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Indian Patent Law: Working within the Trips Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health

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Indian Patent Law: Working within the Trips Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health

Cover Page Footnote

Student Comment

INDIAN PATENT LAW: WORKING WITHIN THE TRIPS AGREEMENT FLEXIBILITIES TO PROVIDE PHARMACEUTICAL PATENT PROTECTION WHILE PROTECTING PUBLIC HEALTH

JAVIER ESPARZA*

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I. INTRODUCTION: PATENT LAW AND THE PHARMACEUTICAL INDUSTRY

Patents are granted by governments to encourage scientific progress and the dissemination of information.¹ They are negative rights which allow the owners the ability to prevent others from making, using, or selling a patented invention for a period of twenty years.² A successful patent enables the patent-holder to exclude others from participating in a market, thereby allowing a premium charge for the use of the invention and consequent recovery of research costs. The price premium often becomes a point of contention in the pharmaceutical industry as the high cost of medicine can result in reduced access within developing countries. Medicine also can be costly because, in the pharmaceutical industry, the demand for medicine is inelastic. That is to say, people often are willing to pay any amount to treat or cure an ailment, thereby increasing the possibility of excessively priced medicine. Inherent in patent law is the struggle between public need and the promotion of scientific progress that each country must balance. This struggle has been exacerbated in

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1. See U.S. CONST. art. I, § 8, cl. 8; Patent Act, R.S.C. 1985, c. P-4 (Can.).
2. 35 U.S.C. § 154(a)(1)-(2) (2012).

recent years with the rise of “evergreening” practices by the large pharmaceutical companies.³

In recent years, there have been fewer new drugs (new molecular entities) discovered and patented despite increased spending by pharmaceutical companies for research and development.⁴ In response to this necessary expenditure increase and fewer patents, companies have resorted to extending the patent life of their “blockbuster” drugs—those that earn in excess of one billion dollars a year.⁵ To protect the income stream generated by these profitable drugs, companies can receive a new patent on the same pharmaceutical product by changing something as trivial as the dosage or by slightly altering the chemical formulation.⁶ In fact, two-thirds of the new drugs approved by the U.S. Food and Drug Administration actually are incremental variations of previously approved drugs.⁷ The new patents on these incremental changes allow companies to extend their patent protection for a drug well beyond the twenty-year statutory period, thereby evergreening their patent protection.

Although some countries, such as the United States, have expansive standards of patentability which allow “anything under the sun”⁸ to be patented, other countries, such as India⁹, have imposed stringent limitations on patentability to curb evergreening. The policies enacted in India are not without controversy and subsequently have been challenged in court. Those decisions illustrate the dichotomy in perspectives on both the role of patents in the pharmaceutical arena and the proper reasons for issuing patents initially.

This Note will argue that, while controversial, India’s patent policies are in compliance with international law. Part II will discuss the history of patent law within India and the international treaties that have shaped India’s modern Patent Act. Part III will discuss Indian courts’ application of section 3(d)

3. Evergreening “is when a company manufactures a product for which it secures a patent. Shortly before the expiration of that patent, the company files a new patent that revises or extends the term of protection. . . . [Evergreening] is a method by which technology producers keep their products updated, with the intent of maintaining patent protection for longer periods of time than would normally be permissible under the law.” Uttam K. Shukla, *‘Ever Greening’ Patents*, SCI. REP., Aug. 2011, at 31.

4. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-49, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS (2006).

5. CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 27 (2011).

6. *Id.* at 29.

7. CONG. BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 14–15 (2006).

8. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

9. See *infra* Part III.

and its compliance with the TRIPS Agreement. Part IV will discuss India's granting of compulsory licenses and its compliance with the TRIPS Agreement as applied. Part V will argue that India's patent policies will not result in the abrogation of pharmaceutical patent holders' rights and that the policies are an acceptable balance between the rights of patent holders and a country's need to protect the public health of its citizens.

II. TRIPS AND THE INDIAN PATENTS ACT, 1970

A. *Indian Patents Act, 1970*

To better understand the significance of India's policies with regard to pharmaceutical patents, one must first gain an understanding of the history of Indian patent law and international intellectual property agreements. Before the passage of the Indian Patents Act in 1970, the Indian marketplace was dominated by foreign multinational corporations that "held about 80–90% of Indian patents, but practiced less than 10% of those patents in India."¹⁰ In addition, the high cost of the drugs made them unaffordable for the majority of India's poor, and instead of spurring innovation, Indian patent law inhibited the growth of India's generic sector.¹¹

To increase the availability of low-cost drugs, the Indian Patent Act of 1970 prohibited the patentability of pharmaceutical products.¹² However, the Act allowed patents on the manufacturing process of said products.¹³ As a direct result of this legislation, India became the largest manufacturer and provider of generic pharmaceutical products in the world.¹⁴ Additionally, the legislation increased the availability of low-cost pharmaceutical products to its citizens¹⁵ and enabled India to be in a position of providing low-cost antiretroviral drugs to African countries where the AIDS epidemic was rampant.¹⁶

10. V. K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 323, 327 (2012) (quoting Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 290 (2008)).

11. *Id.* at 325–26.

12. The Patents Act, No. 39 of 1970, INDIA CODE §5(a)-(5) (2005), vol. 15, available at <http://indiacode.nic.in>.

13. *Id.* § 53.

14. Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 514 (2007).

15. JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE 48–49 (2010).

16. Press Release, Médecins Sans Frontières, Generic Competition Pushing down HIV Drug Prices, but Patents Keep Newer Drugs Unaffordable (July 3, 2013), available at

B. TRIPS Agreement

The rise of the global economy and pressure from developed countries, where most of the large pharmaceutical companies reside, precipitated negotiations in the General Agreement on Tariffs and Trade (GATT) that led to the establishment of minimum standards of patent protection, by the newly established World Trade Organization (WTO).¹⁷ In 1995, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement accomplished this goal and further advanced the harmonization of patent law among WTO members.¹⁸ The TRIPS Agreement set forth requirements addressing patent eligibility, patent standards, and the duration of patent protection.¹⁹ Although the exact definition of what constitutes an invention was not defined, it was understood that patented inventions must be novel, non-obvious, and useful.²⁰ Most importantly for the pharmaceutical sector, the TRIPS Agreement required patents to be available without discrimination as to the field of technology, meaning that countries such as India had to provide patent protection for pharmaceutical products.²¹ Patents also must be issued regardless of the place of invention and without discrimination as to whether products are imported or locally produced.²² Any country failing to comply would be subject to enforcement by a dispute settlement body through WTO, which could result in trade-related sanctions against the offending country.²³

In a concession to the developing countries, the TRIPS Agreement allowed a transitional period of up to 10 years (until 2005) to fully implement the TRIPS Agreement with respect to the patenting pharmaceutical products.²⁴ However, because India did not recognize the patentability of pharmaceutical products, it was required to establish a “mailbox system,” which preserved the initial filing date for any pharmaceutical product application

<http://www.doctorswithoutborders.org/article/generic-competition-pushing-down-hiv-drug-prices-patents-keep-newer-drugs-unaffordable>.

17. *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 26, 2015).

18. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

19. *Id.* art. 27.1.

20. *Id.*

21. *Id.*

22. *Id.*

23. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 736–37 (2d ed. 2010).

24. TRIPS Agreement, *supra* note 18, arts. 65–66.

submitted between 1995 and 2005.²⁵ After that period, the applications would be examined by the Indian Office of the Controller General of Patent Designs and Trademarks.²⁶

Although originally believed to be a major victory for developed countries, led by the United States, India was able to negotiate inclusion of language that preserved major flexibilities in the implementation of the TRIPS Agreement as well as the ability to tailor national patent law to meet the needs of the individual country.²⁷ The TRIPS Agreement, although attempting to establish uniformity of international patent law, allowed each individual country to establish its standards of patentability as long as the standards did not violate the agreement.²⁸ Furthermore, Article 31 of the TRIPS Agreement, without stating the words “compulsory license,” set up a procedure by which a compulsory license could be granted if certain conditions were met.²⁹

A compulsory license allows someone other than the patent owner to use the patented invention without the owner’s permission in exchange for a reasonable royalty as determined by the government.³⁰ Compulsory licenses, although used infrequently in the United States, have been a mainstay of the patent laws in various countries.³¹ Compulsory licenses have been used to prevent the abusive exercise of patent rights and to address any national emergency needs.³²

Under the scheme of the TRIPS Agreement, a country can grant a compulsory license if (among other requirements) the following conditions are met:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;

25. *Id.* art. 70.8.

26. HO, *supra* note 5, at 48.

27. Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 153, 169 (2013).

28. TRIPS Agreement, *supra* note 18, art. 1.1.

29. *Id.* art. 31.

30. THOMAS, *supra* note 23, at 730.

31. *Id.*

32. *Id.*

....

(d) such use shall be non-exclusive;

....

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

....

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member³³

The language of the TRIPS Agreement afforded countries significant latitude in granting a compulsory license, as it did not define when a compulsory license should be granted. After passage of the TRIPS Agreement, it was still unclear what circumstances could precipitate granting a compulsory license or what constituted a national emergency. This ambiguity was a major point of controversy between the developed and developing countries that would not be clarified until 2001.

C. Doha Declaration

The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) reaffirmed the flexibilities embodied in the TRIPS Agreement. It stated that the TRIPS Agreement did “not and should not prevent [countries] from taking measures to protect public health,” and that the TRIPS Agreement should be interpreted in a manner that would allow countries to protect public health and promote access to medicine.³⁴ Furthermore, it clarified that each individual country was free to determine under what circumstances a compulsory license was to be granted and what constituted a national emergency.³⁵

D. Amendments to the Indian Patents Act, 1970

A 1997 decision by the WTO Appellate Body further reinforced the built-in flexibility of the TRIPS Agreement by stating that

33. TRIPS Agreement, *supra* note 18, art. 31.

34. World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 4, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

35. *Id.* ¶ 5(b), (c).

India, as a member of WTO, is “free to determine the appropriate method [for] implementing its obligations under the *TRIPS Agreement* within the context of its own legal system.”³⁶ The decision also precipitated the 1999 amendment establishing the mailbox provision for pharmaceutical products in India.³⁷

After receiving confirmation in the Doha Declaration that each individual country was to determine the circumstances under which a compulsory license would be granted, India passed the 2002 amendment that, among other things, established the prerequisites for granting a compulsory license. The amendment provided that, after a period of 3 years from the grant of a patent, a compulsory license could be obtained if the reasonable requirements of the population with respect to the patent had not been satisfied, “the patented invention [was] not available to the public at a reasonably affordable price,” or the patent was not worked in India.³⁸ It also provided for a compulsory license to be granted in a national emergency such as an epidemic.³⁹

The final step in ensuring that the Indian Patent Act of 1970 was compliant with the TRIPS Agreement came about in 2005. The amendment reestablished patent protection for pharmaceutical products;⁴⁰ however, it provided strict limitations on patentability:

The following are not inventions within the meaning of this Act, –

....

(d) 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.

Explanation. – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be

36. Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 59, WT/DS50/AB/R (Dec. 19, 1997) (internal quotation marks omitted).

37. The Patents (Amendment) Act, 1999, No. 17, Acts of Parliament, 1999 (India).

38. The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India).

39. *Id.* § 92.

40. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

considered to be the same substance, unless they differ significantly in properties with regard to efficacy⁴¹

Section 3(d) primarily is directed at preventing evergreening of pharmaceutical products and accomplishes this through a stringent restriction on patentability. Under the law, a patent can be granted on incremental changes to pharmaceutical products only if they are proven to have a greater efficacy than the previous form. This reaffirmed India's continued commitment to providing low-cost pharmaceutical products and to award patents for only truly innovative drugs. However, a point of contention among critics of the law is the fact that the statute failed to define efficacy and that such ambiguity in the law was detrimental to the industry.⁴² The question as to the definition of efficacy ultimately would be answered in the case against Novartis.

III. INDIA'S SECTION 3(D)

In 2013, the Indian Supreme Court decided the limitations of patentability when it interpreted section 3(d) to deny Novartis a patent in *Novartis v. Union of India*.⁴³ Novartis filed for a grant of a patent on Imatinib free base in 1994 (Zimmerman patent).⁴⁴ In 1998, Novartis subsequently filed for a grant of patent on the cancer drug Imatinib Mesylate in beta crystalline form (Gleevec), an improvement on Imatinib free base.⁴⁵ Under the mailbox provision, the application was placed on hold until 2005, after the passage of the amendments to the Indian Patent Act of 1970 were passed.⁴⁶ In response to the passage of the section 3(d) requirement to show enhanced efficacy, Novartis provided affidavits that stated that "the beta crystalline form of Imatinib Mesylate has much higher bioavailability [the rate at which the medicine is absorbed] as compared to Imatinib in free base form."⁴⁷ The Assistant Controller of Patents and Designs did not agree and determined Gleevec ineligible for patentability based on the failure to show increased efficacy,⁴⁸ a decision subsequently upheld by the Intellectual Property Appellate Court.⁴⁹

41. *Id.* § 3(d).

42. See generally Susan Fyan, *Pharmaceutical Patent Protection and Section 3(d): A Comparative Look at India and the U.S.*, 15 VA. J.L. & TECH. 199 (2010).

43. *Novartis v. Union of India*, (2013) 6 S.C.C. 1, 96 (India).

44. *Id.* at 3.

45. *Id.* at 7.

46. *Id.* at 9.

47. *Id.* at 8.

48. *Id.* at 9.

49. *Id.* at 10–12.

The India Supreme Court determined that the Zimmerman patent disclosed Imatinib Mesylate as an improvement on Imatinib free base.⁵⁰ For the purposes of clarification, Imatinib free base is refined into Imatinib Mesylate, which is further refined into Imatinib Mesylate in beta crystalline form (Gleevec), the invention in question. The court then determined that because the Zimmerman patent disclosed Imatinib Mesylate, it was a known substance and, as such, for the purposes of section 3(d), any evidence for enhanced efficacy between Imatinib Mesylate and Gleevec—not between Imatinib free base and Gleevec—should have been demonstrated.⁵¹ As a result, the court found that because the only evidence submitted to prove enhanced efficacy was an increase in bioavailability between the Gleevec and free base forms, Novartis had not met the requirements established under section 3(d).⁵² Furthermore, the court established that efficacy should be interpreted to mean therapeutic efficacy, although it left unanswered whether therapeutic efficacy should be interpreted narrowly or broadly.⁵³ Under this interpretation, any improvements in purely physical/chemical properties, such as improved flow properties, better thermodynamic stability, and lower hygroscopicity, were irrelevant in determining any increase in therapeutic efficacy because the properties merely showed that Gleevec could be stored more easily.⁵⁴

Particularly damning in the Novartis case was the fact that it appeared the company was trying to obtain a patent on Gleevec while marketing it as Imatinib Mesylate.⁵⁵ Imatinib Mesylate would not be patentable in India because it was disclosed in the Zimmerman patent in 1994 and therefore fell outside of the mailbox period (1995 through 2005). The court stated that this showed Novartis “in rather poor light” because Novartis tried to patent a version of the drug that it was not selling, thereby impermissibly obtaining patent protection for the previous version, Imatinib Mesylate, which would be unpatentable in India.⁵⁶

Although the pharmaceutical industry reacted negatively to this decision, the case is unlikely to produce any significant legal changes. It is very fact specific, and had Novartis filed the Zimmerman patent a year later, it most likely would have turned out differently because Novartis was actually trying to provide

50. *Id.* at 81–82.

51. *Id.* at 88.

52. *Id.* at 88–89.

53. *Id.* at 90–91.

54. *Id.* at 94.

55. *Id.* at 96.

56. *Id.*

patent protection for Imatinib Mesylate. It is important to note that the Supreme Court of India never stated that bioavailability could never be shown to increase therapeutic efficacy, as it very well may be the case that an increase in bioavailability will result in increased therapeutic efficacy. In addition, nothing in the decision questioned the patentability of new substances. If anything, the decision states that section 3(d) primarily is aimed at the pharmaceutical industry's rent-seeking policy of evergreening.⁵⁷ Although this decision may reduce the profits of the pharmaceutical companies, it is a consideration that has no bearing on the legality or interpretation of section 3(d). The case simply reaffirms India's commitment to providing low-cost medicine and granting patents for pharmaceutical products that truly improve treatment for the patient.

Another argument raised by the pharmaceutical industry is that section 3(d) provides for a stricter standard on pharmaceutical patenting than either the United States or the European Union.⁵⁸ This argument is inconsequential as each country is free to set up its own standards of patentability as long as it conforms to the TRIPS Agreement.⁵⁹ Additionally, India's requirement to show increased efficacy was the law in the United States prior to 1995.⁶⁰ It was not until the U.S. Court of Appeals for the Federal Circuit decided *In re Brana* in 1995 that patents could be obtained on pharmaceutical products without showing their effectiveness in treating diseases.⁶¹ This broad grant of patents ultimately helped foster evergreening in the United States.⁶²

Ultimately, the difference in patent standards hinges on balancing policy considerations within the United States and India. The Federal Circuit has determined that to spur innovation, patents should be granted before any efficacy is shown to provide assurance to pharmaceutical companies that their product right will be protected.⁶³ Many continue to ask, however, whether patents should be granted for a product that has not been proven to provide any therapeutic benefit.⁶⁴ India has chosen to provide

57. *Id.* at 11.

58. Frederick M. Abbott, *Inside Views: The Judgment in Novartis v. India: What the Supreme Court of India Said*, INTELL. PROP. WATCH (Apr. 4, 2013 4:33 PM), <http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said>.

59. TRIPS Agreement, *supra* note 18, art. 1.1.

60. Abbott, *supra* note 58.

61. *Id.*

62. *Id.*

63. *Id.*

64. Jay A. Erstling et al., *Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada*, 3 CYBARIS 1, 14 (2012) (discussing

patent protection only for those products proven to be an improvement on a known substance that will advance its curative effect on patients.⁶⁵ These policy considerations and their effect on the patent laws of various countries are fundamentally within the purview of the individual country and are likely to differ. The United States and India have different histories and face dissimilar problems; therefore, it is no surprise that their laws differ to accommodate and address their distinctive health care situations.

The pharmaceutical industry also has questioned whether section 3(d) complies with the TRIPS Agreement. Before the Indian Supreme Court reviewed the case, Novartis argued before the Madras High Court that section 3(d) was inconsistent with the TRIPS Agreement.⁶⁶ The Madras High Court, however, held that it lacked jurisdiction to determine the compliance of Indian law with an international treaty.⁶⁷ Any determination of section 3(d) compliance with the TRIPS Agreement would need to be determined by the WTO. Although the United States has expressed its concern with the section 3(d) requirement of proving enhanced efficacy, it has not yet filed an action with the WTO.⁶⁸ Any claim challenging section 3(d) compliance with the TRIPS Agreement most likely will hinge on whether section 3(d) complies with the TRIPS Agreement as it relates to all inventions as opposed to impermissibly discriminating against a specified field of technology.⁶⁹

Section 3(d) is compatible with the TRIPS Agreement's requirement to grant patents to inventions. Article 27 of the TRIPS Agreement sets out that a patent must be granted for inventions that are new (novel), involve an inventive step (non-obvious), and are capable of industrial application (useful).⁷⁰ It fails, however, to further define the standards of patentability. Therefore, India is free to define its own standards of patentability so long as it does not discriminate against a specific field of technology.⁷¹

Although an argument can be made that section 3(d) discriminates against pharmaceutical patents by requiring a higher standard of patentability, this is unlikely to persuade the

how entire countries have enacted legislation to prevent the patenting of pharmaceutical products that have not been proven to do what is alleged in the patent).

65. Abbott, *supra* note 58.

66. Novartis v. Union of India, 2007 A.I.R. 24795 (Madras H.C.) ¶ 5 (India).

67. *Id.* ¶ 7.

68. OFFICE OF THE U.S. TRADE REP., 2013 SPECIAL 301 REPORT 38 (2013).

69. TRIPS Agreement, *supra* note 18, art. 27.

70. *Id.*

71. HO, *supra* note 5, at 95.

WTO. In a previous case against Canada, a WTO panel stated that Article 27 of the TRIPS Agreement does not prohibit differential treatment to deal with “problems that may exist only in certain product areas.”⁷² Essentially, differentiation is not necessarily discrimination. Evergreening is a problem that primarily is prevalent in the pharmaceutical industry⁷³ and to address this issue, India enacted section 3(d). In light of the WTO panel decision and the fact that the Doha Declaration states that the TRIPS Agreement should be interpreted in a manner that would allow countries to protect public health and promote access to medicine, it is unlikely that section 3(d) will be found to be incompatible with the TRIPS Agreement.

IV. INDIA’S GRANTING OF COMPULSORY LICENSES

Another controversial aspect of India’s patent law is that it allows a compulsory license to be granted for pharmaceutical products.⁷⁴ In response to a compulsory license application from Natco Pharma Limited in 2011, the Controller General of Patents issued a compulsory license for Bayer’s drug Sorafenib (Nexavar) because the reasonable requirements of the public with respect to the patented invention had not been satisfied.⁷⁵ The patented invention was not available to the public at a reasonable price, and it was not worked in the territory of India.⁷⁶

Bayer was issued a patent and received regulatory approval for Nexavar for the treatment of liver and kidney cancers in 2008.⁷⁷ During the next three years, Bayer imported zero bottles of Nexavar per month in India for 2008, 200 bottles per month in 2009, and approximately 500 bottles per month in 2010, even though the monthly need for Nexavar in India was about 23,000 bottles per month.⁷⁸ In essence, Bayer was supplying less than two percent of the needs of the Indian population. As a result, the Controller of Patents determined that a compulsory license should be granted because Bayer did not meet its duty under section 84 of the Indian Patents Act of 1970 when it failed to adequately supply the needs of the Indian public.⁷⁹ In addition, the Controller found

72. *Id.* (quoting Panel Report, *Canada – Patent Protection of Pharmaceutical Product*, ¶ 7.94, WT/DS114/R (Mar. 17, 2000)).

73. *Id.*

74. THOMAS, *supra* note 23, at 730.

75. *In re Natco Pharma Ltd.—Compulsory Licence Application No. 1 of 2011*, ¶ 9 (Controller of Patents, Mar. 9, 2012).

76. *Id.*

77. *Id.* ¶ 3.

78. *Id.* ¶ 10.

79. *Id.* ¶ 10(f).

that Bayer could not rely on the amounts of generic Nexavar supplied by Cipla Limited (a company which had been supplying a generic version of the drug in greater quantities) because Bayer claimed that Cipla was infringing on its Nexavar patent.⁸⁰

Furthermore, Bayer offered a monthly treatment of Nexavar at a cost of 280,000 Indian Rupees (\$4,644) at a time when the average yearly income of the Indian population was 60,455 Indian Rupees (\$1,000).⁸¹ In contrast, Natco proposed to sell a generic form of Nexavar for 8,800 Indian Rupees (\$146) a month.⁸² As a result, the Controller determined that the price requested by Bayer for a monthly supply of Nexavar was unreasonable when compared to the average salary of the Indian population and that a compulsory license should be granted in accordance with section 84(1)(b) of the Indian Patents Act of 1970.⁸³

The Intellectual Property Appellate Board reaffirmed the previous findings by the Controller but came to a different conclusion with regard to the proper definition of “worked within the territory of India.”⁸⁴ The Controller determined that the terminology should be interpreted to mean that the product was manufactured or licensed within India.⁸⁵ The TRIPS Agreement adopted the Paris Convention, which specifies that importation of a patented product shall not entail forfeiture.⁸⁶ The Controller stated that this “suggest[s] that importation could entail something less than forfeiture, such as a compulsory license which the Paris Convention allows.⁸⁷ However, Article 27 of the TRIPS Agreement specifies that patent rights should be enjoyed without discrimination as to whether they were locally produced or imported.⁸⁸ This suggests that any limitation of patent rights which discriminates between products locally produced and those that are solely imported is impermissible.

The Controller’s interpretation of “worked” is problematic because it would mean that a compulsory license could be granted for any invention that is not manufactured or licensed for local

80. *Id.* ¶ 10(e).

81. *Id.* ¶ 11.

82. *Id.* ¶ 6.

83. *Id.* ¶ 11.

84. Bayer v. Union of India, (2013) Intell. Prop. App. Bd., OA/35/2012/PT/MUM (India), available at <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf>.

85. *In re Natco Pharma Ltd.*, *supra* note 75, ¶ 12.

86. Paris Convention for the Protection of Industrial Property art. 5(A)(1), Mar. 20, 1883, as revised July 14, 1967 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]; TRIPS Agreement, *supra* note 18, art. 2(1) (requiring WTO members to comply with Articles 1 through 12 of the Paris Convention).

87. *In re Natco Pharma Ltd.*, *supra* note 75; see Paris Convention, *supra* note 86, art. 5(A)(2) (stating that governments have a right to grant compulsory licenses to prevent abuse of patents).

88. TRIPS Agreement, *supra* note 18, art. 27.

production within India. Such interpretation would force companies to establish manufacturing facilities or license the patent within India. According to the Indian Intellectual Property Appellate Board, section 83(b) of the Indian Patents Act of 1970 states “patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented Articles.”⁸⁹ The Appellate Board stated that the definition of worked should be decided on a case-by-case basis, which can sometimes be met only by way of import.⁹⁰ If the product is only imported into India, the patent holder would have to provide evidence showing why it could not be manufactured locally.⁹¹ However, even this interpretation is problematic because it could allow for the impermissible discrimination of patented products based on local production.

Ultimately, the Indian Supreme Court must interpret the meaning of “worked.” If the court decides that the term means the patented product must be manufactured or licensed in India, the decision will most likely lead to push back from the pharmaceutical companies that do not have manufacturing capabilities in the country. The standard proposed by the Intellectual Property Appellate Board would provide a more flexible approach that would allow the Controller to consider different factors in determining whether the patent was “worked” within India but may still violate Article 27.1 of the TRIPS Agreement.

Either definition of “worked” will lead to a challenge under Article 27 of the TRIPS Agreement, which requires patents to be granted and their rights to be enjoyable without discrimination as to whether they are imported or locally produced.⁹² Although the Doha Declaration states that each country is free to determine the conditions of granting compulsory licenses, the conditions must comply with the TRIPS Agreement.⁹³ The TRIPS Agreement also incorporated Articles 1 through 12 of the Paris Convention.⁹⁴ Under Article 5(A)(2) of the Paris Convention, a compulsory license could be granted for failure to “work” the patented product.⁹⁵ The Paris Convention does not define “work”; however, at the time the Paris Convention was adopted, the term referred to whether the

89. *Bayer*, (2013) Intell. Prop. App. Bd., ¶ 51.

90. *Id.* ¶ 52.

91. *Id.*

92. TRIPS Agreement, *supra* note 18, art. 27.1.

93. Doha Declaration, *supra* note 34, ¶ 5.

94. TRIPS Agreement, *supra* note 18, art. 2(1) (requiring WTO members to comply with Articles 1 through 12 and 19 of the Paris Convention).

95. Paris Convention art. 5(A)(2), *supra* note 86.

patented invention was manufactured locally.⁹⁶ Though the TRIPS Agreement adopts the Paris Convention, the nondiscrimination clause in Article 27 of the TRIPS Agreement limits a country's ability to infringe on the rights of patent holders based on whether products are imported or locally produced.

The Controller's definition of "worked" is incompatible with the TRIPS Agreement because it would limit the rights of patent holders by granting compulsory licenses for patented products that are solely imported and not locally produced. This interpretation would lead to discrimination of imported products which is impermissible under Article 27 of the TRIPS Agreement. The Appellate Board's definition would be less problematic because its analysis for granting a compulsory license does not discriminate between products that are locally produced and those that are imported. However, since the Appellate Board's interpretation would allow for a distinction based on local productions, it may violate the TRIPS Agreement. Under the Appellate Board's analysis, importation of patented products could be enough to defeat the grant of a compulsory license. Its interpretation of "worked" requires that the granting of a compulsory license be reviewed on a case-by-case basis and is more likely to adequately target actual abuses of patent rights.

In addition, the Doha Declaration's calling for a relaxed interpretation of the TRIPS Agreement to promote access to low-cost medicine cannot be relied on because local manufacturing of pharmaceutical products does not necessarily lead to lower costs. At the time the Paris Convention was signed, failing to locally produce a patented product was seen as an abuse of a patent.⁹⁷ This is not necessarily the case today because local production of the product may be impermissibly expensive, as it may be cheaper to manufacture it elsewhere. The Appellate Board's interpretation of "worked" realizes this point, which is why the mere importation of a patented product will sometimes be enough to demonstrate that the product is "worked" within India. Locally producing a patented product in every country where the patent holder has a patent would be impermissibly expensive and would lead to increases in the cost of medicines. If the goal is to promote access to medicine, companies should be allowed to import the patented product as long as this does not lead to an abuse of the patent right. Countries can protect themselves from any abuse of a patent by enacting laws that

96. HO, *supra* note 5, at 130.

97. Paris Convention, *supra* note 86, art. 5(A)(2).

grant compulsory licenses that prevent patent suppression and overpricing of patented products.

India's condition that the grant of compulsory licenses be based on the lack of availability and affordability complies with the TRIPS Agreement. Nothing in the TRIPS Agreement prohibits the granting of compulsory licenses under these conditions and, as clarified in the Doha Declaration, each country is free to determine its own conditions for granting compulsory licenses. Ultimately, any determination that India's policy for granting compulsory licenses is incompatible with the TRIPS Agreement must come from a proceeding under WTO because the Indian courts have stated that they do not have the jurisdiction to determine whether Indian law is incompatible with international agreements.⁹⁸

V. DISCUSSION

The United States has expressed its concern with the recent developments in its patentability standards and grants for compulsory licenses.⁹⁹ In a report by the United States Trade Representative, the United States expressed particular concern with section 3(d) and the interpretation of the term "worked" by India's courts.¹⁰⁰ Such interpretation would limit the patent rights of the owner based on the decision to import products rather than manufacture them in India. In addition, the United States International Trade Commission held hearings in February of 2014 to determine the effects of India's policies on American businesses.¹⁰¹ However, regardless of the United States' discontent with such policies, it has not sought to bring a claim at the WTO. As discussed above, any claim challenging section 3(d) will most likely fail. Furthermore, although the United States might win a claim against India's interpretation of the term "worked," depending on the Indian Supreme Court's interpretation, there are still two other broad conditions, unmet need and unreasonable price, under which India could issue a compulsory license.

The United States' disagreement with India's patent law demonstrates the disagreement about patents and the role they should play in the pharmaceutical industry. If one takes the view that patents are granted as a reward to innovators for producing a product that benefits society, India's policies should be followed.

98. *Novartis v. Union of India*, 2007 A.I.R. 24795 (Madras H.C.) ¶ 6 (2007).

99. OFFICE OF THE U.S. TRADE REP., *supra* note 68, at 38.

100. *Id.* at 38–39.

101. See Mike Palmedo, *Notes on First Hearing of U.S. International Trade Commission Investigation of Trade, Investment, and Industrial Policies in India*, INFOJUSTICE.ORG (Feb. 15, 2014), <http://infojustice.org/archives/32208>.

The United States' lax standards of patentability established by the Federal Circuit in *In re Brana* allow companies to patent pharmaceutical products without first showing even preliminary findings that the product can or will treat a medical condition.¹⁰² The lax standards of patentability also encourage evergreening, which increases the cost of drugs for consumers in the United States.

India has taken the opposite approach—by enacting strict patentability standards to limit evergreening strategies, it ensures that companies are receiving a one-time price premium only on their innovative products. Reducing the pharmaceutical industry's reliance on evergreening will spur innovation because it will provide incentives for the development of new drugs instead of extending the patent term on current products. In fact, India's requirement to show efficacy is the same patentability standard the United States employed prior to 1995. Once again, it is important to remember that section 3(d) does not prevent patents on new drugs but is intended only to prevent evergreening. It does not prevent the patenting of actual innovations within the pharmaceutical sector.

The critical reaction toward India's granting of compulsory licenses is unfounded. Regardless of the ambiguity in the meaning of the term "worked," the present case is not an abusive use of a compulsory license. Although other countries have granted compulsory licenses under questionable circumstances, such as Egypt for Viagra,¹⁰³ that is not the case in India. If anything, India's conditions for granting a compulsory license are intended to remedy serious abuses that can occur as a result of issuing patents for pharmaceutical products.

A patent owner can not only choose not to manufacture its product but can also prevent others from manufacturing the product. Patent suppression is a serious abuse that can delay innovation. Suppression is especially harmful in the pharmaceutical arena because it reduces access to possible life-saving medicine. India's granting of a compulsory license if the needs of the Indian public are not met mitigates this problem. As a result, innovators are encouraged to adequately supply the market or otherwise face the possibility of a compulsory license being issued. This law punishes companies that improperly use their patents to suppress the availability of the patented product.

102. *In re Brana*, 51 F.3d 1560, 1566–68 (Fed. Cir. 1995).

103. Abeer Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. TIMES, Oct. 4, 2002, <http://www.nytimes.com/2002/10/04/business/seeking-investment-egypt-tries-patent-laws.html>.

In addition, India's policy of issuing compulsory licenses for products that are unreasonably expensive also allows the country to ensure that medicine is priced fairly. Demand for pharmaceutical products is inelastic, meaning that the demand for life-saving drugs does not fall as the price of the drug increases. Although patents are meant to be a reward that will allow the patent holder to recover its research and development costs, the possibility for price gouging still exists. By conditioning the grant of a compulsory license on the unaffordability of medicine, the Indian government allows for greater leverage by which it will be able to negotiate better prices for pharmaceutical products, which in turn allows India to better meet the public health needs of its citizens.

Granting a compulsory license to Nexavar is hardly an indication that the floodgates have been opened. In fact, since this compulsory license was granted, India's Controller of Patents has not granted another, even though various applications have been submitted.¹⁰⁴ This judicious granting of compulsory licenses supports the idea that India is intent on providing an adequate review of compulsory license applications and that they will be granted only when the need is evident and justified. In addition, Bayer's progress through the Indian court system demonstrates that even when a compulsory license is granted, the patent owner may seek judicial remedies which may include revocation of the grant of a compulsory license and/or monetary compensation. The judicial review of compulsory licenses also will ensure compulsory licenses are not granted for impermissible reasons and will help guard against the possibility of corruption.

VI. CONCLUSION

Although critics argue that India's patent policies hamper innovation, these arguments are based on disagreements with the fundamental purpose of the patent system. India believes that patents should serve as a reward for a proven innovation. Its differing views on pharmaceutical patents are also shaped by its historical dealings with pharmaceutical patents and its unique social and economic needs. India also has written its patent laws to stay within the flexibilities of the TRIPS Agreement.

The cases do not signal an anti-patent trend in India but merely the implementation of sound patent laws that seek to

104. See, e.g., Peter Leung, *India Rejects Another Compulsory License*, MANAGING INTELL. PROP. (Nov. 1, 2013), <http://www.managingip.com/Blog/3273950/India-rejects-another-compulsory-licence.html>.

balance the rights of patent holders with the needs of the public. Each of the above cases resulted in its respective decision only because the pharmaceutical companies failed in some way to follow proper protocols. Novartis tried to patent an “improvement” Gleevec to impermissibly gain patent protection for Imatinib Mesylate, and three years after Bayer had been granted a patent, it was supplying enough medicine in India to cover only two percent of the need. If anything, these cases are outliers in that they are not an opening salvo in a war against pharmaceutical patents. The cases only prove that India is going to take seriously its commitment to safeguard the public health of its citizens by ensuring that the patent system does not result in patenting policies that needlessly result in high drug prices or a reduced access to life-saving medicines.

