Access to Medicines in India: A Review of Recent Concerns

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Chan Park* and Arjun Jayadev**

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Abstract:

India has long been a central front in the struggle for access to affordable medicines. Because of its dynamic generic pharmaceutical industry, it has become what Médecins Sans Frontières has called the "Pharmacy of the Developing World" (MSF 2007). As a result, it has also been a key battleground on some of the most contentious issues relating to whether, and to what extent, countries retain flexibilities under the WTO's Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement) to ensure that patent protection does not come at the cost of access to safe, effective and affordable essential medicines. This chapter reviews some of the key developments in India, four years on, since the entry into force of the Patents (Amendment) Act of 2005, which introduced product patent protection for pharmaceuticals for the first time since 1972. Although there have been some notable successes for the access to medicines movement, many challenges remain, and the future of India's continuing status as the developing world's pharmacy remains unclear. This paper examines some of the key challenges and opportunities that lie ahead for India.

*** Independent Researcher and Lawyer on Health and IP.**

**** University of Massachusetts Boston and Committee on Global Thought, Columbia University**

I. Introduction and background – patents, medicines and access in India

India has long been a central front in the struggle for access to affordable medicines. Because of its dynamic generic pharmaceutical industry, it has become what Médecins Sans Frontières has called the "Pharmacy of the Developing World" (Médecins Sans Frontières 2007). As a result, it has also been a key battleground on some of the most contentious issues relating to whether, and to what extent, countries retain flexibilities under the WTO's Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement) to ensure that patent protection does not come at the cost of access to safe, effective and affordable essential medicines.

Nowhere is the central role of Indian generic companies more visible than in the provision of affordable medicines to treat HIV. The advent of triple-combination antiretrovirals (hereinafter referred to as "ARVs") for HIV in the mid-90s transformed what had been a fatal disease into a chronic, but largely manageable, lifelong condition. However, due in part to the high costs of these drugs that resulted from patent protection in developed countries, a vast inequity in access to lifesaving treatment emerged: those fortunate few in the developed countries that could afford ARVs at costs exceeding US$ 10,000 per year, and the vast majority of persons living with HIV in the developing world who were denied treatment (MSF 2008).

However, in 2001, an Indian generic company, Cipla, announced that it would provide generic versions of these lifesaving ARVs at a price about thirty times less than the prices what the multinational pharmaceutical companies had been charging. Cipla, and shortly thereafter, other Indian generic manufacturers, were able to enter the market with generic versions of these ARVs as a result of the fact that India, at that time under the Patents Act in force since 1972, did not recognise product patent protection. Now, with a host of other Indian generic makers having entered the market, the prices have fallen to less than US$ 87 per year—over a hundred-fold reduction in prices in a span of seven years (MSF 2008).

With the availability of cheap Indian generic ARVs, it became a realistic possibility to scale-up treatment dramatically throughout the developing world. Between 2003 and 2008, the world witnessed an unprecedented scale-up in treatment, placing almost 3 million PLHIV on treatment in the developing world (Joint United Nations Programme on HIV/AIDS 2008). By and large, these scale-ups were made possible with affordable generic drugs sourced from India.

Even today, the importance of Indian generic manufacturers in supplying affordable medicines throughout the developing world is hard to overstate. In Sub-Saharan Africa, for instance, Indian generic ARVs account for 85% of the total volume of generic ARVs supplied (Avafia, et al 2006). When compulsory licences on several essential medicines were recently issued in places such as Brazil, Thailand, Malaysia and Indonesia, these governments looked to India in order to import affordably priced generic versions.

When India amended the Patents Act, 1970 (the "Patents Act" or "Act") to come into full compliance with the TRIPS Agreement in 2005, there were grave concerns voiced by civil society organisations from both within India and throughout the developing world. The concern among international organisations was understandable: due to India's policy choice since 1972 of not recognising product patent protection on pharmaceuticals, India's generic pharmaceutical industry had thrived, and had become the largest supplier of affordable essential medicines throughout the developing world.

This chapter reviews some of the key developments in India, four years on, since the entry into force of the Patents (Amendment) Act of 2005, which introduced product patent protection for pharmaceuticals for the first time since 1972. Although there have been some notable successes for the access to medicines movement, many challenges remain, and the future of India's continuing status as the developing world's pharmacy remains unclear. This chapter examines some of the key challenges and opportunities that lie ahead for India.

Part one examines the development of the Indian generic pharmaceutical industry during the pre-TRIPS era, demonstrating its continuing ability to manufacture generic versions of key pharmaceutical products, often at a fraction of the cost charged by originator companies. Part two reviews Indian patent law from the perspective of the extent to which India has been able to incorporate some of the key TRIPS "flexibilities" that can facilitate access to medicines. While there are several aspects of the Indian law that could be improved, we conclude that Indian patent law is (or has the potential to be) uniquely progressive. Part three examines some of the key legal developments that have occurred in Indian courtrooms and patent offices since 2005. These decisions demonstrate that Indian patent law jurisprudence is beginning to recognise the need to balance the State's obligations to protect the constitutional rights to life and health with patent protection, and has the potential to create a uniquely progressive body of caselaw. Finally, part four looks ahead to some of the key challenges and opportunities that lie ahead for India; issues that, depending on how they are resolved, have the potential to ensure that India remains a key supplier of affordable essential medicines to its own population and throughout the developing world.

II. The Indian generic pharmaceutical industry: 1947-2005

As is the case with many erstwhile British colonies, India inherited the statutory and legal framework of the United Kingdom when it gained independence in 1947. Among these colonial legacies was the Patents and Designs Act, 1911, which allowed for the patenting of a broad range of inventions, including for pharmaceuticals, for a period of sixteen years after the filing date (Mueller 2007, 506-9). During the colonial period and in the first decades after Indian independence, this law remained in place, during which time "virtually no basic drug manufacture" happened in India, and the vast majority of patent applications were filed by foreigners (Ibid.).

The legal framework that allowed the Indian generic industry to thrive was not implemented until 1972, when the Indian Patents Act, 1970 came into force. The Patents

Act, 1970, was based on the recommendations of a report commissioned by the Indian government in 1957 and submitted two years later, commonly known as the "Ayyangar Report," named after the jurist Rajagopala Ayyangar, who chaired the committee that drafted the report (Ayyengar 1959). The Ayyangar Report recommended a vast overhaul of the Indian patent system, observing that the system in place at the time "has failed in its main purpose, namely, to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public" (Ayyangar 1959). Portions of the Report are worth quoting at some length, both because they lay out the philosophical underpinnings of the Indian law that followed, and because it puts into stark relief the fact that developing countries are now largely precluded from taking similar considerations into account when formulating their own laws in the post-TRIPS world.

In discussing the costs and benefits of a patent system, Ayyangar made the observation that simply having a patent system in place is insufficient to promote innovation and economic development:

> The advantages accruing to a nation's economy from rewarding inventors with the grant of [patents] are dependent on two main factors: (1) The country must be technologically advanced to maintain the rate of invention which is brought forth by the promise of the reward…(2) The patented invention must be worked in the country which grants the patents…
>
> From the above it will be seen that the monopoly created by the patent…offer advantages which have been claimed for the system, only in the highly industrialised countries which have a large capital available for investment in industries and a high degree of scientific and technological education.
>
> It is further obvious however that the system would not yield the same results when applied to under-developed countries (Ayyangar 1959).

Thus, Ayyangar recognised that a "one size fits all" approach to formulating patent policy was inappropriate, and that laws "have to be designed, with special reference to the economic conditions of the country, the sate of its scientific and technological advance, its future needs and other relevant factors…so as to minimise if not eliminate the abuses to which a system of patent monopoly is capable of being put" (Ayyangar 1959). Of particular importance to Ayyangar was the need to ensure the easy availability of affordable medicines. As such, he recommended that Indian law not provide patent protection for pharmaceutical products, in order to ensure that food and medicines are available to the public at reasonable prices (Ayyangar 1959).

Interestingly, this recommendation was based largely on Ayyangar's observation that this was the accepted practice at the time in virtually every European country (Ayyangar 1959). Of course, most countries today (with the exception of a handful of least

developed countries[1] and non-WTO members) are legally prohibited from copying what was near universal European practice just a few decades ago.

Even after the Ayyangar Report was submitted to the Indian government in 1959, it would be over a decade before legislative changes were made to Indian law. "As is not uncommon in Indian legislative measures, change came very slowly" (Mueller 2007). The Patents Act, 1970 incorporated many of the recommendations of the Ayyangar Report; the most significant of which was to exclude pharmaceuticals from patentability. Thus, claims covering a pharmaceutical product itself were deemed to be unpatentable under the 1970 Patents Act, and only processes patents were made available.[2] In addition, the patent term for even these process patents was shortened, to the shorter of five years from grant or seven years of filing,[3] and automatic "licences of right" were made available three years after the grant of the patent (Dhar & Rao 2004, 6). As such, a competitor would be able to obtain an automatic license to practice the patent three years after grant on terms as agreed to by the parties, or failing agreement, on terms as set by the Patent Controller (Patents Act, 1970 §§ 87, 88). As Dhar and Rao have noted, these amendments effectively eliminated patent barriers on pharmaceuticals (Dhar & Rao 2004).

When India adopted its patent law in 1972, which explicitly prohibited product patents in drugs, there was a fear that the country would not have continued access to medicines as multinational companies lost control over existing markets and were disincentivized to bring in new molecules to the country. Contrary to these expectations, however, India has managed to maintain a regular and steady production of the most state-of-the-art medicines over the last three decades. This in turn was due to a combination of factors, including the initial investment of government into laboratories (such as the Central Drug Research Institute) which enabled Indian companies to develop technical and technological expertise. As a result, Indian companies have managed to successfully reverse engineer virtually every viable drug produced by multinational pharmaceutical

[1] Least developed countries (LDCs) that are members of the WTO (and thus bound by the TRIPS agreement) are permitted to exclude pharmaceutical products from patent protection until at least 2016 (WTO 2001).

[2] A "product" patent is distinguished from a "process" patent in that a product patent covers the final product itself (and thereby precludes others from manufacturing the product), whereas a process patent only covers the method by which one makes the product. Thus, the latter form of protection is decidedly narrower: the patenting of a particular process of manufacturing a medicine does not preclude competitors from entering the market with the same product, as long as the competitor is able to devise an alternative means of manufacture. Indeed Ayyangar specifically recommended that India provide process patent protection for medicines, as he was of the view that doing so "would accelerate research in developing other processes by offering an economic inducement to the discovery of alternative processes leading again to a larger volume of manufacture at competitive prices (Ayyangar 1959).

[3] Although TRIPS now mandates a minimum of a 20-year patent term as of the date of filing, many countries (including the US) once started the term of the patent as of the date of grant of patent. In India, the term of a process patent on a pharmaceutical was based on a hybrid formula: the *shorter* of seven years from the filing of the patent application or five years from the grant of a patent. Thus, if company X filed a patent application on 1 January 1980, and the patent office granted the patent on 1 January 1981, the term of the patent would be five years from date of grant – i.e., 1 January 1986, as this would be the shorter of the two options. However, if the patent office did not grant the patent until 1 January 1985, the term of the patent would be seven years from date of filing, i.e., 1 January 1987.

companies. The market share of multinational companies in India has declined from over 60% in 1970 to about 25% in the early 2000s (Chaudhuri, 2005, Federation of Indian Chambers of Commerce and Industry 2005,, 2005). The domestic pharmaceutical industry accounted for 70% of active pharmaceutical ingredients and 80% of formulations in India by 1999, making it "possibly the only developing country in the world that has come this close to achieving so-called self-sufficiency in medicines" (Musungu & Oh 2006, 16). Furthermore, India is now the world's fourth largest producer of drugs (by volume) and with eight percent of the world's drugs being manufactured within its borders.

Within India, in most therapeutic sectors the market leader is almost always a generic manufacturer. The generic market leader's price is lower than the originating firm and market share is almost always dominated by the indigenous Indian industry (see for a particular example, section IV b). Drugs are often produced and marketed in India without the presence of the patent owner in the Indian market[4]. Patent titling abroad appears to provide sufficient information for domestic firms to produce and distribute the molecule, and as long as there is adequate market demand in India, these drugs will be produced for the domestic market by generics.

Table (1) considers the twenty top selling drugs in the US in 2006.Among the top 20 selling drugs in the United States, every molecule had a generic producer in India. However for only 6 of these 20 cases did the patent owner market a brand in India and in only 2 of these 20 was the patent owner the first to bring the drug to the Indian market[5]. Most patent owners had production units in India but the majority chose not to launch their products in the country immediately. While this is not prima facie evidence to suggest that new drugs would not have been marketed in India except for the existence of generic firms, it is certainly reason to question whether multinational corporations would have an incentive to invest in the country, given its relatively small size of market for drugs selling at prices prevailing under patent protection.

Entry into Indian Market of Top 20 Brand Name Drugs

[4] One possible explanation for this is that the Indian market continues to be entirely too small and too competitive for patent owners to consider launching their brand names. Consider the case of Lipitor, Pfizer's blockbuster brand of Atorvastatin which was the world's best selling drug in 2006 with $12.2 billion in sales worldwide. Lipitor has still not been launched in India 8 years after Atorvastatin was launched by domestic producers. The entire Indian market for Atorvastatin in 2006 generated Rs. 226 crores or approximately $50 million dollars (representing less than 0.5% of Lipitor's sales) and was represented by 56 brands

[5] These data are from data collected by ORG-IMS and which was provided to us by CENTAD. We thank CENTAD for their use.

Brand* (Molecule)	Patent Owner	Brand Available in India?	Molecule available in India? **	Was the molecule launched by the patent owner in India?
1.Lipitor (Atorvastatin) [Cholesterol]	Pfizer (United States)	N	Y	N
2.Nexium (Esomeprazole) [Gastroesophageal Reflux]	AstraZeneca (United Kingdom)	N	Y	N
3.Prevacid (Lansoprazole) [Gastroesophageal Reflux]	Novartis (Switzerland)	N	Y	N
4.Advair Diskus (Fluticasone Propionate) [Asthma]	Glaxo Smith Kline (United Kingdom)	Y	Y	N
5.Singulair (Montelukast Sodium) [Asthma]	Merck (Germany)	N	Y	N
6.Effexor XR (Venlafaxine HCL) [Depression]	Wyeth (United States)	N	Y	N
7.Plavix (Clopidrogel) [Coronary Artery Disease]	Sanofi-Aventis (France)	Y	Y	N

8.Zocor (Simvastatin) [Cholesterol]	Merck (Germany)	N	Y	N
9.Norvasc (Amlodipine Besylate) [Angina]	Pfizer (United States)	Y	Y	Y
10.Lexapro (Escitalopram Oxalate) [Depression]	Lundbeck (Denmark)	Y	Y	N
11.Seroquel (Quetiapine Fumarate) [Schizophrenia]	AstraZeneca (United Kingdom)	N	Y	N
12.Protonix (Pantaprazole Sodium) [Gastroesophageal Reflux]	Wyeth (United States)	N	Y	N
13.Ambien (Zolpidem Tartarate) [Insomnia]	Sanofi-Aventis (France)	N	Y	N
14.Actos (Pioglitazone) [Diabetes]	Takeda/Eli Lilly (United States)	N	Y	N
15.Zoloft (Sertraline) [Depression]	Pfizer (United States)	Y	Y	Y
16.Wellbutrin XL (Bupropion) [Depression/Smoking]	Glaxo Smith Kline (United Kingdom)	N	Y	N
17.Avandia (Rosiglitazone) [Diabetes]	Glaxo Smith Kline (United Kingdom)	Y	Y	N
18.Risperdal (Risperidone) [Schizophrenia]	Janssen (Belgium)	N	Y	N
19.Zyprexa (Olanzapine) [Schizophrenia]	Eli Lilly (United States)	N	Y	N
20.Topamax (Topiramate) [Epilepsy]	Ortho-Mcneil (United States)	N	Y	N

Source: *Drug Topics 2006, **Mediclik.com

The price of brand name patented drugs in the U.S market-as might be expected- is often orders of magnitude higher than generic versions in India Such a comparison, it may be argued, overestimates the price reducing impact of generic manufacturers, since the price that patent owners may charge in the absence of competition from generics would be predicated on the market characteristics of Indian demand and thus would be lower. This said, an illustrative example of the cost savings afforded by generic manufacturers in India is to look at prices for the same product in Pakistan which does not have a large generics industry but which shares demographic, economic and disease profiles with India. Looking at 11 drugs used to treat hypotension and other cardiac diseases, Lele

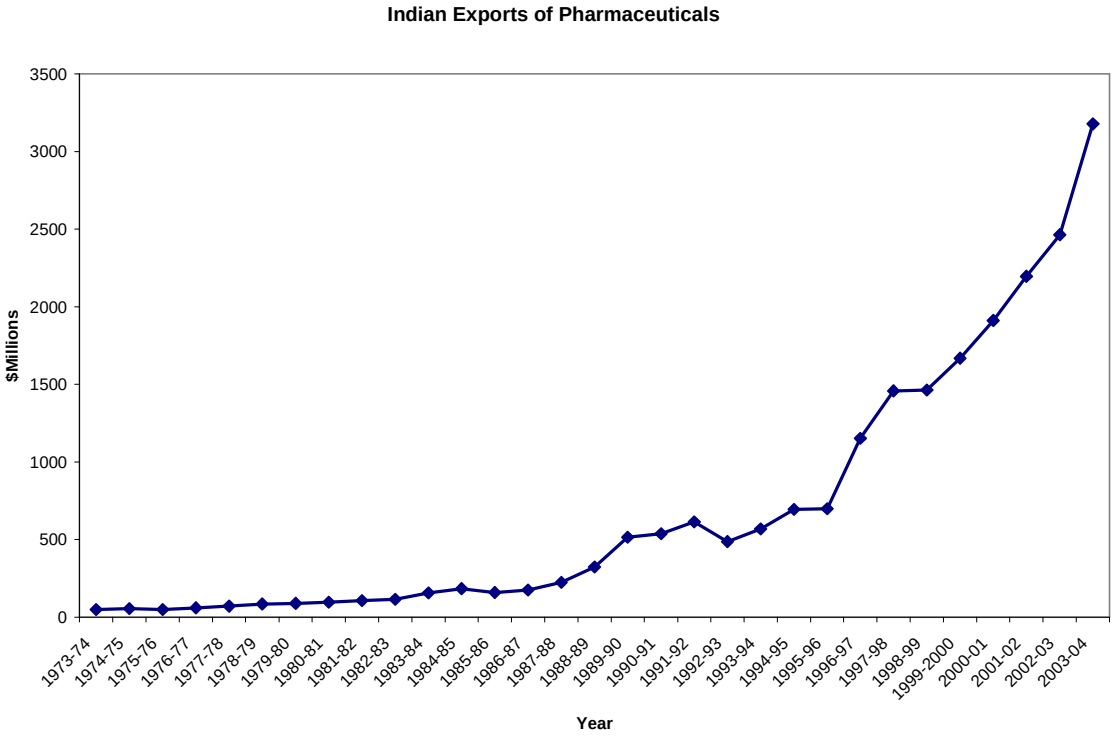
(2005)[6] found significant price differences. The lowest price at which these drugs were sold in Pakistan, where patents were in force ranged from 195% to 2012% more expensive than in India, where generic equivalents were available.

As a result of this ability to produce high-quality low-cost generics, Indian industry has expanded significantly both domestically, but also increasingly through export orientation and internationalization. The ability of Indian companies to produce at low costs, combined with competent certification and business models that encouraged growth through exports has meant that many developing countries have used Indian generic medicines as an affordable source of medicines for public health. Furthermore, Indian generics have recently become critical players in litigation surrounding generics access and patenting as they have begun to export to developed country markets.

Chauduri (2005) shows that export revenues have increased significantly from 1996 onwards, although export activity increased in the late 1980s. In 1996, exports were about $700 million, but by 2006, the figure was over $3 billion. Export revenue constitutes about half of overall revenues of the industry and for some companies, including Ranbaxy, Dr. Reddy's, Lupin, Ipca and Orchid, their export intensity has been even higher[FICCI, 2005, Chaudhuri, 2005]. . Export orientation has changed from a focus on other developing country markets to developed country markets, which accounts in substantial part for the larger volumes in exports following 2000. While certainly a consequence of the maturity and vibrancy of Indian pharmaceuticals, this process can be seen also as a response to the TRIPS agreement. Faced with the certainty of dwindling domestic markets, much of the industry began to focus on external opportunities, particularly on products which were going off patent. Indeed, one of the arguments made to minimize the threat that the agreement posed was to suggest that the immense export opportunities provided by lucrative developed country markets where previously patented drugs are going off-patent were more than adequate to offset the losses of domestic markets as patented products gained protection within Indian jurisdiction. Estimates of the market size that might be available have ranged from $ 40 to $60 billion (Kamal Nath, 2004)

Figure 1

[6] Source : Lele, R.D. "The Prescription that changed practice", IDMA Vol XXXVI (40), 30th October 2005.



This period of success for the generic industry, predicated on an intelligent industrial policy and opportunities provided by other markets is however potentially coming to an end. The challenges that are being faced are described in greater detail in section (IV).

III. Analysis of Indian Patents Act/TRIPS flexibilities: the 2005 patent act

a. The TRIPS era

When World Trade Organization came into being on 1 January 1995 with India as a signatory, it signalled the beginning of the end for the patent regime that had allowed the Indian generic pharmaceutical industry to achieve self-sufficiency. Under the terms of the WTO-mandated TRIPS Agreement, it was obligated to make patents available "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (TRIPS Art. 27.1). Thus, no longer could India exclude from patentability inventions from one (or more) particular area(s) of technology, and was bound to make both products and processes eligible for patent protection. Further, the minimum term of patent protection required under TRIPS was 20 years, thus drastically extending the existing term of protection that India had provided to process patents on medicines.

However, as a developing country that had not previously recognised product patent protection on pharmaceuticals, India was eligible to take advantage of a ten-year transition period – until 1 January 2005 – in which to implement the obligations to introduce pharmaceutical product patent protection (TRIPS Arts. 65.2, 65.4). Although several other developing countries were eligible to take advantage of this transition

period, most did not. Only a total of 13 developing countries notified the WTO of its intention to utilise this transition period, and even amongst these countries, only six: Cuba, Egypt, India, Pakistan, Qatar and the United Arab Emirates were still utilising the transition period as of 2003 (Musungu & Oh 2006, 13). Notably, Brazil, which like India did not recognise product patent protection on pharmaceuticals prior the TRIPS Agreement, declined to take advantage of the transition period, and even extended retroactive patent protection to a large number pharmaceutical products that were invented prior to the entry into force of the TRIPS Agreement (REBRIP 2007). The grant of retroactive patent protection in Brazil has cost its health budget an estimated USD 420 million in higher medicine prices between 2001 and 2005, and Brazilian civil society groups have recently challenged the validity of this law (Rosina et al. 2008).

Of course, during the intervening years between 1995 and 2005, several events put into stark relief the concerns over patent protection on access to essential medicines. First and foremost was the explosion of the AIDS crisis in Africa and other parts of the developing world, which exposed a yawning gap in basic access to patented antiretroviral medicines between those living in the developed versus developing worlds. The inequity in access to lifesaving AIDS medicines, and the global outrage this inequity generated, has been credited with spawning the global access to medicines movement (see, e.g., Kapczynski 2008; 't Hoen 2002).

Largely as a result of this unprecedented global mobilisation (Kapczynski 2008), and the concerns that the movement generated among developing country governments, the WTO member countries agreed in 2001 on the "Doha Declaration on the TRIPS Agreement and Public Health," (the "Doha Declaration") which reaffirmed the existence of flexibilities contained in the TRIPS Agreement that could be utilised to promote access to medicines, and declared that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

Thus, India's decision to maximise its full complement of transition periods available under the TRIPS agreement and delay the implementation of product patent protection on pharmaceuticals had both foreseeable and unforeseeable advantages. Obviously, delaying the implementation of product patent protection allowed Indian generic companies to continue manufacturing affordable versions of patented medicines, thus allowing it to become a major player in the global market. Less foreseeable was the fact that in the intervening period, the access to medicines movement would be born; a well-coordinated network of scholars, activists, and community-based organisations that were highly motivated, increasingly sophisticated and "remarkably aware of esoteric patent law developments" (Mueller 2007, 497).

Undoubtedly, it was the confluence of these two (and other) factors that were responsible for many of the unique provisions that were included in the Patents (Amendment) Act, 2005. Considerations of domestic self-interest in maintaining the sustainability of its generic industry, as well as intense pressure from civil society groups both within and without India resulted in an unprecedented amount of public debate surrounding the pros

and cons of the new patent regime in India. "For the first time in independent India's history, national newspapers carried 4-column headline news covering 'patents'. Patents Bill was also the topic of prime-time news in national TV channels" (Pillai 2005). The convenient (albeit accidental) alignment of interests between the domestic pharmaceutical industry and public health activists resulted in a post-TRIPS patent landscape for India that, while still imperfect, is (or has the potential to be) uniquely progressive in its ability to ensure that patent protection does not unduly hinder the objective of "access to medicines for all."

The following discussion discusses some of the more noteworthy provisions in the Indian Patents Act, 1970 (as amended) and their potential or likely impact on access to medicines, but is in no way a comprehensive critique of the Indian Patents Act (For more comprehensive critiques from varying political perspectives, see, e.g., Mueller 2007, Gopakumar & Amin 2005, Basheer 2005).

b. Patentability standards

Much of the discussion of TRIPS "flexibilities," post-Doha, has been focused freedom countries have in determining whether, and on what grounds, to issue a compulsory license on a patented medicine. By issuing a compulsory license, a country is able to authorise, without the patent owner's consent, the import or production of generic versions of a medicine, often priced at a fraction of the cost of the patented version. Indeed, the Doha Declaration did recognise that countries have the "right to grant compulsory licences," and "the freedom to determine the grounds upon which such licences are granted." And a handful of countries, including Thailand and Brazil, have taken advantage of this flexibility, and issued compulsory licenses on several essential medicines.

However, the immediate effectiveness of a compulsory license in significantly lowering the prices of medicines is largely contingent upon the existence of a pre-existing source from which to procure the generic medicine. Thus, for example, when Thailand issued a compulsory license in 2007 for the heart medication clopidogrel, it was immediately able to realise cost savings from about 70 baht (US$ 2.00) per tablet offered by the patent holding company to 1.01 baht (US$ 0.028) per tablet from an Indian generic company – a savings of over 98% (Third World Network 2007).

However, one of the main reasons that clopidogrel was priced so low in India is the fact that competition for the clopidogrel market in India is fierce. There are no less than 41 separate brands[7] of clopidogrel competing in the Indian market because clopidogrel is not under patent in India (the patent application for the active compound was filed in 1987 – prior to India incurring any obligations under the TRIPS Agreement[8]). This is illustrative

[7] Source: IMS data through Centad

[8] Under the TRIPS Agreement, there are no "obligations to in respect of acts which occurred before the date of application of the Agreement for the Member in question" (Art. 70.1). This means that because India did not recognise product patent protection for medicines prior to the entry into force of TRIPS in 1995, India is under no obligation to provide patent protection for medicines that were invented before

of what has been coined as the "rule of five" – dramatic reductions in the prices of medicines are seen once five or more competitors entering the market for a given drug (Quick 1997). Thus, the dramatic and immediate cost savings that Thailand was able to achieve in issuing a compulsory licence was attributable, in large part, to the fact that the medicine in question was never under patent at all in India.

This highlights the importance of an often-overlooked TRIPS "flexibility" that is of particular significance in the Indian context: setting tougher criteria for patentability. By setting rigorous standards for patentability, countries may be able to significantly reduce the number of patent obstacles that may come in the way of generic competition. Although the TRIPS Agreement requires that patents be made available for "inventions" that are "new" involve an "inventive step" and are capable of "industrial application," none of these terms are specifically defined, and countries have considerable latitude in defining these concepts as they see fit (Correa 2007).

India's Patents Act contains some unique provisions that, taken together, potentially constitute the most rigorous patentability criteria in the world. Section 3 of the Patents Act, through its subsections lettered (a) through (p),[9] lists 15 broad categories as "not inventions within the meaning of this Act." Of special relevance in the pharmaceutical context are provisions excluding from patentability the following: (1) natural substances[10]; (2) new uses of known substances[11]; (3) new forms of known substances, unless the new forms exhibit an increase in efficacy[12]; and (4) methods of treating humans and/or animals.[13]

In addition to these broad substantive safeguards contained in the Patents Act, there is one significant procedural bar on patentability that is of significance. Because India did not recognise product patent protection for pharmaceuticals prior to entering into the TRIPS Agreement on 1 January 1995, it was not bound to give retroactive effect to its TRIPS obligations. Thus, for all new drugs that were "invented" before 1995, they would be ineligible, as a matter of law, for patent protection in India.

The cumulative effect of these provisions is to potentially drastically reduce the number of derivative patents that are common in the pharmaceutical industry. As fewer new molecules are being discovered, commentators have noted the increasing trend in the pharmaceutical industry to extend the patent term of existing medicines by seeking and obtaining patent protection on various secondary or ancillary features of a medicine. For instance, a recent report by the European Commission noted the decline in the number of new medicines reaching the market, the number of patent applications on pharmaceuticals had doubled from 2000 to 2007, with the vast majority (87%) on

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1995. Because the active ingredient for clopidogrel was invented in 1987, it was and remains unpatentable in India.

[9] Subsection (g) of Section 3 was deleted from the Patents Act in 2002, thus resulting in only 15, not 16, subsections lettered (a) through (p).

[10] Seciton 3(c).

[11] Section 3(d)

[12] Ibid.

[13] Section 3(i).

"secondary" patents – i.e., patents not covering the active substance itself, but various ancillary features, such as formulations, salt forms, methods of treatment, etc (European Commission 2008). The proliferation of so many secondary patents on existing medicines has facilitated a practice known as "evergreening," whereby a patent holding company is able to artificially extend the period of market exclusivity by obtaining injunctions against generic competitors by filing patent infringement suits on these secondary patents (United States Federal Trade Commission)

Patent oppositions

A key victory among public health advocates and the Indian generic industry was the retention of the pre-grant opposition procedures in the Patents Act. Despite intense pressure from the multinational pharmaceutical industry to eliminate the pre-grant opposition procedure, the Patents (Amendment) Act, 2005 not only broadened it, but also included a provision for a post-grant opposition (§ 25). The pre-grant opposition provision allows for "any person" to file an opposition at any time before the grant of the patent (§ 25(1)) on any of eleven specified grounds, and requires the Patent Office to grant the opponent a hearing on request (§25(1)(k)). The retention of the pre-grant opposition procedure is in contrast to the general trend in other countries, and "India remains one of only a handful of countries that still permit pre-grant opposition," (Mueller 2007). The US, for instance, has no pre-grant opposition procedure, and only allows for an *inter partes* reexamination of a patent after it has been granted (35 U.S.C. § 311).

A key amendment in the 2005 Act was to change the standing requirements for bringing a pre-grant opposition, from "any person interested" to simply "any person." This change allowed for civil society groups to become involved in the patenting process by filing a number of pre-grant oppositions against patent applications pending before the Indian Patent Offices. Although several Indian generic companies have also taken advantage of this provision, the involvement of civil society in this process has been instrumental in advocating for an approach to patent policy that expressly takes into account public health considerations.

IV. Indian courts – Recognizing the right to access to medicines and right to health

Many of the provisions discussed above are relatively new to Indian patent law, and as such, have yet to be tested or construed in the Indian courts. Because of this, the true measure of their effectiveness in promoting access to essential medicines will not likely be known for years, as currently pending and future disputes wind their way through the Patent Offices and then the courts. Although this will entail a fair amount of uncertainty in the short-term, it also represents a unique, perhaps even historic opportunity for non-traditional actors, such as civil society groups, to actively participate in setting judicial precedents that will shape how the new Indian patent laws will be construed and understood in the future. Given the opportunity, via the pre- and post-grant opposition procedures and other avenues, to engage in some of the core legal disputes that will shape the new law, civil society groups in India have advocated in the Patent Offices and the

courts for the need for patent law and policy to take into account the impact of patent protection on access to medicines. Indeed, in the four years since the 2005 amendments have been in place, there have already been a handful of decisions that have the potential to foster a unique line of Indian jurisprudence that injects fundamental public health considerations into how patent law should be interpreted. At the same time, these cases are illustrative of the limitations inherent in using the law as the primary frame from which to advance the aims of the access to medicines movement.

a. Novartis v. Union of India

One of the most controversial amendments in the 2005 Act, as mentioned, was the inclusion of section 3(d) that, among other things, provided that the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not considered an invention under the Act. As the Explanation to this section makes clear, a wide range of derivative patent claims that are common throughout the pharmaceutical industry, such as claims on a particular salt of an existing drug, or a specific polymorphic form, are deemed not to be patentable unless the new form "differs significantly in properties with respect to efficacy." Judging from the Parliamentary debates, it is clear that the intent of the provision was to prevent a practice that is known pejoratively as "evergreening," whereby patent holders seek to artificially extend the period of market exclusivity on a medicine by subsequently obtaining patent protection on secondary features of existing medicines, and were gravely concerned about the impact of broad patent protection on access to medicines throughout the developing world (Lok Sabha 2005)

Interestingly, several members of Parliament, raised the price differential of Novartis' anti-cancer medicine, imatinib mesylate (markted as Glivec/Gleevec by Novartis) as compared to Indian generic versions (INR 125,000 (USD 2,500) per person per month from Novartis versus 8-10,000 (USD 160-200) per person per month from Indian generics) as a cautionary tale against overbroad patent protection and the potential effects of patent protection on medicine prices (Ibid.).

In a strange twist of fate, Novartis' patent application for imatinib mesylate formed the underlying dispute of the single most significant test of India's post-2005 Patents Act to date. Shortly after the Patents (Amendment) Act, 2005 came into effect in March 2005, Novartis' patent application for imatinib mesylate came up for examination in the Indian Patent Office in Chennai. Taking advantage of the expanded standing provision in the pre-grant opposition procedures in the Act, a civil society group – the Cancer Patients Aid Association (CPAA) – filed a pre-grant opposition against the pending application, as did several Indian generic companies. Novartis' application for imatinib mesylate did not claim the active ingredient as such (imatinib was initially patented in 1993, prior to India incurring any TRIPS obligations, and was ineligible for a patent in India), but claimed a specific polymorphic form of the mesylate salt of the active ingredient .

In the first test of how section 3(d)'s prohibition on new forms of known substances would be construed, the CPAA and the generic companies claimed that the application

failed to qualify as an invention under section 3(d) of the Act (Park 2007). In January 2006, the Patent Office agreed with the opponents, and denied Novartis' application, holding, among other grounds, that the application failed to meet the "efficacy" requirement of section 3(d). Not surprisingly, Novartis appealed to the Madras High Court the decision of the Patent Office in denying the application. In a somewhat more surprising move, Novartis also decided to challenge the validity of section 3(d) itself, claiming, among other things, that the provision was inconsistent with the TRIPS Agreement and that it was violative of the Indian Constitution.[14] As a party to the litigation, the CPAA responded, in relevant part, that given the intention of Parliament (as evidenced by the Parliamentary debates), the legislative intent of this provision was perfectly legitimate: to allow the State to fulfil its fundamental duty to protect the Constitutional guarantee of the right to life under Article 21, and to enact appropriate measures to prevent frivolous patents that could pose a threat to the supply of affordable medicines.

In the first court judgment to adjudicate any aspect of India's Patent Act, the Madras High Court dismissed Novartis' challenge on all grounds, holding that (1) an Indian courts lacked the jurisdiction to declare a domestic statute as inconsistent with an international treaty; (2) that Novartis was not entitled to declaratory relief from the Court declaring section 3(d) as inconsistent with TRIPS; and (3) that section 3(d) was not Constitutionally void for vagueness and arbitrariness. In coming to the last holding, the Court observed, "we have borne in mind the object of [section 3(d)], namely…to provide easy access to the citizens of this country to life saving drugs and to discharge the Constitutional obligation of providing good health care to its citizens" (*Novartis v. Union of India*, (2007) 4 MLJ 1153, ¶ 19). Thus, for the first time in Indian patent jurisprudence, a court explicitly recognised the State's constitutional obligations with respect to "providing good health care to its citizens" as a central consideration when construing and interpreting patent law and policy.

b. Roche v Cipla

Although the *Novartis* judgement was remarkable for its affirmation of the legitimacy of public health considerations in interpreting patent law, its use doctrinally is somewhat limited due to the somewhat unusual set of underlying facts of that case. Although it recognises and affirms the Indian Parliament's duty to consider its constitutional obligations of promoting public health when formulating patent policy, it is more difficult to read the judgment as instructing the courts themselves to take such considerations into account. However, following the *Novartis* decision, a judgement from the Delhi High Court, *F. Hoffman-La Roche ("Roche") v. Cipla*, did precisely that.

Underlying the *Roche v. Cipla* case was a suit brought by the multinational pharmaceutical company Roche against the Indian generic company Cipla for infringing

[14] These two petitions – challenging the Patent Office's rejection and challenging the validity of section 3(d) was subsequently bifurcated, with the former being transferred to the newly-created Intellectual Property Appellate Board (IPAB), and the latter heard by the Madras High Court. The matter before the IPAB is discussed in some detail below, section V.a, infra.

its patent on erlotinib, a medicine approved for the treatment of lung cancer (*Roche v Cipla*, I.A. 642/2008 IN CS (OS) 89/2008). Pending the full adjudication of the underlying patent dispute, Roche sought an interim injunction against Cipla to prevent it from marketing its generic version (Ibid.). Cipla had filed a counterclaim against Roche alleging that the patent was invalid under Indian law. The Delhi High Court, in denying Roche's application for an interim injunction, concluded that it was bound to take into consideration the public interest, including the right to life guaranteed in Article 21 of the Constitution:

> The degree of harm in [if an injunction is granted] is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erloticip are concerned (Ibid. para 85).

Although the judgment of the Delhi High Court is currently under appeal in the Supreme Court, the Court's reasoning, if upheld, potentially opens the door to a form of jurisprudence that allows for what are essentially judicially-created compulsory licences. The possibility will be discussed in more detail in section V.d, infra.

c. Indian Network for People Living with HIV/AIDS v Boehringer Ingelheim

Although the various controversial provisions in the Indian Patents Act will eventually wind their way through the courts, it has been and will continue to be the Patent Offices that will make the initial determinations on many of the as-yet unresolved questions relating to the patent law (Mueller 2007). Because of this, civil society groups in India have made a concerted effort to make the Patent Offices aware of the potential ramifications behind many of their decisions on access to medicines. To date, various civil society organisations in India have filed several pre- and post-grant oppositions against patent applications relating to a variety of medicines. In addition to raising the various technical grounds of opposition as applicable (e.g., obviousness, section 3(d), 3(e), etc.) the oppositions filed by civil society organisations are notable in that they have attempted to place each patent application in the context of the need to interpret and implement the law in a manner consistent with promoting access to medicines.

A recent decision by the Delhi Patent Office, in response to a pre-grant opposition filed by the Indian Network for People Living with HIV/AIDS (INP+), rejected Boehringer Ingelheim's patent application relating to a paediatric formulation of nevirapine, a critical first-line AIDS medicine. In considering the patent opposition, the Patent Office cited to the Madras High Court's judgment in *Novartis*, and agreed with the opponents that it needed to "give a strict interpretation of patentability criteria, as decision…thereof shall affect the fate of people suffering from HIV/AIDS for want of essential medicine" (*INP+ v Boehringer Ingelheim*). Although the Patent Office recognised that these

considerations did not constitute valid grounds of opposition under the Patents Act, it considered them as "facts of law" (Ibid.).

The foregoing discussion illustrates both the promise and limitations of access to medicine movement's engagement with the law in advancing its goals. Undoubtedly, the precedent set by the *Novartis* decision paved the way for the Delhi High Court to explicitly consider public health considerations in its decision to deny Roche an injunction against Cipla, potentially laying down the doctrinal groundwork for a system of judicially-created compulsory licenses. Likewise, the Delhi Patent Office's recognition that it ought to give a "strict interpretation of patentability criteria" on an application for an essential medicine represents a promising recognition by the Patent Office of the need to robustly apply the patentability standards in Indian law.

However, both the *Roche* judgement and the *INP+* decisions explicitly placed the need to promote access to medicines as background considerations within the primary legal framework of the patent law. The *Roche* decision stated, "Undoubtedly, India entered into the TRIPS regime, and amended her laws to fulfill her international obligations, yet the court has to proceed and apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted" (Roche v. Cipla para 85). Similarly, the Delhi Patent office took pains to note that the public health considerations raised by INP+ did not constitute valid ground of opposition, but stated that it would consider them as "facts of law" in evaluating the technical grounds of opposition (*INP+ v Boehringer Ingelheim*).

To be sure, it would have been unacceptable within the existing legal framework for INP+ to argue, and for the Delhi Patent Office to accept, the argument that public health considerations alone are sufficient grounds for rejecting the patent application. However, the very unacceptability of such a prospect seems to reflect the inevitable consequence of what Amy Kapczynski has called the "gravitational pull of law" in the framing processes across a wide range of access to knowledge (A2K) issues (Kapczynski 2008). While the A2K movement has been instrumental in recent years shaping various aspects of IP law, Kapzcynski argues, the law has had an equally powerful impact in shaping the movement, as the "gravitational pull" of the law has influenced the manner in which members of the movement have framed their goals in relation to the law (Ibid.). The "strategic" effect of the gravitational pull, she argues, "leads groups to modulate their claims in narrow fashion in order to gain control over the instrumental power of the law" (Ibid.). Thus, given the pre-existing legal framework (and cumulative gravitational force) of the TRIPS Agreement, the Patents Act, and the Indian common law, civil society actors in India have correspondingly narrowed their claims to fit within these frames, such that a recognition of their concerns as relevant "background" considerations are counted as successes.

None of this, of course, is to disparage the remarkable achievements that Indian civil society groups have thus far been able to attain. The potential for these early successes to

form the basis of an Indian patent law jurisprudence that is uniquely responsive to the needs of public health is clear, and could not have been accomplished without civil society involvement. What this highlights, rather, is the need to recognise both the opportunities and limitations inherent in engaging with the law to achieve the larger aims of ensuring access to essential medicines.

V. Future obstacles/opportunities

Although not without its shortcomings, the Indian Patents Act is, or has the potential to be, uniquely progressive in facilitating access to medicines. The various provisions of section 3, if robustly interpreted and rigorously applied, have the potential to clear the Indian patent landscape of a large number of obstacles to generic production. The cases discussed above have the potential to represent the beginnings of a distinct brand of Indian patent law jurisprudence that is more responsive to the need to promote access to medicines. Some of the key opportunities and obstacles that we see in the months and years ahead will be discussed below.

a. Patent examinations

One of the unresolved issues in the wake of the Madras High Court's *Novartis* decision was the propriety of the Chennai Patent Office denying Novartis a patent on its application for imantinib mesylate. Although Novartis had filed two separate petitions – one appealing the patent office's decision and the other challenging the validity of section 3(d), only the latter petition was ultimately heard and decided by the Court. During the pendency of both petitions a body called the Intellectual Property Appellate Board (IPAB), with exclusive jurisdiction over all appeals arising from the Patent Offices was officially created, and Novartis' appeal was thereby transferred to the IPAB.

Although the appeal before the IPAB has received considerably less attention in the media, its decision could be just as significant as the Madas High Court's. At issue before the IPAB is the question of how the "efficacy" standard in section 3(d) will be interpreted. As mentioned, section 3(d) of the Act excludes any "new form of a known substance" from patentability where there is no "enhancement in the known efficacy" of that substance. As the Explanation to this section makes clear, a wide array of common pharmaceutical derivatives are included within section 3(d)'s ambit, and a "significant difference in properties with respect to efficacy" must be demonstrated in order to be eligible for patentability.

There is a dispute, however, over precisely what "efficacy" means within the context of this section (Basheer & Reddy 2008). Depending on how broadly or narrowly this concept is interpreted by the IPAB, section 3(d) could either serve as an effective bulwark against many forms of secondary patents or be rendered largely toothless in preventing many forms of potential patent abuse. In order to illustrate why this would be so, it is necessary to explore in some detail some of the more common types of secondary patenting in the pharmaceutical context. As the National Institute for Health Care Management observed:

> Drug manufacturers patent a wide range of inventions concerned with incremental modifications of their products, including minor features such as inert ingredients and the form, color, and scoring of tablets. In some cases, these patents may discourage generic companies from trying to develop a competitive product. In others, the generic company may "design around" the new features (NIHCM 2002).

However, even where a generic company is able to successfully "design around" such new features, it is nevertheless possible for patent holding companies to file a patent infringement suit on these secondary patents, and obtain injunctive relief preventing the generic versions from coming to market (Correa 2002).

As the legislative history of section 3(d) as discussed above makes clear, it was precisely this type of potential patent abuse that Parliament intended to prevent (Lok Sabha 2005). But in adopting a loose definition of "efficacy," in which essentially any significantly *beneficial* modification to an existing drug is considered to meet the enhanced efficacy test, the standard would be rendered essentially meaningless. This is because practically all such modifications that are commonly patented, as routine as they may be, can be characterised as significantly *beneficial* in one way or another. For instance, it is common knowledge in the pharmaceutical industry that for some active drug molecules, converting the base compound into a salt form can have any number of useful effects (e.g., improved bio-availability, stability, etc.) (Correa 2007). However, as Carlos Correa has also observed, "patents on salts are one of the main avenues for the 'evergreening' of pharmaceutical patents" (Ibid.). Thus, if the standard of "efficacy" in section 3(d) is interpreted as satisfied upon a mere showing of significant *benefit*, then the primary purpose of Parliament's intention in enacting section 3(d) would appear to be undermined.[15]

The Madras High Court, in upholding the validity of section 3(d)'s constitutionality, provided some indication that it favoured a more restrictive definition of "efficacy":

> The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, ***then the patent applicant should show that the substance so discovered has a better therapeutic effect***. Darland's Medical Dictionary defines the expression "efficacy" in the filed of pharmacology as "the ability of a drug to produce the desired therapeutic effect" and ***"efficacy" is independent of the potency of the drug***…(*Novartis*).

[15] Which is not to say, of course, that all patents on salts would thereby be valid and enforceable in India, as the patent would nonetheless have to independently satisfy the basic requirements of novelty, inventive step and industrial applicability. Other jurisdictions, notably the United States, have invalidated patents on salts on obviousness grounds. *See Pfizer v. Apotex*, 480 F.3d 1348 (2007) (invalidating Pfizer's patent on the besylate salt of amlodipine, as the benefits of converting amlodipine into its salt form would be obvious to a person skilled in the art). Regardless of whether Indian courts ultimately adopt a similar attitude with respect to their inventive step analyses, the point remains that section 3(d) would fail to achieve one of its primary legislative aims.

By defining "efficacy" to mean "therapeutic" efficacy, the Madras High Court appeared to indicate that other benefits commonly claimed by secondary patents, such as ease of manufacturability, improved shelf-life, better bio-availability and the like would fail to pass muster under section 3(d). However, the matter before the IPAB, which calls for an interpretation of section 3(d) in relation to the specific facts of the case, will arguably provide more specific guidance to the Patent Offices as to the precise scope and meaning of the efficacy standard. It is clear that such guidance is urgently needed, as early indications are that the Patent Offices are granting patents that would appear to clearly fall within section 3(d)'s ambit (Unnikrishnan 2008).

In addition, it remains to be seen whether the Indian courts can develop a line of jurisprudence that takes a marked shift away from traditional notions of the basic criteria for patentability. Particularly with respect to the inventive step requirement, Correa has recommended that "the best policy from the perspective of public health would seem to be the application of a strict standard of inventiveness" (Correa 2006). Despite the Delhi Patent Office's recognition that "strict interpretation of patentability criteria" should be applied to patent applications relating to essential medicines, there is thus far little indication that this has become widespread practice. Rather, the current stance of the Indian Patent Offices appears to be to rely primarily on judgments from the UK. Indeed, when the Draft Manual of Patent Practice and Procedure was released for public comment in 2008, the National Working Group on Patent Laws objected to its heavy reliance on foreign judgments (National Working Group on Patent Laws 2008).

There is a dearth of Indian patent caselaw dating from the era during which the 1970 Patents Act was in effect. Perhaps inevitably, the courts and the Patent Offices have attempted to fill this vacuum by placing reliance on foreign judgments that interpret the basic criteria for patentability. However, because none of these judgments are legally binding in India, the possibility remains that the Indian courts can forge its own jurisprudence that takes into account the need to ensure access to affordable medicines in evaluating the basic criteria for patentability. Whether the Indian judiciary can be sufficiently weaned from its reliance on foreign precedent to allow this to happen remains to be seen.

b. Data exclusivity

One of the most significant unresolved issues with respect to India's TRIPS compliance is over the nature and scope of the protection it provides to clinical data submitted by originator companies during the drug regulatory process. Normally, in order for a drug to receive marketing approval from a drug regulatory authority (DRA), the applicant must submit a dossier of clinical data to show that the medicine in question is safe, effective, and of good quality (World Health Organization 2006). This is generally only required of the first, or originator, drug applicant, and subsequent generic versions will only need to establish that they are chemically equivalent to the drug that has already been approved. Thus, a DRA, when presented with evidence that a generic drug is equivalent in all relevant aspects to an already approved medicine, it will only need to refer to the

clinical data already in its possession to conclude that the generic version is also safe and effective (Ibid). Not only does this practice dispense with the time and expense involved in requiring every drug applicant to conduct duplicative clinical trials, but it also avoids grave ethical concerns over repetitive clinical trials on human subjects for a drug that is already known to be safe and effective (Ibid). Such a process speeds the approval of generic competition into the market.

> However, the United States and multinational pharmaceutical industry groups have argued that Art. 39.3 of the TRIPS Agreement requires India to implement a system of "data exclusivity," whereby the DRA is legally prohibited from approving equivalent generic versions for a fixed period (usually between 5-10 years) (United States Trade Representative 2008, Pharmaceutical Research and Manufacturers of America 2008). Indeed, for the last several years, India has been placed on the United States Trade Representative's Special 301 "Priority Watch List" for failure to implement data exclusivity (USTR 2008). Countries that are placed on the "Priority Watch List" are subject to retaliatory trade sanctions by the United States, and thus serves as an effective tool to pressure countries to comply with the USTR's demands.

However, there is broad agreement among scholars, international organisations and independent panels that TRIPS does not require data exclusivity (see, e.g., Correa 2002, CIPIH 2006, World Health Organization 2006). Indeed, these groups and individuals have warned that a system of data exclusivity would unduly delay the entry of generic competition and raise the costs of essential medicines, and have advised developing countries against implementing data exclusivity (Ibid.). In fact, even the Indian government has explicitly recognised that TRIPS does not require date exclusivity, but is nonetheless considering adopting it (Reddy & Sandhu 2007). In May 2007, the Indian Government's inter-ministerial committee, headed by Satwant Reddy, the (retired) Secretary of Chemicals & Petrochemicals, issued a report (the "SRC report") on its recommendations for fulfilling India's obligations under Article 39.3 of TRIPS. The SRC report, despite acknowledging that data exclusivity was not required as part of India's TRIPS obligations, somewhat obliquely recommended that India introduce a system of data exclusivity on pharmaceuticals after the expiration of a "transition period" of unspecified duration. Upon expiration of this "transition period", the report recommended that a five-year data exclusivity period be introduced (Ibid.).

Having understood the obligatory legal requirements around data protection, we now turn to data exclusivity as a policy choice, as recommended by the SRC report to the government of India in 2007.

The question of "protection" or "exclusivity" around clinical test data arises in the first place as a result of the expense of generating such data. In order to probe the economic rationale of data exclusivity, it is useful to revisit the cost/ incentive structure of the pharmaceuticals industry in general.

The pharmaceutical industry's overarching market incentive is the patent system. Patents are granted, typically, to pharmaceutical inventions (new chemical entities "NCE" or new

molecular entities "NME") for a period of 20 years in most countries around the world[16]. Patents, a form of intellectual property, have been articulated as monopolies (albeit for a limited term) granted against the costs of drug discovery. While the exact terms and conditions of the patent system remain contested in several countries as diverse as the USA, Thailand, Brazil, South Africa and India – to name a few – the cost of drug discovery is also a contested figure.

A recent study[17], drawing on prior work in the area, estimated the cost borne while producing a new drug at $802 million. This figure has been accepted by the pharmaceutical industry and is frequently cited in support of industry positions[18]. However it has been criticised by others[19] as being inflated, for (a) undervaluing government assistance in drug development (b) overvaluing the cost of capital and opportunity cost (c) overestimating the size, and therefore, the cost, of clinical trials, and finally (d) for relying on confidential industry data which might be skewed.

It is important to note that the cost of clinical trials (the "data" in question for the purposes of this paper) is only a *part* of the total cost of drug discovery. Expectedly, estimates for the cost of clinical trials vary.

As a solution to the issue of increasing clinical costs, researchers have suggested a system of compensatory liability, whereby each producer would bear a cost of the clinical trials according to a given formula (see Sanjuan et al 2006).Whatever indeed that cost, it is a global cost – one set of clinical trials that applies to every regulatory agency anywhere in the world, even if it has to be submitted separately to each. Countries like India make up less than 1% of the world's pharmaceutical market. For MNC pharmaceutical companies, India typically counts for much less of the world market. This means, that when you factor in the premium pricing that MNCs charge, combined with the "first mover advantage" it provides more than adequate incentive. This is provided of course that MNC pharma take the opportunity to be the first movers- an opportunity they have but do not often take as seen in the analysis above.

c. Limitations on injunctions

As mentioned above, the Delhi High Court's decision in *Roche v. Cipla* raises some intriguing possibilities with respect to the future direction of Indian jurisprudence pertaining to the grant of injunctive relief in patent infringement cases involving essential medicines. Although it is far too early to state with any degree of conviction that Indian jurisprudence will head in this direction, the *Roche* judgement provides much of the doctrinal basis upon which a uniquely progressive view of patent enforcement could be forged in India. And though not discussed in the *Roche* judgement, there appears to be a firm basis in international law upon which such an approach could be justified.

[16] See 1.2
[17] The price of innovation: new estimates of drug development costs-*J.A. DiMasi et al. / Journal of Health Economics 22 (2003) 151–185*
[18] For instance IFPMA July 2007 data excl
[19] Jamie note

As traditionally understood, and as codified in the TRIPS Agreement, a patent confers on the owner exclusive rights to prevent third parties from making, selling, using, etc. the patented product without the owner's consent (TRIPS Art 28). Generally, the manner in which this exclusive right is enforced is through a court-ordered injunction – both at the preliminary stage (interim injunction) and upon a final determination of infringement (permanent injunction) – preventing the alleged infringer from making, selling, using, etc. the patented product. Clearly, the possibility of being enjoined from manufacturing or selling a product that arguably falls within the scope of an existing patent serves as the primary deterrent to entering the market in the first place - the mere threat of being prevented from selling its product, after having made huge up-front investments in bringing a product to market, could deter a generic company from making such investments at all.

However, the exclusive rights described in Article 28 of TRIPS are not absolute. There are recognised exceptions to exclusivity. Article 30 of TRIPS, for instance, provides for limited exceptions to patent rights to be recognised in certain cases. This has been interpreted as allowing for a number of acts that would otherwise be considered patent infringement, such as the "experimental use" exception (Third World Network 2003). Additionally, compulsory licences, as permitted under Article 31 of TRIPS, represent yet another exception to the exclusive rights conferred by a patent, as compulsory licenses, by definition, are issued without the consent of the patent holder.

However, there are instances where the exclusive right of a patent has been abrogated that do not fit neatly into either a limited exception under Article 30 or a compulsory licence under Article 31. In a 2006 United States Supreme Court judgment (*eBay Inc. v. MercExchange LLC*, 126 S. Ct. 1837), the Court overturned what had been a longstanding practice in the lower courts of automatically granting a permanent injunction upon a final determination of patent infringement. The Court held that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards" (Ibid.). Thus, even upon a final determination of patent infringement, the traditional four-factor test must be satisfied before an injunction could issue:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a perpetual injunction (Ibid.).

The lower court, on remand, applied these equitable factors and denied the plaintiff a permanent injunction, finding that monetary damages would be adequate (MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695 (E.D. Va. 2003)).

Essentially, the denial of an injunction despite a finding of patent infringement amounts to a compulsory licence, as the defendant is legally allowed to continue its infringing activities without the patent owner's consent, and the remedies are limited to monetary damages. However, the striking feature of such a "judicially-mandated" compulsory licence is that, as Christopher Cotropia has observed, it does not comply by the rather extensive procedural requirements of a compulsory licence contemplated under Article 31 of TRIPS (Cotropia 2008).

This, however, does not necessarily render the US Supreme Court's *eBay* decision inconsistent with TRIPS. As both James Love and Cotropia have argued, the *eBay* decision can be justified on the basis of Article 44 of TRIPS, which states, in relevant part, that while "The judicial authorities shall have the authority to order a party to desist from an infringement," (Art. 44.1) it notes that "where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available" (Art. 44.2) (Love 2007, Cotropia 2008). As Article 44.1 makes clear, the judicial authorities must be given the authority to issue injunctions as and when they are deemed necessary. However, Cotropia argues, "the second sentence of Article 44.2 defines a universe of "other cases" where, if an injunction is "inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available" ...*eBay* is one of these "other cases," where the United States' remedies laws preclude an injunction under certain circumstances and compensation is awarded instead" (Cotropia 2008).

But once this analysis is accepted, then there is no conceivable reason why countries could not adopt more expansive views of what those "other cases" may be. Clearly, the four-factor equitable test as described in *eBay* is neither mandated by TRIPS nor binding on any courts outside of the United States. There is no reason why the Indian courts (or Parliament, for that matter) could not develop a more expansive test that specifically took public health considerations into account in determining whether an injunction is made available. Indeed, Justice Louis Harms of the Supreme Court of Appeal of South Africa foreshadowed in 2004 – two years before the *eBay* decision came down – that countries could move in this direction, particularly with pharmaceutical patents:

> …[permanent injunctions] are granted as a matter of course in South Africa. Otherwise it would amount to granting the defendant a compulsory licence. It is nevertheless foreseeable that in, say, pharmaceutical patent cases, *where public health concerns or the constitutional rights to health care arises*, a court may have to consider whether or not to leave the rights holder to a damages claim instead of a [permanent injunction] (Harms 2004, emphasis added).

Viewed in light of the above, it is apparent that the Delhi High Court's reasoning in *Roche* is perfectly in line with Justice Harms' prediction that "where public health concerns or the constitutional rights to health care arises," injunctive relief could be justifiably denied. Indeed, the *Roche* judgement cited with approval to the *eBay:* "This view accords with the trend in the United States, where in [*eBay*], the Supreme Court of

United States rendered a significant judgment relevant in the present context." Having taken note of *eBay*, the Court went on to expand the traditional equitable principles of "balance of hardships" and "irreparable harm" beyond the parties to the dispute to explicitly encompass considerations of public health and the constitutional guarantees of right to life and health of the general public. In light of India's Constitutional obligation, as recognised by the Madras High Court, to "provide good health care to its citizens", it may even be viewed a positive obligation of the State to refuse the grant of injunctions where public health concerns are intertwined.

Of course, it remains to be seen whether the Roche judgment will stand on appeal, and whether similar reasoning will be employed if and when a final determination of infringement is made. Moreover, due to the lack of clarity in the Patents Act as to what constitutes adequate remuneration for compulsory licences, there is a danger that the monetary damages awarded in lieu of an injunction will be so high as to make the generic versions only marginally more affordable. Parliament could easily address both these concerns, of course, by making appropriate amendments to the Patents Act. It could, for instance, create a statutory presumption that monetary damages will suffice in cases of patent infringement where public health considerations are involved. And by implementing clear, predictable and affordable remuneration guidelines for compulsory licenses, the courts would have guidance in calculating the appropriate damages. Nevertheless, even without Parliamentary intervention, the principles laid down in the *Roche* judgement could potentially form the basis of a common law jurisprudence that could ensure the continued supply of affordable Indian generic medicines for years to come.

d. Future of Indian generics

Despite the welfare gains from Indian industrial policy towards pharmaceuticals over the last three decades, the signal policy implementation of the last decade—the amendment of Indian Patents Act to be compliant with the TRIPS agreement – may serve to undermine this very success. The adoption of these laws has meant that the generic industry now faces unprecedented challenges. While patent protection is still contentious and many provisions of the Indian patent law are being tested in the courts, companies are scrambling to adopt different business models in anticipation of the drying up of their product chain as drugs invented post 1995 begin to replace pre-1995 drugs. In addition, there have been newer threats to the continued existence of the industry arising from considerations of international law. In particular, the global debates surrounding such issues as data exclusivity and counterfeit drugs are of as much concern to Indian pharmaceutical industry as the imminent entry of multinational pharmaceuticals into the domestic market.

Despite the reasonable current growth of the Indian pharmaceutical sector, there is considerable uncertainty surrounding the revenue stream for Indian manufacturers. As Chauduri (2008) points out, the expected size of developed country markets ($40-$60 billion) that will open to Indian manufacturers is almost certainly an overestimation, since the revenues available in the market will certainly reduce following their opening to

competition. Furthermore, as newer drugs enter the market, the segments that will be open to Indian exports will shrink as consumers and providers move to more current formulations. As such, the revenues provided by export markets, while substantial in the short term, do not represent a long term viable strategy for Indian generic producers.

Given this, there has been substantial increase in research and development by generic manufacturers and a series of high profile R & D partnerships with multinational pharmaceuticals. The Indian industry appears to be split between those firms who wish to maintain the current model by trying to maximize the flexibilities provided by TRIPS and issuing patent challenges versus those which are seeking international partnerships with the aim to becoming part of research based pharma[20]. Thus far however, despite suggestions that India will become the new hub of pharma R & D because of the huge potential cost savings, there have been no significant successes in indigenous drug development thus far. There has, however been a significant casualty in the form of the takeover of Ranbaxy—once the world's seventh largest generic, and the largest company in India-- by Daiichi Sankyo of Japan.

Among the ways in which drug development in India is likely to progress is through contract research and manufacturing service (CRAMS). Contract and Clinical Research tie-ups are likely to lead to different business models, while the growth in disposable income and increased potential for health care coverage is likely to sustain domestic revenue streams for the near future. This said, the most important, and as of yet unanswered question is how, and whether affordable access to medicines will be maintained with greater focus on, and enforcement of, intellectual property.

VI. A few concluding thoughts

As the foregoing discussion indicates, the Indian generic pharmaceutical industry is in the process of undergoing a dramatic sea change – one that will likely continue in the coming years, absent significant policy changes. As the newer drugs come under patent protection in India under the new product patent regime, individual pharmaceutical companies will largely be left with two options: (1) shift to a globally oriented, generally pro-IP segment that serves largely as the outsourced generics arm of multinational pharmaceutical companies, or (2) continue to cater to the domestic and other developing country markets in those shrinking areas where patent barriers do not exist. The net result of this growing divergence in the domestic pharmaceutical industry will be that fewer players (and generally the smaller, less established ones) will continue to serve as providers of affordable medicines for the developing world, and the range of products that they will be able to provide will increasingly be limited.

There are, however, significant policy changes that are available to the Indian government to lessen the impact of these trends. For one, the patentability standards that exist in Indian law are already uniquely progressive, and their strict implementation has the potential to ensure that patent barriers to access are kept to a minimum. However, it

[20] Ranbaxy, for example announced in 1993 that its mission was "to become an international, research based company" (Chaudhuri, 2008).

is far from clear that these strict patentability standards are being applied in a uniform manner, and several patents that would appear to be clearly excluded by existing law have been granted by the Indian Patent Office. The Indian government should provide clear guidance to the Patent Office to strictly and rigorously apply these standards.

For those instances in which patents on essential medicines are nonetheless granted despite India's patentability standards, India retains a host of TRIPS-compliant flexibilities that have yet to be utilised. The issuing of compulsory licences on patented medicines is one such flexibility. Despite the existence of substantive provisions for the issuance of compulsory licences that could have broad application in the access to medicines context, the administrative procedures remain needlessly complicated and without sufficient clarity or guidance. A reform of the compulsory licensing provisions that (1) states a clear policy in favour of granting compulsory licences for public health purpoes; (2) establishes clear and predictable rules on when a licence will be granted, and (3) clearly states what the terms and conditions of such licences shall be could potentially open a significant opportunity for domestic Indian producers to continue to provide affordable versions of patented medicines.

Finally, the Indian judiciary has, in the handful of cases that have come before it, shown a tendency towards recognising the need to take public health considerations into account when interpreting and implementing the provisions of the Patents Act. Although the evolution of a robust body of caselaw on patents and public health will likely take years (if not decades) to develop in India, some of the core principles already laid down in the handful of judgements that have come down have the potential, if extended and broadly applied, to create an environment where patents do not come at the price of access to essential medicines. And as it has been from the start, the evolution of such a body of caselaw will inevitably depend on the active involvement of civil society, framing the issues, challenging conventional wisdom, and pushing the envelope of what is possible in a post-TRIPS world.

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