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## Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India

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# INDIAN PHARMACEUTICAL PATENT LAW AND THE EFFECTS OF *NOVARTIS AG V. UNION OF INDIA*

## I. INTRODUCTION

In recent decades, many nations and international organizations have made a concentrated effort to homogenize the laws governing intellectual property. The attempt at standardization, however, has not been free of dissention, particularly with regard to the laws pertaining to pharmaceutical patents. This is due to the continuing tension that exists between large, multinational pharmaceutical companies (MNCs), and developing nations that lack both the infrastructure and capital to establish their own self-subsisting pharmaceutical industries.<sup>1</sup>

For many years prior to its membership in the World Trade Organization (WTO), India did not recognize product patents for pharmaceuticals.<sup>2</sup> Without product patents with which to contend, Indian pharmaceutical companies were able to churn out countless generic drugs, establishing India as one of the leading generic drug manufacturers in the world.<sup>3</sup> The relative affordability of these generic drugs compared to their patented counterparts has not only enabled India to provide cheap drugs for its own people, but has also made India the *de facto* pharmacy for many developing countries.<sup>4</sup>

Yet in 2005, because of its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), India was

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1. Whereas MNCs desire laws that provide for easy patentability of their products, developing countries many of which are required to look abroad for their pharmaceutical needs believe such laws would stifle the production of affordable generic drugs and concentrate even greater power in the hands of corporations that already dominate the pharmaceutical marketplace. JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE 113 (2010).

2. Antara Dutta, *From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry*, 93 REV. ECON. & STAT. 160, 162 (2011).

3. 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, 514–15 (2007).

4. *Id.* Concerning the costs of generic drugs relative to their patented counterparts:

Companies such as India's Cipla and Lupin have become the primary source of cheap generics of AIDS, cancer and malaria drugs for countries that would never be able to afford branded products. But India's generics industry can sell them at about a tenth of the branded cost because they have no development expense to amortize. That is no different than any generic drug approach except that India has been libertine in terms of ignoring existing patents that are protected elsewhere in the world.

Eric Palmer, *India Set to Rule in Novartis Patent Case*, FIERCEPHARMA (Jan. 4, 2013), <http://www.fiercepharma.com/story/india-set-rule-novartis-patent-case/2013-01-04>.

compelled to amend its laws to provide product patent protection to pharmaceuticals.<sup>5</sup> In an attempt to satisfy the competing demands for inexpensive drugs and effective intellectual property protection, the Indian government created a law that afforded protection to pharmaceuticals only if they constituted brand new chemical substances or enhanced the therapeutic “efficacy” of known substances.<sup>6</sup> This law, which is codified under section 3(d) of the Patents (Amendment) Act of 2005,<sup>7</sup> has not sat well with some MNCs, including the Swiss company Novartis. Following the denial of a patent for its leukemia drug, Glivec,<sup>8</sup> Novartis challenged the validity of section 3(d) under TRIPS and the Indian Constitution.<sup>9</sup> The Indian Supreme Court ruled against Novartis in a decision that has, and will continue to have, broad implications for MNCs, the Indian pharmaceutical industry, and people around the world in need of affordable drugs.<sup>10</sup>

This Note gives a brief overview of Indian patent law as it relates to pharmaceuticals, considers the challenges the law is currently facing, and suggests some possible ways that India may wish to approach those challenges. Part II provides a cursory discussion of India’s pharmaceutical industry and its place in the world today. Part III traces the history of Indian patent law. Part IV focuses on the growing globalization of intellectual property law and India’s involvement in the WTO and adherence to TRIPS. Part V describes TRIPS Section 3(d) and its requirements for patentability, and Part VI gives a procedural history of current cases and recent decisions in India involving pharmaceutical patents, with an emphasis on the Novartis case. Part VII touches upon the TRIPS-compliance issue with section 3(d). Finally, Part VIII presents some of the arguments of proponents of affordable health care, who consider the Novartis decision a triumph for India and other developing countries in desperate need of inexpensive medications. This Note

5. Shamnad Basheer, *India’s Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J.L. & TECH. 15, 16–17 (2005) [hereinafter *India’s Tryst with TRIPS*].

6. SHAMNAD BASHEER, THE “GLIVEC” PATENT SAGA: A 3-D PERSPECTIVE ON INDIAN PATENT POLICY AND TRIPS COMPLIANCE, available at [www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc](http://www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc) [hereinafter *The “Glivec” Patent Saga*].

7. The Patents (Amendment) Act, 2005, No. 15 of 2005, §3(d), Gazette of India, section I(2) (Apr. 4, 2005), available at [http://ipindia.nic.in/ipr/patent/patent\\_2005.pdf](http://ipindia.nic.in/ipr/patent/patent_2005.pdf).

8. The drug is patented in the United States as Gleevec. This Note, however, will refer to it as Glivec.

9. Linda Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 299 (2008).

10. Gardiner Harris & Katie Thomas, *Low-Cost Drugs in Poor Nations Get a Lift in Indian Court*, N.Y. TIMES (Apr. 1, 2013), [http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?\\_r=0](http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?_r=0).

concludes that, while the Indian Supreme Court's ruling in the Novartis case may have beneficial implications for the developing world and individuals in need of affordable drugs, it ultimately represents a wasted opportunity for the Court to clarify section 3(d), which would promote foreign investment and spur growth and innovation in the domestic pharmaceutical and biotech industries.

## II. INTRODUCTION TO INDIA'S PHARMACEUTICAL INDUSTRY

Since World War II, the international pharmaceutical industry has grown significantly.<sup>11</sup> The need for antibiotics during the war led many companies to invest more time and resources into the research and development of new drugs.<sup>12</sup> The years following the war saw a rapid expansion of the industry as companies began to establish themselves as MNCs by infiltrating foreign markets.<sup>13</sup> Today, the international pharmaceutical industry is dominated by a small number of MNCs.<sup>14</sup> These corporations are headquartered in developed nations and carry a great deal of financial clout.<sup>15</sup>

Such corporations, however, are not found in many developing countries.<sup>16</sup> This is primarily due to the high levels of skill, training, technology, and capital necessary to produce new or existing drugs.<sup>17</sup> As a

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11. KUANPOTH, *supra* note 1, at 109.

12. *Id.* at 110. Some companies began the production of specialty drugs, which "led to the discovery of several new drugs, then and later, including several effective antibiotics, tranquilizers, vitamin B, vaccines, contraceptives, and so on." *Id.*

13. *Id.* at 109.

14. Pfizer, Johnson & Johnson, and Bayer are examples of large MNCs. The largest MNCs are headquartered in developed nations such as the United States, United Kingdom, France, Germany, and Switzerland. SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 2* (2005).

15. *Id.* at 3. For instance, in 2003, Pfizer sold \$39.6 billion worth of drugs, which accounted for 8.5% of the global market and exceeded the combined drug sales of all the countries in Asia, excluding Japan. *Id.* at 2. In fact, the sales of each of the top nineteen multinational corporations in 2003 exceeded those of the entire Indian pharmaceutical market, which at the time amounted to \$4.9 billion. *Id.*

16. N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues*, in *INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES* 225 (Kenneth C. Shadlen et al. eds., 2011).

17. KUANPOTH, *supra* note 1, at 111. This is not to say that all developing countries are completely void of a pharmaceutical industry or fail to play any significant role in the development and production of drugs. Although the refinement of raw materials and research necessary for the production of drugs both require a great deal of capital and sophistication, "the formulation and packaging of active ingredients and intermediates into finished product forms are relatively simple and technically straightforward, and technology and capital investment needed in this process are low." *Id.* Consequently, many companies send the prepared raw materials to developing nations for completion. *Id.* (citing G. GEREFFI, *THE PHARMACEUTICAL INDUSTRY AND DEPENDENCY IN THE THIRD WORLD*

result, several developing nations have grown dependent on drug imports from other countries such as India.<sup>18</sup>

Over the years, India has established itself as one of the major producers of affordable generic drugs.<sup>19</sup> The Indian pharmaceutical industry today is “considered the world’s third-largest by volume”<sup>20</sup> and, as of 2010, produces approximately 20% of the world’s generic drugs.<sup>21</sup> Experts anticipate India’s pharmaceutical industry to grow to a value of \$74 billion by 2020,<sup>22</sup> solidifying India as “a global leader in the pharmaceutical industry.”<sup>23</sup>

India is not only a chief exporter of drugs, but also the primary producer of drugs for its own population.<sup>24</sup> India is one of only two countries in the world where generic drug manufacturers control a larger share of the domestic pharmaceutical market than big MNCs.<sup>25</sup> A few indigenous firms are capable of both generic drug production and research

203 (1983)). See generally KUANPOTH, *supra* note 1, at 112–13 (providing a breakdown of the hierarchy of developing nations based on their pharmaceutical manufacturing capabilities).

18. KUANPOTH, *supra* note 1.

19. Mueller, *supra* note 3, at 495.

20. MV Ramsurya, *Pharma, Engineering to Topple IT as Big Paymaster*, ECON. TIMES (June 8, 2010, 6:04 AM), [http://articles.economictimes.indiatimes.com/2010-06-08/news/28423319\\_1\\_salary-hikes-manufacturing-sector-survey](http://articles.economictimes.indiatimes.com/2010-06-08/news/28423319_1_salary-hikes-manufacturing-sector-survey).

21. Lalitha, *supra* note 16. With two-thirds of its domestically manufactured drugs being shipped overseas, India now only trails China in exports of pharmaceuticals among developing countries. Dwijen Rangnekar, *No Pills for Poor People? Understanding the Disembowelment of India’s Patent Regime*, 41 ECON. & POL. WKLY. 409, 411 (2006).

22. Rumman Ahmed & Amol Sharma, *Novartis Fights India for Cancer Pill Patent*, WALL ST. J. (Aug. 19, 2012, 4:50 PM ET), <http://online.wsj.com/article/SB10000872396390444233104577594973786074692.html>. According to PricewaterhouseCoopers LLP, India’s pharmaceutical industry amounted to \$11 billion in 2011. *Id.*

23. Mueller, *supra* note 3, at 500.

The success story of its IT sector is admittedly the clearest example of India’s growing stature in the knowledge economy, but innovation in the pharmaceutical and biotechnology sectors is also on the rise. Many Indian-born scientists who have trained in the U.S. are returning to India, bringing home their experience in pharmaceutical research and development. The country’s ever-expanding pool of scientifically-trained workers is also available to the Indian pharmaceutical industry. Almost forty percent of India’s university graduates obtain their degrees in science and engineering, in contrast with declining enrollments in those fields in the U.S. India’s pharmaceutical industry is fast becoming a force to be reckoned with in the global marketplace because of its strikingly lower costs of drug research and clinical testing.

*Id.* at 500–01 (internal citations omitted).

24. Lalitha, *supra* note 16. “Drugs produced in India satisfy 95 per cent of the domestic demand.” *Id.* (citing *Indian Pharmaceutical Industry: Surging Globally*, Mumbai: EXIM Bank Occasional Paper No. 119, 2007).

25. Lee, *supra* note 9, at 296. The only other nation where generic drug manufacturers predominate is Japan. *Id.*

and development, while many smaller companies specialize exclusively in reverse-engineering drugs from overseas.<sup>26</sup>

Yet while the production of drugs is not a problem in India, general access to drugs is.<sup>27</sup> The affordability of pharmaceuticals and lack of a comprehensive health insurance system have heavily influenced the evolution and development of India's patent laws and its participation in international intellectual property agreements.

### III. HISTORY OF INDIA'S PATENT LAWS

India passed its first patent law in 1856 during British colonial rule.<sup>28</sup> This law was based on the British Patent Law of 1852, which provided privileges to inventors for a period of fourteen years.<sup>29</sup> Following a number of modifications, this law later gave way to the Inventions and Designs Act of 1888.<sup>30</sup> Although India was beginning to industrialize at this time, its pharmaceutical industry was still in its infancy.<sup>31</sup>

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26. Indigenous firms such as Ranbaxy Laboratories Ltd., Cipla Ltd., and Dr. Reddy's Laboratories Ltd., are a few of the major players in the Indian pharmaceutical industry that are capable of both generic drug production and original research and development. Mueller, *supra* note 3, at 537. See also Kuanpoth, *supra* note 1, at 129 ("Although generics continue to play a major part in their very success, several Indian companies have already begun to adjust their business models. Some large companies have started to invest substantially in basic research for drug discovery and branded drug development, in order to compete in international markets"). Smaller indigenous pharmaceutical firms, on the other hand, continue to reverse-engineer drugs that are still protected under foreign patents. Mueller, *supra* note 3, at 537.

27. Unlike many developed nations, India lacks a highly developed insurance system that, although improving, still forces most Indians to pay for medications out of their own pockets. Mueller, *supra* note 3, at 542–43; Kuanpoth, *supra* note 1, at 135. Thus, notwithstanding its status as a burgeoning leader in the pharmaceutical and biotech industries, India continues to face difficulties concerning drug pricing and affordability. Chaudhuri, *supra* note 14, at 58. Despite India's growing middle class, which has increased the demand for pharmaceutical products, the vast majority of the population "face[s] a health care system that has been described as operating in a state of perpetual crisis." Mueller, *supra* note 3, at 542–543 (citing Yusuf K. Hamied, *Indian Pharma Industry: Decades of Struggle and Achievement*, at 7 (Apr. 2, 2005) (on file with author)) (internal quotation marks omitted).

28. KALYAN C. KANKANALA ET AL., *INDIAN PATENT LAW AND PRACTICE* 1 (2010).

29. *Id.* at 1–2.

30. Mueller, *supra* note 3, at 506–07. The 1856 Act was first modified in 1859 to grant "exclusive privileges . . . to inventors for making, using, and selling their inventions within India for a period of fourteen years from the date of filing of the specification." Kankanala et al., *supra* note 28, at 2. 1872 saw the passage of the Patterns and Designs Protection Act, which was subsequently combined with the Protection of Inventions Act of 1883 to create the Inventions and Designs Act of 1888. *Id.*

31. During this time, India began to industrialize, excelling in areas such as textile production, food processing, and metals. Mueller, *supra* note 3, at 507 (citing TIRTHANKAR ROY, *THE ECONOMIC HISTORY OF INDIA 1857–1947* 158 (2000)).

In 1911, the British replaced the Inventions and Designs Act of 1888 with the Indian Patents and Design Act.<sup>32</sup> The 1911 Act established India's first system of patent administration and remained in effect until 1972.<sup>33</sup> As with the 1856 Act and all subsequent acts, the 1911 Act provided for the patentability of pharmaceutical products and therefore enabled foreign companies to block the production of their patented drugs in India.<sup>34</sup> Domestic drug fabrication remained stagnant up until World War II.<sup>35</sup>

With its independence from Britain in 1947, India was confronted with a number of challenges. As one of the poorest countries in the world, the increasingly problematic issue of providing affordable health care for the masses was not lost on Indian leaders.<sup>36</sup> Because affordable health care naturally entails affordable pharmaceuticals, Indian officials began an extensive review of the 1911 Indian Patents and Design Act shortly after independence.<sup>37</sup> The Government of India appointed two committees to spearhead this effort: the Patent Enquire Committee (1948–50) and the Patents Revision Committee (1957–59).<sup>38</sup> The goal was to “review the patent laws in India with a view to ensure that the patent system was more conducive to national interests.”<sup>39</sup> The reports of the two expert

32. Kankanala et al., *supra* note 28, at 2.

33. Mueller, *supra* note 3, at 507 (citing P. NARAYANAN, PATENT LAW 4 (3d ed. 1998)).

34. Chaudhuri, *supra* note 14, at 128–29. “Under the Act of 1911, the MNCs legally prevented the indigenous companies from manufacturing most of the new drugs developed by them during the patent term of sixteen years which could be extended by another ten years if the working of the patent had not hitherto been sufficiently remunerative to the patentee.” *Id.* at 129.

35. Mueller, *supra* note 3, at 508 (citing Yusuf K. Hamied, *Indian Pharma Industry: Decades of Struggle and Achievement*, at 2 (Apr. 2, 2005) (on file with author)). There was “virtually no basic drug manufacture in the country” at the time. *Id.* (internal quotation marks omitted). Interestingly, the pharmaceutical industry was not the only domestic industry that was slow in terms of innovation: “By the time of independence in 1947 when India’s population was approximately 400 million persons, only 2,610 patent applications (on all types of inventions) were filed annually with the Indian Patent Office.” *Id.* at 508 (citing Ved P. Mithal, *Patents in India*, 30 J. PAT. OFF. SOC’Y (IN) 62, 64 (1948)).

36. *Id.* at 509. “The unfortunate legacy of British-imposed, foreign-favoring patent laws and a largely agrarian economy was a health care system in which most modern medicines were manufactured abroad, imported into India and sold there at some of the highest prices in the world.” *Id.* at 509–10. At the time of independence, foreign multinational corporations dominated India’s pharmaceutical industry. “Critical drugs such as insulin and penicillin were wholly imported.” *Id.* at 510 (citing Planning Commission, Government of India, 1<sup>st</sup> Five Year Plan, Ch. 32 ¶¶ 96, 99 (Dec. 7, 1952)).

37. Rangnekar, *supra* note 21, at 410.

38. Kuanpoth, *supra* note 1, at 46. Justice Bakshi Tek Chand led the Patent Enquire Committee, while Justice N. Rajagopla Ayyangar led the Patents Revision Committee. *Id.*

39. Mueller, *supra* note 3, at 511 (quoting Shri Justice N. Rajagopala Ayyangar, Report on the Revision of the Patents Law (Sept. 1959), at Preface (on file at National Law School of India University, Bangalore)(internal quotation marks omitted)).

committees paved the way for the eventual enactment of the Patents Act of 1970.<sup>40</sup>

The India Patents Act of 1970, which repealed the 1911 Act and took effect in 1972,<sup>41</sup> had a significant impact on the pharmaceutical industry.<sup>42</sup> Instead of giving recognition to product patents, which was the norm among developed nations, the Act reserved protection only for process patents.<sup>43</sup> Under this patent regime, Indian drug manufacturers could copy pharmaceutical products that were otherwise patented in foreign nations, leading to a boom in the production of generic drugs.<sup>44</sup> By departing from the harsh, “draconian”<sup>45</sup> patent laws of the British colonial era, the Indian

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40. Kuanpoth, *supra* note 1, at 46. The second of the two reports (The Ayyangar Report, 1959) has been considered the most influential in establishing Indian’s modern patent regime. Mueller, *supra* note 3, at 511–12. The report proffered a three-pronged strategy:

- (i) identification of the types of inventions for which patent protection should be available;
- (ii) determination either to prohibit the granting of Indian patents to foreign entities or to require working of such patents in India; and (iii) determination to withstand international pressures on India to join international intellectual property conventions such as the Paris Convention, which required national treatment.

*Id.* (citing Parameswaran Narayanan, Intellectual Property Law 2 (2005)).

41. Mueller, *supra* note 3, at 513.

42. See Dutta, *supra* note 2, at 162; Lee, *supra* note 9, at 290–91; Rangnekar, *supra* note 21, at 410–11.

43. Dutta, *supra* note 2, at 162.

In a departure from the customary practice in most developed countries, this new legislation provided official recognition to process rather than product patents for pharmaceuticals. Process patents allowed a small modification in the synthesis of a known chemical entity to yield a new patent and enabled several firms to produce essentially the same drug. As a result, drugs that were still protected by patent rights in much of the developed world were marketed locally by Indian firms at a fraction of the [research and development] cost. While domestic firms thrived under the opportunity provided by the 1970 Patent Act, the act’s controversial provisions caused the exit of many multinational drug manufacturers from India. Consequently, between 1970 and 1993, the market share of multinational pharmaceutical companies in India fell from 80% to 39%.

*Id.* “By fiscal year (FY) 1978–79, the number of foreign-owned patent applications filed in India had decreased to 1,010, less than one quarter of the 4,248 applications filed by non-Indians ten years prior in 1968.” Mueller, *supra* note 3, at 513–14 (citing Amiya Kumar Bagchi, Parthasarathi Banerjee & Uttam Kumar Bhattacharya, *Indian Patents Act and Its Relation to Technological Development in India: A Preliminary Investigation*, 19 ECON. & POL. WKLY. 293 (1984)).

44. Mueller, *supra* note 3, at 514. It is also worth noting that even the patents for processes usually lasted a relatively short period of time. “[P]rocess patents lasted only for the shorter of five (5) years from sealing or seven (7) years from the date of the patent, while the term of all other types of patents (e.g., mechanical devices) was fourteen (14) years from the date of the patent.” *Id.* (citing The Patents Act, 1970 § 53(a)-(b), reprinted in P. NARAYANAN, PATENT LAW 543–97 (Appendix 1) (3d ed. 1998)). Mueller, *supra* note 3, at 526–27. (construing SUSAN K. SELL, POWER AND IDEAS: NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST (1998)).

45. Mueller, *supra* note 3, at 508 (citing Yusuf K. Hamied, *Indian Pharma Industry: Decades of Struggle and Achievement*, at 3 (Apr. 2, 2005) (on file with author)).



pharmaceutical industry was able to prosper, fostering the growth of the country's "indigenous scientific and technological capacity."<sup>46</sup>

#### IV. INDIA AND THE GLOBALIZATION OF INTELLECTUAL PROPERTY LAW

The World Trade Organization came into existence on January 1, 1995, and along with it came the TRIPS Agreement.<sup>47</sup> "The TRIPS Agreement is, by its coverage, the most comprehensive international instrument on intellectual property rights," instituting high minimum standards on a variety of forms of intellectual property.<sup>48</sup> Industrialized nations pushed the agreement as a means of strengthening intellectual property rights

46. Rangnekar, *supra* note 23, at 410. In addition to the benefits it provided for India's pharmaceutical and healthcare industries, the 1970 Act in many ways demonstrated India's desire to cast off the remaining vestiges of colonialism and "[codify its] dissatisfaction with prevailing international principles governing technology transfer." *Id.*; Mueller, *supra* note 3, at 514.

47. Chaudhuri, *supra* note 14, at 61. The WTO, which replaced the General Agreement on Tariffs and Trade (GATT), was designed to be a permanent fixture in the regulation and enforcement of trade between nations. *Id.* See FLEUR CLAESSENS, INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES: BALANCING RIGHTS AND OBLIGATIONS 9–37 (2009) for a more in depth discussion of previous international trade/intellectual property agreements such as the Berne and Paris Conventions. The WTO fulfills its duties by ensuring compliance with TRIPS, the Multilateral Trade Agreements (MTAs), and the General Agreement on Trade in Services (GATS). The Uruguay Round, which precipitated the establishment of the WTO, "required a 'single undertaking approach', implying that one [member nation] could not pick and choose agreements to meet national interest and needs, but that membership to the WTO entailed accepting all the results of the Round without exception." *Id.* at 39. Consequently, all WTO member nations are obligated to sign onto and follow the provisions of the TRIPS Agreement. Michael Blakeney, *A Critical Analysis of the TRIPS Agreement*, in THE INTELLECTUAL PROPERTY DEBATE 17, 17 (Meir Perez Pugatch ed., 2006).

48. CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 1 (2000). "The Agreement established minimum standards on: copyright and related rights, including computer programs and databases; trademarks; geographical indications; industrial designs; patents; integrated circuits; and undisclosed information (trade secrets)." *Id.* TRIPS contains "three broad components": (1) Parts I and II (Articles 1–40) establish the goals, objectives, and standards of intellectual property rights; (2) Parts III, IV, and V (Articles 41–61) establish the means of enforcement of intellectual property rights; (3) Parts VI and VII (Articles 65–73) deals with the needs of developing countries, "such as transitional arrangements, technology transfers and technical cooperation, and the institutional arrangements of monitoring and review." Chaudhuri, *supra* note 14, at 62. The primary provisions of TRIPS concerning patents are:

(i) 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; (ii) The term of protection must be a minimum of 20 years from the date of filing; (iii) The exclusive rights of the patentees include the right of 'making, using, offering for sale, selling, or importing'; (iv) Limited exceptions to such exclusive rights are possible; (v) Compulsory license can be granted subject to certain conditions. A compulsory or 'non-voluntary' license is an authorization by a government to non-patentees to use the subject matter of a patent without or against the consent of the patentee; (vi) In case of infringements, the burden of proof will be on the alleged infringer rather than on the right holder.

*Id.* at 62–63.

because infringement of those rights was seen as “trade distorting.”<sup>49</sup> The developing world, however, feared that the more stringent patent laws in TRIPS would drive up costs and stifle the generic drug industry.<sup>50</sup>

Like many developing nations, India was initially opposed to TRIPS.<sup>51</sup> Nevertheless, as a member of the WTO, India was required to modify its domestic intellectual property laws in order to comply with the agreement.<sup>52</sup> Although India had to implement certain provisions of TRIPS immediately, article 65.2 of the agreement granted developing nations a transition period for the implementation of other provisions.<sup>53</sup> One such provision gave nations without patent protection for pharmaceutical products a ten-year period to bring their laws into compliance with TRIPS.<sup>54</sup> Thus, India had until January 1, 2005, to make its patent laws relating to pharmaceuticals and agricultural chemicals TRIPS-compliant.<sup>55</sup>

Indian law went through three stages between 1995 and 2005 in order to conform with TRIPS.<sup>56</sup> First, in 1999, India instituted the “mailbox” requirement of article 70.9, which enabled entities to submit product patent applications for pharmaceuticals and agricultural chemicals to the patent office that would be held until examination in 2005.<sup>57</sup> Second, India introduced the Patents (Amendment) Act of 2002, which further integrated Indian law by extending patent terms to twenty years as stipulated by TRIPS.<sup>58</sup> Third, and lastly, the Patents (Amendment) Act of 2005 brought

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49. Blakeney, *supra* note 47, at 17. Around the time of the Uruguay Round, the United States reported that U.S. traders purportedly suffered approximately \$60 billion in annual losses due to international intellectual property infringement. *Id.* Significant losses were found in Europe as well. *Id.*

50. Dutta, *supra* note 2, at 160. See Correa, *supra* note 48, at 5–6 for a brief discussion on the asymmetries between the northern and southern hemispheres (developed v. developing nations) and TRIPS’s impact on that divide.

51. See Rangnekar, *supra* note 21, at 412 (discussing resistance to TRIPS).

52. Chaudhuri, *supra* note 14, at 63.

53. TRIPS: 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, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]; Mueller, *supra* note 3, at 518.

54. Mueller, *supra* note 3, at 518–19.

55. *Id.* TRIPS took effect the same day as the WTO (January 1, 1995). *Id.*

56. Chaudhuri, *supra* note 14, at 65.

57. *Id.*; Mueller, *supra* note 3, at 519; Rangnekar, *supra* note 21, at 409. The “mailbox” requirement was initially implemented by Presidential decree in 1995, but was not codified until 1999 when the United States, through the WTO, challenged India’s compliance with TRIPS. Mueller, *supra* note 3, at 519. See Mueller, *supra* note 3, at 519–26 for more information about the WTO dispute between the United States and India over the “mailbox” requirement as well as the Patents (Amendment) Act of 1999.

58. Mueller, *supra* note 3, at 526. While the 2002 amendment made a number of changes to India’s patent laws, the most significant was the twenty-year extension of patent terms. *Id.* See Mueller, *supra* note 3, at 526–28 for a more in depth discussion of this amendment.

India into compliance with TRIPS by giving full patent protection to pharmaceutical products.<sup>59</sup> It is this final Amendment that has been the source of controversy in recent years.

#### V. INDIAN PATENT LAW TODAY

While India made the necessary adjustments to its laws to satisfy the requirements of TRIPS, “criticism and concern about the effect of pharmaceutical patents on domestic drug prices [compelled] the Indian government [to retain] legitimate means for balancing innovation incentives against the social costs of pharmaceutical product patents.”<sup>60</sup> A significant means by which the Indian government can “limit the reach of product patent protection” is section 3(d) of the Patents (Amendment) Act of 2005.<sup>61</sup>

Section 3(d) essentially provides for a tougher standard for securing patents.<sup>62</sup> Companies that introduce new versions of their pharmaceutical products must demonstrate that the new versions are “therapeutically more beneficial than earlier versions on which patents had expired.”<sup>63</sup> Through section 3(d), India is able to prevent “evergreening,” which critics characterize as a “common abusive patenting practice”<sup>64</sup> where pharmaceutical companies attempt to extend patent protection by making

59. Basheer, *supra* note 5, at 16.

60. Dutta, *supra* note 2, at 162.

61. Lee, *supra* note 9, at 294. Section 3(d) states:

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

The Patents (Amendment) Act, 2005, No. 15 of 2005, § 3(d), Gazette of India, section I(2) (Apr. 4, 2005), available at [http://ipindia.nic.in/ipr/patent/patent\\_2005.pdf](http://ipindia.nic.in/ipr/patent/patent_2005.pdf).

62. Ahmed & Sharma, *supra* note 22.

63. *Id.*

The underlying assumption behind section 3(d) is that derivatives, such as salt forms, polymorphs, isomers etc.] that are structurally similar to known pharmaceutical substances are likely to be functionally equivalent as well, and if this is not the case and the new form of an existing substance works better than the old form, it is up to the patent applicant to demonstrate this and justify the claim to a patent.

Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing Out the Creases in Section 3(d)*, 5 SCRIPTED 232, 239 (2008) [hereinafter *The “Efficacy” of Indian Patent Law*].

64. Leena Menghaney, *India’s Patent Law on Trial*, BMJ GROUP BLOGS (Sept. 27, 2012), <http://blogs.bmj.com/bmj/2012/09/27/leena-menghaney-indias-patent-law-on-trial/>.

minor changes to existing drugs.<sup>65</sup> Predictably, India's strict patent regime has spawned discontent among large multinational pharmaceutical corporations interested in tapping into India's growing market.<sup>66</sup>

## VI. THE NOVARTIS CASE

Recently, some large multinational pharmaceutical corporations have taken their frustrations with the Indian patent system to court.<sup>67</sup> Novartis's struggles with the Indian patent regime began in 1993, when it filed patents around the world for its synthesis of the molecule imatinib.<sup>68</sup> According to Novartis, however, the molecule can only be administered to cancer patients as imatinib mesylate.<sup>69</sup> The resulting drug is currently patented in forty countries as Glivec (Gleevec in the United States).<sup>70</sup>

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65. Helen Pidd, *Indian Court to Hear Crucial Novartis Patent Case on Cut-Price Generic Drugs*, GUARDIAN (Aug. 21, 2012, 10:27 AM), <http://www.guardian.co.uk/business/2012/aug/21/novartis-court-battle-glivec-patent>. Such "minor changes" include "reformulating [the drugs] or changing the delivery system." Ahmed & Sharma, *supra* note 25.

66. See *Taking Pains: Indian Patent Rules Infuriate Big Pharma*, ECONOMIST (Sept. 8, 2012), <http://www.economist.com/node/21562226> [hereinafter *Taking Pains*].

67. In addition to the Novartis case, another major dispute that made waves in the pharmaceutical world involved the German pharmaceutical giant, Bayer. In March 2012, India's Controller General of Patents issued a compulsory license to Natco Pharma, an Indian drug company, allowing it to manufacture a generic version of Bayer's patented Nexavar. Vikas Bajaj & Andrew Pollack, *India Orders Bayer to License a Patented Drug*, N.Y. TIMES (Mar. 12, 2012), <http://www.nytimes.com/2012/03/13/business/global/india-overrules-bayer-allowing-generic-drug.html>; Menghaney, *supra* note 64. Prior to the decision, Bayer sold Nexavar—a drug used in the treatment of liver and kidney cancers—in India for 280,000 rupees (\$5,600) per month. Bajaj & Pollack, *supra*. The subsequent compulsory license, which reflected the Indian government's concern with the drug's cost, enabled Natco to produce a generic version of Nexavar at a fraction of the price—8,800 rupees (\$176) per month, or 3% of Bayer's price. *Id.* Natco is still required to pay Bayer a 6% royalty on its net sales, and the drug is only available for purchase in India. *Id.* MNCs were "dismayed" by this decision, which Bayer has appealed to India's Intellectual Property Appellate Board. Ahmed & Sharma, *supra* note 22. Bayer has also sued Cipla Ltd. for patent infringement of Nexavar. *Taking Pains*, *supra* note 66.

68. *Glivec Patent Case in India: Fact vs. Fiction*, NOVARTIS, [http://www.novartis.com/downloads/newsroom/glivec-information-center/Fact\\_vs\\_fiction\\_of\\_Glivec\\_India\\_Case.pdf](http://www.novartis.com/downloads/newsroom/glivec-information-center/Fact_vs_fiction_of_Glivec_India_Case.pdf) (last visited Oct. 29, 2012). Because India did not patent pharmaceutical products at the time, Novartis did not file there.

69. *Id.*

The misconception regarding the innovation is based on a patent that was granted in 1993 (not in India) for the synthesis of the molecule imatinib. This molecule, however, *could not be administered to patients* and represented only the first step in the process to develop Glivec as a viable treatment for cancer. We developed the mesylate salt of imatinib and then the beta crystal form of imatinib mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine.

*Id.* Glivec is now considered safer and easier to use: "[T]he body [absorbs] the medicine 30% more easily." *Taking Pains*, *supra* note 66. Shamnad Basheer and T. Prashant Reddy provide a more detailed breakdown of the steps involved in the creation of Glivec:

Following the formation of the WTO and passage of TRIPS in 1995, Novartis filed a patent application for Glivec in India in accordance with the “mailbox” requirement.<sup>71</sup> In January 2006, when the Glivec patent came before the Madras Patent Office, it was rejected on the grounds that it was “an unpatentable modification of an existing substance, imatinib.”<sup>72</sup> Pursuant to section 3(d) of the 2005 Act, the Patent Office concluded that Glivec failed to show “novelty and inventiveness,” as well as increased efficacy as required by the law.<sup>73</sup> In response, Novartis petitioned the

(i) Synthesizing imatinib as its free base, a compound that was patented in the US, EU and several other countries. However, this could not be patented in India, owing to the fact that in 1993, India did not provide product patents for pharmaceutical substances; (ii) Converting the free base to a particular salt form, imatinib mesylate, by adding methanesulfonic acid; (iii) Crystallising [sic] the imatinib mesylate to obtain the beta crystalline form, which is allegedly the most stable polymorphic form of the salt. A patent application was filed for this and it is this application that is the subject matter of dispute; (iv) Formulating the beta crystalline form of imatinib mesylate into a pharmaceutically useful drug, Glivec.

Basheer & Reddy, *supra* note 63, at 239.

70. Pidd, *supra* note 65.

71. Shamnad Basheer, *First Mailbox Opposition (Gleevec) Decided in India*, SPICY IP (Mar. 11, 2006), <http://spicyindia.blogspot.com/2006/03/first-mailbox-opposition-gleevec.html>. See Lee, *supra* note 9, at 297–98 for more details about Novartis’s involvement in India prior to 2006. Novartis also applied for and was granted an exclusive marketing right (EMR) in 2003, pending grant of the patent. Novartis then went on to sue generic drug makers, including Ranbaxy and CIPLA. As Basheer and Reddy describe the EMR issue,

The Madras High Court upheld the EMR and restrained the said drug producers on various grounds, including, *inter alia*, the fact that Novartis ran a free patient access programme [sic] titled “GIPAP” (Glivec International Patients Assistance Program) and undertook to make this programme [sic] even more user friendly to patients that could afford the drug. This, the court held, was sufficient to take care of any “public interest” ground that might have militated against the grant of an injunction. The Bombay High Court however disagreed with the ruling of the Madras High Court, noting that the validity of the recently issued EMR had been seriously challenged by the defendants. Besides, the fact that the drug was more expensive and was being imported by the plaintiff (triggering fears of sustained supplies of such a critical life-saving drug in India) influenced the court to deny the grant of an injunction.

Basheer & Reddy, *supra* note 63, at 236–37 (citing *Novartis AG v. Mehar Pharma & Anr.*, 2005 (30) P.T.C. 160 (Bom)).

72. *Taking Pains*, *supra* note 66. It is also worth noting that with the rejection of the patent, “the EMR by Novartis died a natural death.” Basheer & Reddy, *supra* note 63, at 237.

73. Basheer, *supra* note 71, at 2. The Patent Controller held:

I do not agree with the contention of the Applicant that the 1993 patent discloses only the free base. The 1993 patent discloses methanesulphonic acid as one of the salt forming groups and also the 1993 patent specification states that the required acid addition salts are obtained in a customary manner. Further, claims 6 to 23 of the 1993 patent claim a 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.* The Assistant Controller, also commenting on the “increased efficacy” question, stated:

Madras High Court in May 2006, arguing that the Controller General of Patents<sup>74</sup> “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 India because it was discriminatory against Novartis.”<sup>75</sup> The Madras High Court heard Novartis’s challenges to section 3(d)’s constitutionality and compliance with TRIPS, while the Intellectual Property Appellate Board (IPAB)<sup>76</sup> reviewed the Patent Controller’s rejection of the Glivec patent.<sup>77</sup> Both the High Court and the IPAB returned decisions against Novartis.<sup>78</sup>

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As per the affidavit the technical expert has conducted studies to compare the relative bioavailability of the free base with that of beta crystalline form of imatinib mesylate and has said that the difference in bioavailability may be due to the difference in their solubility in water. The present patent specification does not bring out any improvement in the efficacy of the beta crystal from over the known substances—rather it states the base can be used equally in the treatment of diseases in the preparation of pharmacological agents wherever the beta crystal is used. Even the affidavit submitted on behalf of the Applicant does not prove any significant enhancement of known efficacy.

Basheer & Reddy, *supra* note 63, at 240 (citing *Novartis AG v. Natco Pharma and Others*, Indian Patent Office, Application No. 1602/MAS/1998 (Jan. 25, 2005)).

74. The Office of the Controller General of Patents, Designs, and Trademarks, which administers the patent laws, is a subordinate office under the Department of Industrial Policy and Promotion. See Lee, *supra* note 9, at 286–90 for a brief discussion of the basics of the Indian judicial and patent administration systems.

75. Lee, *supra* note 9, at 299. Article 14 of India’s Constitution 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. With regard to its constitutional claim, Novartis argued that section 3(d) “impinges on the fundamental rights of the petitioner” by using such “vague and arbitrary” terms such as “enhancement of known efficacy” and “differ significantly in prosperities with regard to efficacy” without any clear guidance. Basheer & Reddy, *supra* note 63, at 241. The Madras High Court, however, disagreed with Novartis’s constitutional argument, stating, *inter alia*, that the standard for arbitrariness is quite high, that even “skeletal” legislation is not necessarily arbitrary, and that it is ultimately an issue for the legislature. *Id.* at 241–42.

76. The Intellectual Property Appellate Board (IPAB) is a special tribunal that was created to hear appeals from decisions from the Register of Trademarks and Geographic Indications and the Controller of Patents. Lee, *supra* note 9, at 287–88. The IPAB has jurisdiction over administrative patent challenges, including disputes over grants of patents, patent invalidation and upholding, and compulsory licensing. Tarun Mathur, *Patent Litigation Trend in India* (unpublished manuscript, June 22, 2007), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=995994](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=995994). See Kankanala et al., *supra* note 28, at 75–78 for more information on the IPAB and the types of disputes over which it has jurisdiction.

77. Lee, *supra* note 9, at 299.

78. Shannad Basheer, *Novartis Loses at the High Court: Focus Now Shifts to IPAB*, SPICY IP (Aug. 6, 2007), <http://spicyip.com/2007/08/novartis-loses-at-high-court-focus-now.html> [hereinafter *Novartis Loses at the High Court*]; Shannad Basheer, *Breaking News: Indian IP Tribunal Denies Patent to Novartis’ Glivec*, SPICY IP (Jul. 3, 2009), <http://spicyipindia.blogspot.com/2009/07/breaking-news-novartis-loses-glivec.html> [hereinafter *Indian IP Tribunal Denies Patent*].

The IPAB held that while the claim covering the beta crystalline (BC) version of IM (Imatinib Mesylate) is both novel and inventive, it fails the test under section 3(d), which requires a demonstration of “significantly enhanced efficacy” . . . the only kind of efficacy that would satisfy section 3(d) is therapeutic efficacy. Novartis’s BC version may possess

With regard to the TRIPS compliance question, however, the Madras High Court simply concluded that it was beyond the Court's jurisdiction, and that the proper venue for such an issue would be the WTO.<sup>79</sup> Novartis subsequently appealed to the Indian Supreme Court.<sup>80</sup>

The Indian Supreme Court followed suit, handing down a decision on April 1, 2013, in which it echoed the previous court rulings that Novartis failed to demonstrate Glivec's enhanced or superior efficacy in accordance with section 3(d).<sup>81</sup> The Court, however, did not deem it necessary to articulate a single, definitive definition of "enhanced (therapeutic) efficacy" in order to render a decision.<sup>82</sup> The Court also noted that its ruling in the Novartis case should not be read as a general prohibition of all patents for "incremental inventions of chemical and pharmaceutical substances."<sup>83</sup>

#### VII. IS SECTION 3(d) IN VIOLATION OF TRIPS?

One of Novartis's major allegations was that section 3(d) is not in compliance with TRIPS.<sup>84</sup> Some commentators argue that, if this issue were to go before the WTO, it is highly unlikely that the organization

improved bioavailability, thermodynamic stability, improved flow properties and lower hygroscopicity, but this does not amount to an increase in "therapeutic efficacy."

*Id.*

79. Basheer, *supra* note 6, at 8.

80. Ahmed & Sharma, *supra* note 22. Other companies that have had issues with India include Gilead Sciences, Inc., which had its patent application for its HIV medication, Viread, rejected by India's patent office, and Roche Holding AG, which has been unsuccessful in getting the Indian courts to bring an end to the sale of knockoff versions of its anticancer drug, Tarceva. *Id.*

81. *India's Novartis Decision*, N.Y. TIMES (Apr. 4, 2013), [http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html?\\_r=0](http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html?_r=0).

82. *Novartis AG v. Union of India and Others*, Unreported Judgments 2013, 93–94, available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>. In its decision, the Court acknowledged the opinions of Anand Grover, who appeared on behalf of one of the "Objectors," the Cancer Patients Aid Association, and Professor Basheer, who appeared purely in academic interest as an intervenor-cum-amicus. *Id.* Mr. Grover opined that "efficacy" has an established meaning within the field of pharmaceuticals and should be given a narrow definition so as to not include enhanced affinity, potency, or bioavailability. *Id.* at 92–93. Dr. Basheer, on the other hand, took "a less rigid position," by asserting that such factors as a drug's safety or significantly reduced toxicity should be taken into consideration when determining its enhanced therapeutic efficacy under section 3(d). *Id.* at 93. The Court, however, stated that it did "not propose to make any pronouncement on the issues raised by [Mr. Grover and Dr. Basheer], as this case [could] be finally and effectively decided without adverting to the different points of view noted [in the decision]." *Id.* at 93–94.

83. *Id.* at 95.

84. Basheer, *supra* note 6.

would rule in favor of Novartis.<sup>85</sup> This opinion is based on article 27 of the TRIPS Agreement, which gives member states a fair amount of flexibility when enacting patent laws that conform to and protect their national interests.<sup>86</sup> The resulting patent laws of the member states, however, cannot be “entirely arbitrary.”<sup>87</sup>

Article 27 of the TRIPS Agreement states, “[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>88</sup> Fortunately for WTO member states such as India, many of the terms included in TRIPS have been left undefined, including “inventive step.”<sup>89</sup> By leaving terms like “inventive step” open for interpretation, article 27 has allowed India to devise its own standards for patentability, as exemplified by the section 3(d) requirement that a pharmaceutical product must demonstrate “enhancement of the known efficacy” to be patentable.<sup>90</sup> The Indian Supreme Court in *Novartis AG v. Union of India* reiterated similar points in its discussion concerning the legitimacy of Indian patent laws under TRIPS, despite lacking ultimate jurisdiction to rule conclusively in such matters.<sup>91</sup>

Yet while it appears that India’s patent law may successfully withstand Novartis’s TRIPS challenge if it were to reach the WTO,<sup>92</sup> there still

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85. *Id.* See also Lee, *supra* note 9, at 309 (“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)”).

86. Basheer, *supra* note 6 (citing Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* 114 (2002), <http://www.iprcommission.org>). Specifically, The Doha Declaration, which was adopted by the fourth WTO Ministerial Conference in 2001, reaffirmed the need for flexibility under TRIPS for the sake of developing countries with significant public health concerns and insufficient pharmaceutical manufacturing capabilities. *Novartis AG*, Unreported Judgments 2013, at 35–37.

87. Basheer, *supra* note 6.

88. TRIPS Agreement, *supra* note 53, art. 27.

89. Lee, *supra* note 9, at 309.

90. The Patents (Amendment) Act, 2005, *supra* note 61, § 3(d). Former WIPO director, Nuno Pires de Carvalho, when asked about section 3(d)’s compliance with TRIPS, stated,

WTO members can individually define the term invention for purposes of patentability, subject to meeting the TRIPS criteria of “novelty,” “inventive step” and “industrial application potential,” of the substance concerned. Therefore, what India did through Section 3(d) was to make it clear that a number of technical creations are not inventions, unless they present a significant increase in efficacy.

Manisha Singh Nair, *Section 3(d) Well Within TRIPS*, IPFRONTLINE (Nov. 30, 2007), <https://www.ipfrontline.com/depts/article.aspx?id=16824&deptid=6>.

91. *Novartis AG*, Unreported Judgments 2013, at 26–37.

92. It appears that the Swiss government has little intention in bringing Novartis’s section 3(d) challenge before the WTO. *Swiss Govt Not to Take Novartis Case to WTO*, BUS. STAND. (Aug. 8, 2007), <http://www.business-standard.com/india/news/swiss-govt-not-to-take-novartis-case-to-wto/293771/>.



remains some uncertainty. Professor Shamnad Basheer<sup>93</sup> contends that whether section 3(d) actually meets the requirements of TRIPS or falls short may depend on the construction of the term “efficacy.”<sup>94</sup> He argues that if efficacy is given a fairly narrow construction, so as to essentially reserve patent protection for new chemical entities only, then section 3(d) may in fact violate TRIPS.<sup>95</sup> The proper construction of “efficacy” highlights one of the major concerns with the law, not only as it relates to the matter of TRIPS compliance, but also to the more fundamental question of what is and is not patentable under Indian law. This is an issue that will be given further consideration in the following parts.

#### VIII. THE NOVARTIS DECISION AND PUBLIC HEALTH CONCERNS

A significant reason why the Novartis case drew considerable attention from the global community was the impact the decision would likely have on the availability of generic drugs in the developing world. Many proponents of affordable healthcare feared a decision in favor of Novartis would be a “death sentence” for patients struggling to pay for treatment.<sup>96</sup> The challenge of providing affordable pharmaceuticals is especially pronounced in countries like India, where there is no developed insurance system.<sup>97</sup>

The concern over affordable drugs in India and elsewhere was an important factor in the IPAB’s decision to reaffirm the patent office’s denial of the Glivec patent application.<sup>98</sup> Section 3(b) of the Patents (Amendment) Act of 2005 holds that “patents cannot be granted to an

93. Professor Shamnad Basheer is Chair Professor of Intellectual Property at National University of Juridical Sciences of Kolkata (NUJS).

94. Basheer, *supra* note 6.

95. *Id.*

96. Pidd, *supra* note 65. Prior to the Supreme Court’s ruling, Leena Menghaney, a lawyer and India manager of the Access Campaign at *Medecins Sans Frontieres*, summed up the possible consequences of a Novartis court victory:

A win for Novartis would set a dangerous precedent, severely weakening India’s legal norms against evergreening and inevitably leading to patents being granted far more widely in the country. Filing patent applications covering simple changes in the chemistry or formulation of existing pharmaceutical products is a lucrative game for the pharmaceutical business, but also a deadly one for patients: it would prevent generic competition for these products and allow pharmaceutical companies to continue charging high prices, which can mean the difference between life and death.

Menghaney, *supra* note 64.

97. Mueller, *supra* note 3, at 542; KUANPOTH, *supra* note 1, at 135.

98. Priyanka Golikeri and KV Ramana, *Glivec Patent Ruling a Welcome Turn for Novartis*, DAILY NEWS & ANALYSIS (July 8, 2009, 1:00 AM), <http://www.dnaindia.com/money/report-glivec-patent-ruling-a-welcome-turn-for-novartis-1272042>.

invention, the primary or intended use or commercial exploitation of which could be contrary to public order, or morality, or which causes serious prejudices to human, animal or plant life or health or to the environment.”<sup>99</sup> Following this provision, the IPAB concluded that the Glivec patent failed not only due to the drug’s lack of enhanced efficacy pursuant to section 3(d), but also because its exorbitant price was seen as placing the drug “beyond the reach of the common man.”<sup>100</sup>

The Supreme Court similarly expressed “bewilderment” over the excessive price of Glivec.<sup>101</sup> Indeed, the justices even complained to Novartis about the drug’s cost prior to rendering their decision.<sup>102</sup> Novartis, however, has attempted to stave off these complaints by drawing public attention to the fact that 90% of Indian patients diagnosed with the form of leukemia that Glivec is designed to combat receive the drug for free through Novartis’s donation program.<sup>103</sup> But not everyone is convinced; as one commentator bemoaned, “health policy cannot be hostage to corporate charity.”<sup>104</sup>

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99. Priyanka Golikeri & KV Ramana, *Glivec Patent Ruling a Welcome Turn for Novartis*, DAILY NEWS & ANALYSIS (July 8, 2009, 1:00 AM), <http://www.dnaindia.com/money/report-glivec-patent-ruling-a-welcome-turn-for-novartis-1272042>.

100. *Id.* Interestingly, many commentators, including Professor Basheer, have come out against the IPAB’s use of section 3(b) in its denial of Novartis’s Glivec patent. *Id.* Basheer stated that “the use of pricing as a criterion for denying patent would be against the wordings of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization, which India is party to. There is no support for such a ludicrous legal proposition for either Indian or international patent law.” *Id.* (internal quotation marks omitted). The idea that a patent can be denied on the grounds that it will be expensive, and therefore out of the reach of ordinary people, does seem highly unusual, especially from the perspective of someone who is more familiar with American patent law, for instance. Such a barrier would certainly prevent the issuance of numerous patents, and considering that a driving incentive of securing a patent is for economic reasons, it appears that Section 3(b) flies in the face of conventional intellectual property law. Additionally, section 3(b) provides little guidance or clarification as to what qualities or, in this case, price, a product/invention must have to be denied a patent under Section 3(b). See The Patents Act, 1970, No. 39 of 1970, § 3(b), available at [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=128092](http://www.wipo.int/wipolex/en/text.jsp?file_id=128092).

101. *Novartis AG*, Unreported Judgments 2013, at 49 n.1.

102. Ed Silverman, *Indian Court to Novartis: Lower Gleevec Price*, PHARMALOT (Sept. 12, 2012, 12:59 PM) (on file with the WASH. U. GLOBAL STUD. L. REV.).

103. Ed Silverman, *Novartis, A Gleevec Patent & India: Herrling Explains*, PHARMALOT (Aug. 20, 2012, 8:48 AM), available at NOVARTIS, <http://www.novartis.com/downloads/newsroom/product-related-info-center/pharmalot-novartis-a-gleevec-patent-and-india-herrling-explains.pdf> [hereinafter *Herrling Explains*].

104. Hans Löfgren, *David and Goliath: Novartis Challenges India’s Patent Law*, CONVERSATION (Nov. 19, 2012, 7:28 PM), <http://theconversation.edu.au/david-and-goliath-novartis-challenges-indias-patent-law-9880#http://www.thehindubusinessline.com/opinion/article3373972.ece?homepage=true>.

IX. THE NEED FOR CLARIFICATION OF SECTION 3(d) AND GREATER  
PROTECTION FOR INTELLECTUAL PROPERTY

Although the Indian Supreme Court's ruling in the Novartis case may have beneficial implications for the developing world and individuals in need of affordable drugs, there are two notable problems with it. First, section 3(d) of the Patents (Amendment) Act of 2005 still requires greater clarification. The Indian Supreme Court's decision leaves enough ambiguity regarding the meaning of "enhanced efficacy" that both multinational and Indian pharmaceutical companies must continue to pursue industry patents without the benefit of a bright-line rule. Second, the Court's narrow interpretation of section 3(d) will likely discourage future foreign investment in India and potentially harm India's own growing pharmaceutical industry.

As touched upon in previous parts, a lingering issue with section 3(d) is the ambiguity surrounding the meaning of "enhancement of the known efficacy of [a known] substance."<sup>105</sup> Paul Herrling, head of corporate research at Novartis and chair of its Institute for Tropical Disease, had originally hoped that the Novartis litigation would result in some clarity regarding section 3(d)'s language.<sup>106</sup> Prior to the Court's ruling, Herrling told Reuters that "[t]he patent for Glivec is not really the issue here . . . [i]t is just an example of us wanting very clear legal clarity about what kind of innovation is patentable."<sup>107</sup>

Defining "enhanced efficacy" in order to create a bright-line rule, however, is easier said than done. Professor Basheer maintains that enhanced efficacy can easily be construed to benefit either side of the debate.<sup>108</sup> If enhanced efficacy is given the narrow, "therapeutic efficacy"<sup>109</sup> definition, as it was by both the Madras High Court and the

105. Lee, *supra* note 9, at 310–11.

106. Silverman, *supra* note 102.

107. *Novartis Argues for Glivec Patent at India's Top Court*, REUTERS, Sept. 11, 2012, available at <http://www.reuters.com/article/2012/09/11/us-india-novartis-glivec-idUSBRE88A0BN20120911>. Herrling's claim that "[t]he patent for Glivec is not really the issue here," is supported by the fact that a loss for Novartis would be but a hiccup for the company financially. *Id.* (internal quotation marks omitted).

A loss for Novartis in the case would not have a big financial impact since India is never likely to account for more than a small fraction of Glivec's global sales, which totaled \$ 4.7 billion last year. [Again,] [t]he real concern for the industry is that a rebuff would confirm India as a country where patents are exceptionally hard to secure.

*Id.*

108. Basheer, *supra* note 6.

109. "[I]n the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy.' The question then arises, what would be the parameter of therapeutic efficacy

Supreme Court in the Novartis matter, then few derivate drugs (i.e., existing drugs or chemical compounds that have been modified in some way) will make the cut for patentability under section 3(d).<sup>110</sup> Under this construction of the term, Glivec was denied a patent because, while the beta crystal form of imatinib mesylate is safer and easier to use, it is not any more effective for the actual treatment of cancer.<sup>111</sup> Thus, pharmaceutical corporations such as Novartis tend to be in favor of a lower standard and broader definition of enhanced efficacy so as to

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and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the ‘therapeutic efficacy’ of a medicine must be judged strictly and narrowly.” *Novartis AG*, Unreported Judgments 2013 at 90–91.

110. Basheer, *supra* note 6. The Madras High Court relied on the Darland’s Medical Dictionary for its definition of the term, “efficacy.” *Novartis AG v. Union of India and Others*, (2007) 4 MLJ 1153, 1290. The Court held:

The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect. Darland’s Medical Dictionary defines the expression “efficacy” in the field of Pharmacology as “the ability of a drug to produce the desired therapeutic effect” and “efficacy” is independent of potency of the drug. Dictionary meaning of “Therapeutic”, is healing of disease - having a good effect on the body.” Going by the meaning for the word “efficacy” and “therapeutic” extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the “therapeutic effect” of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, —we state—for any Patent applicant to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy.

*Id.* This is the definition of “efficacy” that proponents of affordable pharmaceuticals support as a means of preventing evergreening.

Consumer groups wish to peg the “efficacy” standard as high as possible in order to ensure that there are very few pharmaceutical patent grants. Illustratively, in their pre-grant opposition filed against the application at the patent office, the CPAA [(Cancer Patients Aid Association)] recommended that “efficacy” be interpreted in a drug regulatory manner. More interestingly, in a submission made to the Mashelkar Committee, the Affordable Medicines Treatment Campaign (AMTC) supported the introduction of a clause that would have restricted patentability to only new chemical entities (NCE’s)—in other words, it advocated a total ban on any kind of incremental pharmaceutical patenting.

Basheer, *supra* note 6 (citing Dr. R. A. Mashelkar et al., *Report of the Technical Expert Group on Patent Issues* (Dec. 2006), available at [http://ipindia.nic.in/ipr/patent/mashelkar\\_ommittee\\_report.doc](http://ipindia.nic.in/ipr/patent/mashelkar_ommittee_report.doc)).

111. Vikas Bajaj & Andrew Pollack, *India’s Supreme Court to Hear Dispute on Drug Patents*, N.Y. TIMES (Mar. 6, 2012), [http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&_r=0); *Glivec Patent Case in India: Fact vs. Fiction*, *supra* note 68.

include modifications relating to an existing drug's safety and ease of use.<sup>112</sup>

Though it may appear that the Indian courts did in fact provide a clearer meaning to section 3(d) by following a strict and narrow interpretation of "enhanced efficacy," the Supreme Court ultimately left the issue open. The Court entertained the opinions of proponents on both sides of the narrow/broad-definition debate,<sup>113</sup> but concluded it was unnecessary for it to articulate a definitive standard for enhanced efficacy that could be applied in future patent disputes.<sup>114</sup> Rather, the narrow approach the Court took in the Novartis case was purely for the purpose of judging the patentability of Glivec under the Patents (Amendment) Act of 2005.<sup>115</sup> Future claims that an incremental innovation, such as a new drug's comparative increase in bioavailability<sup>116</sup> or reduction in toxicity, constitutes an enhancement of therapeutic efficacy will be evaluated on a case-by-case basis.<sup>117</sup>

This remaining uncertainty as to what may in fact be patentable under the Patents (Amendment) Act of 2005, as well as the limited precedent set by the Court's Novartis decision requiring drugs to meet a certain degree of enhanced efficacy, will, at least for the near future, discourage foreign investment in India. While the Supreme Court requested that its decision not be read as a prohibition on patents for all incremental innovation,<sup>118</sup> the reality is that many MNCs will question their ability to secure patents for their products in India. Foreign firms will simply abstain from

112. Bajaj & Pollack, *supra* note 111; Basheer, *supra* note 6. "On the other hand, multinational pharmaceuticals wish to peg the 'efficacy' standard as low as possible. In fact, Novartis would prefer that section 3(d) not exist at all. Which is essentially why it challenged section 3(d) as violating TRIPS, and the constitution of India." *Id.* Interestingly, Professor Basheer suggests that India could actually look to the United States for guidance on patent laws as they relate to pharmaceutical derivatives. *Id.* In the United States,

[T]he patentability of a pharmaceutical derivative such as a new salt form or polymorph hinges to some extent on whether or not such derivative demonstrates 'unexpected or surprising results.' Under this standard, 'unexpected results' would include not just 'therapeutic' efficacy, but any other significant advantage as well, such as enhanced bioavailability, heat stability, humidity resistance, etc.

*Id.* (citing Pfizer v. Apotex, 480 F.3d 1348 (Fed. Cir. 2007)). See *id.* for a more in-depth comparison of section 3(d) to United States pharmaceutical patent law.

113. See *supra* note 82.

114. *Novartis AG*, Unreported Judgments 2013, at 93–95.

115. *Id.*

116. Bioavailability is "the degree and rate at which a substance (as a drug) is absorbed into a living system or is made available at the site of physiological activity." *Bioavailability*, MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/bioavailability> (last visited Mar. 14, 2014).

117. *Id.*

118. Unreported Judgments 2013, at 95.

investing in India, perhaps by withholding the introduction of new products to the Indian market, or by refusing to create new high-paying jobs there.<sup>119</sup> This possibility is troubling in the face of India's increasing need to attract foreign investment in order to bolster its weak currency, and to meet the demands of its growing middle class.<sup>120</sup>

Additionally, the Novartis decision is detrimental to innovation and will likely harm India's own growing pharmaceutical industry. Chip Davis, the executive vice president of advocacy at the Pharmaceutical Research and Manufacturers of America, characterized the innovation environment in India as "deteriorating," and said that the recent Novartis decision highlights his group's belief that the Indian government and courts do not "recognize the value of innovation and the value of strong intellectual property . . . ."<sup>121</sup> By failing to promote broader protection for pharmaceutical patents, India runs the risk of dampening the kind of innovation that leads to the creation of new medicines.<sup>122</sup>

Under the prevailing interpretation of section 3(d), it is very difficult to acquire a patent for a drug with incremental improvements because it will likely fail to meet the "enhanced therapeutic efficacy" threshold.<sup>123</sup> Although many affordable drug advocates view this interpretation as an effective means of ensuring affordable drugs and preventing the practice of evergreening by large MNCs,<sup>124</sup> it ultimately harms domestic drug

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119. Harris & Thomas, *supra* note 10; Ahmed & Sharma, *supra* note 22. "Novartis says India is discouraging innovation by weakening patents—reducing the incentive for big companies to invest time and money to discover new drugs." *Id.* Before the Supreme Court's ruling in *Novartis v. Union of India*, Ranjit Shahni, Novartis India's managing director, stated that clarity of the Indian law is necessary for future investment in India by large firms: "We are seeking clarity on the application of patent law in India . . . [k]nowing we can rely on patents in India benefits government, industry and patients because research-based organizations will know if investing in the development of better medications for India is a viable long-term option." *Id.* Following the Court's decision, Novartis decided that it would only release new drugs in India after it had secured a patent on those drugs, and would also refrain from conducting research and development activities there for the time being. Kaustubh Kulkarni & Suchitra Mohanty, *Novartis Loses Landmark India Cancer Drug Patent Case*, REUTERS, Apr. 1, 2013, available at <http://www.reuters.com/article/2013/04/01/us-india-novartis-patent-idUSBRE93002I20130401>.

120. Ahmed & Sharma, *supra* note 22.

121. Chip Davis *quoted in* Harris & Thomas, *supra* note 10 (internal quotation marks omitted).

122. Kulkarni & Mohanty, *supra* note 119.

123. Basheer & Reddy, *The "Efficacy" of Indian Patent Law*, *supra* note 63, at 244.

124. It may seem difficult to counter the arguments made by affordable healthcare advocates, but there are reasons for why their views may actually be shortsighted. Professor Basheer contends,

Of course, were one to see intellectual property policy through a long-term dynamic innovation lens, one will appreciate that even consumers will benefit from more innovation—if there is no drug, there is no question of access to the drug. Unfortunately, most public health groups and civil society activists resort to a myopic "pricing" lens i.e. beat the price down to the lowest possible level, without regard for anything else.

companies that have just recently begun to invest in their own research and development.<sup>125</sup> Because India's major domestic pharmaceutical companies have yet to accrue the infrastructure and capital to make major leaps in drug innovation, a number of them have focused on "incremental innovation."<sup>126</sup> One Indian parliamentarian suggested that patents should be made available for incremental innovations because "Indian scientists do not have the know-how or capital to come up with new chemical entities, but do have the know-how to make improvements."<sup>127</sup> As is the general argument in favor of the protection of intellectual property, the failure to ensure patent coverage for even these incremental inventions is bound to stifle innovation, which is an unfortunate prospect in a country that is quickly emerging as a global player in the realm of science and technology, and will likely be in such a position for years to come.<sup>128</sup>

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Basheer, *supra* note 6. Additionally, there are arguably more significant factors that impede or limit accessibility to drugs, such as poor diagnosis, infrastructure, and distribution. Ahmed & Sharma, *supra* note 22. For instance, India's lack of a comprehensive insurance system may be a greater barrier to affordable drugs than a bolstering of patent protection for pharmaceutical products. According to Malvinder Mohan Singh, chairman of Fortis Healthcare, a New Delhi-based medical company, less than 20% of Indians are covered by healthcare insurance policies (compared to China, where 95% of the population is covered by some form of health insurance). Bruce Einhorn, *India Needs Doctors, Nurses, and Health Insurance*, BLOOMBERG BUSINESSWEEK (May 30, 2012), <http://www.businessweek.com/articles/2012-05-30/india-needs-doctors-nurses-and-health-insurance>. Unfortunately, "[g]iven the many other challenges India's poor face, expanding health insurance coverage isn't going to top the agenda for the country's politicians . . . [w]hile there might be some talk among policy makers about enacting some changes, anything dramatic is years away." *Id.* (internal quotation marks omitted). India also faces a shortage of doctors, as it only has six doctors per 10,000 (compared to the United States, which has 27 doctors per 10,000 people). *Id.*

125. While some of the large pharmaceutical companies in India export many of their drugs to developed markets such as the United States, "there is a great untapped rural market for medicines in India, [and thus] it is possible that the Indian market will grow exponentially in the coming years." Basheer & Reddy, *supra* note 63, at 264.

126. Basheer, *supra* note 6. Such incremental innovations include new heat stable forms, drug delivery systems, and extended release capsules. *Id.* Basheer additionally notes for illustrative purposes that "under a restrictive efficacy standard, Ranbaxy's [major domestic pharmaceutical company] incremental innovation which enabled Bayer's famed anti-anthrax drug, Cipro to be taken just once a day, will not gain patent protection." *Id.* (citing Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, UNITED NATIONS UNIVERSITY INSTITUTE FOR NEW TECHNOLOGIES, available at <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf>).

127. Mr. Kharabela Swain, a member of the Indian Parliament, made this comment during the debate over the 2005 Amendment. Basheer, *supra* note 5, at 34 n.60 (citing Lok Sabha Debate, Mar. 22, 2005, available at <http://164.100.24.230/Webdata/datalshom001/dailydeb/22032005.htm>).

128. "If the nonobviousness standard is set so high that it effectively bars patentability of most incremental pharmaceutical innovations, that rule may contravene TRIPS and be detrimental to the Indian pharmaceutical industry by failing to provide proper incentives for research and development for the long term." Lee, *supra* note 9, at 312.

## X. CONCLUSION

The concern for securing access to affordable drugs is a real one, and there are strong moral arguments for why increasing patent protection for the products of powerful MNCs works only to hurt the common man. The reality, however, is that the protection of intellectual property rights provides these corporations with the needed incentive to invent and manufacture the drugs on which patients around the world rely, whether branded or generic. In theory, India could continue down its current path where its generics industry simply reverse-engineers the pharmaceuticals that are researched and developed elsewhere. But if India desires to grow into its role as a major scientific and technological powerhouse, then it must work to protect intellectual property rights, as opposed to doing the bare minimum to ensure compliance with TRIPS. It is no mystery why Indian pharmaceutical patent law has developed the way it has, but India has also changed significantly since it enacted its first patent laws.

The Novartis case was, in many ways, a missed opportunity for India to redefine its place in the international debate over intellectual property rights. The decision may serve the immediate interests of India's generics industry and supporters of inexpensive pharmaceuticals, but may ultimately hinder the growth of research and development, both at home and abroad.

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