

TRIALS AND TRIPS-ULATIONS: INDIAN PATENT LAW AND *NOVARTIS AG v. UNION OF INDIA*

By Linda L. Lee

I. INTRODUCTION

When pharmaceutical company Novartis challenged the rejection of its patent application for the leukemia drug Gleevec in *Novartis AG v. Union of India*,¹ it became the first major legal challenge to India's newly amended patent law. In 2005, India purportedly made the final changes required to bring its intellectual property laws in compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS), the World Trade Organization's (WTO) minimum standards for intellectual property protection,² but its patent law is still fraught with a number of controversial provisions. The ability of pharmaceutical companies such as Novartis to secure patent protection in India not only is important in creating incentives for pharmaceutical research, but also greatly affects the Indian generic drug industry, and therefore the price of medicine available to patients. India is the world's second most populous country³ and the second-fastest growing major economy,⁴ but has 70% of its population living on less than \$2 per day,⁵ making *Novartis AG* of paramount importance.

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1. *Novartis AG v. Union of India*, (2007) 4 MADRAS L.J. 1153, available at <http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India>.

2. 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, 33 I.L.M. 81 (1994) [hereinafter TRIPS], arts. 27-38 (setting forth obligations for patent protection). The WTO granted developing countries and least developed countries (LDC) transitional periods to comply with all the provisions of TRIPS. See TRIPS, art. 65.4 (“To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, . . . it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”). Under this provision, India had a January 1, 2005 deadline to fully comply with TRIPS. See *infra* Part II.D.3.

3. Central Intelligence Agency, Rank Order—Population, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html> (last visited Apr. 5, 2008). See also CENTRAL INTELLIGENCE AGENCY, THE 2007 WORLD FACTBOOK 261 (2006).

4. U.S. Dept. of Agriculture, Economic Research Service, Briefing Room—India, <http://www.ers.usda.gov/Briefing/India/> (last visited Oct. 28, 2007).

5. Fareed Zakaria, *India Rising*, NEWSWEEK, Mar. 6, 2006, at 38.

India joined the WTO at the end of the twentieth century,⁶ marking India's entry into the global economy, but also requiring compliance with international standards for its intellectual property regime. Under TRIPS obligations, developing countries such as India must strengthen its intellectual property rights (IPRs) to conform to the stronger intellectual property regimes prevalent in developed countries in order to be members of the WTO.⁷ Changes in Indian intellectual property law would undoubtedly affect many different sectors,⁸ but its influence on public health is of particular concern.⁹ Like many developing countries prior to joining the WTO, India's patent law only allowed for process, but not product, patents for pharmaceutical inventions.¹⁰ Inventors generally prefer to have stronger patent protection through product rather than process patents,¹¹ and the patent regimes of developed countries predominately protect end products.¹² In contrast, developing nations prefer regimes that only recog-

6. India and the WTO: Member Information, http://www.wto.org/english/thewto_e/countries_e/india_e.htm (last visited Oct. 28, 2007).

7. Some scholars see TRIPS as a product of unequal bargaining between developed and developing countries, or as a result of coercion by developed countries. Developing countries were unsatisfied with the imposition of strong IPRs, but had to agree to the demands of developed countries in order to enjoy the benefits of international trade. See Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 370-79 (2006).

8. *Id.* at 383. (“[I]t is no surprise that less developed countries have been concerned about the heightened protection required by the TRIPs Agreement and its deleterious impact in the areas of agriculture, health, environment, education, and culture.”).

9. Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 3 (2001) (contending that IPRs and their impact on access to medicines can have “life-or-death consequences”).

10. The 1970 Patents Act, § 5, stated:

In the case of inventions—(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical class, semi-conductors and inter-metallic compounds), *no patent shall be granted in respect of claims for the substances themselves*, but claims for the methods or processes of manufacture shall be patentable.

The Patents Act, 1970, Act No. 39 of 1970, 27 India A.I.R. Manual 450, available at http://www.wipo.int/clea/docs_new/pdf/en/in/in004en.pdf [hereinafter 1970 Act] (emphasis added).

11. Process patents often pose enforcement problems such as difficulty in detecting infringement (patentee may be unable to obtain evidence regarding the ultimate use of a product). Furthermore, process patents are subservient to product patents because a process patent cannot be obtained when a patent on the composition is still in effect. ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 387-92 (4th ed. 2007).

12. See *infra* note 100.

nize process patents such that their domestic industries can benefit by inventing cheaper methods of making expensive patented products.¹³ Thus, India's former patent regime favored domestic generic manufacturers who had been able to produce drugs for a fraction of the prices in the United States and Europe.¹⁴

Under the 2005 amendments to the Indian patent law, one of the most significant changes was the extension of product patents to pharmaceutical substances,¹⁵ creating an intellectual property regime that shifts the balance from domestic generic manufacturers in favor of multinational pharmaceutical companies. On one hand, given the high cost of health-related innovation, strong intellectual property rights are crucial in providing incentives for the private sector to engage in costly and risky research and development in the fields of pharmaceuticals and biotechnology.¹⁶ Patents motivate companies to engage in capital-intensive and inherently risky biomedical research because of the possibility of charging monopoly prices and reaping high profits.¹⁷ On the other hand, that very monopoly prevents generic manufacturing and affects the price and availability of the finished medicine to consumers.¹⁸ A successful intellectual property regime must strike a balance between creating incentives for innovation and protecting consumers' access to essential medicine.¹⁹ Developing countries argue that because the needs and interests of their countries are different than those of developed countries, they should have flexibility in enacting intellectual property regimes that offer the proper balance for their individual situations.²⁰

The debate about balancing strong IPRs and access to essential medicine is especially important to India. Historically, India has possessed a

13. Srividhya Ragavan, *A "Patent" Restriction in Research & Development: Infringers or Innovators?*, 2004 U. ILL. J.L. TECH. & POL'Y 73, 76 (2004).

14. Rishi Gupta, *TRIPS Compliance: Dealing With the Consequences of Drug Patents in India*, 26 HOUS. J. INT'L L. 599, 602 (2004).

15. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, available at http://www.wipo.int/clea/docs_new/pdf/en/in/in018en.pdf. Section 5 of the original India Patents Act, 1970, was deleted.

16. Correa, *supra* note 9, at 3.

17. Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 479 (2003).

18. Correa, *supra* note 9, at 3.

19. *Id.*

20. For example, less developed countries may prefer to promote the transfer of technologies needed for development, rather than create strong monopolies. *See id.* at 4-6.

thriving generic drug manufacturing industry²¹ that provided affordable medicine to the Indian population and other developing countries.²² More recently, India is becoming known as a science and technology innovator, rather than just an imitator,²³ which has stimulated a need for stronger IPRs. The 2005 amendments to the Indian patent law have the potential to considerably upset the existing state of affairs. In this context, it is not surprising that the TRIPS-imposed changes to India's patent law and their effects on public health prompted many constituencies to voice concerns, including those from multinational pharmaceutical companies,²⁴ domestic Indian pharmaceutical manufacturers,²⁵ Western governments,²⁶ groups

21. Janice 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, 495 [hereinafter Mueller, *The Tiger Awakens*].

22. India exports two-thirds of its generic drug production to other developing countries, most of which lack any domestic manufacturing capability. *Id.* See also Vijay Yalamanchili, *State of India's TRIPS-compliant Patent Regime*, 26 BIOTECH. L. REP. 211, 211 (2007) (explaining that India generic manufacturers supply over 50% of all antiretroviral drugs used to treat AIDS patients in developing countries, at 5% the price of what US and European pharmaceutical companies charge).

23. Mueller, *The Tiger Awakens*, *supra* note 21, at 500 (explaining that while India has been well-known for its contributions in information technology and software, India is starting to innovate in other industries as well).

24. See Press Release, Pharmaceutical Research and Manufacturers of America (PhRMA), PhRMA Welcomes Passage of Patent Bill in India (Mar. 23, 2005), http://www.phrma.org/news_room/press_releases/phrma_welcomes_passage_of_patent_bill_in_india (last visited Dec. 20, 2007) (applauding India's Patents (Amendment) Act of 2005, but remaining concerned that particular sections of the Act rendered India non-compliant with minimum TRIPS obligations). See also The Organisation of Pharmaceutical Producers of India's (OPPI) Position on Trade Related Aspects of Intellectual Property Rights (TRIPS) (on file with Berkeley Technology Law Journal), <http://www.indiaoppi.com/pharminindia.htm> (last visited Dec. 20, 2007) (stating that Indian's patent law does not recognize incremental innovations and such patents for incremental innovations would hinder long-term research and development). PhRMA represents the interests of leading U.S. pharmaceutical and biotechnology companies, and OPPI is an Indian trade group representing MNCs' interests in India.

25. See Indian Drug Manufacturer's Association (IDMA), <http://www.idma-assn.org/Patents.html> (last visited Dec. 20, 2007) (taking the position that the 2005 Amendment would have adverse effects on public health and the Indian pharmaceutical industry because generic companies can no longer reverse engineer, resulting in multinational firms monopolizing the pharmaceutical industry in India). IDMA has a membership of over 600 wholly-Indian large, medium and small companies.

26. Letter from Representative Henry A. Waxman, 30th District of California, to Daniel Vasella, Chairman and CEO of Novartis, *available at* <http://oversight.house.gov/Documents/20070213183300-13686.pdf> (last visited Dec. 20, 2007) (urging Novartis's CEO to reconsider Novartis's position in India). See also Letter from Five Members of the European Parliament to Novartis CEO Daniel Vasella, *available at*

concerned with access to medicine,²⁷ and lawyers and commentators from around the world.²⁸ Finding a practical balance between long-term investment in the pharmaceutical industry and keeping essential medicines affordable is therefore a continuing point of tension.

Novartis AG came amidst these competing concerns. It is a challenge to one of the most controversial provisions introduced by the 2005 amendments, Section 3(d), which protects against patenting trivial improvements of known molecules.²⁹ This provision is widely regarded as a “public health safeguard”³⁰ that aims to prevent “evergreening,” a practice by which pharmaceutical companies attempt to extend patent protection by filing new patents over the process, dosage form, or method of administration, rather than the active ingredient itself.³¹ Section 3(d) attempts to regulate the granting of such patents by limiting the scope of protection available for derivatives of known substances and new uses of known substance.³² After the Indian patent office rejected Novartis’s patent application for Gleevec on Section 3(d) grounds, Novartis sued the Government of India on a number of claims, including a challenge on the TRIPS-compliance of Section 3(d).³³

Part II of this Note places *Novartis AG* in context of the historical development of patent law in India (including India’s recent and final steps in bringing its patent law in compliance with TRIPS) and the expansion of the pharmaceutical industry in India. Part III reports on Novartis’s current

<http://www.cptech.org/ip/health/c/india/meps02092007.html> (last visited Dec. 20, 2007) (reaffirming European Parliament’s support of India’s implementation of pro-public health patent laws).

27. See NGO statement on Novartis challenge to Indian Patents Act, <http://www.cptech.org/ip/health/c/india/meps02092007.html> (last visited Dec. 20, 2007) (expressing the joint views of several NGOs and urging Novartis to drop its case in India).

28. See, e.g., Janice Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENGL. J. MED. 541 (2007) [hereinafter Mueller, *Taking TRIPS to India*].

29. Vijay, *supra* note 22, at 223. Other commentators contend that Section 3(d) is a codified nonobviousness standard for pharmaceutical substances. Essentially, Section 3(d) requires a higher nonobviousness standard for pharmaceutical and chemical substances. See Posting of Shammad Basheer to Spicy IP, India Patent Act Faces TRIPS Challenge, <http://spicyipindia.blogspot.com/2006/09/indian-patent-act-faces-trips.html> (Oct. 1, 2006). See *infra* note 212 and surrounding text.

30. Vijay, *supra* note 22, at 223.

31. See Mueller, *The Tiger Awakens*, *supra* note 21, at 550-51.

32. Derivatives of known substances must show “enhancement of . . . known efficacy” and new uses of known substances must “[result] in a new product or [employ] a new reactant.” See *infra* Part IV.

33. See *infra* Section III.C.

litigation in India, including the role of the newly formed Intellectual Property Appellate Board (IPAB). Part IV describes the elements of Section 3(d) and argues that Section 3(d) is not a radical departure from the approaches taken by developed countries to limit the patentability of derivatives and new uses of existing pharmaceutical compounds. Finally, this Note concludes with some recommendations on how India should balance protecting access to affordable medicine and creating incentives for increased innovation.

II. INDIA'S LEGAL SYSTEM, PATENT LAW, AND PHARMACEUTICAL INDUSTRY

A. Basics of Indian Legal System and Intellectual Property Regime

The modern Indian legal system is based primarily on the British common law model.³⁴ After gaining independence from the British empire, India passed a national constitution in 1950.³⁵ The main sources of law in India include the constitution, statutory laws, customary laws and case law.³⁶ Hindu and Muslim law are still prevalent for some matters such as family law.³⁷

The types of intellectual property that are protected by law in India include patents, trademarks, copyrights, geographic indications, industrial designs, designs of integrated circuits, and plant varieties.³⁸ India is a member of several international organizations and a signatory of several treaties, including the World Intellectual Property Organization (WIPO), the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, and the Patent Cooperation Treaty (PCT).³⁹

B. Administrative Regulation of Patent Regime

The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM), a subordinate office under the Department of Industrial Policy and Promotion (DIPP), administers laws relating to patents,

34. Jayanth K. Krishnan, *India*, in LEGAL SYSTEMS OF THE WORLD : A POLITICAL, SOCIAL, AND CULTURAL ENCYCLOPEDIA 693-95 (Herbert M. Kritzer ed., 2003).

35. *Id.*

36. *Id.*

37. *Id.*

38. India Department of Industrial Policy & Promotion, Intellectual Property, <http://dipp.nic.in/ipr.htm> (last visited Dec. 20, 2007).

39. *Id.*

trademarks, industrial designs, and geographic indications.⁴⁰ The CGPDTM oversees the functioning of the Indian Patent Office, based in Kolkata with branches in Chennai, New Delhi, and Mumbai.⁴¹ The central government appoints the Controller of Patents, patent examiners, and various officers.⁴² The Patent Act vests most powers in the Controller of Patents and stipulates that the Controller may delegate powers to subordinate officers.⁴³

C. Indian Judiciary and the IPAB

A unique feature of the Indian judicial system is that although its federal system is composed of autonomous states united by a federal government, India has a single integrated system of courts characterized by a high degree of uniformity.⁴⁴ The Supreme Court sits at the top, followed by High Courts for each state, followed by a hierarchy of subordinate courts.⁴⁵ The Supreme Court of India hears appeals from subordinate courts and public-interest cases; it has original jurisdiction over disputes either between the central government and individual states, or between the states.⁴⁶ Each state and union territory has a High Court that has appellate and some original jurisdiction.⁴⁷

The Indian judicial system also comprises specialized tribunals, including the Intellectual Property Appellate Board (IPAB).⁴⁸ The Indian

40. India Controller General of Patents, Designs and Trademarks, <http://www.ipindia.nic.in/> (last visited Dec. 20, 2007). Other governmental departments administer laws relating to other forms of intellectual property. For example, the Department of Higher Education administers copyright laws. India Department of Industrial Policy & Promotion, Intellectual Property, *supra* note 38.

41. Addresses and Names of the Contact Persons of the Intellectual Property Offices, http://ipindia.nic.in/ipr/patent/ipo_office_add.htm (last visited Dec. 20, 2007).

42. Shammad Basheer, “Policy Style” Reasoning at the Indian Patent Office, 3 INTELLECTUAL PROPERTY QUARTERLY 309, 319 (2005), available at <http://ssrn.com/abstract=829464>. See also Posting of Shammad Basheer to Spicy IP, A Bureaucratic Babu as IP Chief!!, <http://spicyipindia.blogspot.com/2005/12/bureaucratic-babu-as-ip-chief.html> (Dec. 16, 2005) (criticizing the Indian government for appointing Controller of Patents without appropriate technical and legal qualifications).

43. See Basheer, “Policy Style” Reasoning at the Indian Patent Office, *supra* note 42, at 319.

44. Krishnan, *supra* note 34 at 693.

45. *Id.* at 698.

46. *Id.* at 696.

47. *Id.* at 697. There are twenty-one High Courts in India. Three of them have jurisdiction over more than one state.

48. See Intellectual Property Appellate Board, <http://www.ipab.tn.nic.in/> [hereinafter IPAB] (last visited Dec. 20, 2007).

government established the IPAB on September 15, 2003⁴⁹ to hear appeals from the decisions of the Registrar of Trademarks and Geographic Indications, and as of April 2007, from the Controller of Patents.⁵⁰ The IPAB is headquartered in Chennai and has additional branches in Mumbai, New Delhi, Kolkata, and Ahmedabab.⁵¹ A key difference between the IPAB and other judicial tribunals is that the composition of the IPAB must include at least one “technical” member in the board in addition to at least one “legal” member.⁵² The Indian government appoints all members of the IPAB.⁵³ Before the creation of the IPAB, the High Courts heard appeals from the various intellectual property administrative offices.⁵⁴ Following the creation of the IPAB, cases pending before the High Courts that fell under the jurisdiction of the IPAB were transferred to the IPAB.⁵⁵ While the IPAB now has jurisdiction over administrative patent challenges, the District Courts still have original jurisdiction over patent infringement disputes.⁵⁶ The High Courts have jurisdiction over infringement suits involving a challenge on the validity of the patent.⁵⁷

In the past, the IPAB was active in adjudicating trademark cases⁵⁸ but not patent matters because the government had not appointed to the board a “technical” member familiar with patent law until April 2007.⁵⁹ Thus,

49. *Id.*

50. When the IPAB was established in 2003, it had jurisdiction only over appeals against the Registrar of Trademarks and Geographic Indications. The Indian government added jurisdiction over appeals against the Controller of Patents through a notification promulgated on April 3, 2007, *available at* http://ipindia.nic.in/ipr/patent/gazetteofindia_apr2007.pdf [hereinafter April 3, 2007 Gazette] (last visited Dec. 20, 2007).

51. IPAB, *supra* note 48.

52. *Id.*

53. Novartis: Frequently Asked Questions, <http://www.novartis.com/newsroom/india-glivec-patent-case/faq.shtml#9> (last visited Dec. 20, 2007).

54. Posting of Shamnad Basheer to Spicy IP, Novartis Case Before the IPAB?, <http://spicyipindia.blogspot.com/2007/04/novartis-case-before-ipab.html> (Apr. 3, 2007).

55. However, infringement and criminal proceedings would be continued in the High Courts. IPAB, *supra* note 48.

56. Tarun Mathur, *Patent Litigation Trend in India*, June 22, 2007, <http://ssrn.com/abstract=995994>, 14. Administrative challenges are cases that involve the Patent Office as the defendant, including disputes on grant of a patent, patent invalidation, and compulsory licensing.

57. *Id.*

58. Even though the IPAB technically has jurisdiction over patent cases, the official IPAB website frequently only mentions trademark law and disputes. *See* IPAB, *supra* note 48.

59. Novartis Case Before the IPAB?, *supra* note 54.

until *Novartis AG*, the patent division of the IPAB existed in theory but was not in operation with functioning board members.⁶⁰

Given that the IPAB is newly established, the outcome of having a dedicated tribunal to hear appeals of intellectual property cases in India is uncertain. For example, there is no provision for any further appeals from a decision of the IPAB, and it appears that further appeals would make their way back to the High Courts.⁶¹ Furthermore, all patent infringement proceedings are heard by the District and High Courts, even if the proceedings involve a challenge to revoke a patent issued by the Controller of Patents.⁶² Will the IPAB lead to more speedy and fair resolution of cases?⁶³ Or will the relative inexperience of the IPAB, in particular with patent cases, mean that adjudication within the state and federal court system would be more prudent at this stage?⁶⁴

D. Development of Patent Law in India

The historical development of India's patent regime can be divided into three stages.⁶⁵

1. *India's Colonial Era to 1970: Recognition of Need to Reform Indian Patent Law to Increase Patent Filing and Stimulate Innovation*

The first stage covers India's colonial era through 1970. During colonial India, the British administration implemented India's first patent statute, India's Act VI of 1856, which was based on British patent law of 1852.⁶⁶ The law provided certain exclusive privileges to inventors of new manufacturers for a fourteen-year term.⁶⁷ In 1911, the British enacted the Indian Patents and Designs Act, which created a Controller of Patents to

60. *Id.* S. Chandrasekharan, former Controller of the Madras Patent Office, was appointed as the technical member in June 2007. *See infra* Section III.D.

61. *Novartis Case Before the IPAB?*, *supra* note 54.

62. Mathur, *Patent Litigation Trend in India*, *supra* note 56. In contrast, the Federal Circuit in the United States has exclusive jurisdiction over appeals from all cases arising in part from the patent laws, including patent validity and infringement. 4 JOHN GLADSTONE MILLS III ET AL., *PAT. L. FUNDAMENTALS* § 20:110 (2d ed. 2002).

63. India's judicial system is notoriously slow. Some sources have described a backlog of 18 million pending cases, of which 16 million cases are criminal ones. *See, e.g.*, India to set up fast track courts, http://news.bbc.co.uk/2/hi/south_asia/5227038.stm (last visited Dec. 20, 2007).

64. *See Novartis Case Before the IPAB?*, *supra* note 54 (describing that practicing attorneys in India are skeptical of the IPAB).

65. *See* Mueller, *The Tiger Awakens*, *supra* note 21, at 504-31.

66. *Id.* at 506.

67. *Id.*

oversee patent administration in India.⁶⁸ Despite these developments and the emergence of an industrialized economy,⁶⁹ patent filing in India remained low.⁷⁰

Shortly after India gained independence from Great Britain in 1947, the new government appointed a committee to review and revamp the patent law.⁷¹ Recovering from the oppressive colonial rule, the Indian government wanted a “patent system [that] was more conducive to national interests.”⁷² In 1950, the committee issued the Chand Report, which revealed the need to “stimulate invention and encourage exploitation of new inventions for industrial purposes” and recommended changes such as introducing compulsory licensing provisions.⁷³

The government commissioned a second report, the Ayyangar Report, in 1959.⁷⁴ The Ayyangar Committee found that multinational companies were exploiting India’s patent system to achieve monopolistic control; foreigners held about 80-90% of Indian patents, but practiced less than 10% of those patents in India.⁷⁵ The report recommended “radical” modifications to India’s patent law and became the foundation of the modern Indian patent system.⁷⁶ Reform, however, would not come until 1970, after more than a decade of long negotiations and debates in the Indian parliament.⁷⁷

2. *1970 to 1986: The India Patents Act of 1970 Prohibits Patents on Pharmaceutical Products, Stimulating India’s Generic Drug Manufacturing Industry*

The second stage of Indian patent law began when India enacted its first independently drafted patent law, the India Patents Act of 1970 (1970 Act), which repealed the 1911 Act.⁷⁸ The 1970 Act expressly revoked the

68. *Id.* at 507.

69. *Id.* By World War I, India was ranked fourteenth among industrialized nations of the world. Production of textiles, food processing, and metals were among the dominant industries. *Id.*

70. *Id.* at 508 (noting that by India’s independence, in 1947, the Indian Patent Office received only 2,610 annual filings despite a population of about 400 million).

71. *Id.* at 510-11.

72. *Id.* at 511.

73. *Id.*

74. *Id.* at 511-12.

75. Shamnad Basheer, *India’s Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15, 18 (2005), available at <http://ssrn.com/abstract=764066>.

76. Mueller, *The Tiger Awakens*, *supra* note 21, at 511-12.

77. *Id.* at 512.

78. *Id.*

patentability of pharmaceutical products.⁷⁹ The 1970 Act prohibited patents on “substances intended for use, or capable of being used as food or medicine or drug, or . . . relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds).”⁸⁰ However, the 1970 Act permitted patents on processes for making pharmaceutical compounds.⁸¹ Through the 1970 Act, the Indian government made a deliberate choice to stimulate the lagging Indian economy by promoting domestic drug manufacturing.⁸² Over the ensuing years, India developed a worldwide reputation as a producer of low-price generic drugs.⁸³ India is currently the biggest producer of generic drugs by volume⁸⁴ and the leading exporter of medicine to developing countries,⁸⁵ and it supplies a large percentage of AIDS medicines used in developing countries.⁸⁶

79. 1970 Act, *supra* note 10, §5. Both the 1856 and 1911 Acts permitted patenting of pharmaceutical products, even though the domestic pharmaceutical industry was a minor sector at that time. Mueller, *The Tiger Awakens*, *supra* note 21, at 508.

80. 1970 Act, *supra* note 10, § 5(a)-(b).

81. 1970 Act, *supra* note 10, § 5. The patent term of process patents for pharmaceutical compounds was shorter than the term of other types of patents:

[I]n respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter; . . .

Id. § 53(a).

82. Mueller, *The Tiger Awakens*, *supra* note 21, at 514.

83. *Id.*

84. MÉDECINS SANS FRONTIÈRES (DOCTORS WITHOUT BORDERS), UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES 4 (8th ed. 2005), available at <http://www.doctorswithoutborders.org/publications/reports/2005/untanglingthewebv8.pdf> (last visited Dec. 20, 2007).

85. Press Release, Oxfam, Oxfam Targeted with Email Campaign as Novartis' Legal Action against India Approaches Climax (Feb. 15, 2007), http://www.oxfam.org/en/news/2007/pr070215_novartis (last visited Dec. 20, 2007).

86. See Press Release, Médecins Sans Frontières (Doctors Without Borders), Patent Application For AIDS Drug Opposed For First Time in India: Patents in India Endanger Global Access to Affordable Medicines and Treatment Scale-up (Mar. 30, 2006), available at http://www.doctorswithoutborders.org/pr/2006/03-30-2006_1.cfm (last visited Mar. 28, 2008) (“Of the over 60,000 patients in nearly 30 countries in MSF projects, 84 percent receive generic AIDS medicines made in India.”).

3. *1986 to Present: An Uncertain Future for Generic Drug-manufacturing After India Reforms Patent Law to be TRIPS-Compliant.*

The third stage encompasses the period from India's participation in the GATT (and later the WTO) to the present.⁸⁷ India was one of the original 140 member nations who became WTO members on January 1, 1995.⁸⁸ Like many other developing countries at the time, India first opposed the inclusion of intellectual property rights in an international trade agreement.⁸⁹ However, in light of India's declining economy in the 1980s and fearing that it would be cut off from valuable western markets, India agreed to conduct more serious negotiations on intellectual property provisions in the WTO.⁹⁰ Throughout the negotiations, India maintained the position that patent protection should be tailored to the level of an individual country's economic development.⁹¹

In order to belong to the WTO, India was required to comply with TRIPS, which set out minimum standards of intellectual property protection.⁹² The basic provision of TRIPS delineating the scope of patentability, Article 27.1, states that all member nations must make patents "available for any inventions, whether products or processes, in all fields of technology," subject to standard requirements of novelty, utility, and nonobviousness.⁹³ Under the broad language of Article 27, all members must provide full patent protection to pharmaceuticals.⁹⁴

87. Mueller, *The Tiger Awakens*, *supra* note 21, at 505.

88. India and the WTO: Member Information, *supra* note 6.

89. Brazil, Argentina and Mexico were among the other countries initially opposed to TRIPS. Mueller, *The Tiger Awakens*, *supra* note 21, at 517.

90. *Id.* at 517-18.

91. *Id.* at 518.

92. See TRIPS, *supra* note 2, arts. 27-38.

93. Article 27.1 is known as the "non-discrimination" clause. It states:

Subject to the provisions of paragraphs 2 and 3, 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

TRIPS, *supra* note 2, art. 27.1. Article 27.2 provides for an "ordre public" exception:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the envi-

The WTO granted India, as a developing country, a transition period to bring its domestic intellectual property laws in compliance with TRIPS.⁹⁵ Most notably, India had to amend its patent law to make patents available for pharmaceutical products by January 1, 2005.⁹⁶ In the interim, the 1970 Act underwent three amendments. The first amendment implemented the “mailbox” rule, which stipulated that (a) India must provide a system so that patent applications could be filed during the transition period, and (b) the Indian Patent Office would examine those applications when India started to grant pharmaceutical product patents.⁹⁷ The second amendment

ronment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Id. art. 27.2. Article 27.3 provides further exception. Of relevance to pharmaceuticals and health is clause (a), which exempts diagnostic, therapeutic and surgical methods:

Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Id. art. 27.3.

94. Notwithstanding the broad language of Article 27.1, TRIPS also contains certain provisions to moderate Article 27.1’s coverage with regard to public health. For example, Article 31 sets out specific provisions that member countries should follow under a compulsory license, which enables a government to license of the use of a patented invention to a third party or government agency without the consent of the patent holder. *See id.* art. 31. Article 6 and footnote 6 addresses parallel importation, stating that patentees may not challenge the importation of a patented product marketed in another country because their rights have been exhausted upon sale of the product. *See id.* art. 6. Furthermore, the Doha Declaration on the TRIPS agreement and public health, adopted by the WTO Ministerial Conference in Doha in 2001, reaffirmed that TRIPS does not prevent member countries from “taking measures to protect public health.” World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 ILM 755, 755 (2002), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Dec. 20, 2007).

95. *See generally* TRIPS, *supra* note 2, art. 65.

96. *See id.* art. 65.4.

97. *See id.* art. 70.8. Patent applications for pharmaceutical products would be accepted and put away in a “mailbox” until 2005. Applications would be judged for “novelty” on the basis of the filing date and not with reference to 2005, the year in which pharmaceutical product patents were first incorporated into the patent regime. *Id.* In 1997, the US complained to WTO’s Dispute Settlement Body (DSB) that India’s patent system was noncompliant with respect to its lack of a mailbox system as required by Ar-

lengthened the patent term to twenty years and modified the compulsory licensing requirements and the burdens of proof for patent infringement.⁹⁸ Finally, in 2005, the Indian government took its latest (and purportedly last) step towards achieving TRIPS compliance by making pharmaceutical products patentable.⁹⁹ The availability of patent protection for pharmaceutical products, as required by TRIPS Article 27.1's broad nondiscrimination provision, has been a key difference between the patent regimes of developed and developing countries.¹⁰⁰

The Patents (Amendment) Act of 2005 (2005 Amendment) removed the prohibition of product patents for pharmaceutical compounds, allowing any company to seek both product and process patents in India.¹⁰¹ However, other provisions in the 2005 Amendment could potentially limit the reach of product patent protection. One of the newly introduced provisions, Section 3(d), which is the subject of the Novartis litigation, states that the following are not patentable inventions:

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.

ticle 70.8. The DSB held that India failed to meet its TRIPS obligations. Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 97, WT/DS50/AB/R (Dec. 19, 1997), available at http://www.wto.org/english/tratop_e/dispu_e/tripab.pdf (last visited Dec. 20, 2007).

98. Mueller, *The Tiger Awakens*, *supra* note 21, at 519, 526-28.

99. Mueller, *Taking TRIPS to India*, *supra* note 28, at 542; *see also* Mueller, *The Tiger Awakens*, *supra* note 21 529-31.

100. Before TRIPS, most developing countries did not have pharmaceutical patents. Correa, *supra* note 9, at 2. Surprisingly, many industrialized countries excluded pharmaceutical products from patentability in early phases of their development. Pharmaceutical patents were first authorized in Japan in 1976, Switzerland in 1977 and Italy in 1978, and were unavailable in Finland, Greece, Iceland, Monaco, Norway, Portugal and Spain as late as 1988. MERGES & DUFFY, *supra* note 11, at 186-87.

101. Many commentators contend that the 2005 Amendment illustrates a compromise between the obligation to recognize pharmaceutical product patents and the desire to restrain overbroad IPRs. The 2005 Amendment began as the Patents (Amendment Bill) of 2003, but the Bill lapsed due to a change in government. Legislators feared that India would not meet its 2005 TRIPS deadline and instead passed the Bill as a temporary Presidential Ordinance in 2004. Due to intense public debate and pressure from the "Left" (Communist) party (representing the interest of India's poor), the final version of the Patents (Amendment) Act of 2005 was significantly different from the 2004 Ordinance. *See, e.g.*, Mueller, *The Tiger Awakens*, *supra* note 21, at 529-531.

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

This controversial amendment is aimed at preventing frivolous patents that are only trivial modifications of existing inventions. Some commentators have alleged that the objective of Section 3(d) is to prevent “ever-greening.”¹⁰²

E. Development of the Indian Pharmaceutical Industry

The changes in India’s patent regime should be viewed in the context of the development of the Indian pharmaceutical industry. Much of the debate and many of the changes in the patent law were directly related to the demands of both multinational pharmaceutical companies and domestic pharmaceutical manufacturers.

India had virtually no domestic pharmaceutical industry during the British colonial rule.¹⁰³ As India began to industrialize during the first half of the twentieth century, that industry failed to develop.¹⁰⁴ Although both the 1856 and 1911 Acts technically allowed patents for pharmaceutical products, other policies, which favored British pharmaceutical company’s interests with little regard for India’s welfare, hindered the growth of a domestic pharmaceutical industry.¹⁰⁵

By the time of India’s independence, India’s healthcare system was in disarray.¹⁰⁶ While India was then one of the world’s poorest countries, it imported medicines and sold them to Indian patients at some of the highest prices in the world, often exceeding the prices in Western countries.¹⁰⁷ Multinational pharmaceutical companies dominated what little drug manufacturing that existed in India.¹⁰⁸ In this context, both the Chand Report of

102. *See supra* note 31 and surrounding text.

103. Mueller, *The Tiger Awakens*, *supra* note 21, at 507-08.

104. *Id.* at 507-08.

105. *Id.* The 1911 Act established an intra-British Empire priority system where British applicants for Indian patents that had filed within the U.K. for the same invention benefited from the earlier filing date. Foreign corporations reportedly used the 1911 Act to prevent Indian manufacturers from producing drugs invented abroad. *Id.*

106. *Id.* at 508-10.

107. *Id.* at 509-10.

108. *Id.*

1950 and the Ayyangar Report of 1959 called for the need to encourage innovation and prevent foreign monopolization.¹⁰⁹

By explicitly abolishing patents for pharmaceutical products, the 1970 Act generated immediate and dramatic results. Within a decade, the number of foreign-owned patent applications filed decreased sharply.¹¹⁰ Because pharmaceutical products patented outside of India could be reverse engineered and manufactured, India developed a capable generic drug manufacturing industry reputed for producing generic versions of branded drugs at low cost.¹¹¹

Today, India still has a thriving domestic generic drug industry that competes directly with brand-name drug manufacturers from the U.S. and Europe.¹¹² Indeed, India and Japan are the only two countries where generic drug manufacturers dominate over multinational corporations.¹¹³ The domestic industry is itself divided between several large companies (such as Ranbaxy, Cipla, and Dr. Reddy's Laboratories), which engage in some original research and development in addition to generic drug production, and hundreds of smaller companies, which exclusively reverse engineer and manufacture generics.¹¹⁴ Both segments rely heavily on export markets.¹¹⁵ Meanwhile, a growing Indian middle class and an expanding health insurance system have increased the demand for medicines within India. Annual sales have been predicted to triple to \$20 billion by 2015.¹¹⁶

The landscape of the multinational pharmaceutical industry in India is also changing. Multinational companies traditionally manufactured drugs outside of India and then exported them into India.¹¹⁷ Recently, multinationals are leveraging India's low labor costs and skilled workforce to

109. *Id.* at 510-12.

110. *Id.* at 513-14 (noting 4,248 non-Indian applications in 1968 compared to 1,010 a decade later).

111. *Id.* at 514-15.

112. Aaron Smith, *Report: Indian Drug Market to Reach \$20B*, CNNMONEY.COM, Aug. 22, 2007, http://money.cnn.com/2007/08/22/news/companies/india_pharma/index.htm (last visited Dec. 20, 2007).

113. In 2004, multinational firms held only a 23% share of the Indian pharmaceutical market as compared to domestic companies' 77% market share. Mueller, *The Tiger Awakens*, *supra* note 21, at 532-33.

114. *Id.* at 537.

115. *Id.* at 537-40. Larger companies export to regulated markets such as with higher entry barriers, such as the US, Western Europe, Japan, Australia and New Zealand. Smaller drug manufacturers tend to export to markets characterized as "unregulated," such as Vietnam, Syria, Jordan, Brazil, China, Korea, Taiwan and Egypt.

116. Smith, *supra* note 112.

117. Mueller, *The Tiger Awakens*, *supra* note 21, at 533.

conduct manufacturing, R&D, and clinical testing in India.¹¹⁸ Yet, India must compete with countries such as Singapore or China for foreign investors who prefer more stringent patent rights.¹¹⁹

The fragmented Indian pharmaceutical industry has led to a wide disparity of interests with respect to patent protection. Not only do multinational drug companies want enhanced patent protection, but some domestic companies—primarily those who have significant research and development operations—also want a stronger patent regime.¹²⁰ Other domestic companies, however, fervently oppose patent law reform, fearing that it would lead to patent-based monopolies and destroy their imitation-based business models.¹²¹

III. GLEEVEC PATENT REJECTION AND NOVARTIS AG

A. Background: Novartis's Patent Application

Gleevec is used for the treatment of chronic myeloid leukemia (CML), a disease that afflicts nearly 5,000 new patients in the United States each year.¹²² Studies have shown that Gleevec, which targets specific cancer proteins, is almost ten times more effective than traditional interferon therapy.¹²³ In 1993, Novartis filed patents worldwide for the active molecule imatinib.¹²⁴ Novartis did not patent imatinib in India because the 1970 Act did not allow patenting of pharmaceutical products at that time.¹²⁵ After India's entry into the WTO in 1995, Novartis filed a "mailbox" patent application¹²⁶ in the Madras Patent Office for imatinib mesylate, a beta

118. *Id.* at 533-35.

119. *See generally* Hitesh Gajaria, Protecting IP for Prosperity, *ECONOMIC TIMES (India)* (Aug. 3, 2007), available at http://economictimes.indiatimes.com/Guest_Writer/Protecting_IP_for_prosperity/articleshow/2251915.cms (expressing need for IP protections to compete in the region).

120. Mueller, *The Tiger Awakens*, *supra* note 21, at 540.

121. *Id.* at 539-40.

122. American Cancer Society, How Many People Get Chronic Myeloid Leukemia? (Aug. 14, 2007), http://www.cancer.org/docroot/CRI/content/CRI_2_2_1X_How_many_people_get_chronic_leukemia_62.asp (last visited Dec. 20, 2007).

123. American Cancer Society, Gleevec's New Successes Show Growing Promise of Targeted Therapies (May 22, 2002), http://www.cancer.org/docroot/NWS/content/NWS_1_1x_Gleevec_s_New_Successes_Show_Growing_Promise_of_Targeted_Therapies.asp (last visited Dec. 20, 2007).

124. Novartis, History of Glivec in India, <http://www.novartis.com/downloads/about-novartis/glivec-history-india.pdf> (last visited Dec. 20, 2007).

125. *Id.*

126. *See supra* note 97 and surrounding text.

crystalline form of the free base imatinib.¹²⁷ In 2002, Novartis started its Gleevec donation program in India to provide Gleevec to patients who were unable to afford the medicine, but halted that program after Indian drug manufacturers began to produce a generic version of Gleevec.¹²⁸ In 2003, the Patent Office granted Novartis Exclusive Marketing Rights (EMR)¹²⁹ in India, which allowed Novartis to enjoin generic Gleevec manufacturers and raise the price of Gleevec almost ten-fold.¹³⁰ When the Gleevec mailbox application came up for examination in 2006, some commentators suspected that the application was fast-tracked due to controversies over the donation program and the divisive rise in price.¹³¹

In January 2006, the Madras Patent Office refused to grant Novartis a patent for imatinib mesylate.¹³² The first major ground for rejection was that because imatinib mesylate was a salt form of the free base imatinib,¹³³ and Novartis claimed all pharmaceutical salt forms of imatinib in its 1993 patents, the Indian application therefore lacked novelty and inventiveness.¹³⁴ The second major ground for rejection was based on Section 3(d)

127. Posting of Shamnad Basheer to Spicy IP, First Mailbox Opposition (Gleevec) Decided in India (Mar. 11, 2007), <http://spicyipindia.blogspot.com/2006/03/first-mailbox-opposition-gleevec.html>.

128. Stephanie Strom & Matt Fleischer-Black, *Drug Maker's Vow to Donate Cancer Medicine Falls Short*, N.Y. TIMES, June 5, 2003, at A1. Novartis started the donation program in India with the warning that it would be halted should any Indian company launch a generic version.

129. See TRIPS, *supra* note 2, art. 70.9. During a member country's transition period, it must grant patent applicants "exclusive marketing rights" (EMRs) which last for five years or until the issuance or rejection of a patent. *Id.*

130. Ganapati Murdur, *Indian Patients Go to Court Over Cancer Drug*, 329 BRIT. MED. J. 419 (2004), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15321889>. One month's dose of Gleevec costs \$2,600, roughly ten times more than the generic versions.

131. Basheer, First Mailbox Opposition (Gleevec) Decided in India, *supra* note 127.

132. *Id.*

133. A free base is converted a salt form by adding acid, in this case, methanesulfonic acid to the free base imatinib. The beta crystalline form of the salt is allegedly the most stable form of the salt. Posting of Shamnad Basheer to Spicy IP, US Enablement Case: Relevance for the Novartis Patent Case in India, <http://spicyipindia.blogspot.com/2007/10/us-enablement-case-relevance-for.html> (Oct. 29, 2007).

134. In the Matter of an Application for Patent No. 1602/MAS/98 (Jan. 26, 2006), available at <http://www.scribd.com/doc/416824/Patent-office-Order-India-Glivec>. The Patent Controller wrote:

I do not agree with the contention of the Applicant that the 1993 patent discloses only the free base. The 1993 patent discloses mathanesulfonic acid as one of the salt forming groups and also the 1993 patent specification states that the required acid additions salts are obtained in a customary manner. Further, claims 6 to 23 of the 1993 patent claim a

of the 2005 Amendment, which required that new forms of a known substance could only be patented as a product if they demonstrated “enhanced efficacy.”¹³⁵ Although Novartis disclosed information that imatinib mesylate had a 30% increase in bioavailability (the percentage of the drug absorbed into the bloodstream) as compared with imatinib, the Patent Office found this insufficient to meet the “enhanced efficacy” requirement of Section 3(d).¹³⁶

B. Procedural History of Novartis’s Appeal

In May 2006, Novartis petitioned the Madras High Court, opposed by the Indian Government, the Patent Office, several Indian generic drug manufacturers¹³⁷ and an Indian public interest group.¹³⁸ Novartis claimed that the Patent Controller erred in rejecting the Gleevec patent application, that Section 3(d) was not compliant with TRIPS, and that Section 3(d) was vague, ambiguous and in violation of Article 14 of the Constitution of India¹³⁹ because it was discriminatory against Novartis. The case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB). The challenges on TRIPS compliance and constitutionality of Section 3(d) were heard by the Madras High Court, which issued a judgment against Novartis on August 8, 2007.¹⁴⁰ The IPAB pro-

pharmaceutically acceptable salt of the base compound. The patent term extension certificate for the 1993 patent issued by the US Patent Office specifically mentions imatinib mesylate (GleevecR) as the product. All these points clearly prove that imatinib mesylate is already known from the prior art publications.

Id. (quoted in Basheer, First Mailbox Opposition (Gleevec) Decided in India, *supra* note 127).

135. *Id.* See also Basheer, First Mailbox Opposition (Gleevec) Decided in India, *supra* note 127 (discussing ruling)

136. The Patent Controller wrote, “As per the affidavit the technical expert has conducted studies to compare the relative bioavailability of the free base with that of crystal form of imatinib mesylate and has said that the difference in bioavailability is only 30% and also the difference in bioavailability may be due to the difference in their solubility in water.” Basheer, First Mailbox Opposition (Gleevec) Decided in India, *supra* note 127.

137. These manufacturers are Natco Pharma, Cipla, Hetro Drugs, Ranbaxy, Sun Pharmaceuticals. See *Novartis AG v. Union of India*, (2007) 4 MADRAS L.J. 1153, § 1.

138. Cancer Patient Aid Association. *Id.*

139. Article 14 states, “The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.” INDIA CONST. art. 14.

140. Posting of Shamnad Basheer to Spicy IP, *Novartis Loses at the High Court: Focus Now Shifts to IPAB*, <http://spicyipindia.blogspot.com/2007/08/novartis-loses-at-high-court-focus-now.html> (Aug. 7, 2007).

ceedings on the merits of Novartis's appeal on the rejection of the Gleevec patent are currently pending.¹⁴¹

C. Issues at the Madras High Court

The Madras High Court entertained three issues: First, whether courts in India have jurisdiction to review if Section 3(d) of the 2005 Amendment is compliant with Article 27 of TRIPS, and alternatively, whether courts in India can grant declaratory relief that Section 3(d) is not compliant with TRIPS. Second, if courts do have jurisdiction, whether Section 3(d) complies with Article 27 of TRIPS. Third, whether Section 3(d) violates Article 14 of the Constitution of India because it is vague, arbitrary and confers uncontrolled discretion to the Patent Controller.¹⁴² This Section will review the Madras High Court's holding on each issue.

1. Jurisdiction

The Madras High Court held that it did not have jurisdiction to decide a case concerning the compliance of a domestic Indian law with an international treaty.¹⁴³ In support of its arguments, Novartis relied on a case from the United Kingdom, *Equal Opportunities Commission & Another v. Secretary of State for Employment*, in which the court held that British courts had jurisdiction to decide a case concerning the compatibility of a British law with the European Community Law.¹⁴⁴ The Madras High Court distinguished the facts of the *Novartis* dispute with those under *Equal Opportunities Commission*, because the European Community Law had been "domesticated" as the domestic law of England through the European Communities Act, whereas the Indian government had not "domesticated" TRIPS.¹⁴⁵ Furthermore, the Madras High Court asserted that the nature of an international treaty is contractual, and accordingly contains provisions for dispute settlement.¹⁴⁶ Since Article 64 of TRIPS expressly provides that disputes should be taken to the Dispute Settlement Body of the WTO, the Madras High Court held that Novartis should seek to enforce TRIPS through that mechanism and not an Indian court.¹⁴⁷

Concerning the alternative argument of granting of declaratory relief, the Madras High Court asserted that courts have broad discretionary power to grant declaratory relief under Article 32 of the Constitution of

141. See *infra* Section III.D.

142. *Novartis AG*, § 5.

143. *Id.* § 7.

144. *Id.* § 6.

145. *Id.*

146. *Id.*

147. *Id.*

India.¹⁴⁸ The court held, however, that declaratory relief should not be given where it would serve no useful purpose to the petitioner.¹⁴⁹ Because Novartis could not compel the Indian parliament to enact or amend a law even if Novartis were to get a declaration that Section 3(d) was noncompliant with TRIPS, the court held that Novartis was not entitled to declaratory relief.¹⁵⁰

2. *Compliance with TRIPS*

Because the Madras High Court held that it did not have jurisdiction to decide whether a domestic law violated an international treaty, it refused to decide whether Section 3(d) is compliant with TRIPS.¹⁵¹ Nevertheless, the court opined that TRIPS allows flexibility for the individual needs and situations of every member country.¹⁵² In complying with the TRIPS obligations, India has a constitutional duty to provide good health care to its citizens, including giving them access to affordable drugs.¹⁵³ Thus, the court opined that the validity of Section 3(d) should be analyzed with consideration of its objectives of preventing evergreening and making generic drugs available.¹⁵⁴

3. *Constitutionality*

The court held that Section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary, and did not confer uncontrolled discretion to the Patent Controller.¹⁵⁵ The court rejected Novartis's arguments that Section 3(d), which denies patents to new uses of known substances unless the patentee can show "enhancement of the known efficacy" or "differing significantly in properties with regard to efficacy," was ambiguous and unclear.¹⁵⁶ While these two phrases are not explicitly defined, the court held that it was common practice for the legislature to use general language and leave the courts to interpret the language based on the context and facts of each case.¹⁵⁷ Moreover, the court held that Novar-

148. *Id.* § 9.

149. *Id.*

150. *Id.*

151. *Id.* § 8.

152. *Id.* § 15. The Madras High Court interpreted TRIPS as granting member countries enough flexibility to comply with TRIPS, but at the same time enacting laws benefiting the social and economic welfare of each country. *See id.*

153. *Id.*

154. *Id.*

155. *Id.* § 19.

156. *Id.* § 11.

157. *Id.* § 14.

tis was a sophisticated party who had the technological expertise to comprehend the enhanced efficacy requirement.¹⁵⁸

The court also rejected Novartis's argument that Section 3(d) was arbitrarily enacted.¹⁵⁹ Novartis argued that the actual amended Section 3(d) was not the same as the one originally proposed to the Parliament, which made no mention of an efficacy requirement, and was substituted in the current form of Section 3(d) without explanation.¹⁶⁰ The court held that Section 3(d) was not arbitrarily enacted, referring to the parliamentary debates leading to the 2005 Amendment.¹⁶¹ The debates revealed that there was widespread fear that the earlier proposed amendments would deny Indian citizens of access to affordable medicines and open up the possibility of evergreening.¹⁶² Thus, the court found that the legislature did not arbitrarily enact Section 3(d) in its final form.¹⁶³

Finally, the court held that Section 3(d) did not confer unlimited discretionary power to the Patent Controller and was not discriminatory.¹⁶⁴ The court emphasized that discretionary power did not necessarily mean that it would be discriminatory.¹⁶⁵ The Patent Controller's discretionary power under Section 3(d) in deciding whether a known substance has enhanced efficacy did not automatically lead to an arbitrary exercise of discretionary power or discrimination against Novartis.¹⁶⁶ Furthermore, the court opined that the judiciary should be more deferential to the legislature in the field of economic regulation.¹⁶⁷ Because the Patent Act was designed to encourage the economic interests of India, the courts should be especially cautious before overruling the legislature.¹⁶⁸

158. *Id.* § 13 (“The writ petitioner is not a novice to the pharmacology field but it, being pharmaceutical giant in the whole of the world, cannot plead that they do not know what is meant by enhancement of a known efficacy and they cannot snow [sic] that the derivatives differ significantly in properties with regard to efficacy.”).

159. *Id.* § 12.

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.* § 16.

165. *Id.* § 17 (quoting *Selvi. J. Jayalalitha v. The Union of India*, 2007-1-LW, at 724: “We cannot presume that the authorities will administer the law ‘with an evil eye and an unequal hand.’”).

166. *Id.* § 16.

167. *Id.* § 17.

168. *Id.*

D. Issue at the IPAB

In April 2007, while the case was still pending before the Madras High Court, the Indian government put into operation the patent division of the IPAB¹⁶⁹ and transferred the challenge on the merits of the denial of Novartis's patent application to the Chennai-based IPAB.¹⁷⁰ The government appointed S. Chandrasekharan, a former Controller of the Madras Patent Office, as the "technical member."¹⁷¹ Subsequently, Novartis objected to the appointment of S. Chandrasekharan on the ground that he was the Controller, although not the examining officer, when Novartis's Gleevec patent application was rejected.¹⁷² The IPAB dismissed this objection, and Novartis appealed to the Madras High Court to remove Chandrasekharan.¹⁷³ The Madras High Court heard the appeal on October 9, 2007, when the Indian government proposed revising the composition of the board to hear the Novartis dispute by removing altogether the "technical member."¹⁷⁴ Even though Novartis agreed to this proposal, Hyderabad-based generic drug manufacturer Natco Pharma Ltd, the main corporate opponent to Novartis in the case, argued that the board should not hear the case without a technical member present.¹⁷⁵ After the Madras High Court ruled that the case could proceed at the IPAB without a technical member, Natco appealed to the Supreme Court of India.¹⁷⁶ On January 28, 2008, the Supreme Court issued a stay order on the Madras High Court judgment.¹⁷⁷ As this Note went into publication, it is unclear if and when the IPAB proceedings will continue.

169. See April 3, 2007 Gazette, *supra* note 50.

170. Basheer, *Novartis Case Before IPAB?*, *supra* note 54.

171. Patents: Appellate Board Becomes Functional, MEDINDIA.COM, Apr. 10, 2007, http://www.medindia.net/news/view_news_main.asp?x=19886 (last visited Dec. 20, 2007).

172. Posting of Shamnad Basheer to Spicy IP, *Novartis Case at IPAB Stayed*, <http://spicyipindia.blogspot.com/2007/08/novartis-case-at-ipab-stayed.html> (Aug. 10, 2007).

173. *Id.*

174. C. H. Unnikrishnan, *Order Deferred in Glivec Case*, LIVEMINT.COM, Oct. 23, 2007, <http://www.livemint.com/2007/10/23234424/Order-deferred-in-Glivec-case.html>.

175. *Id.* (quoting Natco company secretary Adi Narayana: "Our argument is that since the points to be raised in the IPAB hearing are highly technical in nature, it will be almost impossible for the board to take a balanced view unless it heard by an expert in this subject.").

176. Bhuma Shrivastava & C. H. Unnikrishnan, *SC Issues Stay Order Against Appeal Hearing*, LIVEMINT.COM, Jan. 29, 2008, <http://www.livemint.com/2008/01/29001921/SC-issues-stay-order-against-a.html>.

177. *Id.*

IV. ANALYSIS OF SECTION 3(D)

As previously discussed, the Indian government introduced Section 3(d) to prevent multinational pharmaceutical companies from extending the life of a patent. Because pharmaceutical inventions rarely relate to new chemical entities or novel active ingredients that have never before been available for therapeutic use, pharmaceutical companies often prolong patent protection by obtaining separate patents on multiple attributes of a single product.¹⁷⁸

This Part will describe how Section 3(d) regulates the granting of pharmaceutical product patents by limiting the scope of protection available for derivatives and new uses of a known substance. Section 3(d) essentially codifies distinct patentability criteria for pharmaceutical and chemical substances to prevent patents on trivial modifications of known substances. This Part argues that because other countries have taken more indirect routes to achieve similar objectives, Section 3(d) is not a radical departure from international practices.

A. Derivatives of Known Substances

1. India

The first clause of Section 3(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,”¹⁷⁹ prohibits patents of derivatives of known substances, unless such derivatives display “enhanced efficacy.” The explanation following the rule clarifies which substances will be considered derivatives of known substances and further requires that efficacy must “differ *significantly*.”¹⁸⁰

Pharmaceutical companies often file independent patent applications on variations of known substances to extend their protection on known active ingredients.¹⁸¹ For example, some therapeutically active ingredients are present in polymorphic forms (crystallization in different forms) that may have different therapeutic properties.¹⁸² Pharmaceutical companies often file composition patents protecting the formulated product contain-

178. These attributes include processes of manufacture, formulations, systems of delivery, new uses and different chemical forms of a known product such as salts, isomers, metabolites and polymorphic forms. Correa, *supra* note 9, at 14, 29-32.

179. The Patents (Amendment) Act, 2005, *supra* note 15, § 3(d).

180. *Id.* (emphasis added).

181. Correa, *supra* note 9, at 30.

182. *Id.*

ing active ingredients and appropriate additives.¹⁸³ They also seek patents on the active metabolite, the compound that forms in the patient's body after the drug is ingested and produces the desired therapeutic effect in the body.¹⁸⁴

2. *Other Countries*

The efficacy requirement is controversial because it has no explicit parallel in any other patent regime in the world.¹⁸⁵ Efficacy of pharmaceutical substances is usually addressed through drug safety regulation, and has no effect on the patentability of substances.¹⁸⁶ The language of Section 3(d) seems to have been taken directly from a European legislative directive dealing with drug safety regulation.¹⁸⁷ Furthermore, Section 3(d) raises questions as to what kind of data is required to establish efficacy and how much an improvement results in significantly enhanced efficacy.¹⁸⁸

While Section 3(d) has no direct counterpart in other patent laws, other countries such as the United States have myriad indirect ways to deal with

183. *Id.* (discussing composition patents, combinations of previously known products, allowing the patentee to extend the term of protection granted under the basic patent).

184. *Id.*

185. Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, *supra* note 75, at 24.

186. *Id.*

187. *Id.* Article 10(2)(b) of Council Directive 2004/27/EC defines a "generic medicinal product" as:

a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixture of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

Council Directive 2004/27, art. 10(2)(b), 2004 O.J. (L 136) 39 (EC).

188. Mueller, *The Tiger Awakens*, *supra* note 21, at 553 (describing questions as both qualitative and quantitative).

patents on insubstantial modifications of known active ingredients. For example, U.S. courts have invalidated patents on derivatives of known substances under the doctrine of inherent anticipation. In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, the Federal Circuit invalidated a patent on the metabolite of antihistamine drug because the metabolite “necessarily and inevitably” formed upon ingestion of previously patented antihistamine under normal conditions.¹⁸⁹

In addition, U.S. courts prevent the patenting of derivatives under the complex doctrine of double patenting, which aims to prevent a patentee from holding more than one patent with claims to the same invention or obvious modifications or variations of the same invention.¹⁹⁰ In the United States, prohibition against double patenting has both a statutory basis, which prohibits a patentee from holding more than one patent with identical claims,¹⁹¹ and a judicially-created equitable doctrine, which provides that a patentee may not have a later-issued patent with claims directed to an obvious variation of the subject matter of claims in an earlier-issued patent.¹⁹²

Another approach in the United States is the patent misuse doctrine, which prevents pharmaceutical companies from extending patent rights by obtaining multiple patents covering essentially the same invention.¹⁹³ Finally, U.S. courts draw upon the 35 U.S.C. § 103 nonobviousness doctrine¹⁹⁴ when invalidating certain pharmaceutical patents. In *Pfizer, Inc. v.*

189. 339 F.3d 1373, 1378 (Fed. Cir. 2003).

190. See generally Emily Evans, *Double Patenting Recapitulated*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 625 (2005) (examining the doctrine in detail); see, e.g., *In re Longi*, 759 F.2d 887, 892-97 (Fed. Cir. 1985) (affirming rejection of a patent application upon a holding of obviousness-type double patenting over the claims of three commonly-owned patent applications).

191. Evans, *supra* note 190, at 625. The statutory basis is 35 U.S.C. § 101, which states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor . . .” The word “a” has been interpreted to mean that a patentee may have only a single patent covering a claimed invention. *Id.*

192. Evans, *supra* note 190, at 625-26. See also Dan Burk & Mark Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 741 n.214 (2004) (suggesting that strengthening the obviousness standard will deter pharmaceutical companies from unjustifiably extending the effective patent life). For a more detailed discussion of the doctrine of double patenting, see 4 DONALD CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT ON PATENTS § 9.01 (2007).

193. Burk & Lemley, *supra* note 192, at 742.

194. 35 U.S.C. § 103(a) states, “A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

Apotex, Inc., the Federal Circuit invalidated Pfizer's patent on a hypertension drug on nonobviousness grounds because the active ingredient of the drug was merely a salt form of a known substance.¹⁹⁵

B. New Uses of Known Substances

1. India

The second clause of Section 3(d), "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,"¹⁹⁶ regulates the granting of "new use" patents.¹⁹⁷ Patents are frequently issued for new therapeutic uses of known products.¹⁹⁸ New use patents are critical to the patent strategy of pharmaceutical companies, who rely on new use patents to extend the commercial life of product patents.¹⁹⁹

195. 480 F.3d 1348, 1364 (Fed. Cir. 2007). Pfizer argued there was no easy way to predict, and therefore rendering the invention nonobvious, the influence of a different salt form on the active part of the drug. The court opined, "[A] rule of law equating unpredictability to patentability, applied in this case, would mean that any new salt . . . would be separately patentable, simply because the formation and properties of each salt must be verified through testing. This cannot be the proper standard since the expectation of success need only be reasonable, not absolute." *Id.*

196. The Patents (Amendment) Act, 2005, Section 3(d), *supra* note 15.

197. Mueller, *The Tiger Awakens*, *supra* note 21, at 557-59.

198. Edson B. Rodrigues Jr. & Brian Murphy, *Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines*, 16 ALB. L.J. SCI. & TECH. 423, 430 (2006). Rodrigues and Murphy point to a 2002 study done by the National Institute of Health Care Management (NIHCM) Research and Education Foundation found that in 1989-2000, only 35% of the 1035 new drugs approved by the US FDA entailed a new active principle. *Id.* (citing THE NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION, CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION (2002), available at www.nihcm.org/~nihcmor/pdf/innovations.pdf).

199. Rodrigues & Murphy, *supra* note 198. This procedure is known as "evergreening" and may have anticompetitive effects. However, some scholars believe patent protection for drugs, which has an "effective patent life" between product launch and patent expiration of only about 11 years, is too short for firms to capture the value of its research and development investment. Process patents on new therapeutic uses developed as a way for firms to capture more value by extending the commercial life of the patent. See Rebecca Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 717, 722-25 (2005).

2. *Other Countries*

The patentability of new uses of known substances is controversial and is often treated inconsistently by other countries.²⁰⁰ In the United States, a new use of an existing product can be protected by a process patent.²⁰¹ The patent is confined to the particular method of use and does not encompass protection of the product.²⁰² Patent holders do not prefer process patents, which are not easily enforceable and cannot be used to stop competitors from selling the same product for other uses.²⁰³

Europe has a more expansive approach to new use patents.²⁰⁴ In Europe, a new use can either be a product claim or a process claim, depending on whether the product had previous pharmaceutical use. A new therapeutic use of a known product having no previous pharmaceutical use, known as a “first indication” or “first medical use,” can be protected by a product patent.²⁰⁵ This specialized form of product patent claim is known as “purpose-limited-product” claim, which limits the scope of the patent protection to the particular purpose or use of the product.²⁰⁶ However, a new use for a product that already has an existing pharmaceutical use, known as a “second indication” or “second medical use,” is protected by a process patent.²⁰⁷ The claim format is known as a “Swiss claim” and is merely limited to the new use of the known compound or composition.²⁰⁸

C. Section 3(d) and TRIPS

The above discussion indicates that the objective of India’s Section 3(d) is not a radical departure from international practices to regulate the

200. Jean Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 95 (2002).

201. Eisenberg, *The Problem of New Uses*, *supra* note 199, at 724. A case often cited for the proposition that a new use for an existing product should be covered by a process patent is *Rohm & Haas Co. v. Roberts Chemicals, Inc.*, 245 F.2d 693, 699 (4th Cir. 1957).

202. Eisenberg, *The Problem of New Uses*, *supra* note 199, at 724.

203. *Id.* Enforcement is not easy because patent holders would have to enforce the use claim against patients taking the drug for the patented use, doctors prescribing it for such use, or pharmacists who fill the prescriptions. Enforcement against drug manufacturers who produce the drug would be difficult because they would be liable for contributory infringement, and there may be substantial non-infringing uses of the product.

204. Correa, *supra* note 9, at 14-15.

205. *Id.*

206. Ragavan, *supra* note 13, at 83-84.

207. *Id.*

208. *Id.* Thus, third party inventing a new use of a patented or known product can get patent protection limited to the marketing the product for the new use.

patenting of derivatives and new uses. Nevertheless, Novartis claimed that Section 3(d) was not compliant with TRIPS Article 27. Assuming that the patent laws of other countries are TRIPS-compliant and absent WTO ruling on the contrary, Novartis has likely overstated the noncompliance of Section 3(d).²⁰⁹

TRIPS Article 27.1 states, “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.” This provision obliges member countries to grant product and process patents in all fields of technology and sets up three criteria, novelty, inventive step, and industrial applicability, for patentability. Inventive step and industrial applicability correlate to the concepts of nonobviousness and utility in the United States.²¹⁰

The 2005 Amendment extended product patent protection to pharmaceutical substances in order to fulfill Article 27.1’s requirements. However, “novelty,” “inventive step” and “industrial application” are not defined in TRIPS; member countries arguably have considerable flexibility in applying these three criteria.²¹¹ One perspective is that Section 3(d) is merely a codified nonobviousness standard in the context of pharmaceutical substances, and therefore permissible under TRIPS.²¹² India has limited discretion under TRIPS to decide the subject matter entitled to patent protection, but it has greater discretion to fine tune its patent regime by limiting the scope of protection available for derivatives and new uses by adjusting the inventive step criteria.²¹³

209. Treaty interpretation principles are beyond the scope of this Note. This Section discusses generally requirements under TRIPS and presents viewpoints on the interpretation of TRIPS Article 27. However, it is interesting to note that the Swiss government has declined to take Novartis’s challenge of the noncompliance of India’s patent law to the WTO. Swiss Government Not to Take Novartis Case to WTO—Reports, <http://www.forbes.com/markets/feeds/afx/2007/08/08/afx3997818.html> (last visited Dec. 20, 2007).

210. UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, 359-61 (2005). Footnote 5 to Article 27.1 states that “inventive step” and “capable of industrial application” is synonymous with “non-obvious” and “useful.”

211. *Id.* at 358. This is the view taken by many academic commentators and NGOs. While member countries must apply those three criteria, the WTO Dispute Settlement Board (DSB) has never directly addressed *how* member countries must implement them. In one of the few WTO cases concerning Article 27, the Dispute Settlement Board (DSB) opined that member countries can adopt different rules for particular product areas, as long as those differences represent bona fide purposes. *Id.* at 370-71.

212. Basheer, *India Patent Act Faces TRIPS Challenge*, *supra* note 29.

213. One early view expressed by academics after TRIPS was promulgated is that the WTO should be more deferent to developing countries with respect to inventive step than

TRIPS is also silent on the issue of whether new medical uses, which itself is controversial and inconsistently treated by developed countries, is patentable.²¹⁴ Some commentators assert that new use patents lack novelty because they are mere discoveries of new properties of existing products. The EU approach sidesteps this obstacle by recognizing it as a “legal fiction” in which an invention can draw novelty from a new use.²¹⁵ Furthermore, since new use patents frequently refer to new medical uses of known pharmaceutical substances, they may fall under the TRIPS exception on patenting of a therapeutic method.²¹⁶

D. The Novartis Dispute Should Encourage Clarity in Indian Patent Law

India’s patent law needs to be clear and reliable in order to effectuate the purpose of advancing innovation. The 2005 Amendment and Section 3(d) introduced considerable uncertainty into Indian patent law. Therefore, India must be cautious in interpreting the provisions of Section 3(d).²¹⁷ For example, as previously described, although Section 3(d)’s limitation on patenting derivatives of known substances is not without parallels in other patent regimes, the problem stems from uncertainty about how the India patent office and judiciary will interpret “enhanced efficacy.” The 2005

to subject matter issues. See Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT’L L. 275, 282-304 (1997). However, the issue of permissible nonobviousness standards under TRIPS is widely debated on both sides. Some commentators have contended that nonobviousness is the most problematic issue in international harmonization of intellectual property protection. See J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT’L L. & POL. 11, n.62 and surrounding text.

214. Rodrigues & Murphy, *supra* note 198, at 430.

215. Furthermore, this “legal fiction” is not universally accepted. The British Patents Office took the position that this is an indefensible legal fiction and avoided these patents for unjustifiably extending the period of protection of the invention, regardless of the existence of a genuine inventive activity. See *id.* at 432.

216. *Id.* TRIPS Article 27.2(a) reads: “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” TRIPS, *supra* note 2, art. 27.2.

217. Recent cases confirm that Section 3(d) will be a continuing issue in patent litigation in India. Closely following behind the Novartis litigation, F Hoffman-La Roche sued to enjoin Indian generic manufacturer Cipla in January 2008 after Cipla launched a generic version of Roche’s lung cancer drug Tarceva. Cipla asked the Delhi High Court to revoke the Tarceva patent, claiming that the patent was invalid under Section 3(d) because Tarceva was a mere derivative of an older drug. At the time of writing, the case is currently pending at the Delhi High Court. See Bhuma Shrivastava, *Roche-Cipla Row Test Case for Balancing Health Issues, Patents*, LIVEMINT.COM, Feb. 9, 2008, <http://www.livemint.com/2008/02/08230319/RocheCipla-row-test-case-for.html>.

Amendment does not define “efficacy.” Nor is it defined in the Indian Manual of Patent Practice and Procedure (MPPP), a publication of the Indian Patent Office.²¹⁸ *Novartis AG* suggests that a 30% bioavailability enhancement is not sufficient for the Patent Office to grant a patent. While the Madras High Court did not directly address the issue of what kind of data would establish enhanced efficacy, the court relied on a medical dictionary definition to opine that “efficacy” means “therapeutic” efficacy.²¹⁹ Some commentators have noted that efficacy should not be limited to merely therapeutic efficacy because a broader definition of efficacy, for example, one that includes practical efficiencies such as enhanced heat stability of drugs, would actually reward genuine advances.²²⁰ But until IPAB settles the pending case, there is no conclusive statement on how efficacy in Section 3(d) will be interpreted.

Although TRIPS sets out minimum requirements for intellectual property protection, it is dubious that member countries are obliged to expand beyond that.²²¹ On the other hand, a patent system should provide incentives for technical progress, and India may benefit from stronger patent protection. India is technologically more advanced than many other developing countries, and more and more of its domestic pharmaceutical companies are engaging in original research.²²² For example, some of these domestic companies may have the technological capacity to develop new medical uses, and therefore would benefit from a regime that recognizes new use patents.

218. Mueller, *The Tiger Awakens*, *supra* note 21, at 554 (discussing INDIAN PATENT OFFICE, MANUAL OF PATENT PRACTICE AND PROCEDURE (2005), available at <http://patentoffice.nic.in/ipr/patent/manual-2052005.pdf> (last visited Dec. 20, 2007)).

219. *Novartis AG v. Union of India*, (2007) 4 MADRAS L.J. 1153, § 13 (“Darland’s Medical Dictionary defines the expression ‘efficacy’ in the field of Pharmacology as ‘the ability of a drug to produce the desired therapeutic effect.’ . . . Dictionary meaning of ‘therapeutic’ is healing of disease—having a good effect on the body”).

220. Posting of Shamnad Basheer to Spicy IP, *Novartis Patent Dispute: Of Spins and Empty Rhetoric*, <http://spicyipindia.blogspot.com/2007/08/novartis-patent-dispute-of-spins-and.html> (Aug. 11, 2007).

221. *Id.* Other commentators note that availability of new use patents are negotiated under “TRIPS-plus” agreements, bilateral or regional free trade agreements. If new use patents were obligated under TRIPS, then TRIPS-plus agreements would be redundant. See Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT’L ECON. L. 77, 88-89, n.44 (2005).

222. See *supra* Section II.E.

While Section 3(d) aims to prevent trivial patents, incremental inventions can often embody considerable innovation.²²³ In particular, in the pharmaceutical industry, patents rarely involve new chemical entities but rather incremental improvements over prior inventions. If the nonobviousness standard is set so high that it effectively bars patentability of most incremental pharmaceutical innovations, that rule may contravene TRIPS²²⁴ and be detrimental to the Indian pharmaceutical industry by failing to provide proper incentives for research and development for the long term.

V. CONCLUSION

In the short term, the outcome of the Novartis litigation will guide the Indian patent offices and judiciary in interpreting the scope of patentability under India's new patent law. However, *Novartis AG* is also a small piece in a much larger puzzle: how developing countries can fashion intellectual property regimes to deliver better healthcare to their citizens. India is a noteworthy case study because its immense population is rapidly transforming into a global force. Its vast generic drugs industry, which supplies drugs to both developing and developed nations around the world, is also beginning to have the capacity to leverage India's skilled workforce and conduct original R&D. Other countries are also keeping a close eye on how India's patent law is developing; more than ten countries

223. This is the view taken by Shammad Basheer, Visiting Associate Professor of Law at George Washington University Law School and a prominent commentator on India's IP regime. He also keeps the blog, *Spicy IP*. In the face of the Novartis litigation, the government of India commissioned a group of experts, widely known as the "Mashelkar Committee," to comment on whether the recent amendments to India's patent law was TRIPS compliant. The Intellectual Property Institute (IPI), a think tank located in England, commissioned Basheer to write a paper to submit to the Mashelkar Committee. Both Basheer and the final Mashelkar Committee Report contend that limiting pharmaceutical patents to "new chemical entities" would not be TRIPS compliant. However, it is important to note that the Mashelkar Committee Report does not directly address Section 3(d). The Mashelkar Committee Report was later withdrawn after allegations that the Committee plagiarized from Basheer. On his blog, Basheer states that these allegations are unfounded. Posting of Shammad Basheer to *Spicy IP*, *Deconstructing the Mashelkar Committee Report Controversy: Part I*, <http://spicyipindia.blogspot.com/2007/02/deconstructing-mashelkar-committee.html> (Feb. 26, 2007).

224. India would be in breach of Article 27.1 if its nonobviousness standards were so rigid such that an invention would require an "inventive leap" rather than an "inventive step." See Dreyfuss & Lowenfeld, *supra* note 213, at 298.

in the Asia-Pacific region are actively considering adopting provisions similar to Section 3(d) in their own patent laws.²²⁵

The effects of a country's patent system on the domestic industries and public health are evident, and India should be cautious in going forth with any decisions that would alter India's traditionally conservative approach to patent policy. For example, after Italy introduced pharmaceutical patents in 1978, multinational companies took over many local companies, and exports of generic drugs declined while imports of patented drugs increased.²²⁶ The history of India's patent system demonstrates that India's generic drugs industry was built because of a deliberate move by the Indian government in shaping a conservative patent policy in 1970. But India's pharmaceutical industry today is far different than what it was in 1970. Stronger IPRs, such as new use patents or patents on derivatives of known substances, while likely not obligated under TRIPS, may benefit India's pharmaceutical companies by encouraging path-breaking research and development.

225. Gireesh Chandra Prasad, Copycats Popping Patent Law Pill, *ECONOMIC TIMES* (India), August 13, 2007, http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare_Biotech/Pharmaceuticals/Copycats_popping_patent_law_pill/articleshow/2276358.cms (last visited Dec. 20, 2007).

226. COMM'N ON INTELL. PROP. RIGHTS, *INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY* 37 (2002), available at http://www.iprcommission.org/graphic/documents/final_report.htm.