEPO Position Paper, Quality of Examination at the EPO, May 2004, 5.

[34] US Patent and Trademark Office: Transforming To Meet the Challenges of the 21st Century, National Academy of Public Administration, 2005, xviii.

ten examiners that joined, five left.[35] The upshot was a comparatively inexperienced workforce. Only 45% of its workforce had more than five years experience. Training examiners is not cheap. The same report pointed out that $22 million had been spent on training junior patent examiners in financial year 2000.[36]

6. Patent Optimism in China, Brazil and India

The POs from Brazil, China and India have close links with the Trilateral Offices. For example, the USPTO has been helping the Indian PO train examiners in pharmaceutical patent examination, and the India PO has signed an MOU with the EPO. According to the Chinese PO's annual report, by the end of the 2000, 63 examiners from the Chinese PO had been sent to the EPO for training or study.[37] There are many more examples one could give. The governments of all three countries have made the modernisation of their POs a high priority, and all have achieved ISEA status under the PCT. It is also clear that these three countries have accepted pharmaceutical patenting as part of the price of entering a globalised economy, and may even see economic advantages for themselves in such patenting. For example, interviews conducted by the author in India in 2005 suggest that at least some senior policy makers believe that India can be an eventual winner from pharmaceutical patenting based on the strength of India's research infrastructure.

6.1 China

In 1984 the Standing Committee of the Sixth National People's Congress adopted a patent law that become effective in 1985.[38] Its principal features included a 15 year patent term,[39] the exclusion from patentability of pharmaceutical products and substances produced from chemical processes,[40] an 18 month publication rule,[41] deferred examination,[42] pre-grant opposition,[43] and a compulsory licensing system based on a local working requirement.[44] The MOU of 1992 between China and the US resulted in some significant changes to China's patent law; China agreed to a 20 year patent term,[45] the patentability of all chemical inventions, including

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[35] *Ibid,* at 80

[36] *Ibid,* at 81

[37] http://www.sipo.gov.cn/sipo_English/laws/annualreports/ndbg2000/200202/t20020227_34014.htm

[38] An English translation of this 1984 law is available in D B Kay, "The Patent Law Of The People's Republic Of China In Perspective" (1985) 33 *UCLA Law Review* 331, Appendix.

[39] Article 45.

[40] Article 25 excluded food, beverages, flavourings, pharmaceutical products and substances obtained by chemical processes.

[41] Article 34

[42] Article 35 required an applicant to request examination within three years of the date of filing.

[43] Article 41 allowed any person to oppose the application within three months from the date of announcement of the application.

[44] Article 51 obliged the patentee to make the product or use the process in China or authorize other persons to do so.

[45] Article 1.1(c).

pharmaceuticals,[46] and a compulsory licensing provision that followed what was then draft TRIPS language.[47] China enacted these reforms by 1 January 1993. In a talk given in 1996 the then Commissioner of Patents, Gao Lulin described the 1993 reforms as creating "a favourable legal environment for expanding international trade, promoting technological exchange with foreign countries, and attracting foreign investment," as well as creating "favourable conditions for China to accede to the World Trade Organization."[48]

6.2 Brazil

In 1971 Brazil completely revised its patent law via Law No. 5772, which came into force on 21 December 1971. An extensive list of non-patentable subject matter included substances obtained by chemical processes and pharmaceutical processes and products. Considerable trade pressure was put on Brazil by the US in respect of this law. In 1996 the Brazilian Congress and President Cardoso passed Law 9,279, which repealed the 1971 patent law and introduced a revised patent law that met Brazil's obligations under the TRIPS Agreement. Pharmaceutical products and processes were now once again patentable in Brazil.[49] Unlike India, Brazil did not take advantage of the transitional provisions in TRIPS to delay the introduction of a product patent regime for pharmaceuticals till 1 January 2005.[50] Brazil's strategy appears to be to invest in the modernisation of its PO, let it play a major role in spreading IP culture through a multitude of training courses, and, with the assistance of the US, build a court system that really understands intellectual property, and hope that a sufficient number of Brazilian firms are able to capture economically significant patent monopolies. The areas in which this is thought most likely to happen are biofuels and biotechnology more broadly, even though, for the time being, Brazil does not have a significant share of the world's biotechnology patents.[51]

6.3 India

India's 1970 *Patents Act* is a good example of the way in which a developing country can successfully re-design an institution that was imposed upon it during colonisation. The monopoly privileges that the patentee obtained under the 1970 Act were nested amongst a set of regulatory levers, some of which could be pulled by government and

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[46] Article 1.1(a).

[47] Article 1.1(d)(ii).

[48] G Lulin, "New Development of the Chinese Patent System" (1996) 7(1) *World Libraries*, at http://www.worlib.org/vol07no1/lulin_v07n1.shtml#about

[49] For the list of current exclusions from the meaning of invention see Article 10 of Law No. 9,279 of 14 May 1996.

[50] The 1996 law had transitional provisions providing for protection of pending applications – see Articles 230 and 231. But the full application of a product patent regime appears to have been dragged out by Provisional Measure No. 2014-1 of 30 December 1999 which qualifies the operation of pipeline protection for patent applications caught by the transitional provisions of the 1996 patent law. This measure also allows for the deferral of decisions on some product patent applications until 31December 2004. For a discussion see R Gossain and H Sherrill, "Significant Patent Developments in Brazil" (May 2000) 122 *Patent World* 12.

[51] See Figure 3.3.2 in Compendium of Patent Statistics, OECD, 2007, 20.

some by private actors in order to overcome the anti-competitive effects of a monopoly. So, for example, the central government could, if it took the view that the invention was not available to the public at a reasonable price, apply to the Controller to have a patent endorsed with the words "licences of rights" meaning that the patentee had to grant a licence to any person interested in working the patent.[52] If the parties could not agree terms, the Controller had to settle the terms, but in the case of patents related to pharmaceutical process patents, the royalty could not exceed 4% of the "net-ex-factory sale price in bulk."[53] There were also detailed provisions designed to encourage the working of inventions in India on a commercial scale, and to allow individuals to obtain compulsory licences.[54]

A separate Chapter of the Act regulated the right of the Indian government to use and acquire patented inventions.[55] The scope of invention was carefully delineated with a considerable number of things excluded from the meaning of invention, including methods of agriculture, and horticulture and processes for medicinal, surgical, curative and prophylactic treatment of human beings.[56] Patent claims for substances intended for use as a food, medicine or drug, as well as substances produced from chemical processes, could not be granted, but claims relating to the processes for manufacture of such substances were allowable.[57] The term "medicine or drug" was defined in the widest possible way to include, for example, insecticides, germicides, intermediates in the preparation of medicines and substances intended to be used in the maintenance of public health.[58] The patent term for process patents for food, medicines or drugs was reduced from the term of 14 years to 5 years from the date of sealing of the patent or 7 years from the date of patent, whichever one being the shorter period.[59]

Under its TRIPS deadline, India had until 1 January 2005 to bring its patent law into full compliance with the patent provisions of TRIPS. The final step meant introducing patent product protection for pharmaceuticals and chemicals. Thus, in 2005 an amendment was passed that omits the restriction on the patenting of substances intended for use as a food, medicine or drug, or substances produced by chemical processes.[60]

7. Regulating Patent Offices in Developing Countries

Given that all the major developed and developing states have facilitated the expansion of the patent system and its administration, especially in the pharmaceutical

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[52] See Sub-section 86(1) and Sub-section 88(1) of the 1970 Act.

[53] See Sub-sections 88(2) and (5) of the 1970 Act.

[54] See Chapter XVI of the 1970 Act.

[55] See Chapter XVII of the 1970 Act.

[56] See Section 3 of the 1970 Act.

[57] See Section 5 of the 1970 Act.

[58] See Paragraph 2(l) of the 1970 Act.

[59] See Paragraph 53(1)(a) of the Act.

[60] Patents (Amendment) Act 2005. A copy of this legislation is available at the Indian Patent Office website: http://ipindia.nic.in/ipr/patent/patents.htm

sector, it is clear that governments will have to consider alternatives that can co-exist with the patent system. It is also reasonable to assume that the continued increase in pharmaceutical patenting in developed and developing countries will not make access to medicines by the poor any better. Indeed, it is entirely possible that access problems will become worse. Large numbers of patents act as a selection mechanism. A firm's ability to survive in commercial terms depends as much on its capacity to hire lawyers to fight patents as it does on the efficacy of its products.

Fighting patents is a deeply resource intensive exercise; resources that are difficult to find, especially in developing countries. 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.[61] The patent on Dideoxy Purine Nucelosides was a broad formulation patent and issued to pharmaceutical company Bristol-Myers Squibb on 22 January 1998.[62] 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 Bristol-Myers Squibb withdrew the patent. Fighting this one patent involved a large number of government and civil actors in Thailand, and it 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. Developing countries have an interest in high patent quality. Competition in the marketplace amongst pharmaceutical companies is the best way to bring down prices. Thailand's experience with the ddl patent strongly suggests that a guiding principle for developing countries should be prevention rather than cure (i.e., it is much better to find ways to prevent pharmaceutical patents of doubtful validity getting onto the patent register, rather than trying to remove them through costly litigation).

Brazil has developed a regulatory model designed to improve the quality of pharmaceutical patents. In 1999 it passed a law that made the grant of patents on pharmaceutical products and processes dependent upon the consent of the National Sanitary Surveillance Agency (ANVISA).[63] Patent applications concerning pharmaceuticals are processed by the Brazilian PO in the normal way, but the final grant of the patent depends on ANVISA's consent. ANVISA carries out a substantive analysis of the patent application to determine whether in fact there really is an

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[61] 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), www.accessmed-msf.org.

[62] 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" (2005) 267–71.

[63] ANVISA's regulatory jurisdiction over pharmaceutical patent and product processes commenced with Provisional Measure 2.006 of 15 December of 1999 and was consolidated in Article 229-C of Law 10.196/2001. It reads as follows: "The allowance of patents to pharmaceutical products and processes will depend upon the previous consent of the Brazilian Sanitary Surveillance Agency – ANVISA". The text of this law was provided to the author by Ms Ana Paula Jucá Silva of ANVISA by email on 11 July 2007.

invention and that it is novel.[64] ANVISA's examiners, who have been given training in patent examination, have rejected patent applications that have been approved by Brazilian PO examiners, something that has led to criticism from the patent attorney profession.[65] Brazilian patent law firms, some of which have helped train Brazilian PO examiners,[66] have complained about the fact that an independent group of health experts with patent training now have a veto role over pharmaceutical patent examinations, but from a social welfare point of view, this Brazilian model does offer one way in which developing countries can improve the quality of examination in a sector of vital national interest.

8. Summary and Conclusion

Pharmaceutical patenting has been one the faster growing areas of the general growth in patenting. There is no reason to suppose that this trend will reverse itself. As a result of the PCT system and the close co-operation of all POs, patenting is being made ever cheaper and faster. Electronic filing now exceeds paper filing in the PCT system.[67] As a result, companies can obtain patents in many more of the world's main markets than ever before. This is especially true in the pharmaceutical sector where the world's major developing countries have fully accepted pharmaceutical patenting.

Formally, national POs remain sovereign patent-granting entities. In reality patent administration has become increasingly dominated by those offices that have achieved ISEA status under the PCT. In practice, many POs, especially those in developing countries, already defer to the examination results of these offices. This trend will continue and will become more formalised. Those offices that are ISEAs will compete with each other for the custom of TNCs. They will compete in terms of speed and cost. KIPO, for example, already advertises the fact that it has the fastest patent examination service in the world (pendency is a little under 10 months).[68] The current superhighways of cooperation will become highways of competition.

All offices will talk about quality, but the reality will be that most patent applications will see less than 20 hours processing time by an office prior to grant. Other filtering mechanisms such as pre or post-grant opposition or litigation will capture only a small percentage of the many tens of thousands of pharmaceutical patents that will be issued each year (even in the US only about 1-2% of patents are litigated).

If developing countries want to avoid the political fights and trade pressures that surround the use of compulsory licensing of medicines, they should take a lot more interest in what their POs are doing. In particular, developing countries have to focus on improving the quality of pharmaceutical patent examination. Ultimately, no

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[64] Information provided by Ms Ana Paula Jucá Silva of ANVISA to the author by email on 11 July 2007.

[65] For more details on ANVISA's role from a patent attorney perspective see R Gosain, "A worthless investment?: hurdles to obtaining patents in Brazil" (2004) 163 *Patent World* 13.

[66] On the training of patent examiners by local attorney firms see "On the cusp of new technologies" (October 2001) 113 *Managing Intellectual Property* 62, at 63.

[67] See, The International Patent System in 2006: PCT Yearly Review, WIPO, Geneva, 2.

[68] See its Annual Report for 2006.

amount of tinkering with patent law will help unless patent examiners are given the time and resources to do high quality examination work. Moreover, as we have seen, patent quality is an issue that is of interest in some European countries, raising the possibility of a developed-developing country coalition on patent quality issues. Importantly, countries retain sovereignty over how they run their POs. The opportunity for regulating the work quality of POs in ways that improve access to medicines for citizens exists, at least for the time being.