

**COMING INTO COMPLIANCE WITH TRIPS:  
A DISCUSSION OF INDIA'S NEW PATENT LAWS**

INTRODUCTION.....	877
I. BACKGROUND.....	878
A. <i>Patent Rights in India Prior to Recent Amendments</i> .....	878
1. Background of the TRIPS Agreement.....	883
II. RECENT DEVELOPMENTS IN INDIA'S PATENT LAWS.....	887
A. <i>Patents (Amendment) Act, 2005</i> .....	888
III. ANALYSIS OF THE NEW PATENT REGIME: DIFFERENT PERSPECTIVES ON THE NEW LAWS.....	892
A. <i>Enforcement Questions of the New Patent Regime</i> .....	894
1. Recent Developments in Indian IP Protection..	897
B. <i>Continuing Problems with the Cost of Medicine</i> .....	899
1. Claims by Non-Government Organizations.....	899
2. Other Perspectives on Cost of Medicines.....	901
C. <i>Relevant Cases Concerning the increase in IP Protection.</i>	904
IV. SOME MODIFICATIONS TO THE CURRENT SYSTEM.....	907
A. <i>Establishing a Specialized IP Court</i> .....	907
B. <i>A Comparative Approach</i> .....	909
CONCLUSION.....	911

INTRODUCTION

Protection for intellectual property is a pillar of modern economic policy and is "a catalyst for development."<sup>1</sup> Stronger patent protection can enhance competitiveness in the world market and accelerate economic development for developing countries.<sup>2</sup> Based on these principals, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),<sup>3</sup> signed in 1994, recognized that member countries would establish certain minimum standards in their intellectual property laws and would prioritize international trade obligations as a means of achieving

---

<sup>1</sup> Ali Imam, *How Patent Protection Helps Developing Countries*, 33 AIPLA Q.J. 377, 380 (2005) (citation omitted).

<sup>2</sup> *Id.*

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

national goals.<sup>4</sup> By setting out minimum standards of protection for intellectual property rights, TRIPS intended to create equal trading partners among World Trade Organization ("WTO") Members.

This Note suggests that India's new patent laws, passed to strengthen the country's patent regime, have brought India into compliance with the TRIPS Agreement, but are inadequate to deal with a variety of problems in India and still require substantial revisions. This Note will look at the revised patent laws from the perspective of the Indian pharmaceutical companies and the Indian government discuss some of the merits and downfalls of the laws, and suggest some modifications to the current system. Part I outlines a brief history of patent law in India and provides some background on the TRIPS Agreement. Part II explains the recent developments in Indian patent law and discusses key provisions of the new laws. Part III analyzes the new laws from different perspectives and discusses the benefits and detriments of the new system. Finally, Part IV of this Note offers an alternative approach to solving some of the problems with the Indian patent system.

## I. BACKGROUND

### A. *Patent Rights in India Prior to Recent Amendments*

India was an English Colony for more than one hundred years before obtaining its independence in 1947, and India's earliest patent laws were based upon those of England.<sup>5</sup> The East India Company introduced patent laws in India with the Patents Act of 1856, which resulted from the recommendations of the Lord Macaulay Law Commission.<sup>6</sup> This Act was followed by a

---

<sup>4</sup> See generally DANIEL J. GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 3-28 (1998) (describing the development of TRIPS within the Uruguay Round); David Nimmer, *GATT'S Entertainment: Before and NAFTA*, 15 *LOY. L.A. ENT. L.J.* 133, 137-142 (1995) (providing the historical background of TRIPS); MICHAEL BLAKENEY, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT* (1996).

<sup>5</sup> Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 *VAND. J. TRANSNAT'L L.* 507, 518 (1996).

<sup>6</sup> Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 *MARQ. INTELL. PROP. L. REV.* 273, 278 (2006).

The first Law Commission was established in 1834 under the Charter Act of 1833 and under the Chairmanship of Lord Macaulay. This Commission was responsible for the codification of the Penal Code, the Criminal Procedure Code, and other legislation. The second, third, and fourth Law Commissions were instituted in 1853, 1861, and 1879, respectively. During a span of fifty years, the various commissions recommended legislation on a variety of subjects, based mostly on the adaptation of English laws to Indian conditions. The Patents Act was one such piece of legislation. The first Indian patent legislation was modeled along the same lines as the British Patent Act of 1852.

series of amendments, such as the 1859 amendment which introduced "exclusive privileges for making, selling, licensing, and using inventions."<sup>7</sup> The Patterns and Designs Protection Act of 1872 provided protection for industrial designs and was followed by the Protection of Inventions Act of 1883.<sup>8</sup> The Acts of 1872 and 1883 were combined to make the Inventions and Designs Act in 1888.<sup>9</sup> The Indian Patents and Design Act of 1911 replaced all previous legislation.<sup>10</sup> India was fighting for independence throughout this period, and all of these patent laws were passed to accommodate the needs of the colonial British Empire at the expense of India.<sup>11</sup>

At the time of independence, the British based Indian Patents and Design Act of 1911 was still the existing patent law.<sup>12</sup> After independence, India altered its patent system to better suit its own national goals.<sup>13</sup> The Indian government appointed two committees, the first in 1949, the Tek Chand committee (1948-1950), and the second in 1957, the Ayyangar committee (1957-1959), to review India's patent law system and to suggest modifications to the law.<sup>14</sup> The Tek Chand committee found that India's ill-defined patent provisions enabled multi-national companies to gain patent rights beyond the scope of their inventions, and it recommended the incorporation of compulsory license provisions to reduce the potential for abuse of monopolies.<sup>15</sup> Based on the interim report, the Patents and Design Act of 1911 was modified in 1952, and in 1953 the Controller of Patents became authorized to grant licenses, not patents, on foods, medicines, etc.<sup>16</sup> The Tek Chand committee did not lead to many lasting improvements to the patent laws, however, and a second committee was needed.

The Ayyangar Report of 1959 is significant for India and other less developed nations because it analyzed "the adaptability of foreign patent regimes and policy options to address national issues"<sup>17</sup> and "highlighted the best practices in foreign patent

---

*Id.* at 278.

<sup>7</sup> *Id.* (footnote omitted).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* The Patents and Design Act of 1911 introduced the concept of the Controller of Industrial Patents and Designs. *Id.* at 278.

<sup>11</sup> *Id.* at 279.

<sup>12</sup> Adelman & Baldia, *supra* note 5, at 518.

<sup>13</sup> *Id.*

<sup>14</sup> India Patent Office, Manual of Patent Practice and Procedure 1, 7 (2005) [hereinafter Manual of Patent Practice], available at <http://www.patentoffice.nic.in/ipr/patent/manual-2052005.pdf>.

<sup>15</sup> Ragavan, *supra* note 6, at 279.

<sup>16</sup> Manual of Patent Practice, *supra* note 14, at 7.

<sup>17</sup> Ragavan, *supra* note 6, at 281.

regimes and examined their suitability to address public health and economic concerns of underdeveloped economies.<sup>18</sup> The Ayyangar Committee examined some issues that continue to be debated in the WTO today, including: "(1) whether patenting food, chemical, and pharmaceutical inventions can affect the underprivileged section's accessibility to these products; and (2) whether compulsory licensing can enable accessibility while at the same time promoting innovation."<sup>19</sup>

After a lengthy study and much debate, the reports of these two committees led to the Patents Act of 1970 ("Patents Act, 1970").<sup>20</sup> "The objectives of the Act as listed in its text are unapologetically protectionist, which is not surprising in view of the Committee's findings. Modern India had set a goal to free itself from foreign monopolies and establish strong domestic industries."<sup>21</sup> Under the Patents Act, 1970, the examination and opposition procedures were lengthy. Patent examiners had to ensure applications were in compliance with the procedural requirements of the Patent Act,<sup>22</sup> and to determine whether there was any "lawful ground of objection to the grant of the patent"<sup>23</sup> Patent examiners had to file a report with the Controller of Patents listing any objections to the grant of the patent within eighteen months after receiving a patent application.<sup>24</sup> Objections could relate to the claims and the specification or anticipation of any claims.<sup>25</sup> The Controller had to report any objections to the applicant and give the applicant an opportunity to amend its application.<sup>26</sup> If the applicant fixed all of the objections and the Controller accepted the complete specification, it was then advertised in the Official Gazette.<sup>27</sup> After public advertisement, any person could give notice of opposition to the patent within four months of the publication date.<sup>28</sup> If there was a public

---

<sup>18</sup> *Id.* at 282.

<sup>19</sup> *Id.*

<sup>20</sup> The Patents Act, No. 39 of 1970; India Code (2003) [hereinafter Patents Act, 1970]. The Patent Bill, 1965, was based in large part on the recommendations of the Ayyangar Report, and incorporated, in particular, changes relating to process patents for food, drug, medicines, and was introduced in the lower house of Parliament on 21st September, 1965. *Manual of Patent Practice*, *supra* note 14, at 7. The bill was passed by the Parliament and the Patents Act, 1970, came into force on April 20, 1972, along with Patents Rules, 1972. *Id.*

<sup>21</sup> Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 *Ky. L.J.* 911, 921 (2003).

<sup>22</sup> Patents Act, 1970, *supra* note 20, § 12(1)(a).

<sup>23</sup> *Id.* § 12(1)(b).

<sup>24</sup> *Id.* § 12(2).

<sup>25</sup> *Id.* § 13.

<sup>26</sup> *Id.* §§ 14-15.

<sup>27</sup> *Id.* § 23.

<sup>28</sup> *Id.* § 25(1).

The grounds for opposition are: 1. obtaining invention wrongfully; 2. prior

opposition, the Controller had to "notify the applicant and . . . give the applicant and the opponent an opportunity to be heard before deciding the case." If the application was finally accepted, a patent would be granted if the applicant requested sealing.<sup>29</sup>

The Patents Act, 1970, was very weak for particular inventions, especially pharmaceuticals. The Act did not provide protection for products vital to the Indian economy, such as agricultural and horticultural products, atomic energy inventions, and all living things.<sup>30</sup> A "stated objective[] of the Indian Patents Act, 1970, was the development of an independent Indian pharmaceutical industry. The abolition of pharmaceutical product protection from the inherited British colonial law was seen as the key element in advancing this objective."<sup>31</sup> The Patent Act provided protection for method or processes of manufacture, but did not provide protection for compositions of matter such as medicine or drugs, food, or any other substance "prepared or produced by [a] chemical process."<sup>32</sup>

In addition, the method or process patents for medicines, food, or drugs expired quickly and lasted only "five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter. . . ."<sup>33</sup> Because medicine process patents expired either five years from the grant of the patent, after overcoming opposition and passing examination, or seven years from the time of application, whichever is shorter, "it is possible that a patent which is opposed will expire before the opposition is concluded."<sup>34</sup> Under India's patent regime, patents for other inventions expired after only fourteen years from the date of the patent.<sup>35</sup> In contrast to these short periods, the minimum term of protection under the TRIPS Agreement is

---

publication in any Indian specification or prior publication in any other document in India or elsewhere; 3. prior claim in a concurrent application; 4. prior public use or public knowledge in India; 5. obviousness and lack of inventive step; 6. invention not patentable under the Act; 7. insufficient description of invention; 8. failure to disclose information relating to foreign applications; 9. in case of a convention application, not made within the prescribed time.

Adelman & Baldia, *supra* note 5, at 522 n.65.

<sup>29</sup> Patents Act, 1970, *supra* note 20, § 43.

<sup>30</sup> Manual of Patent Practice, *supra* note 14, at 7-8.

<sup>31</sup> Carsten Fink, *Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry*, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 227, 229 (Carsten Fink & Keith E. Maskus eds., 2005).

<sup>32</sup> Patents Act, 1970, *supra* note 20, § 5.

<sup>33</sup> *Id.* at § 53. "Sealing" of patents is discussed in § 43 (sealing occurs after all examination and opposition procedures to the patent, if any, are terminated).

<sup>34</sup> Adelman & Baldia, *supra* note 5, at 523.

<sup>35</sup> Patents Act, 1970, *supra* note 20, § 53.

twenty years from the date of filing for any kind of patent.<sup>36</sup>

Under the weak regime of the Patents Act, 1970, there was little incentive for pharmaceutical companies in India to perform original research and to develop new drugs. Because pharmaceutical compounds could not be patented, and because process patents expired rather quickly, there was little financial incentive to perform long and costly research and development. To account for India's pharmaceutical needs, a large generic pharmaceutical industry with over sixteen thousand firms developed.<sup>37</sup> These firms were well suited to reverse-engineer pharmaceuticals developed and patented in foreign countries, and to design a new process for producing the same patented drug in large quantities.<sup>38</sup> The Patents Act, 1970, gave the Indian generic pharmaceutical industry great competitive advantages by allowing Indian firms to copy patented pharmaceuticals developed by foreign pharmaceutical companies by simply designing a new method to make the same patented drug.<sup>39</sup> Additionally, the Act placed the burden of proof on the patentee to prove infringement.<sup>40</sup>

To successfully claim infringement of process patents, a patent holder must prove that his particular product could only have been made through his patented process — if the product could be made through any other possible process, the suit for infringement would fail. Because the Indian firms did not have to spend the same amount of time and money in research and development that other pharmaceutical companies did, they could sell the same drugs at a fraction of the price in the United States and Europe.<sup>41</sup> "Indian drug makers have manufacturing costs almost 50 percent below that of multinational drug makers in Europe and the United States, and India's drug discovery cost remains at almost one-tenth of that in the Western world."<sup>42</sup>

Today, India is the world's fourth largest producer of pharmaceuticals, and India's domestic drug industry employs over

---

<sup>36</sup> TRIPS, *supra* note 3, Art. 33.

<sup>37</sup> Rishi Gupta, *TRIPS Compliance: Dealing with the Consequences of Drug Patents in India*, 26 HOUS. J. INT'L L. 599, 602 (2005) (footnote omitted).

<sup>38</sup> *Id.*

<sup>39</sup> Patents Act, 1970, *supra* note 20, § 5

<sup>40</sup> *Id.* § 107

<sup>41</sup> Gupta, *supra* note 37, at 602. "For example, ranitidine (for the treatment of ulcers and gastroesophageal reflux disease) is 56 times more expensive in the United States and 26 times more expensive in the United Kingdom than in India. Similarly, ciprofloxacin (an antibiotic) costs 15 times more in the U.S. and 10 times more in the U.K. than in India." *Id.* at 602 n.14 (citations omitted).

<sup>42</sup> Rochelle Chodock, *TRIPS: Transformation of the Indian Patent System and Its Effects on the Indian Pharmaceutical Sector*, 2 ABA SCITECH LAW. 4, 4 (2005).

460,000 people.<sup>43</sup> India's pharmaceutical sector, however, still has tremendous room for growth.<sup>44</sup> As of 2004, an estimated 1.1 billion people lived in India, but Indians had a very low consumption rate of pharmaceuticals.<sup>45</sup> "Domestic per capita spending stood at only US\$8, bringing India's total spending on pharmaceuticals to US\$8.5 billion. This ranks among the lowest of domestic pharmaceutical expenditures in the Asia-Pacific region. It has been predicted that market growth should push India's total spending on drugs to US\$11 billion by 2007."<sup>46</sup>

Presently, patents in India are governed by the Patents Act, 1970, as amended by the Patents (Amendments) Acts of 1999, 2002, and 2005, and the Patents Rules, 2003, ("Patents Rules, 2003") as amended by the Patents (Amendments) Rules of 2005 and 2006.<sup>47</sup> The present laws are the outcome of various amendments made to the Patents Act, 1970, and the Patent Rules, 2003, designed mainly to meet the requirements of TRIPS and India's obligations under international agreements.<sup>48</sup> Some of the largest changes were made concerning the mandatory requirement of introducing product patents for drugs, food products and chemicals by January 1, 2005.<sup>49</sup> TRIPS, however, does not extend to drugs that were already on the market, and only covers a newly discovered chemical entity.<sup>50</sup>

### 1. Background of the TRIPS Agreement

Effective January 1, 1995, the TRIPS Agreement was a compromise between developed countries that had strong Intellectual Property laws and less-developed countries that had weak or no IP laws.<sup>51</sup> Developed countries argued for an increase in intellectual property protection in the less-developed countries, and the less-developed countries wanted broader access to the open market and increased access to life-saving medicines.<sup>52</sup> "In other words, the patent systems of the developed countries created positive externalities for the developing nations, which were free-

---

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> India Patent Office, <http://www.patentoffice.nic.in/ipr/patent/patents.htm> (last visited August 25, 2007).

<sup>48</sup> Rajkumar Dubey, *Making It Trips Way - India's New Patent Regime*, MONDAQ, 2005 WLNR 11268677 (July 18, 2005).

<sup>49</sup> *Id.*

<sup>50</sup> Fink, *supra* note 31, at 250.

<sup>51</sup> Clark A. D. Wilson, *The TRIPS Agreement: Is It Beneficial to the Developing World, Or Simply a Tool Used To Protect Pharmaceutical Profits for Developed World Manufacturers?*, 10 J. TECH. L. & POL'Y 243, 245 (2005).

<sup>52</sup> *Id.*

riding on the technological information produced in more developed countries. The goal of the developed nations (led by the U.S.) was to increase IP protections in developing countries."<sup>53</sup> In the United States, "IP industries account for over half of all U.S. exports. They represent 40 percent of our economic growth and employ 18 million Americans, who earn 40% more than the average U.S. wage."<sup>54</sup> Strong patent protection is especially necessary in the area of pharmaceuticals because the cost of developing a new pharmaceutical product is extremely high, and the relative cost of copying a product once it enters the market is low.<sup>55</sup> One study showed that "in the United States between 1981 and 1983, 65% of pharmaceutical inventions would not have been introduced, and 60% would not have been developed, had patent protection not been obtainable."<sup>56</sup> In exchange for strengthening their intellectual property laws, developing countries could become WTO members and obtain more open markets in developed nations for their textile and agricultural products.<sup>57</sup> "In effect, the TRIPS negotiations may be viewed as a form of Coasian bargain, with developing countries accepting valuable consideration in exchange for their agreement to adopt a legal system addressing the positive externalities problem."<sup>58</sup>

The TRIPS Agreement set out certain minimum international patent obligations and provided an extremely high standard for patent protection. TRIPS set forth the subject matter that is protected, the rights that are conferred, the permissible exceptions to those rights, and the minimum duration of the protection.<sup>59</sup> The Agreement states that "patents shall be 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."<sup>60</sup> The TRIPS

---

<sup>53</sup> John F. Duffy, *Harmony and Diversity in Global Patent Law*, 7 BERKELEY TECH. L.J. 685, 695 (2002).

<sup>54</sup> *Intellectual Property Rights CQ Congressional Testimony: Hearing on H.R. 32 and H.R. 3632 before Oversight of Government Management, the Federal Workforce, and the District of Columbia, Senate Homeland Security and Governmental Affairs*, 109th Cong. 2 (2006) (2006) (testimony of Chris Israel, U.S. Department of Commerce).

<sup>55</sup> Imam, *supra* note 1, at 383. See Press Release, Tufts Center for the Study of Drug Development, Tufts Center for the Study of Drug Development Pega Cost of a New Prescription Medicine at \$802 Million (Nov. 30, 2001), available at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6> (revealing that as of 2001, the development of a typical new drug may cost pharmaceutical companies as much as \$800 million).

<sup>56</sup> Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986).

<sup>57</sup> Duffy, *supra* note 53, at 695-96.

<sup>58</sup> *Id.* at 696.

<sup>59</sup> TRIPS, *supra* note 3.

<sup>60</sup> TRIPS, *supra* note 3, Art. 27. A footnote to this Article notes: "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be



Agreement was codified as part of the General Agreement on Tariff and Trade (GATT) treaty.<sup>61</sup> To become a member of the WTO, a nation must agree to the broad GATT treaty, which means it must agree to the TRIPS patent provisions. As of 2001, the WTO had 134 members.<sup>62</sup> It is argued that "[m]embership in the WTO has become a practical necessity for international trade today."<sup>63</sup>

The TRIPS Agreement is flexible in national patent-protection system design, and allows variations from country to country in a number of aspects to permit members to structure their protection systems to suit unique situations in the various countries.<sup>64</sup> "Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice."<sup>65</sup> Member states can implement more extensive protection than is required by TRIPS.<sup>66</sup> Article 8, § 1 states that members can organize their intellectual property rules however they want, as long as they are consistent with the other provisions of TRIPS.<sup>67</sup> This flexibility in the Agreement allows developing country members to format their intellectual property schemes to best match the particular needs of the country. Countries can decide to exclude certain inventions from patent protection, such as "rules and methods for mental activities, methods for diagnoses and treatments of diseases, and animal and plant varieties. However, it must be emphasized that the conflict between statutory subject matter and excluded categories is a national concern in all the countries."<sup>68</sup> The TRIPS Agreement also provides for differing levels of national development by granting a ten year transition period for countries to bring their national systems into compliance with the new minimum standards.<sup>69</sup>

The TRIPS Agreement defines some specific circumstances in which a country's human rights needs outweigh the importance of strong patent protection. The TRIPS Agreement allows

---

synonymous with the terms 'non-obvious' and 'useful' respectively." *Id.* at Art. 27 n.5.

<sup>61</sup> General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

<sup>62</sup> Howard C. Anawalt, *Intellectual Property Scope: International Intellectual Property, Progress, and the Rule of Law*, in *ECONOMICS, LAW AND INTELLECTUAL PROPERTY* 55, 59 (Ove Granstrand ed., 2003).

<sup>63</sup> *Id.*

<sup>64</sup> TRIPS, *supra* note 3, § 5.

<sup>65</sup> World Trade Organization, Intellectual Property, Overview: The TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited Aug. 25, 2007).

<sup>66</sup> TRIPS, *supra* note 3, Art. 1, § 1.

<sup>67</sup> TRIPS, *supra* note 3, Art. 8, § 1.

<sup>68</sup> Gladys Mirandah, *India: A Stronger Intellectual Property Rights Regime*, 20 BNA WORLD INTELL. PROP. REP. 08, d33 (Aug. 1, 2006).

<sup>69</sup> TRIPS, *supra* note 3, Art. 66 § 1.

government members of the WTO to intentionally override a patent and to use protected technology through a "public health license" or a "compulsory license." Article 30 of TRIPS allows a government to grant public health licenses to the extent that such actions "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner . . . ." <sup>70</sup> At the Fourth Ministerial Conference in Doha, Qatar, in November 2001, WTO members agreed to work on the implementation of the present agreements, as well as to launch new negotiations to benefit the least developed countries.<sup>71</sup> The Doha Declaration emphasizes that the TRIPS Agreement does not prevent member countries from acting to protect public health, and clarifies the flexibility available to members, particularly with regard to compulsory licensing and parallel importing.<sup>72</sup>

There are numerous articles published on whether the TRIPS Agreement is beneficial to developing countries, or whether it is simply a tool used to protect large pharmaceutical companies from developed nations.<sup>73</sup> Some critics of TRIPS conclude that the strong patent protection in TRIPS was enacted to benefit the private pharmaceutical industry at the expense of poorer nations, rather than to promote innovation and benefit society as a whole.<sup>74</sup> On the other hand, some scholars have argued that compliance with the TRIPS Agreement may be "costly initially for developing countries . . . but in the long term there is the possibility of significant economic growth."<sup>75</sup>

<sup>70</sup> *Id.* at Art. 30.

<sup>71</sup> World Trade Organization, Doha WTO Ministerial Declaration (2001), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm).

<sup>72</sup> *Id.*

<sup>73</sup> See generally Ragavan, *supra* note 6; Wilson, *supra* note 51; Barnes, *supra* note 21; Brigitte Binkert, *Why the Current Global Intellectual Property Framework under TRIPS is not Working*, 10 INTELL. PROP. L. BULL. 143 (2006).

<sup>74</sup> See Ragavan, *supra* note 6 (arguing that inequalities in the development of nations lead to problems with the TRIPS Agreement.)

The Doha Declaration on TRIPs and Public Health epitomizes the failed attempt at Uruguay to create equality amongst inequals by signing the TRIPs Agreement. In granting concessions to the inequals, paragraph 6 of the Doha Declaration acknowledges the extent of that inequality by stating that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement."

*Id.* at 276. See also Barnes, *supra* note 21, at 917.

Professor A. Samuel Oddi, an authority on international patents, explained the adoption of TRIPS in the following critical manner: Industry groups (lobbyists) in developed countries, particularly in the United States, found a receptive government ear to their plea that their intellectual property was being "counterfeited," "pirated," "stolen," and "infringed" to their detriment and to the detriment of intellectual property-exporting countries by a generally bad lot in certain countries.

*Id.* (citing A. Samuel Oddi, *TRIPS-Natural Rights and a "Polite Form of Economic Imperialism,"* 29 VAND. J. TRANSNAT'L L. 415, 424 (1996)). See generally Wilson, *supra* note 51.

<sup>75</sup> See Imam, *supra* note 1, at 394-95 (arguing that increased patent protection benefits

## II. RECENT DEVELOPMENTS IN INDIA'S PATENT LAWS

The Patents Act, 1970, is still the principal Act when it comes to patent legislation in India. The subsequent patent amendments (1999, 2002, and 2005) all build upon the principal legislation, rather than amending the newest Act. So the patent system in India is currently governed by the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 and the Patents Rules, 2003, as amended by the Patents (Amendment) Rules 2006.<sup>76</sup>

The new patent amendments have been a series of steps designed to bring India into compliance with the TRIPS Agreement. The Patents (Amendment) Act, 1999 laid down the provisions for filing applications for product patents in the fields of drugs or medicines, with a retroactive effect from January 1, 1995, and the grant of Exclusive Marketing Rights ("EMRs") on those products.<sup>77</sup> The Patents (Amendment) Act, 2002 provided twenty year terms for patents, and reversal of the burden of proof of infringement of patents.<sup>78</sup> The third amendment was the Patents (Amendment) Ordinance 2004, which came into force on January 1, 2005, (as required by the ten year least-developed country member transition period of TRIPS)<sup>79</sup> and incorporated the provisions for granting product patents in all fields of technology including chemicals, food, drugs and agrochemicals.<sup>80</sup> This Ordinance was replaced by the Patents (Amendment) Act 2005, which is in force now having a retroactive effect from January 1, 2005.<sup>81</sup>

Under the Patents Act, 1970, the Government of India has the power to make rules for implementing the Patents Act and regulating the Patent Administration.<sup>82</sup> Accordingly, the Government passed the Patents Rules, 1972.<sup>83</sup> The Patents Rules, 1972 were amended in 1999, and replaced by the Patents Rules,

---

both developed and developing countries). By creating stronger patent protection systems, developing countries can: (1) reduce the number of innovative scientists fleeing to developed countries to obtain better protection for their inventions, which helps them invest their talents into the local technological market; (2) improve the quality of health; and (3) generate an increased flow of FDI and R&D investments into the developing countries' marketplaces. *Id.*

<sup>76</sup> India Patent Office, General Information for Filing Patent Application in India, 1, available at [http://www.patentoffice.nic.in/ipr/patent/patents\\_filing.pdf](http://www.patentoffice.nic.in/ipr/patent/patents_filing.pdf) (last visited Aug. 25, 2007).

<sup>77</sup> Manual of Patent Practice, *supra* note 14, at 8.

<sup>78</sup> *Id.*

<sup>79</sup> TRIPS, *supra* note 3, Art. 66, § 1.

<sup>80</sup> Manual of Patent Practice, *supra* note 14, at 8.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

2003.<sup>84</sup> The Patents Rules, 2003, were amended by the Patents (Amendment) Rules, 2005, and the Patents (Amendment) Rules, 2006, which is now in force.<sup>85</sup> “The Rules include provisions relating to time-lines with a view to introducing flexibility and reducing processing time gradually for patent applications, and simplifying and rationalizing procedure for grant of the patent.”<sup>86</sup>

A. *Patents (Amendment) Act, 2005*

The Patents (Amendment) Act, 2005, (“Patents Act, 2005”) was signed into law by the President of India on April 4, 2005, published in the Gazette of India,<sup>87</sup> and brought India’s patent laws fully into compliance with TRIPS. “This bill amends India’s previous Patents Act to incorporate stricter patent laws, while simultaneously continuing to protect India’s domestic pharmaceutical sector and the public health of her citizens.”<sup>88</sup> The Patents Act, 2005, altered the former definition of “pharmaceutical substances” to “any new entity involving one or more inventive steps.”<sup>89</sup> This means that the pharmaceutical must be new and not just an insignificant change from a previously patented entity.<sup>90</sup> The new law states:

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 or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.<sup>91</sup>

This means that small, insignificant improvements in known compounds, such as just adding a simple chemical group such as salts, esters, ethers, etc., or the discovery of any new property or new use of a known substance will not result in a patentable invention unless there is substantial improvement in efficacy.<sup>92</sup> For example, a product, such as aspirin, can not be re-patented every time someone discovers a new use for aspirin.<sup>93</sup> This modification of the law prevents drug manufacturers from making variations on the same drug to extend the patent life beyond the

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> The Patents (Amendment) Act, 2005, No. 15 of 2005; India Code (2005) [hereinafter Patents Act, 2005], available at

[http://www.patentoffice.nic.in/ipr/patent/patent\\_2005.pdf](http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf) (last visited Aug. 31, 2007).

<sup>88</sup> Chodock, *supra* note 42, at 4.

<sup>89</sup> Patents Act, 2005, *supra* note 87, at comment 2(h).

<sup>90</sup> Chodock, *supra* note 42, at 4.

<sup>91</sup> Patents Act, 2005, *supra* note 87, at comment 3.

<sup>92</sup> Chodock, *supra* note 42, at 4-5.

<sup>93</sup> *Id.*

original 20 years and thus delaying the entry of generics into the market.<sup>94</sup>

The Patents (Amendments) Act, 2005, is literally a list of amendments to the Patents Act, 1970, not a reprinting of the law as a whole, and incorporates several major changes to the old patent act. The Patents Act, 2005 omits section 5 of the Patents Act, 1970, to allow product patent protection in addition to the existing process patent regime in all fields of technologies including the areas of food, medicine, and drugs.<sup>95</sup> The new Act also includes a provision for publication of patent applications.<sup>96</sup> New applications are to be published eighteen months from the date of filing or from the date of priority, whichever is earlier; there is also an option for an early publication of the application if requested by applicant.<sup>97</sup> The Patents Act, 2005 also rewrote the sections on opposition to patents, pre-grant and post-grant.<sup>98</sup> Pre-grant opposition can now be filed anytime after publication but before the grant of patent.<sup>99</sup> Prior to this amendment, the time

<sup>94</sup> Dubey, *supra* note 48.

<sup>95</sup> Patents Act, 2005, *supra* note 87, at comment 4; Dubey, *supra* note 48. This change brings India into compliance with TRIPS, *supra* note 3, Art. 27, § 1.

<sup>96</sup> Dubey, *supra* note 48.

<sup>97</sup> *Id.*

<sup>98</sup> Patents Act, 2005, *supra* note 87, at comments 23-25.

<sup>99</sup> *Id.* at comment 23. Grounds for pre-grant opposition are now:

(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;

(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim—

(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or (ii) in India or elsewhere, in any other document: Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or sub-section (3) of section 29;

(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

(d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.

*Explanation* — For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;

(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;

(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the

period for pre-grant opposition was only four months from the date of advertisement of the acceptance of a complete specification.<sup>100</sup> Post-grant opposition to a patent can now be filed up to one year from the date of publication of the grant of a patent.<sup>101</sup> The amendment also rewrote all grounds for pre-grant and post-grant opposition to comply with TRIPS.<sup>102</sup>

Several provisions in the Patents Act, 2005 speed up the process of reviewing and granting patents. The time frame for examination of patent applications was substantially changed by the new law.<sup>103</sup>

Earlier, the time period to put the application in order for acceptance was 12 months from the date of the first office action. In the meantime, the first office action had to be replied to within four months of its receipt. The new Rules prescribe a total time period of six months to put the application in order for grant. This period is extendable by three months. Upon filing the RFE, the Controller of Patents will refer the application to an Examiner. The law does not prescribe a time limit to do so. The Examiner, on receipt of such reference, must issue an Office Action within one month and not later than three months from the date of reference.<sup>104</sup>

In addition, "[p]rovisions relating to acceptance of complete specification, advertisements of acceptance of complete specification and effect of acceptance of complete specification have been omitted. There will now be direct grant of Patent."<sup>105</sup> The old provisions which dealt with the requirement of sealing of Patent were also omitted by the new Act.<sup>106</sup> Indian legal officials have also recently opened at least ten new regional patent offices

---

invention or the method by which it is to be performed;

(h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;

(i) that in the case of convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

*Id.*

<sup>100</sup> Dubey, *supra* note 48.

<sup>101</sup> *Id.*; Patents Act, 2005, *supra* note 87, at comment 23.

<sup>102</sup> Patents Act, 2005, *supra* note 87, at comment 23.

<sup>103</sup> Mirandah, *supra* note 68.

<sup>104</sup> *Id.*

<sup>105</sup> Dubey, *supra* note 48.

<sup>106</sup> Patents Act, 2005, *supra* note 87, at comments 32-34, 52.

in order to speed up the patent process.<sup>107</sup> The processing time limits for examination of patents have been reduced from forty-eight months to thirty-six months.<sup>108</sup> "Apart from major changes, one of the positive aspects of the present Act is that by amending the various sections rigidity in the time-line is replaced by greater flexibility."<sup>109</sup>

When India joined the WTO in 1995, India was forced to create a means for filing pharmaceutical product applications. However, India did not have to review these applications until January 1, 2005, when the developing member transition period ended.<sup>110</sup> To satisfy this requirement, India set up a "mailbox" system to receive, but not review, pharmaceutical applications.<sup>111</sup> Under the Patents Act, 2005, patent applications in the mailbox before January 1, 2005, receive patent rights only from the date of the patent grant, not from the date of filing.<sup>112</sup> Because the 20-year patent protection period begins from the date of filing, however, some pharmaceutical patents will have a short patent life once issued.<sup>113</sup> In addition, after a patent is granted, patent-holders are only entitled to receive reasonable royalties from

---

<sup>107</sup> Chodock, *supra* note 42 (citing *Legal News-India to Set Up Patents Court*, BUS. MONITOR INT'L, Feb. 2, 2005).

<sup>108</sup> Dubey, *supra* note 48.

<sup>109</sup> *Id.*

<sup>110</sup> TRIPS, *supra* note 3, Art. 70, § 8.

<sup>111</sup> Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 321 (2005).

India took advantage of the transition period allowed by Article 65.4 of the TRIPS Agreement, which must be read in conjunction with Article 70.8-9. Article 65.4 permits developing members that had not previously granted patent protection for pharmaceutical products until January 1, 2005, to initiate such protection, while Article 70.8-9 provides for the establishment of a patent application "mailbox" and the availability of "exclusive marketing rights" for pharmaceutical (and agricultural chemical) products. Under Article 70.8 a member that did not provide pharmaceutical product (or agricultural chemical product) patent protection was required, commencing on January 1, 1995, to accept such patent applications for filing and store them until protection was provided. At that later point, the applications would be withdrawn from the mailbox and examined, with patentability criteria applied as if the applications were being reviewed when the applications were filed, thereby preserving patentability against acts that might otherwise be disqualifying. If the application were to result in the grant of a patent, the term of the patent would commence on the filing date of the mailbox application. *Id.* at 321 n.24. "By January 2005, more than 12,000 applications waited in the mailbox. It is expected to take at least 18 months from the opening of the mailbox for the first product patent to be issued." Chodock, *supra* note 42, at 5 n.2. In addition, it is important to note:

[T]he Indian controller of patents may take a different view of the validity of subject matter claimed in certain applications from that of the U.S. Patent and Trademark Office or the European Patent Office. There is some indication that Indian generic producers and Pharma companies have different expectations regarding the extent to which patents will be granted on mailbox applications.

Abbott, *supra* note 111, at 322 (2005) (citations omitted).

<sup>112</sup> Patents Act, 2005, *supra* note 87, at comment 10(c). TRIPS, *supra* note 3, Art. 70, § 8(c).

<sup>113</sup> Chodock, *supra* note 42, at 5 n.12; TRIPS, *supra* note 3, Art. 70, § 8(c).

enterprises which have made significant investments and were producing and marketing the newly patented product prior to January 1, 2005, and which continue to manufacture the product even after grant of the patent, and no infringement actions can be brought against such companies.<sup>114</sup> “[R]oyalty payments commence on the date of the patent grant and . . . no retroactive royalties from the patent’s filing date have to be paid.”<sup>115</sup> “This ‘means Indian companies have as good as got compulsory licenses for the 200-odd new molecules that have been patented in the past five years.’”<sup>116</sup>

The Patents Act, 2005, also provides compulsory licensing for the manufacture and export of pharmaceutical products to any country having insufficient or no manufacturing capacity of its own to address public health problems.<sup>117</sup> This allows the Indian government to license the use of a patent to a third party, without the patent owner’s consent, for domestic production in India.<sup>118</sup> Before granting the compulsory license, the applicant must only make efforts to obtain a license from the patent holder for a “reasonable period,” which is “construed as a period not ordinarily exceeding a period of six months.”<sup>119</sup> If the “compulsory license is granted with a pre-dominant purpose of supply in Indian market the licensee may also export the patented product, if need be”<sup>120</sup> “Finally, a compulsory license may be issued that allows a patented product to be exported in order to remedy an anticompetitive practice. These provisions benefit India’s generic pharmaceutical companies, encourage domestic production, and protect the public health of her citizens by preventing abuse of an invention’s patent protection.”<sup>121</sup>

Because English in India is the most prevalent, second language, after the national language, India does not require the translation of patent specifications.<sup>122</sup>

### III. ANALYSIS OF THE NEW PATENT REGIME: DIFFERENT PERSPECTIVES ON THE NEW LAWS

Some scholars have praised the achievements made by the Indian government concerning intellectual property protection,

<sup>114</sup> Patents Act, 2005, *supra* note 87, at comment 10(c).

<sup>115</sup> Chodock, *supra* note 42, at 5 n.14.

<sup>116</sup> *Id.* at 5 (citing *Patently Left and Right, Too*, BUS. WORLD MAG., Apr. 4, 2005, available at [www.securities.com](http://www.securities.com).)

<sup>117</sup> Patents Act, 2005, *supra* note 87, at comment 55.

<sup>118</sup> Chodock, *supra* note 42, at 5.

<sup>119</sup> Patents Act, 2005, *supra* note 87, at comment 52.

<sup>120</sup> *Id.* at comment 54.

<sup>121</sup> Chodock, *supra* note 42, at 5 (citation omitted).

<sup>122</sup> Gladys Mirandah, *supra* note 68, at 2.



while others have pointed out the weaknesses that still exist concerning enforcement and the cost of medicines.<sup>123</sup>

To pharmaceutical companies, "India might appear to be the Garden of Eden . . . due to her low manufacturing costs, large number of educated Indian nationals, and huge domestic economy with vast market growth potential . . ." <sup>124</sup> "Pharmaceutical industry experts have estimated that the Patents Act, 2005, could trigger direct investment into India of as much as US\$10 billion."<sup>125</sup> Because of the increased patent protection, several major pharmaceutical companies such as "GlaxoSmithKline, Germany's Merck KGaA, Roche, Bayer, AstraZeneca, and Eli Lilly have recently announced expansions of their Indian operations."<sup>126</sup>

There are, however, still some major deterrents to investing in India.<sup>127</sup> There are concerns that Indian pharmaceutical companies do not have the capacity to create new drugs and to conduct clinical trials.<sup>128</sup> There are also questions over enforcement of the new patent bill and the prevention of infringement, which may lead companies to invest cautiously in India over the next few years. In response to the new TRIPS compliance measures, the Indian government has also placed a ceiling on pharmaceutical price increases.<sup>129</sup> "The National Pharmaceutical Pricing Authority (NPPA) keeps prices as low as possible, even at the expense of allowing prices to rise with inflation. Furthermore, the NPPA limits the profits of pharmaceutical companies to 8-13 percent of pretax sales."<sup>130</sup> This cap on profits will deter some foreign pharmaceutical companies from investing as much money as they would otherwise invest, and could potentially "cost the Indian economy and its welfare more in the long-run than the short-term gains received from the prevention of pharmaceutical price inflation."<sup>131</sup>

One benefit to the people of India from the new patent laws, in the long run, is that the new system should stimulate risky and expensive research and development activity.<sup>132</sup> "Specifically, patents in developing countries such as India are likely to fuel

---

<sup>123</sup> See generally Chodock, *supra* note 42, at 6; but see Pruzin, Daniel, *Trade: WTO TRIPS/Medicines Deal Fails to Stem Rising Costs of Key Medicines*, NGOS Say, PATENT, TRADEMARK & COPYRIGHT LAW DAILY (Nov. 15, 2006).

<sup>124</sup> Chodock, *supra* note 42, at 6.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.*

<sup>132</sup> Gupta, *supra* note 37, at 603.

research into diseases such as malaria and tuberculosis that are specific to those areas and that have not previously drawn much attention from industry because of the unavailability of patent protection."<sup>133</sup>

Despite the potential benefits of the new system, critics have pointed to a few major difficulties of compliance with TRIPS. There are questions of whether the new laws will be strictly and adequately enforced in India.<sup>134</sup> There is also concern over the potential rise in the cost of prescription drugs. The cost of medicine is a large concern in India, "where only a small percentage of the population can afford prescription drugs even at currently depressed prices."<sup>135</sup> There is also a concern that the new patent laws will benefit large multinational pharmaceutical companies at the expense of the Indian industry and jobs.<sup>136</sup> It is possible that the Indian generic firms could be driven out of business unless they find a way to compete with multi-national corporations ("MNCs") in discovering new drugs.<sup>137</sup> If the Indian firms cannot compete, Indian pharmaceutical workers could lose their jobs, and they might not be hired by the MNC, because of their ability to set up their manufacturing operations anywhere in the world, not just in India.<sup>138</sup> "Moreover, large amounts of wealth that previously remained within India to be re-invested domestically will likely leave the country via the MNCs."<sup>139</sup>

#### A. *Enforcement Questions of the New Patent Regime*

Even though India's Patents Act, 2005, brought India into compliance with the patent provisions of TRIPS, there is still a question of whether the new laws will be strictly enforced. "India has had for a long time strong anti-patent beliefs, and these will take some time to overcome."<sup>140</sup> In 1995, it was India's Parliament that insisted on the ten-year transition period for developing countries to pass new legislation that would comply with TRIPS.<sup>141</sup> "Such historical aversion to patents is not easily reversed. At a minimum, it is reasonable to assume that the government is not fully and absolutely committed to increased patent protection."<sup>142</sup>

In addition to the possible leniency by the government, the

---

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 615.

<sup>135</sup> *Id.* at 604.

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at 605.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 615.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

Indian Drug Manufacturers' Association ("IDMA"), a powerful and vocal lobby for the very large generics industry of India, has consistently argued against the new stricter patent regime.<sup>143</sup> The IDMA argues against the stronger patent laws, and even "published a book several years ago devoting five full chapters to a description of the adverse effects of patents."<sup>144</sup> After the new laws were passed in 2005, the IDMA is sure to apply considerable political pressure to ensure that patent enforcement is not as strict as it might be.<sup>145</sup>

A look at the Indian patent office and the Indian judiciary further reveals that weak enforcement of patents is a distinct possibility. "India's version of the Patent & Trademark Office (PTO) in 1993-94 spent about \$330,000, whereas the United States PTO in the late 1980's spent approximately \$300 million a year."<sup>146</sup> Additional funds, however, are gradually being devoted to the development of a stronger intellectual property administration infrastructure, but India is still spending far less on their patent infrastructure than such countries as the U.S.<sup>147</sup>

In addition to the smaller budget for intellectual property, there is a question of whether or not the courts will be willing to enforce the new laws.<sup>148</sup> "There exists evidence to suggest that India's judiciary is, as a rule, not well versed in economic theory and often makes decisions that are hostile to good economic judgment."<sup>149</sup> Thus when the negative aspects of patents, such as higher prices are immediate and easy to see, and the upside of increased patent protection is more long-term and more obscure, it could affect judicial decision-making.<sup>150</sup> "[J]udges in India, as elsewhere, are not immune to public opinion, and they may have a difficult time making decisions that will ostensibly raise drug prices and cost their fellow citizens jobs."<sup>151</sup>

The United States has shown concern that India will not effectively enforce the new patent laws. Under TRIPS, members are required not only to come into compliance with the minimum standards set out in the Agreement, they must also properly enforce those rights.<sup>152</sup> On May 4, 2004, the United States placed India on the Priority Watch List for lax IP laws along with 14 other

---

<sup>143</sup> *Id.* at 616.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 616-17.

<sup>147</sup> *Id.* at 617.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> TRIPS, *supra* note 3, at Part III.

countries.<sup>153</sup> The Office of the United States Trade Representative (USTR) views India's new Patents Act "as a 'significant positive step' but is wary of India's dedication to enforcement of the new laws."<sup>154</sup> Even with the new law, the USTR urges India to increase protection for undisclosed pharmaceutical data to prevent unfair commercial use.<sup>155</sup>

The USTR is optimistic about India's 2005 Patent Amendment Ordinance but remains concerned about enforcement of the Act. For example, the USTR notes that the new law does not permit holders of newly issued patents from the "mailbox" applications to enforce their rights against generics, and India has yet to implement safeguards of confidential test information submitted by pharmaceutical companies seeking market approval from the Indian government.<sup>156</sup>

Before the Patents Act, 2005, India did not have a noted problem with enforcement of the IP rights for processes and methods of pharmaceutical production because the production of pharmaceuticals requires such large facilities.<sup>157</sup> "However, now that pharmaceutical products also receive patents, a reevaluation of India's enforcement mechanisms must occur. For example, patent law experts have already suggested that India set up a special court to handle the expected rise in intellectual property cases."<sup>158</sup>

In India the average amount of time to enforce a patent, the length of a patent trial, is between two and three years.<sup>159</sup> This amount of time is actually relatively better than some of the smaller European countries.<sup>160</sup> One important note though is that most of the judges are not technically qualified to handle this work.<sup>161</sup> Judges must rely on the submissions of counsel and the testimony of expert witnesses before deciding a particular case.<sup>162</sup> In addition, although India has a common law system, "Indian courts have been reluctant to rely on cases decided in other Commonwealth jurisdictions, beside the UK."<sup>163</sup> On the other

---

<sup>153</sup> Sreenivasarao Vepachedu & Martha M. Rumore, *Patent Protection and the Pharmaceutical Industry in the Indian Union*, INTELL. PROP. TODAY 4 (Oct. 2004) (citing United States Trade Representative's 2004 Special 301 Report, May 4, 2004).

<sup>154</sup> Chodock, *supra* note 42, at 5 (citing United States Trade Representative, Special 301 Report (2005)).

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> Chodock, *supra* note 42, at 5 (footnote omitted).

<sup>158</sup> *Id.*

<sup>159</sup> Patrick Mirandah, *Enforcement of Patent Rights in India and South East Asia: A Comparative Analysis*, 20 BNAI WIPR 6 (June 1, 2006).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

hand, some countries like the Philippines, rely on U.S. cases as precedent.<sup>164</sup> India only allows civil actions against alleged infringers, they do not allow criminal actions.<sup>165</sup> In recent times, there has been an increase in the number of patent cases in India. However, reported patent cases for the lawyers and judges to refer and rely on are rare.<sup>166</sup>

The United States government has placed much emphasis on enforcement of IP laws in foreign countries like India.<sup>167</sup> As part of various free trade agreements, the U.S. Trade Representative has offered training and technical assistance on ways for various countries to increase their protection of IP laws.<sup>168</sup> This effort has placed U.S. businesses in touch with businesses in developing countries in order to provide examples of how better enforcement should work.<sup>169</sup> "The goal of these outreach efforts, according to Wilson [director of the U.S. Commerce Department's Office of Intellectual Property Rights], is to move 'beyond IP 101' with foreign businesses, to offer more long-term, comprehensive assistance, tailored to meet the needs of a specific country." There is still a large problem with counterfeiting in foreign countries that is undermining some of these efforts though.<sup>170</sup> According to Wilson, "People are stealing; we have to show them they are better off respecting IP, than stealing it [.]"<sup>171</sup> In India, however, software piracy levels have actually recently diminished because of growth in India's domestic information technology industries.<sup>172</sup>

### 1. Recent Developments in Indian IP Protection

On December 1, 2006, Ashwani Kumar, Minister of State for Industries, acknowledged that India is very aware that protection of intellectual property is closely related to investor confidence and that India is taking several steps to provide better safeguards against counterfeiting and piracy.<sup>173</sup> India recently signed an agreement with France on intellectual property protection, and is planning on signing "similar agreements with 'a number of

---

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> Patrick Mirandah, *Enforcement of Patent Rights in India and South East Asia: Comparative Case Law*, 20 BNAI WIPR, 5 (May 1, 2006).

<sup>167</sup> *Conferences: IP's Role In Global Development is Explored at Policy Forum*, PATENT, TRADEMARK & COPYRIGHT LAW DAILY, 2 (May 1, 2006).

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> Vir Singh, *Indian Government is Serious about Protecting Intellectual Property, Official Says*, PATENT, TRADEMARK & COPYRIGHT LAW DAILY, at 1 (Dec. 4 2006).

Countries' to give a 'comfort factor' to foreign investors."<sup>174</sup>

Kumar indicated that "several state governments [in India] have created special intellectual property rights cells in their law enforcement systems, adding that IPR enforcement is being closely monitored by India's National Crime Records Bureau for the first time."<sup>175</sup> Some private firms have also started a campaign against software piracy in India.<sup>176</sup> In addition, India has established toll-free telephone numbers for enforcement agencies to assist with the reporting of counterfeiting and piracy.<sup>177</sup> Kumar also said the government and some private firms have launched a series of training programs aimed at helping police officers, judges and others in the area of intellectual property protection.<sup>178</sup>

The industries in India most hurt by counterfeiting and piracy are film, pharmaceutical, and computer software.<sup>179</sup> A recent study by the International Data Corporation "estimated that a mere 10 percent reduction in piracy in India could create 115,000 new jobs in information technology, \$5 billion in additional revenue and \$386 million in additional tax revenue per year."<sup>180</sup>

On December 6, 2006, in another recent development, Ajay Dua, head of the Department of Industrial Policy and Promotion at India's Ministry of Commerce and Industry, stated that "he expects India's patent office to be certified by the World Intellectual Property Organization [WIPO] as an international search authority and as a world class authority for conducting preliminary examinations of patent applications by March 2007."<sup>181</sup> India has hired more patent examiners, and is in the process of modernizing its patent offices.<sup>182</sup> As a result, "India received about 25,000 patent applications last year — roughly five times more than the number received a year earlier."<sup>183</sup> On the other hand, a top trade official stated on December 4, 2006, that India's patent laws are still "not up to 21st century standards."<sup>184</sup> In addition, Under Secretary of Commerce for International Trade Franklin Lavin "noted that about 74 percent of computer software used in India is pirated, and that the country is one of the

---

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.* at 2.

<sup>180</sup> *Id.*

<sup>181</sup> Vir Singh, *India Expects WIPO Recognition by March, But U.S. Official Faults Country's IP Regime*, BNA'S PATENT, TRADEMARK & COPYRIGHT JOURNAL NEWS, 1 (Dec. 8, 2006).

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

world's leading makers of counterfeit pharmaceuticals. He said India's entertainment industry has suffered because of the failure to adequately protect its movies and music."<sup>185</sup>

## B. Continuing Problems with the Cost of Medicine

### 1. Claims by Non-Government Organizations

The high cost of pharmaceuticals is a considerable problem in India. "The World Trade Organization's agreement on improving access to essential medicines is failing to lower the cost of critical pharmaceuticals in poor countries, mainly because of continued patent barriers, a group of non-governmental organizations ["NGOs"] said Nov. 14 [2006]."<sup>186</sup> Five years after the adoption of the 2001 Doha Declaration<sup>187</sup> on access to essential medicines, the NGO group, which includes Oxfam International and Medecins Sans Frontiers ("MSF," also known as, Doctors Without Borders), said "developing countries have been unable to take advantage of the declaration because of a subsequent decision in 2003 which imposed 'overly cumbersome' restrictions on the right of countries to bypass patent rules in order to import generic medicines."<sup>188</sup>

In August 2003, WTO members agreed on a procedure for allowing developing countries to issue compulsory licenses for the import of generic copies of patented drugs.<sup>189</sup> The agreement was designed to correct an anomaly in the TRIPS Agreement which allowed governments to issue compulsory licenses only if the license was used principally for the supply of the domestic market.<sup>190</sup> This mechanism was adopted as a temporary waiver to WTO rules, but was transformed into a final solution in December 2005 by the General Counsel of the WTO in the form of Article 31

<sup>185</sup> *Id.* at 2.

<sup>186</sup> Pruzin, *supra* note 123, at 1.

<sup>187</sup> At the WTO talks in Doha in late 2001, the delegations from India and a number of other developing countries secured a significant concession regarding compulsory licenses, embodied in the Doha WTO Ministerial Declaration on TRIPS and Public Health. Section 5(b) of the Doha Declaration provides that "[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." The WTO now recognizes that in national emergencies or other circumstances of extreme urgency, which are explicitly defined to include public health crises, nations are permitted to grant compulsory licenses on patented compounds to generic manufacturers who will produce the drug at low cost.

Gupta, *supra* note 37, at 612-13 (citations omitted).

<sup>188</sup> Pruzin, *supra* note 123, at 1.

<sup>189</sup> *Id.* Compulsory licenses are granted by a government and allow a party to use a patent without the consent of the patent holder.

<sup>190</sup> *Id.*

bis of the Agreement.<sup>191</sup> Two-thirds of the WTO's 149 members must ratify the Amendment to make it formal.<sup>192</sup> The Amendment allows for a compulsory license granted in one country to be exercised in another.<sup>193</sup> "This change, a major deviation from existing intellectual property principles, restructures the way pharmaceutical products can be manufactured under a compulsory license system to the benefit of poor or small countries lacking the ability to produce the products themselves." The system, however, is procedurally complex; it sets out extensive procedural obligations and safeguards.<sup>194</sup> Failure to comply with the whole procedure by either the beneficiary and/or the exporting member would effectively amount to an infringement of the TRIPS Agreement.<sup>195</sup>

MSF has argued that instead of lowering drug prices for medicines needed to combat pandemic diseases such as HIV/AIDS, the prices of some medicines have actually increased since the Doha Declaration was adopted.<sup>196</sup> The price of "first-line" AIDS drugs has fallen by 99 percent since 2000, but the price for "second-line" drugs, which patients need when a resistance develops to the "first-line" medicines, remains high due to the increased patent barriers in generic-producing nations such as India.<sup>197</sup> The switch from first-line to second-line medicines, consists of a twelve-fold price increase.<sup>198</sup> The increase in price is even more steep in middle income countries where the annual cost of treatment could jump from \$365 a year to \$5200 a year, an increase of more than fourteen times the previous cost.<sup>199</sup> This difference in price is the result of the new second-line medicines falling under the new strict patent protection in key producer countries like India, while the first-line medicines were not protected under the pre-TRIPS regime.<sup>200</sup>

The British-based charity group Oxfam has argued that rich, highly developed countries, like the United States, "are 'bullying' developing countries to impose strict restrictions on compulsory licenses in their bilateral free trade agreements. Rich countries 'are taking little or no action towards their obligations [under the

---

191 Andrew Law, *New Rules for Pharmaceutical Compulsory Licenses*, BNAI WIPR, 1 (Sept. 1, 2006).

192 *Id.*

193 *Id.*

194 *Id.* at 3.

195 *Id.*

196 Pruzin, *supra* note 123, at 1.

197 *Id.*

198 *Id.*

199 *Id.*

200 *Id.* at 1-2.



Doha declaration] and are in some cases actually undermining the declaration . . . .”<sup>201</sup> Oxfam further alleges that “[t]he U.S. and the pharmaceutical industry are actively challenging any developing country that has tried to assert its rights and interpret global intellectual property laws in order to protect public health.”<sup>202</sup> Under the August 2003 agreement, developing countries must notify the WTO if they intend to use the new rules to import generic medicines. No country, however, has notified the WTO of its intention to use the new rules.<sup>203</sup>

MSF has said that the compulsory licensing mechanism has not been utilized by developing countries because the procedure is too time-consuming and burdensome.<sup>204</sup>

Developing countries must first engage in negotiations with the patent holder for a voluntary license. If those negotiations fail, the developing country must not only issue its own compulsory license, but must also secure a compulsory license in the country where the generic medicines producer is based. In addition, the license applications must stipulate the destination and the quantity of drugs to be purchased and exported. Once the licenses are secured, the imported drugs must be clearly identified through specific labeling and marketing, imposing additional costs.<sup>205</sup>

The failure to utilize these new rules that are supposed to actually help countries prevent hurtful price increases in medicines is a problem that does not yet have a solution.

## 2. Other Perspectives on Cost of Medicines

The pharmaceutical industry has dismissed the NGO claims that patents are preventing access to essential medicines in developing countries.<sup>206</sup> The Geneva-based International Federation of Pharmaceutical Manufacturers and Associations (“IFPMA”) has said that very few medicines on the World Health Organization’s list of essential medicines are covered by patents: “95 percent are not patented anywhere in the world, and 99 [percent] are not patented in sub-Saharan Africa, where the need for medicines is most critical.”<sup>207</sup> IFPMA also argued that while

---

<sup>201</sup> *Id.* at 2.

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 3.

<sup>207</sup> *Id.*

India did not respect foreign patents before its amendments in 2005 and India's generic manufacturers were able to copy ARVs still under patent elsewhere, "actual access to ARVs in India was (and remains) on a par with sub-Saharan Africa."<sup>208</sup>

Some scholars have argued that the idea that pharmaceutical prices will increase greatly as a result of the Patents Act, 2005, receives too much attention, and is not as critical as some groups believe.<sup>209</sup> Non-governmental organizations (NGOs) and health advocacy groups who are critical of the Patents Act, 2005 provisions for the production of generic drugs, have claimed the Act is "the beginning of the end of affordable generics."<sup>210</sup> MSF has stated that "India's generic industry could potentially cease to exist as a result of TRIPS compliance, and hence compulsory licenses allowed by the WTO would be meaningless."<sup>211</sup> These claims have not proven to be true so far.<sup>212</sup>

Some scholars have stated that, "[t]he argument that Indians will lose access to generic medications subsequent to India's compliance with TRIPS has little merit."<sup>213</sup> Fluoroquinolones, a class of antibiotics comprising ciprofloxacin (cipro) and levofloxacin that provide treatment for a wide variety of urinary tract, respiratory, and gastrointestinal infections as well as sexually transmitted diseases, has been used to prove this point.<sup>214</sup>

Fluoroquinolones remain under patent protection in the United States, and patent applications for fluoroquinolones had been waiting before January 1, 2005, in India's mailbox for review. Many generic pharmaceutical companies in India currently produce fluoroquinolones and provide them to the domestic population at deeply discounted prices. A paper published in 2003 estimated that patent enforcement for the quinolone group would result in a welfare loss of US\$713 million for the Indian economy. Additionally, the research report concluded that foreign multinationals that gained a patent monopoly over the fluoroquinolones in India would expect to receive a meager profit of US\$57 million and that domestic producers would only lose US\$50 million from their inability now to produce these generic antibiotics. The argument that Indians will lose access to fluoroquinolones after implementation of the Patents Act, 2005,

---

<sup>208</sup> *Id.*

<sup>209</sup> See Chodock, *supra* note 42, at 2.

<sup>210</sup> *Id.* (citing *Indian Parliament Approves Controversial Patent Bill*, BRIDGES WEEKLY TRADE NEWS DIGEST (Mar. 23, 2005), available at <http://www.ictsd.org/weekly/05-03-23/story1.htm>).

<sup>211</sup> *Id.* at 3.

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

fails for at least three reasons. First, 97 percent of the drugs produced by Indian generics makers are off patent and therefore, will not be affected by the new legislation. Second, even under the new patent bill, patent protection will only be granted on applications that have been received since 1995. Finally, as the authors of the fluoroquinolone project noted, the study had been completed in the absence of compulsory licenses and price controls; however, these two safeguards continue to remain present in the Patents Act, 2005.<sup>215</sup>

One of the key aspects in the idea of rising drug prices is that India's laws are not retroactive, so drugs that are already patented elsewhere and that are already being produced generically when the legislation went into effect, will not be protected by patent in India.<sup>216</sup> The prices of drugs already for sale are probably not going to change.<sup>217</sup> It is only the new drugs that are discovered after the new laws went into effect that will be afforded patent protection and whose prices might remain higher during the patent period.<sup>218</sup> "Thus, overall spending on pharmaceutical drugs will rise only gradually over time as new drugs are patented in India and then approved for sale; the country will not suffer a sudden shock from immediate price increases . . . the biggest drawback of granting product patents will be phased in slowly over time."<sup>219</sup>

India can also use price controls to protect consumers and local companies from the rising cost of medicines under the TRIPS Agreement.<sup>220</sup> India still has price controls on some compounds, which are subject to strict controls, and there is no reason why this regulation cannot be extended to new drugs that are discovered and patented after the new laws went into effect in 2005.<sup>221</sup> Price controls are a strong means to keep prices down, and could be used if necessary.

India can also use its buying power to bargain with drug companies for lower prices.<sup>222</sup> "Private health insurance is extremely undeveloped in India, with less than four percent of drug purchases paid for by private insurance companies. Another seventy-five percent of prescription drug spending is out-of-pocket. The remaining twenty or so percent of drug spending is paid for

---

<sup>215</sup> *Id.*

<sup>216</sup> Gupta, *supra* note 37, at 607-08.

<sup>217</sup> *Id.* at 608.

<sup>218</sup> *Id.*

<sup>219</sup> *Id.*

<sup>220</sup> *Id.* at 609.

<sup>221</sup> *Id.*

<sup>222</sup> *Id.* at 611.

by the Indian government."<sup>223</sup> The Indian government is the single largest purchaser of prescription drugs in the country, and it could use its significant bargaining power to negotiate with pharmaceutical companies for lower drug prices.<sup>224</sup> The use of the government buying power might be less offensive to the pharmaceutical industry than strict price controls, because it actually involves the pharmaceutical firms in the process.<sup>225</sup>

### C. Relevant Cases Concerning the increase in IP Protection

In recent times, Indian courts have been more willing to award substantial damages in infringement actions, showing that protecting intellectual property rights has become a larger priority.<sup>226</sup> In *Time Inc. v. Lakesh Srivastav*, a trademark infringement case, the court awarded Ind Rs 500,000 (US \$11,221) for general damages and an additional Ind Rs 500,000 for punitive damages.<sup>227</sup> In *Adidas-Saloman A G & Ors v. Jagdish Grover*, a trademark infringement case involving the "Adidas" mark, the court awarded the plaintiff damages of Ind Rs 1.5 million (US\$33,663).<sup>228</sup> In a copyright infringement case concerning software piracy, *Microsoft Corp. v. Yogesh Papat*, the court awarded Ind Rs 1.975 million (US\$44,323) to the Plaintiff.<sup>229</sup> In *Microsoft Corp. v. Kamal Wahi* the court awarded the plaintiff Ind Rs 2.3 million (US\$51,617), the largest damages award in Indian history.<sup>230</sup> These cases show that the Indian courts are more serious about protecting intellectual property rights, a good sign for rights owners in India.<sup>231</sup>

"A recent development not in the courts, but at the Indian Patent Office, would be the Patent Office's rejection of Novartis's patent application for Gleevec, an anti-cancer drug."<sup>232</sup> In 1998, Novartis filed a patent application in India for the "Beta Crystalline form of Imatinib Mesylate" and applied for Exclusive Marketing Rights ("EMR") pending grant of a product patent in the WTO/Mailbox.<sup>233</sup> Novartis was granted EMR by the Patent Controller in 2003, and proceeded to bring lawsuits for

<sup>223</sup> *Id.*

<sup>224</sup> *Id.*

<sup>225</sup> *Id.*

<sup>226</sup> Gladys Mirandah, *supra* note 68, at 3.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> Patrick Mirandah, *supra* note 158, at 8.

<sup>233</sup> *Id.*

infringement against Indian generic drug makers before the High Courts of Madras and Bombay, based on the strength of the EMR.<sup>234</sup>

The two High Courts, however, made conflicting rulings.<sup>235</sup> The Madras High Court held that the EMR was valid, but the Single Judge at the Bombay High Court took the opposite view.<sup>236</sup> The key argument of the generic drug makers was "anticipation by publication and/or claiming of the Imatinib Mesylate prior to the priority date of the Indian patent application."<sup>237</sup> Novartis argued that an EMR application was required to be examined only with respect to "sections 3 and 4 of the Patents Act [as per Section 24-A, which has been repealed by the Patents (Amendment) Act, 2005] and the question of anticipation by prior publication or prior claim is not relevant to the examination of an EMR application."<sup>238</sup> The Madras High Court agreed with the argument of Novartis, but the Bombay High Court did not.<sup>239</sup>

The Patent Controller's decision to reject the patent application "is pursuant to multiple pre-grant oppositions filed against the product patent application for Gleevec numbered 1602/MAS/1998."<sup>240</sup> Several generic drug companies, including the Cancer Patients Aid Association, India, opposed the patent primarily on grounds of "anticipation, Section 3(d), obviousness, and wrong priority."<sup>241</sup> The Assistant Controller of Patent, who heard the pre-grant opposition, found that Novartis' invention was not patentable based on the aforesaid grounds.<sup>242</sup> The largest objection to the patent was the argument based on Section 3(d) of the Patents Act, whereby it was argued by the generic drug manufacturers that the "claimed invention was directed at a new polymorphic form of imatinib mesylate which did not differ significantly in properties with regard to efficacy, hence it was unpatentable."<sup>243</sup>

Another illustrative case of patent law in India is *Fabwerke Hoesht Aktiengesellschaft v. Unichem Laboratories et al*, AIR 1969 Bombay 255.<sup>244</sup> In this case, the court held:

an invention consisting of the production of new substances

---

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> *Id.* at 9.

<sup>241</sup> *Id.*

<sup>242</sup> *Id.*

<sup>243</sup> *Id.*

<sup>244</sup> *Id.*

from known materials by known methods cannot be held to possess new subject matter merely on the ground that the substances produced are new, for the substances produced may serve no useful purpose, in which case the inventor will have contributed nothing to the common stock of useful knowledge (the methods and materials employed being already known) or of useful materials (the substances produced being, ex hypothesi, useless).<sup>245</sup>

This case shows the new heightened requirement of patentable subject matter.

Another relevant case is *ASTRAZENECA / Priorities from India*,<sup>246</sup> which concerned the question of:

whether a European patent application filed in the first place as an international application under the Patent Cooperation Treaty (PCT) could validly claim the priority of an Indian application at a time when India was a party to the Agreement establishing the World Trade Organization (WTO) and Annex 1C thereto, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement), but not yet a party to the Paris Convention for the Protection of Industrial Property (the Paris Convention).<sup>247</sup>

The case concerned European patent applications filed as international applications under the PCT at the Swedish Patent Office on March 12, 1996, claiming priority from applications filed in India respectively on March 13 and 23, 1995.<sup>248</sup> India became a member of the WTO in 1995, but only became a party to the Paris Convention with effect from December 7, 1998.<sup>249</sup> After joining the Paris Convention, priorities claimed from first filings in India have been recognized by the European Patent Office (EPO) pursuant to Art.87(1) EPC.<sup>250</sup> "It was not until a Notification dated May 20, 2003 published in the Gazette of India that the EPO was

---

<sup>245</sup> *Id.*

<sup>246</sup> 2004 WL 1929040 (EPO (Enlarged Bd App)), [2004] E.P.O.R. 39.

<sup>247</sup> *Id.* at 397.

<sup>248</sup> *Id.*

The PCT is designed to serve those who seek broad protection early while wishing to defer most of the global patent procurement expense until a later time. A PCT application is an international application, making it possible to simultaneously protect an invention in as many as 125 PCT contracting states. The 125 PCT member countries account for almost 98 percent of the world pharmaceutical market. Notable non-PCT countries are Argentina, Pakistan, and Taiwan.

Robert Silverman, *Patent Filing Strategies for Pharmaceutical Products: A simple cost-benefit analysis based on filing costs and pharmaceutical sales*, 33 AIPLA Q.J. 153, at 156 (2005).

<sup>249</sup> *ASTRAZENECA*, *supra* note 244, at 397. "A number of States joined the WTO/TRIPs Agreement before the Paris Convention took effect for them and there are still some members of the TRIPs Agreement which are not yet party to the Paris Convention. *Id.* at 398.

<sup>250</sup> *Id.* at 397.

included in the list of countries, including groups or unions of countries or inter-governmental organisations, recognised as convention countries under the Paris Convention ( [2003] O.J. EPO 529)."<sup>251</sup> Because the EPO was not a country and not a member of the TRIPS Agreement, the law to be applied to the case was governed by the provisions of the EPC only, and as such, the TRIPS Agreement did not entitle the applicant to claim priority from the India application.<sup>252</sup>

#### IV. SOME MODIFICATIONS TO THE CURRENT SYSTEM

India has made vast improvements to its intellectual property laws in the past decade; however, changes still need to be made to the current system. India has passed laws to bring the country into full compliance with the TRIPS Agreement, but the system needs modifications to make it more efficient.

##### A. *Establishing a Specialized IP Court*

India needs a better system to enforce the new patent laws. India should set up a specialized court to deal with patent and other intellectual property cases. The United States has the U.S. Court of Appeals for the Federal Circuit, which has nationwide jurisdiction in a variety of subject areas including international trade, patents trademarks, etc. Many judges in the Federal Circuit have training in the sciences and engineering, and are better able to interpret patent claims and claim construction. Implementing a specialized court like this in India would give the patent laws a unified final interpretation, rather than having different courts finding inconsistent verdicts. Having judges with background in the sciences and engineering will also ensure a quicker appeals process and judgments that come from a better understanding of the underlying technologies.

Japan recently established the Intellectual Property High Court ("IP High Court") on April 1, 2005, and can serve as a guide for India.<sup>253</sup> The court is based on the U.S. Court of Appeals for the Federal Circuit and was established to "ensure more effective and speedy trial proceedings in IP cases, based on the understanding that the role of the judiciary has become more important in the proper protection of intellectual property . . . thereby enhancing the judicial services specializing in handling IP

---

<sup>251</sup> *Id.* at 398.

<sup>252</sup> *Id.* at 408.

<sup>253</sup> Intellectual Property High Court, <http://www.ip.courts.go.jp/eng/aboutus/history.html> (last visited Aug. 18, 2007).

cases."<sup>254</sup> The IP High Court has jurisdiction to hear appeals from district courts in Japan on patent actions and suits against appeal/trial decisions made by the Japanese Patent Office. Because of the highly technological nature of IP cases, Japan has "judicial research officials," or "permanent court officials whose role is to assist judges by conducting research on technical matters when necessary to hear and resolve IP cases."<sup>255</sup> Having highly trained expert advisors prevents the judges from relying solely on the parties' attorneys and experts. The court also has independent authority with respect to case docketing, which means that it can focus on cases in which similar lawsuits have received different rulings or rulings that may influence business activities.<sup>256</sup>

India should also look to the IP High Court's website as another useful tool. The website records all of the major events and decisions occurring at the court. It also provides the full text and summary of judgments handed down by the court, as well as a list of other concluded cases, with major points and issues thereof. The court established its own Guidelines in order to resolve hearings efficiently and expeditiously. India, with its lack of published patent cases, could make its system run more efficiently by introducing such an up-to-date website concerning the latest developments in Indian patent law.

In addition to setting up a specialized IP court, India should also make some improvements to its current intellectual property infrastructure. Some general improvements that could be made include: more standardization of the patent-examination system; training of patent lawyers to have the expertise to cope with the new complex reforms; adopting a new patent examination manual; better formal training for patent examiners; and developing searchable electronic patent and trademarks databases, such as the ones in the U.S. and Japan.

One important note to the abovementioned reforms, however, is that there are still widespread issues of poverty in India. It is estimated that nearly one quarter of the population in India was living below the poverty line in 2004-2005, and that "34.7% of India's poorest population still live on less than US \$1 a day and 79.9% live on US \$2 per day."<sup>257</sup> Although the Japanese IP High Court consists of only 51 employees, 18 of which are

---

<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Standard of Living in India*,

[http://en.wikipedia.org/wiki/Standard\\_of\\_living\\_in\\_India](http://en.wikipedia.org/wiki/Standard_of_living_in_India) (last visited Aug. 18, 2007).



judges, establishing a specialized court for better patent standardization is going to cost money that the government can credibly argue needs to be spent elsewhere. A better Internet site for publishing all of the recent patent decisions and patents granted, and better training of judges and enforcement agencies, is a somewhat less cost-restrictive solution to some problems to the current system.

### B. *A Comparative Approach*

India should look to other countries for guidance in further structuring its intellectual property laws and with its enforcement efforts. Although India is still considered a developing country, it is a leader among the developing nations because of its many resources, and soon might look at the developed countries for guidance. Because of the large, fragmented generic pharmaceutical industry in India, the United States does not provide much guidance, but Canada, with its large generic industry, may provide a better example.

The United States Patent System is not a good model for India to emulate, and it recently came under attack by a report issued on November 28, 2006 by the Council of Foreign Relations.<sup>258</sup> The report, written by economist Keith Mascus of the University of Colorado, Boulder, stated that the U.S. patent system makes it "too easy to obtain and defend patents and too costly to challenge them," which has increased the number of "questionable patents" and the cost of litigation.<sup>259</sup> The report included a list of possible reforms, including:

[M]ore rigorous standards for determining whether an invention is obvious or novel, retention of enough fees the Patent and Trademark Office to fund an expanded examining corps, third-party submissions of prior art relevant to patent applications, an effective and expeditious system for post-grant opposition of patents, elimination of automatic injunctions against alleged infringers, limitations on the grounds for willful infringement findings, and legitimate prior-user rights defenses against infringement.<sup>260</sup>

The report also suggested that the U.S. should establish an "office of competition advocacy" within the PTO "to consider the economic implications of broad patent claims before they are granted."<sup>261</sup> The report urged the U.S. to adopt a more flexible

---

<sup>258</sup> U.S. Patent System 'Misguided,' Impedes Innovation, Report Says, PATENT, TRADEMARK & COPYRIGHT LAW DAILY, Dec. 5, 2006, 1.

<sup>259</sup> *Id.*

<sup>260</sup> *Id.* at 3.

<sup>261</sup> *Id.*

framework for patents, rather than the harmonized "TRIPs-plus" standards (a protection standard stricter than that of the TRIPs Agreement) that the U.S. wants other countries to adopt.<sup>262</sup>

In addition to the criticism of this report, other scholars have pointed out problems with the United States' Hatch-Waxman Act of 1984, concerning pharmaceuticals.<sup>263</sup>

Since the enactment of the Hatch-Waxman Act in 1984, brand name drug manufacturers have found many ways to use the provisions of the Hatch-Waxman Act to protect patented new drugs from generic competition. Using these provisions, brand name manufacturers have employed delay tactics and executed anti-competitive agreements with generic manufacturers in order to prevent generic manufacturers from entering the market. Although Congress, the FDA, and the courts have taken action to prevent brand name manufacturers from abusing the provisions of the Hatch-Waxman Act, brand name manufacturers have continued to find ways to do so.

The patent laws of United States, especially ones which could be used to harm generic manufacturers, are not a paradigm for India to follow in further crafting its own laws.

A recent study in India is not as important for its conclusion, but for how it came to its results. In *Report of the Technical Expert Group on Patent Law Issues*,<sup>264</sup> a study published by the Indian Patent Law Office in December 2006, an expert committee analyzed two current issues over the new patent laws: "whether it would be TRIPs compatible to limit the grant of patent for pharmaceutical substance to *new chemical entity* [NCE] or to *new medical entity* [NME] involving one or more inventive steps; and whether it would be TRIPs compatible to exclude micro-organisms from patenting."<sup>265</sup> These two questions arose in March 2005 when the Patents (Amendment) Bill, 2005 was introduced in both of the Houses of the Indian Government, and the study was assigned to this five-member committee on April 5, 2005.<sup>266</sup>

To come to its conclusion, the expert group sought input from "different stake holders such as industry associations, non-governmental organizations, intellectual property attorneys, etc. through written submissions, presentations, etc. The Group

---

<sup>262</sup> *Id.*

<sup>263</sup> Brian Porter, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177, 177 (2005).

<sup>264</sup> Patent Office, India, *Report of the Technical Expert Group on Patent Law Issues*, (Dec. 2006), available at

[http://www.patentoffice.nic.in/ipr/patent/mashelkar\\_committee\\_report.doc](http://www.patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc)

<sup>265</sup> *Id.* (emphasis added).

<sup>266</sup> *Id.* at 2, 4.

studied the inputs received and also took into account other relevant literature to arrive at their assessment."<sup>267</sup> The group also studied the patenting practices relating to new chemical entities and micro-organisms in several countries including the United Kingdom, China, the European Union, Japan, the United States, Australia, and Brazil.<sup>268</sup> In making its final recommendations, the group was further "guided by the need for access of affordable medicines to Indian people at large, encouraging innovation by Indian industry, its current capabilities in R&D, and balancing of India's obligations under international agreements with the wider public interest."<sup>269</sup> Through this analytical and thorough balancing approach, the committee was able to offer its recommendations to the above questions.

India should use this same type of comparative approach when dealing with the above mentioned problems of affordable pharmaceuticals and stricter enforcement of the patent laws. The drawback to this approach is that this recent study only concerned how best to define "a pharmaceutical substance" and whether the government could exclude micro-organisms from patenting. Further, the study took more than a year and a half to arrive at its final conclusion. A question over the interpretation of the laws is much simpler than the complex internal struggles India faces with its own patent law system. A complete study of the issues India faces over its own system, using a similar approach, may take several years to complete. However, it would be more beneficial for India to take the time to complete such a study, rather than looking at short term quick solutions. Considering the fact that \$5 to 5.5 trillion of economic activity — about 45 percent of the U.S. economy — is related to IP protection,<sup>270</sup> a long term study and solution to the current problems in India would be in the country's best economic interests.

#### CONCLUSION

India has made tremendous strides in its IP laws in the last eleven years and has come into full compliance with TRIPS through the Patents (Amendment) Act, 2005. India's pharmaceutical industry is very promising and has much room for growth, especially with the increased protection afforded by the new laws. India, however, still faces several challenges with the cost of medicine and effective enforcement of the new system.

---

<sup>267</sup> *Id.* at 5.

<sup>268</sup> *Id.* at 13-17.

<sup>269</sup> *Id.* at 2.

<sup>270</sup> Singh, *supra* note 179, at 1-2.

With the rapid increase in protection, caused by the ten year limit for complying with TRIPS, India has had to pass some laws that they do not have the capacity to enforce, and to tailor specifically to different Indian industries. With such a strict timeline, India as of yet, has not had enough time to study all of the interests and alternatives and specifically design its own system to benefit its people the most. The IP departments in India are moving in the proper direction though, and by setting up a specialized IP Court, by revamping the intellectual property infrastructure and by studying the benefits and detriments of foreign intellectual property schemes, India has the resources and potential to become a leader in worldwide intellectual property.

*Jeffrey Colin\**

---

\* Articles Editor, Cardozo Arts & Entertainment Law Journal; J.D. Candidate, 2008, Benjamin N. Cardozo School of Law; B.S., 2005, Columbia University School of Engineering and Applied Science. Many thanks to Professor Barton Beebe for his insightful comments, to the editorial board of the AELJ for their contributions toward the publication of this Note, and to my family and friends for their support. ©2007 Jeffrey Colin.