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Transformation of the Indian Patent System and Its Effect on the Indian Pharmaceutical Sector

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India is the world's fourth largest producer of pharmaceuticals, with approximately 3,250 pharmaceutical manufacturers and 250 large research-based manufacturers.[1] Furthermore, India's domestic drug industry employs a resounding 460,000 people.[2] Additionally, 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.[3]

India's pharmaceutical sector has astounding domestic growth potential. As of 2004, an estimated 1.1 billion people lived in India and had a strikingly low consumption rate of pharmaceuticals. Domestic per capita spending stood at only US$8, bringing India's total spending on pharmaceutical to US$8.5 billion.[4] 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.[5]

This article will demonstrate that as India constructed patent laws to comply with the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, it has supported a booming pharmaceutical sector and provided for the public health of its citizens. The first section of this article discusses India's new Patents (Amendment) Act, 2005. Next, this article considers the accessibility of medicine available to India's citizens after the implementation of TRIPS compliant patent laws. Finally, this article comments on the expected effect of the new laws on India's pharmaceutical sector.

Patents (Amendment) Act, 2005

Upon joining the WTO on January 1, 1995, India did not grant intellectual property rights to pharmaceutical products and only provided for a patent protection term not exceeding seven years, from the date of filing of the patent application, for pharmaceutical processes and methods.[6] To become a WTO member, India had to promise compliance with the TRIPS Agreement, an agreement protecting intellectual property rights, by January 1, 2005.[7] An example of a TRIPS Agreement requirement includes granting pharmaceutical products a 20-year term of patent protection.[8]

On April 4, 2005, the president of India signed into law the Patents (Amendment) Act, 2005 (Patents Act, 2005), patent amendments necessary to bring India's patent laws fully in compliance with TRIPS.[9] 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. For example, the new laws prevent evergreening of patents, lengthening the patent term by filing applications that only protect nominal advances over the original product. The Patents Act, 2005, defines "pharmaceutical substances" as "any new entity involving one or more inventive steps."[10] Hence, the entity must be "new" and not just a mere change from a previously patented substance. Furthermore, the laws dictate that the discovery of a substance not resulting in the enhancement of the known efficacy of that substance or the discovery of any new property or new use of a substance will not result in a patentable invention. Thus, a product, such as aspirin, could not be repatented

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every time discovery of a new use occurs. Also, the laws consider the addition of chemical groups, such as salts, esters, ethers, and so forth, to a compound to be the same substance as the parent compound unless the two products differ significantly in their efficacy.

By India's date of entry into the WTO, India had to *accept* pharmaceutical product applications but did not have to begin reviewing them until January 1, 2005.[11] Therefore, India set up a "mailbox" system whereby since January 1, 1995, pharmaceutical applications have been received but not reviewed.[12] Under the Patents Act, 2005, patent applications in the mailbox before January 1, 1995, receive rights of a patentee only from the date of the patent grant.[13] Moreover, companies that made significant investment and produced and sold a product as of January 1, 2005, for which an application had been pending in the mailbox can pay "reasonable" royalties as of the day of the patent grant in order to continue producing the product.[14] Additionally, the patentee or licensee cannot sue the company, which has previously produced and continues to produce the now patented product, for patent infringement.[15] 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."[16]

The Patents Act, 2005, expands the capability to obtain and use a compulsory license, the ability of the Indian government to license to a third party the use of a patent without the patent owner's consent, for domestic production. First, it specifies that the applicant only needs to try for six months to obtain a license from the patentee.[17] Second, the Act now allows that "when compulsory licence [*sic*] is granted for pre-dominant purpose of supply in Indian market, the licensee may export the patented product, if need be."[18] 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.[19]

India's Patents Act, 2005, as it relates to pharmaceutical patents, appears to be compliant with TRIPS. The Office of the United States Trade Representative (USTR) views India's new Act as a "significant positive step" but is wary of India's dedication to enforcement of the new laws.[20] Additionally, the USTR urges India to increase protection for undisclosed pharmaceutical data from unfair commercial use.[21] 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.

The TRIPS Agreement requires that Members not only have a patent bill compliant with TRIPS provisions but also that they enforce these intellectual property rights.[22] India has not been noted to have an endemic problem with enforcement of the intellectual property rights for processes and methods of pharmaceutical production that had been protected before the Patents Act, 2005. Because processes and methods of pharmaceutical production require a large facility for their use, they are not as easy to pirate as methods and processes for other types of intellectual property. 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.[23] Indian legal officials also appreciate this concern since at least 10 new regional patent offices have recently opened.[24]

Access to Medicine Post-TRIPS Compliance

The argument that pharmaceutical prices will astronomically increase as a result of the Patents Act, 2005, receives a disproportionate amount of attention. Claims have been made that because health care insurance in India is extremely rare, any increase in pharmaceutical prices will have a potentially devastating impact on the poor.[25] Thus, nongovernmental organizations (NGOs) and health advocacy groups critical of the legislation's provisions for the production of generic drugs, proclaim that the Patents Act, 2005, represents "the beginning of the end of affordable generics."[26] Medecins Sans Frontiers (MSF) continues to aggressively lobby against India's compliance with TRIPS. MSF reasons 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.[27] Other issues of complaint about the Patents Act, 2005, from the NGOs include failure to set a limit on the rate of royalties to be paid to patent holders, a process to challenge compulsory licenses, and a time limit in which compulsory licenses must be issued.[28]

The argument that Indians will lose access to generic medications subsequent to India's compliance with TRIPS has little merit. The case of 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, will be used to exemplify this point.[29] 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.[30] 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.[31] 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.[32] The argument that Indians will lose access to fluoroquinolones after implementation of the Patents Act, 2005, 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.[33] Second, even under the new patent bill, patent protection will only be granted on applications that have been received since 1995.[34] 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.

The Present and Future of India's Pharmaceutical Sector

Pharmaceutical industry experts have estimated that the Patents Act, 2005, could trigger direct investment into India of as much as US$10 billion.[35] GlaxoSmithKline, Germany's Merck KGaA, Roche, Bayer, AstraZeneca, and Eli Lilly have recently announced expansions of their Indian operations.[36] However, even with the inflow of money, companies are still concerned that Indian companies do not have the capacity to innovate and conduct clinical trials in a system that has been largely fragmented in the past.[37] Moreover, pharmaceutical companies may cautiously invest in India for the next few years until the enforcement of the new patent bill has shown to be effective at preventing infringement.

Although India might appear to be the Garden of Eden for pharmaceutical companies due to her low manufacturing costs, large number of educated Indian nationals, and huge domestic economy with vast market growth potential, deterrents to investment in India continue to exist. In response to the forthcoming TRIPS compliance measures, the Indian government has capped pharmaceutical price increases. The National Pharmaceutical Pricing Authority (NPPA) keeps prices as low as possible, even at the expense of allowing prices to rise with inflation.[38] Furthermore, the NPPA limits the profits of pharmaceutical companies to 8–13 percent of pretax sales.[39] This cap on profits placed by the Indian government on pharmaceuticals will deter foreign pharmaceutical companies from investing the quantity of money they would otherwise invest and thus will most likely 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.

Conclusion

The future potential of India's pharmaceutical sector seems to outshine the large advances that the pharmaceutical industry has already achieved. India has accomplished this vast growth while implementing TRIPS compliant patent laws. For the last 10 years it has fine-tuned its patent system in order to develop a pharmaceutical sector that no longer needs to rely on pirating medicines but rather can earn economic gains through the possession of domestic intellectual property rights. Hence, the recent strategies and legislation utilized and enacted by India regarding its compliance with TRIPS should be very instructive for other developing countries. Furthermore, as demonstrated by India's Patents Act, 2005, patent laws can be constructed that utilize the flexibilities provided in the TRIPS framework in order to develop patent laws that help build a domestic economy while continuing to protect the public's health.

Endnotes

1. *Pharmaceuticals & Healthcare Forecast—Q4 2004*, BUS. MONITOR INT'L, Dec. 1, 2004 (remarking that this accounts for just below 10 percent of global production).

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. The Patents Act, 1970 (Act 39 or 1970) Sept. 19, 1970, §§ 5, 53.

7. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement on Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

8. *Id.* at Articles 27.1, 33.

9. The Patents (Amendment) Act, 2005 (No. 15 of 2005), THE GAZETTE OF INDIA: EXTRAORDINARY (Apr. 5, 2005) [hereinafter Patents Act, 2005].

10. *Id.* at comment 2(h).

11. TRIPS Agreement, *supra* note 7, at Article 70.8.

12. 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. Additionally, the 20-year patent protection began from the date of *filing* (date of entering the mailbox); therefore, some pharmaceutical patents will have a nominal patent life once eventually issued.

13. Patents Act, 2005, *supra* note 9, at comment 10(c).

14. Note that the royalty payments commence on the date of the patent grant and that no retroactive royalties from the patent's filing date have to be paid.

15. Patents Act, 2005, *supra* note 9, at comment 10(c).

16. *Patently left and right, too*, BUS. WORLD MAG., Apr. 4, 2005, *available at* www.securities.com.

17. Patents Act, 2005, *supra* note 9, at comment 52.

18. *Id.* at comment 54.

19. *Centre to curb evergreening of patents in amended Bill*, FIN. EXPRESS, Mar. 21, 2005.

20. UNITED STATES TRADE REPRESENTATIVE, SPECIAL 301 REPORT (2005).

21. *Id.*

22. TRIPS Agreement, *supra* note 7, at Part III.

23. *Legal News—India to Set Up Patents Court*, BUS. MONITOR INT'L, Feb. 2, 2005.

24. *Id.*

25. Ouseph Tharakan, *FE Insight—Access to drugs the key issue*, FIN. EXPRESS, Apr. 6, 2005, *available at* www.securities.com.

26. *Indian Parliament Approves Controversial Patent Bill*, BRIDGES WEEKLY TRADE NEWS DIGEST (Mar. 23, 2005), *at* http://www.ictsd.org/weekly/05-03-23/

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27. *Project News—Ethical and Generic Drugmakers Dispute IP Law*, BUS. MONITOR INT'L, Feb. 4, 2005.

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

29. DAVID C. HOOPER, PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES, 5TH ED. 414 (Gerald L. Mandell, John E. Bennett & Raphael Dolin, eds. Churchill Livingstone 2000); *see also* CDC, Fact Sheet: Quinolones, *at* http://www.cdc.gov/ncidod/hip/Lab/FactSheet/quinlolones.htm (last visited Apr. 28, 2005).

30. *See, e.g.*, Cadila Pharms. Ltd., *available at* http://www.cadilapharma.com/index.htm (last visited Apr. 28, 2005); *see also* Ranbaxy Labs. Ltd., *available at* http://www.ranbaxy.com (last visited Apr. 28, 2005).

31. SHUBHAM CHAUDHURI, PINELOPI K. GOLDBERG, AND PANLE JIA, THE EFFECTS OF EXTENDING INTELLECTUAL PROPERTY RIGHTS PROTECTION TO DEVELOPING COUNTRIES: A CASE STUDY OF THE INDIAN PHARMACEUTICAL MARKET 2, 33 (Nat'l Bureau of Econ. Research, Working Paper No. 10159, 2003).

32. *Id.*

33. *Company News Alert—Indian Government Rebuts Patent Price Fears*, BUS. MONITOR INT'L, Jan. 7, 2005.

34. Tharakan, *supra* note 23.

35. *Project News—Challenges to Indian Pharma's New Era*, BUS. MONITOR INT'L FEB. 18, 2005.

36. *Company Finance Alert-Mixed Feelings Greet India's New Patent Framework*, BUS. MONITOR INT'L, Jan. 5, 2005.

37. *Id.*

38. Tharakan, *supra* note 25.

39. *Id.*