A Healthy Solution for Patients and Patents: How India’s Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights

ABSTRACT

The Swiss drug company Novartis challenged India’s status as the “Pharmacy of the Developing World” when it initiated a lawsuit against the Indian government on February 15, 2007. In 2005, India updated its Patents Act to comply with the World Trade Organization’s (WTO) intellectual property requirements. Before 2005, India only granted patents to processes, not products, which facilitated the development of the country’s booming generic drug industry. On January 25, 2006, India’s Office of the Controller General of Patents, Designs and Trademarks denied Novartis’s patent application for its cancer-fighting drug Glivec on the grounds that it was not substantially different from an earlier, unpatented version of the drug. Novartis challenged both the constitutionality of the Indian Patents Act and its compliance with the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While the Indian High Court asserted that it lacked jurisdiction to rule on the Indian Patents Act’s compliance with TRIPS, it determined that the Act was constitutional and did not require further amendments.

The Novartis decision has had important implications for both developed countries that house the pharmaceutical industry and developing countries that cannot afford patented versions of essential medications. Had Novartis won its case against the Indian government, the practice of granting patents for inventions that resulted from “evergreening” would not only have been tolerated but protected, thus striking a serious blow to developing countries that rely on generic drugs from India.

This note analyzes the controversial section of India’s Patents Act by comparing its language to the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health, and similar laws of India’s fellow WTO members. In conclusion, the note asserts
that although India’s Patents Act is TRIPS compliant, the Indian government should more clearly define the relevant criteria for determining whether a particular modified drug has sufficiently enhanced its efficacy in order to qualify for patent protection. Finally, the note argues that India’s decision to protect its pharmaceutical industry and the health of the developing world through section 3(d) of its Patents Act, rather than by relying on compulsory licenses, is a solution that should be employed by other developing countries concerned with TRIPS compliance.

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This [decision] is a huge relief for millions of patients and doctors in developing countries who depend on affordable medicines from India.

- Tido von Schön-Angerer

There’s no faster way to kill access to the latest life-saving drugs for people in India than to avoid offering patent protection.

- John Gilardi

Your life may depend on a patent. According to several public health advocates and organizations, this statement is not an exaggeration. Intellectual property rights and human rights are often at odds where the pharmaceutical industry is concerned. Generating profits and increasing access to essential medications are often incompatible goals. Therefore, there will always exist a certain tension between pharmaceutical companies that research and develop new drugs to combat the world’s maladies and third world countries unable to afford the patented versions of such drugs. Due to the human rights implications of this tension, this polarizing subject continues to surface in international forums and spark heated debate among state governments, pharmaceutical companies, non-governmental organizations (NGOs), and human rights groups. Most recently, the debate made international headlines when the Indian High Court in Madras handed down a decision against Novartis, a Swiss pharmaceutical company, on August 6, 2007.

The case


4. For a discussion of the growing tensions between human rights and intellectual property law, of which pharmaceutical patents are just one important example, see Laurence R. Helfer, Toward a Human Rights Framework for Intellectual Property, 40 U.C. DAVIS L. REV. 971 (2007).

highlighted a potential conflict between Indian patent law and the intellectual property protection requirements of the World Trade Organization (WTO).

Before India joined the WTO in 1995, it had been “a patent-free zone where generic drug-makers flourished.”6 Although India had allowed pharmaceutical patents for manufacturing processes used to produce drugs before it decided to join the WTO, it had not permitted patents for products.7 This system was designed “to encourage companies to compete in low-cost manufacturing, developing the nation’s industry and making medicines widely available at low prices.”8 When India decided to join the WTO, it had to agree to update its patent laws in order to comply with the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.9 Since the WTO categorized India as a developing nation, TRIPS granted the country ten years to update its patent laws to conform fully to WTO standards.10 India’s Patents (Amendment) Act 2005 (Patents Act) requires India to provide patents on a much larger and specific scale—including patents on pharmaceuticals—in order to comply with the WTO’s minimum protections for intellectual property.11

These stricter standards present a challenge for India’s pharmaceutical industry since it largely depends on its ability to produce generic drugs for much cheaper prices than its patented counterparts.12 Although the Indian government asserts that its

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8. Id.


updated patent laws are “WTO compliant.” India does not want to threaten its position as the “Pharmacy of the Developing World” by making its updated laws too restrictive on the domestic pharmaceutical industry.\footnote{See Press Release, Mèdecins Sans Frontièrs, Indian Court Ruling in Novartis Case Protects India as the “Pharmacy of the Developing World,” (Aug. 6, 2007), http://www.accessmed-msf.org/media-room/press-releases/.} Specifically, the Indian government rejected the widespread industry practice of extending a drug’s period of patentability by making minor, insignificant alterations to medications, commonly known as “evergreening.”\footnote{See Novartis Patent Challenge Dismissed in India, supra note 1.}

In an attempt to test the boundaries of India’s updated patent laws, Novartis filed suit against the Indian government on February 15, 2007, after India’s Office of the Controller General of Patents, Designs and Trademarks (Patent Office) had refused to grant a patent to the drug-maker’s cancer-treating medicine Glivec.\footnote{Novartis v. Union of India, W.P. Nos. 24759 & 24760 of 2006, at para. 1 (Madras H.C. June 8, 2007), available at http://judis.nic.in/chennai/qrydisp.asp?tfid=11121; see Gentleman, supra note 5 (noting that the drug is called Gleevec in the United States).} According to the Patent Office, the new version of Glivec was not sufficiently different from the old, unprotected version to warrant a patent.\footnote{See Gill, supra note 6.} This meant that the Indian pharmaceutical industry could continue producing the generic form of the drug for a much cheaper price than if the drug were patented.\footnote{Press Release, Oxfam International, Novartis Lawsuit Threatens Access to Medicines for Millions (Jan. 29, 2007), http://www.oxfam.org/en/news/2007/pr070219_novartis (“Glivec sells for $27,000 per patient per year in India, but the generic version sells for $2,000 per patient per year.”).} Novartis clearly recognized the negative impact this decision by India’s Patent Office would have on its potential profits for a patented version of Glivec.\footnote{See id.}

In its complaint, Novartis argued that India’s Patents Act violated both the Indian constitution and WTO standards.\footnote{Novartis, W.P. Nos. 24759 & 24760 of 2006, at para. 2; Press Release, Mèdecins Sans Frontièrs, supra note 13.} Specifically, Novartis claimed that section 3(d) of the Act, denying patents to “a new form of a known substance which does not result in the enhancement of the known efficacy of that substance,”\footnote{The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 3(d), available at http://www.patentoffice.nic.in/spr/patent/patent_2005.pdf} was too vague to be enforceable.\footnote{Novartis, W.P. Nos. 24759 & 24760 of 2006, at para. 2; see Novartis Patent Challenge Dismissed in India, supra note 1.} In addition, Novartis pointed out that the
law also specifically “denies patent protection to new versions of drugs invented before 1995,” the year India joined the WTO.\textsuperscript{22} Novartis was particularly frustrated with the Patent Office’s decision because patents for the beta crystal form of Glivec\textsuperscript{23} had been granted in nearly forty other countries, including Russia, Taiwan, and China.\textsuperscript{24} However, despite Novartis’s detailed and specific objections to India’s new patent laws, the Indian High Court dismissed the suit.\textsuperscript{25}

The Indian High Court’s decision to deny Novartis’s challenge to India’s Patents Act has far-reaching implications for the global community. The decision to uphold the Act protects India’s hugely successful generic pharmaceutical industry because “[t]he stringent standards of patentability upheld by the court mean that fewer medicines will be eligible for patents.”\textsuperscript{26} However, the Indian High Court declined to address Novartis’s claim that India’s Patents Act violated the TRIPS requirements, asserting that it lacked jurisdiction to rule on international treaties.\textsuperscript{27} The court suggested that the WTO was the proper forum in which Novartis could challenge India’s compliance with TRIPS.\textsuperscript{28}

Not surprisingly, NGOs and aid organizations such as Médicins Sans Frontières (Doctors Without Borders), which had sponsored a petition signed by almost half a million people urging Novartis to drop the case, praised the Indian High Court’s ruling as a victory for the “‘rights of patients over patents.’”\textsuperscript{29} By contrast, Novartis argued that the decision “will have long-term negative consequences for research and development into better medicines.”\textsuperscript{30} While the decision made international headlines, the news generated equal attention in India.\textsuperscript{31}

\begin{itemize}
\item \textsuperscript{22} Novartis, W.P. Nos. 24759 & 24760 of 2006, at para. 2; see Gentleman, \textit{supra} note 5.
\item \textsuperscript{23} See \textit{infra} notes 72-73 and accompanying text.
\item \textsuperscript{24} Press Release, Novartis, Novartis Concerned Indian Court Ruling Will Discourage Investments in Innovation Needed to Bring Better Medicines to Patients (June 8, 2007), http://cws.huginonline.com/N/134323/PR/200708/1144199_5_2.html.
\item \textsuperscript{25} See \textit{Novartis Patent Challenge Dismissed in India, supra} note 1.
\item \textsuperscript{26} Id.
\item \textsuperscript{27} Novartis, W.P. Nos. 24759 & 24760 of 2006, at para. 4.
\item \textsuperscript{28} \textit{Novartis Patent Challenge Dismissed in India, supra} note 1.
\item \textsuperscript{29} Gentleman, \textit{supra} note 5.
\item \textsuperscript{30} Press Release, Novartis, \textit{supra} note 24.
\end{itemize}
The head of the Mumbai cancer patients’ support group, Y. K. Sapru, was thrilled with the decision, stating:

“This is a very major victory domestically and internationally . . . . India has a $5 billion pharma industry, and 65 percent of those drugs are sold to the developing world and poorer people in the developed world. All that would have been suspended if the judgment had gone the other way, and there would have been a dearth of affordable drugs. That calamity has been prevented.”

Supporters of India’s pharmaceutical industry clearly viewed the decision as a victory for both India’s pharmaceutical industry and the developing world.

Although Novartis claims that it has no current plans to request that the Swiss government bring the case before the WTO, the company has already appealed the Patent Office’s earlier denial of the requested patent to India’s Intellectual Property Appellate Board (IPAB), a procedure entirely separate from its lawsuit challenging India’s Patents Act. Regardless of the outcome of Novartis’s appeal before the IPAB, the Indian High Court’s interpretation of India’s challenged patent law may be rendered moot if the Indian government responds to pressure from WTO Members to amend its already-updated patent laws.

This note argues that India should not acquiesce to pressure from developed countries within the WTO to amend the controversial wording of section 3(d) of India’s Patents Act because the language of the Act satisfies TRIPS requirements. Additionally, the language of India’s Patents Act, while strikingly similar to patent laws of other WTO members, attempts to achieve the same goals as those of other members. Thus, if India’s Patents Act is not considered TRIPS compliant, then neither are the laws of several other prominent WTO members. India’s victory against Novartis should encourage WTO members to reassess their own patent law regimes in light of both the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration).

Part I of this note contextualizes the WTO’s plan to internationalize intellectual property rights through the TRIPS Agreement. In particular, this part discusses the WTO’s concessions to the developing world through an analysis of the Doha Declaration and the effects of patent “evergreening” on developing countries’ access to essential medications. Part I will also address India’s

32. Gentleman, supra note 5 (quoting Y.K. Sapru, head of Mumbai cancer patient’s support group).
34. See Bidwai, supra note 31.
35. See infra notes 150-71 and accompanying text.
reasoning behind the controversial section 3(d) of India’s updated Patents Act, as well as the specifics of Novartis’s challenge to the Act. Part II discusses whether India’s Patents Act offers sufficient protection for intellectual property rights according to TRIPS requirements and compares the language of section 3(d) to similar provisions contained in the patent laws of other WTO Members. Part III argues that although India’s updated Patents Act satisfies WTO requirements, the Indian government should more clearly define the criteria for determining whether a particular modified drug has sufficiently enhanced its efficacy in order to qualify for patent protection. Finally, in Part III, this note asserts that India’s decision to protect its pharmaceutical industry and the health of the developing world through section 3(d) of its Patents Act, rather than by relying on compulsory licenses, is a solution that should be employed by other developing countries concerned with TRIPS compliance.

I. STRENGTHENING INTERNATIONAL PATENT PROTECTION: THE EFFECT OF THE TRIPS AGREEMENT ON DEVELOPING COUNTRIES

Before the WTO adopted the TRIPS Agreement in 1994, countries were able to determine whether they would grant patents and how to design their patent systems. Several countries specifically decided not to grant patents for pharmaceuticals. However, the coming into force of the TRIPS Agreement and the expiration of most of its transitional periods meant that all major WTO members had to adopt patent laws to apply to pharmaceuticals. This current patent-friendly environment allows inventors to obtain patents for newly invented, or in some cases “enhanced,” pharmaceutical products in order to prevent competitors from creating cheaper generic versions of the drug for the duration of the patent’s life.

While this new arrangement protects the intellectual property rights of drug developers, it also creates tension with developing countries that are unable to afford patented medication. In the years following the coming into force of TRIPS, discontent with the agreement began to surface in developing countries, especially in

37. HESTERMeyer, supra note 36, at xxxiv.
38. Id.
39. Id.
India and Brazil.\textsuperscript{40} One former Indian Supreme Court judge warned that “the WTO may well spell re-colonisation [sic] of the newly freed nations.”\textsuperscript{41} After a few years of withstanding pressure from developing countries, the developed countries within the WTO determined that dissatisfaction regarding the third world’s access to essential medicines could no longer be ignored.\textsuperscript{42}

\textit{A. Appeasing Developing Countries via TRIPS and the Doha Declaration}

TRIPS was supposed to be the WTO’s answer to the dilemma. However, even though it added a level of predictability to trade-related intellectual property rights, it also initiated controversy regarding the imbalance of benefits that it established between developed countries and the third world.\textsuperscript{43} In June 2001, at a special session of the TRIPS Council, the WTO’s then-Director General, Mike Moore, described the goal of the session:

\begin{quote}
[The TRIPS Agreement] strikes a carefully-negotiated balance between providing intellectual property protection—which is essential if new medicines and treatments are to be developed—and allowing countries the flexibility to ensure that treatments reach the world’s poorest and most vulnerable people.
\end{quote}

Countries must feel that they can use this flexibility. The work started today in the TRIPS Council should reinforce that security.\textsuperscript{44}

After several contentious debates regarding the balance between patents and human rights, the TRIPS Council passed the Doha Declaration.\textsuperscript{45}

The Doha Declaration’s attempt to balance the interests of both developed and developing countries is apparent from the beginning of the document. The Declaration begins by recognizing “the gravity of the public health problems afflicting many developing and least-
developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” While WTO members stress the importance of intellectual property protection in developing countries for the creation of new medicines, they also “recognize the concerns about its effects on prices.” Additionally, the Doha Declaration concedes that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health,” and it supports the “WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

While the Doha Declaration espouses the principles of fairness and flexibility with regard to the TRIPS Agreement, the language of the document cleverly balances the goal of accommodating developing members’ concerns while recognizing developed members’ reluctance to alter the TRIPS Agreement. For example, the signatories agreed “to reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2” of the TRIPS Agreement. However, the Doha Declaration also permits developing countries to issue compulsory licenses in the form of government-mandated patent exceptions, and it leaves each member free to determine what constitutes a national public health emergency. In theory, these important concessions to developing countries were intended to serve as reassurance that intellectual property rights would not overshadow the sovereign right of a nation to protect its citizens during a public health emergency. In actuality, developed members of the WTO have repeatedly opposed developing members’ decisions to issue compulsory licenses.

47. Id. at para. 3.
48. Id. at para. 4.
49. HESTERMeyer, supra note 36, at 259.
50. Doha Declaration, supra note 46, at para. 7.
51. Id. at para. 5(b)-(c).
52. See Do Hyung Kim, Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries, GLOBALEX (Feb. 2007), http://www.nyu.edu/globalex/TRIPS_Compulsory_Licensing.htm#A._Ambiguities_of_Compulsory%20Licens (“[M]any still argue that the compulsory licensing provisions have not helped bring drugs to those in need. Some low-income nations like Thailand, Colombia, and South Africa have been pressured by powerful nations like the U.S. to adopt more rigorous intellectual property laws during free trade negotiations.”).
Although the Doha Declaration makes several concessions regarding the potential flexibility of intellectual property rights for developing countries, there is disagreement within the international community about the legal status of the Declaration. While a “declaration” is technically not a legally binding document, most authors view the Doha Declaration as binding on its members. Additionally, no member has questioned whether the Doha Declaration constitutes an interpretation of the TRIPS Agreement. Thus, “it is most convincing to regard the Declaration as a binding authoritative interpretation.”

B. The Difficulty of Discouraging “Evergreening” While Promoting “Incremental Innovation”

The Doha Declaration allows developing countries to protect the health of their populations by circumventing the TRIPS Agreement’s patent protection during situations of “extreme urgency,” recognizing the effects of intellectual property protection on medication prices. Nevertheless, pharmaceutical companies continue to attempt to extend the lives of their already-existing patents for as long as possible. Although pharmaceutical companies play a crucial role in improving the health of the world’s population, the pharmaceutical industry seeks to turn a large profit from its investments in developing new medications, just as India intends to preserve its lucrative niche in the generic drug market.

53. HESTERMEYER, supra note 36, at 279.
54. Id. at 279-80.
55. Id. at 281.
56. Id.
57. Doha Declaration, supra note 46, at para. 5(c).
58. Id. at para. 3.
60. See TRIPS Agreement, supra note 9, pmbl. The TRIPS Agreement addresses the pharmaceutical industry’s concerns in the beginning of the Agreement by recognizing that intellectual property rights are “private rights.” Id.; see also Malvinder Mohan Singh, India Now Emerging as Roaring Tiger, ECON. TIMES, Jan. 4, 2008, http://economictimes.indiatimes.com/Features/Corporate_Dossier/India_now_emerging_as_roaring_tiger/rssarticleshow/2673478.cms (noting that it is “estimated that drugs worth $70 billion, will additionally go off patent in the next few years, thus opening up a huge market opportunity for Indian companies?”); Press Release, Oxfam International, supra note 17 (“Glivec sells for $27,000 per patient per year in India, but the generic version sells for $2,000 per patient per year.”).
While newly discovered uses and improved versions of existing drugs undoubtedly benefit patients, it is important to distinguish between innovations that advance the industry’s ability to produce new drugs and those that are designed solely to extend the patent life of already-existing drugs. The Pharmaceutical Research and Manufacturers of America (PhRMA) asserts that second-use patents are “conducive to future research and development of life-saving medicines.”61 “Second and subsequent use patents protect discoveries of new uses for [the same] substances, active principles, molecules, or compounds that have been previously patented or are already [on the market].”62 Additionally, drug manufacturers frequently attempt to increase the effectiveness of a drug so that it warrants a new patent.63 These processes, referred to as “incremental innovation,” are distinguishable from “evergreening,” which occurs when a drug manufacturer “stockpiles’ patent protection by obtaining separate 20-year patents on multiple attributes of a single product.”64

The practice of obtaining multiple patents on similar inventions prevents the introduction of generic drugs into the market and allows for the possibility that patents on certain multi-use drugs could run indefinitely.65 The ability of companies to acquire additional patents on the same drugs forms a cornerstone of the industry.66 The National Institute of Health Care Management Research and Education Foundation conducted a study in May 2002 and found that, “between 1989 and 2000, only 35% out of the 1035 new drugs approved by the USFDA entailed a new active principle.”67 In other words, pharmaceutical companies were able to extend the lives of nearly two-thirds of their already-patented drugs by making alterations to the drugs’ methods of production, forms, or uses. Furthermore, in India “[t]here are an estimated 9,000 patent applications waiting to be reviewed by Indian authorities of which roughly 7,000 are believed to be modifications of old drugs.”68 This

62. Rodrigues, Jr. & Murphy, supra note 59, at 430 (citation omitted).
65. See Rodrigues, Jr. & Murphy, supra note 59, at 431.
66. See id.
67. Id.
68. Press Release, Oxfam International, supra note 17 (quoting Celine Charveriat, Oxfam’s Make Trade Fair head).
means that developing countries with limited resources may be denied access to previously patented medications by virtue of their newly discovered uses or altered forms. While it is undoubtedly important to encourage innovative uses for drugs that are already on the market, this poses a particularly difficult situation for developing countries that are waiting for patents on drugs to expire so that they can purchase cheaper, generic versions.

**C. Novartis’s Challenge to India’s Patents Act**

Novartis decided to enter the Indian market during the period when India began the process of updating its patent laws to comply with the requirements of the WTO’s TRIPS Agreement.\(^6^9\) The company formally entered India in 1998, before the government amended its 1970 Patents Act.\(^7^0\) Although Novartis obtained patents for Glivec in the United States and other countries in 1993, it did not attempt to secure a patent for Glivec in India until 1998.\(^7^1\) Since Glivec was not patented in India, generic forms of the imatinib-free base drug could be made available to cancer patients in the country.\(^7^2\)


\(^7^0\). *Id.*

\(^7^1\). *Id.* In January 2003, India granted Novartis Exclusive Marketing Rights (EMR) to Glivec. Cancer Patients Aid Association, *The Glivec Story*, http://www.cpaaindia.org/aboutus/theglivecstory.htm (last visited Feb. 21, 2008). Thereafter, “Indian courts forbade 6 out of 9 generic producers to market Imatanib Mesylate.” *Id.* Although this benefited Novartis, there were negative consequences for the Indian people as Glivec was not affordable for many. *See id.*

As a result: The 3 generic companies could not cover the entire country, CPAA and other charitable agencies could not take up the burden of supplying the drug at subsidized rates or free. Thousands of CML patients suffered and many became bankrupt as they tried to buy Glivec and many even died. *Id.*


When Novartis finally presented its application for an updated form of Glivec to the Indian Patent Office in 1998, the patent was placed in a “mailbox”74 until India’s Patents Act was updated and no longer provided patents for “a new form of a known substance.”75 The Patent Office evaluated Novartis’s application for an enhanced form of Glivec pursuant to amended section 3(d) of India’s 2005 Patents Act, which provides instructions regarding the granting of patents for

- 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.76

Although Novartis attempted to demonstrate an enhancement of the drug’s efficacy before the Patent Controller, the Patent Office determined that Novartis’s data was not convincing evidence that the drug’s efficacy had been sufficiently enhanced in accordance with India’s Patents Act.77 Novartis responded to the Controller’s decision not to grant the patent by initiating two separate proceedings. First, it appealed the Patent Office’s decision to the Intellectual Property Appellate Board, hoping that the IPAB would reconsider the Patent Office’s denial.78 Second, Novartis directly challenged section 3(d) of

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78. See Press Release, Novartis, supra note 24.
India’s Patents Act in the High Court, claiming that the Act was “arbitrary, illogical, vague,” and unconstitutional,79 and that it violated India’s compliance with the TRIPS Agreement.80

Since evergreening and incremental innovation are not often easily distinguishable and section 3(d) uses neither of these terms, the Indian High Court attempted to clarify the rationale behind the law.81 The High Court viewed “enhancement of a known efficacy” as a term of art, arguing that Novartis, “being [a] pharmaceutical giant in the whole of the world, [could not] plead that they [did] not know what is meant by enhancement of a known efficacy.”82 The court went on to assert that the Patent Controller did not abuse his discretion in rejecting the Glivec application83 and that section 3(d) of the Patents Act did not violate India’s constitution.84

Proponents and opponents of pharmaceutical patents have analyzed the Indian High Court’s reading of section 3(d) of India’s Patents Act very differently. For example, advocates of the decision assert that the law is meant “to allow genuine improvements and at the same time bar frivolous ‘tweaking’ which are passed under the garb of incremental innovation.”85 Supporters also herald section 3(d) as a “trendsetting provision,” and view it as “the first legal provision in the world not to be found in the patent legislation of any country, which provides a check on frivolous patenting.”86 In other words, supporters of India’s Patents Act view section 3(d) as a check on “evergreening.” However, opponents argue that the law’s requirement of “enhancement of the known efficacy” of a drug stifles “incremental innovation.”87 Carrie Scott, spokesperson for Novartis, asserted that Novartis’s case before the Indian High Court was always about understanding “how innovation is valued and protected in India.”88

79. Novartis, W.P. Nos. 24759 & 24760 of 2006, at para. 3. Novartis specifically argued that India’s Patents Act violated Article 14 of India’s Constitution, which addresses equal protection under the law. See INDIA CONST., art. 14 (“The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.”).
81. See id. at paras. 6-7.
82. Id. at para. 13.
83. Id. at para. 16.
84. Id. at para. 19
86. Id. India’s section 3(d) uses almost identical language as the similar laws of several of India’s fellow WTO members. See infra notes 150-87 and accompanying text.
88. Id. (quoting Carrie Scott, spokesperson for Novartis).
She argued that “[m]edical progress occurs through incremental innovation, and Section 3(d) excludes these important developments, ultimately denying patients in India new and better medicines.”

The High Court’s rejection of Novartis’s challenge to India’s Patents Act on constitutional grounds and its decision not to address the TRIPS Agreement claim signal a bold move for the country with regard to its pharmaceutical industry. Novartis’s challenge to India’s Patents Act was the first of its kind and, unless India decides to amend section 3(d), the country will continue to face pressure from other WTO members that are home to the pharmaceutical industry.

The Indian government is still considering amending section 3(d) to allow for “evergreening,” a modification that would reflect an argument advanced in Novartis’s complaint against the Act and that is also supported by the pharmaceutical industry. While an amendment to the controversial section of India’s Patents Act would render the High Court’s interpretation of the Act moot, it would also reinforce other WTO members’ influence over India in relation to TRIPS and set a precedent for stricter interpretation of the TRIPS Agreement in relation to other developing countries. In other words, India’s patent law could become more greatly influenced by the international community than by its own domestic needs and concerns.

89.  Id. (quoting Carrie Scott, spokesperson for Novartis).
90.  See Praful Bidwai, High Stakes in Attack on Indian Patent Law, ONeworld.net, Feb. 2, 2007, http://us.oneworld.net/article/view/145742/1/. India had already received pressure to revise its newly-amended patent laws prior to the Novartis decision. See Bidwai, supra note 31. India’s patent laws had been challenged before in the WTO Dispute Settlement Board, so the country was particularly cautious in ensuring that its new Patents Act was TRIPS compliant. See World Trade Organization, India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm (last updated Jan. 22, 2008). India made its own attempt to ensure that its new Patents Act was TRIPS compliant. The Indian government appointed a committee to research the compliance of the Patents Act, which was ultimately discredited once it became apparent that the Mashelkar Report had been plagiarized from a study by the UK-based think tank Intellectual Property Institute. The committee turned out to be funded by Interpat, an association of twenty-nine drug companies, including Novartis. See Posting of Shamnad Basheer to SPICY IP, http://spicyipindia.blogspot.com/2007/01/mashelkar-committee-report-on-patents_28.html (Jan. 28, 2007, 14:16); see also Ravi Sharma & Sara Hiddleston, Mashelkar Committee on Patent Law Withdraws Report; Seeks More Time, HINDU, Feb. 22, 2007, http://www.hindu.com/2007/02/22/stories/2007022206751200.htm.
91.  See Bidwai, supra note 31.
II. BOLDLY DEFENDING ITS GENERIC INDUSTRY: INDIA RECONCILES ITS PATENTS ACT WITH HUMAN RIGHTS CONCERNS

The Indian High Court declined to address Novartis’s claim regarding the failure of India’s patent laws to conform to the TRIPS Agreement on jurisdictional grounds. However, India’s Patents Act should still be evaluated in light of the TRIPS Agreement because the WTO Dispute Settlement Body will likely face the patentability issue as other pharmaceutical companies attempt to obtain patents for their drugs in India and other developing countries. As long as India’s Patents Act, particularly section 3(d), satisfies the flexible requirements outlined in Article 27 of the TRIPS Agreement, then India has not violated TRIPS because “members may, but shall not be obliged to, implement in their law more extensive protection than is required by [the] Agreement.” In short, members may not provide less legal protection for intellectual property rights than the minimum standards outlined in the Agreement, although they could theoretically require more. While India’s Patents Act meets the minimum TRIPS patentability requirements, especially when considered in light of the Doha Declaration, India should still clarify its patent standards in order to facilitate international investment in its pharmaceutical industry, protect public health, and avoid the WTO Dispute Settlement Body.

A. Why India’s Patents Act Is WTO Compliant

Although the language regarding patent standards in the TRIPS Agreement is often unclear, as long as India’s Patents Act is not any less restrictive than the flexible Article 27 standards, the Act meets the TRIPS Agreement’s requirements. The TRIPS Agreement uses broad language and only specifies that patents must be made “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.” Article 27, which

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93. See World Trade Organization, Index of Dispute Issues, http://www.wto.org/ english/tratop_e/dispu_e/dispu_subjects_index_e.htm# patents (last visited Feb. 21, 2008) (revealing that as of February 21, 2008, the WTO Dispute Body has only handled eleven cases relating to patents).

94. TRIPS Agreement, supra note 9, art. 1, ¶ 1.

95. See id.

96. Id. art. 27, ¶ 1.
defines “patentable subject matter,” specifically explains that “the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively.”97 By making this qualification, WTO members directly echoed the patentability requirements present in U.S. patent law.98 However, member states are not required to interpret the terms according to the U.S. definitions, as evidenced by the use of “may” instead of “shall.”99 Instead, the flexible language permits members “to fine-tune their inventive-step criteria to reflect national socioeconomic conditions.”100 Since the TRIPS Agreement clearly allows each member to design its patent laws as it sees fit as long as the law satisfies Article 27 requirements, each member state “can decide for itself what they consider to be an ‘invention’ and deserving of twenty years of patent protection.”101

Although allowing members latitude to interpret the requirements of Article 27 in order to tailor patent requirements to their specific needs seems reasonable, the broad language could also create confusion and prevent the establishment of uniform patentability requirements. Since members may, but are not required to, adopt U.S. definitions regarding patentability requirements, members may be using the same legal terms with different interpretations. Ironically, members’ attempts to clarify the requirements of Article 27 by referencing U.S. patent law terms renders the already broad language even more ambiguous when one considers that the U.S. Supreme Court recently redefined the “non-obvious” standard under U.S. law.102 If the basic patentability requirements under U.S. law are subject to reinterpretation, then it is unrealistic to expect WTO members to interpret the standards of

97. Id. art. 27, ¶ 1 n.5
98. See 35 U.S.C. §§ 101-103 (2000) (providing that in order to obtain a patent under US law, an invention must satisfy the requirements of novelty, non-obviousness, and utility).
100. Mueller, supra note 99.
novelty, non-obviousness, and utility consistently within their own patent regimes.

In April 2007, the Supreme Court tightened the requirements for determining when a combination of existing elements deserves patent protection in *KSR Intern Co. v. Teleflex Inc.* In *KSR*, an exclusive licensee of a patent for a position-adjustable vehicle pedal assembly sued its competitor for infringement. The United States District Court for the Eastern District of Michigan granted summary judgment for the competitor on the ground of obviousness and the licensee appealed. Although the Court of Appeals reversed, the Supreme Court unanimously held that the patent claim was invalid as obvious, since mounting an available sensor on a fixed pivot point of the competitor’s pedal “was a design step well within the grasp of a person of ordinary skill in the relevant art” and the benefit of doing so was obvious.

Even though the *KSR* case involved the patentability of a machine component instead of a pharmaceutical, the language of the opinion is directly relevant to the Indian High Court’s decision rejecting Novartis’s patent application. Specifically, the High Court’s determination that the new version of Glivec did not satisfy India’s Patents Law’s requirement regarding the “enhancement of a known efficacy” is analogous to the U.S. Supreme Court’s discussion of obviousness. In *KSR*, Justice Kennedy reasoned that “[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.” The Supreme Court ultimately relaxed the standards for determining when a requested patent is obvious, thus reducing the number of patents that companies and individuals will likely obtain.

The Indian High Court demonstrated a similar reasoning when it argued that Novartis “is not a novice to the field but on the other
hand it is one of the pharmaceutical giants in the world.” In defending section 3(d) of India’s Patents Act, the High Court reasoned that “[t]he efficacy of a known substance is well-known and it is definitely known to everyone in the pharmaceutical field.” Mirroring the effects of the relaxed obviousness standard for patents in the U.S., the Indian High Court also likely reduced the amount of patents that companies like Novartis will obtain if they fail to meet the efficacy (obvious) standard under India’s Patents Act.

Emery Simon, a supporter of the U.S. Supreme Court’s *KSR* decision and counselor to the Business Software Alliance, argues that the *KSR* decision created a “better opportunity for examiners to weed out patents or applications that are not worthy of getting patents, and it will go a long way toward re-establishing patent quality.” However, in *KSR*, the Court did not clearly define the exact requirements for determining obviousness, thus leaving U.S. standards for determining patentability fairly ambiguous. The Court’s decision indicates that the meaning of the three requirements of patentability in Article 27 may vary over time and that different national governments may adopt different interpretations of those requirements.

The requirements of India’s Patents Act, though broad, are no less restrictive than the TRIPS Agreement requires and are, therefore, fully compliant with TRIPS. Specifically, controversial section 3(d) of India’s Patents Act is no less vague than the minimum standards required in Article 27 of TRIPS. Section 3(d) of India’s Patents Act requires an “enhancement of the known efficacy” of a “new form of a known substance” and goes on to list specifically the elements that are considered to be the same substance. In particular, the section explains:

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

111. *Id.*
113. See *id.*
114. TRIPS Agreement, *supra* note 9, art. 27, ¶ 1.
116. The Patents (Amendment) Act, § 3(d).
117. *Id.*
By including this explanation, India wisely clarified what might otherwise have been completely ambiguous patentability requirements that could have generated arbitrary Indian Patent Board decisions.\footnote{Novartis chose not to pursue an argument against section 2(ja) or (ta) of the Patents Act, which define “inventive step” and “pharmaceutical substance,” respectively. \textit{Id.} \textsection{2(ja),} (ta). The Act defines “inventive step” as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person not skilled in the art.” \textit{Id.} \textsection{2(ja). The Act’s definition of “inventive step” includes a non-obvious requirement that mirrors exactly the language of the TRIPS Agreement. \textit{See TRIPS Agreement, supra} note 9, art. 27. The Act defines a “pharmaceutical substance” as “any new entity involving one or more inventive steps.” The Patents (Amendment) Act, \textsection{2(ta). Novartis probably decided not to object to either of those definitions, which are pertinent to its case involving a pharmaceutical substance, since both definitions involve an “inventive step,” which is specifically listed as one of the key patentability requirements in Article 27 of the TRIPS Agreement. \textit{See TRIPS Agreement, supra} note 9, art. 27, \textsection{1}} Much like the recent U.S. Supreme Court decision in \textit{KSR}, the Indian High Court’s decision against Novartis merely determined that one specific patent application did not meet India’s patentability requirements, which, when translated into Article 27 TRIPS language, meant that Glivec was not “new,” and that the alterations to the drug had not constituted an “inventive step” that was “capable of industrial application.”\footnote{TRIPS Agreement, \textit{supra} note 9, art. 27.}

Although the Indian High Court did not create a specific test for determining when the enhanced efficacy requirement would be met, its methodology is remarkably similar to the logic applied in the \textit{KSR} case in which the U.S. Supreme Court did not clearly outline the criteria for its new “obviousness” test. The Novartis decision could be viewed as the case that began to set boundaries for India’s patent law and helped to determine criteria regarding efficacy. As the Indian High Court rules on more challenges to India’s Patents Act, the growing case law will establish clearer guidelines for future patent seekers.

\section*{B. How India’s Patents Act Reconciles the Doha Declaration and TRIPS Without Relying on Compulsory Licenses}

As discussed above, even if the Indian Patents Act is only analyzed according to the specific language in the TRIPS Agreement (absent the Doha Declaration), section 3(d) still meets TRIPS’s broad standards regarding patentability. However, in addition to analyzing India’s compliance with the TRIPS Agreement according to the specific language of the Agreement, the compatibility of India’s Patents Act with TRIPS must also be considered in light of the Doha
Declaration, which was created to support the “WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”  

While TRIPS was designed to allow WTO members interpretive flexibility regarding intellectual property laws, the Doha Declaration went a step further by emphasizing that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” Since the Doha Declaration was intended to offer additional flexibility with regard to intellectual property protection, the TRIPS Agreement cannot be properly interpreted without also considering the object and purpose of the Doha Declaration.

Realizing the potential conflict between the intellectual property protection guarantees espoused in the TRIPS Agreement and the human rights focus of the Doha Declaration, Novartis claimed that, by bringing its suit against India, it sought to clarify how the two documents worked together. Novartis argued that the “provisions and flexibilities” referred to in the Doha Declaration apply to “compulsory licensing for medicines in case of a national health crisis,” which Novartis asserted was “completely unrelated to patent laws and patentability of medicines.” Compulsory licensing is one method that least developed countries may use to safeguard public health, but Novartis’s statement claiming that compulsory licenses have nothing to do with patent laws is misleading. Compulsory licenses have everything to do with patent law since there is no need for a government to issue them unless patents have already been granted on essential medications.

Although the Doha Declaration specifically mentions compulsory licenses among the many flexible strategies that it permits states to employ to protect public health, the list is not exhaustive when read concurrently with the object and purpose of TRIPS. Specifically, the introduction to the TRIPS Agreement recognizes “the special needs of the least-developed country Members” and offers them “maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”

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120. Doha Declaration, supra note 46, at para. 4.
121. Id.
123. Id.
124. See TRIPS Agreement, supra note 9, pmbl.; Doha Declaration, supra note 46, at para. 5(a).
125. TRIPS Agreement, supra note 9, pmbl.
Compulsory licenses provide governments with a means of circumventing patent law for a limited period. Compulsory licenses may be “granted by the government without the consent of the patent holder, permitting someone else (or the government itself, which is then called ‘government use’) to produce the patented product or use the process.” These licenses serve three main goals: (1) safeguarding the domestic market supply of a patented product, (2) promoting competition by establishing domestic competitors, and (3) promoting a domestic industry. During the negotiations of the TRIPS Agreement, developing countries wanted to give governments broad powers to grant compulsory licenses, while developed countries desired an extremely restrictive approach for granting such licenses. Both groups recognized that the granting of compulsory licenses translates to a suspension of a patent holder’s right, which means that revenue from the patent will also be suspended in the event of an emergency. Unsurprisingly, developed countries hoped to limit the granting of these licenses to protect their revenue while developing countries, many of which had no capability to produce their own pharmaceuticals, desired to create a system in which compulsory licenses could be more easily granted, thus insuring the health of their and the world’s poorer citizens in times of crisis.

Even though compulsory licenses “are no panacea for the lack of access to medicine, [they] are a valuable tool in promoting such access,” and India has one of the world’s “broadest and most comprehensive” compulsory license provisions. India’s liberal laws concerning compulsory licenses may prove extremely valuable during public health emergencies. According to the TRIPS Agreement,

126. See id. art. 31(c).
127. HESTERMeyer, supra note 36, at 239.
129. See WTO OMC, Fact Sheet, supra note 128, at 6.
131. See HESTERMeyer, supra note 36, at 239.
132. Id. at 240 (internal footnote omitted).
compulsory licenses only apply to products and inventions that have been patented in a particular state and can only be issued under circumstances governed by Article 31. In order to issue a compulsory license, a government or third party must first attempt to get authorization from the right holder except in the case of a “national emergency or other circumstances of extreme urgency,” or in cases of “public, non-commercial use.” In addition, “the scope and duration of such use shall be limited to the purpose for which it was authorized.” Furthermore, Article 31(f) mandates that compulsory licenses must be granted “predominantly for the supply of the domestic market” of the country granting the compulsory license. However, the seemingly stringent language of Article 31 takes on a much more flexible meaning when read concurrently with the Doha Declaration.

Paragraph 5(c) of the Declaration provides that

[each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.]

India’s current patent law exhibits a trend toward liberally permitting the issuance of compulsory licenses, including offering them for drugs that are not available for a “reasonably affordable price.” Although India’s patent laws regarding the issuance of compulsory licenses are extremely broad, India has rarely granted them. India’s reluctance to grant compulsory licenses is understandable given that India probably does not wish to risk facing a challenge before the WTO Dispute Settlement Board on the question

134. See TRIPS Agreement, supra note 9, art. 31.  
135. Id. art. 31(b).  
136. Id. art. 31(c).  
137. Id. art. 31(f); see WTO OMC, Fact Sheet, supra note 128 (providing details about how the article has been expanded to include countries that lack the capability to produce their own pharmaceuticals and rely on imports instead).  
138. Doha Declaration, supra note 46, at para. 5(c). The Declaration also recognizes that some WTO members with “insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.” Id. at para. 6.  
140. Mueller, supra note 133, at 108. As of November 16, 2005, India’s Patent Office admitted to issuing less than six compulsory licenses over the entire existence of the Indian patent regime. Id. at 109. These low numbers are likely partially attributable to India’s previous patent law (before 2005) which did not require patents for pharmaceuticals. Id.
of its laws’ compliance with the TRIPS Agreement’s compulsory license requirements. After all, the Doha Declaration clearly does not allow members to disregard the TRIPS Agreement,\(^{141}\) and it is still unclear exactly how the two can be harmoniously interpreted. However, it would clearly be against the object and purpose of the TRIPS Agreement for India to circumvent TRIPS’s requirements by declaring numerous public health “emergencies” and granting compulsory licenses for its patented drugs. Although the Doha Declaration allows members to determine “what constitutes a national emergency,” this safeguard must not be abused if India hopes to avoid opposition from developed WTO member-countries.\(^{142}\) Indeed, India should reserve issuing compulsory licenses for clear public health emergencies in order to avoid overusing the important safeguard.\(^{143}\) By sidestepping its compulsory license laws, India may have successfully, and perhaps unintentionally, reconciled the Doha Declaration and the TRIPS Agreement through the careful construction of section 3(d) of the Patents Act.

Since the WTO has not yet determined exactly how compulsory licenses may be granted without violating either TRIPS or the Doha Declaration, India has attempted to preserve its autonomy as a generic drug superpower by avoiding the issue of compulsory licenses, instead focusing its attention on reworking its patentability standards, as exemplified in section 3(d). The Doha Declaration specifies that compulsory licenses are one method that members may use “to promote access to medicines for all,”\(^{144}\) but members must also read the Declaration in light of the object and purpose of the TRIPS Agreement, which includes allowing least developed countries “maximum flexibility” in implementing their domestic laws.\(^{145}\) Section 3(d) promotes such “maximum flexibility” by attempting to prevent patent evergreening while allowing incremental innovation of already-existing products as long as their efficacy is sufficiently enhanced.\(^{146}\) Therefore, when read in light of both the TRIPS Agreement and the

\(^{141}\) Doha Declaration, \textit{supra} note 46, at para. 5(a).

\(^{142}\) \textit{See id.} at para. 5(c).

\(^{143}\) In determining the types of epidemics that qualify as national emergencies, India should focus on paragraph 1 of the Doha Declaration, which specifically recognizes “HIV/AIDS, tuberculosis, malaria and other epidemics” as grave threats to public health. \textit{Id.} at para. 1. Governments still face opposition from developed countries even when they issue compulsory licenses for the diseases enumerated in the Doha Declaration. \textit{See infra} note 183.

\(^{144}\) Doha Declaration, \textit{supra} note 46, at para. 4.

\(^{145}\) TRIPS Agreement, \textit{supra} note 9, pmbl.

Doha Declaration, section 3(d) satisfies TRIPS’s requirements and presents a method for developing countries to apply favorably the requirements of both agreements without relying too heavily on compulsory licenses.

Although Novartis claimed that it brought its suit against India, at least partially, to clarify how TRIPS and the Doha Declaration worked together, Novartis clearly wanted its application for Glivec granted to ensure that India would interpret its Patents Act more liberally and grant more patents for pharmaceuticals. If India had granted Novartis’s patent for Glivec and then attempted to issue a compulsory license on the patented drug, Novartis would have been in a much better position to oppose India’s action since it would already have legal rights under both Indian patent law and the TRIPS Agreement. Because the legal foundations for granting compulsory licenses are limited to a narrow set of circumstances and there are often political obstacles to granting such licenses, even when read in light of the Doha Declaration, it is in the best interest of pharmaceutical companies to pursue patents on as many drugs or variations of drugs as possible with the knowledge that they will have guaranteed legal protection under a given state’s patent law and TRIPS. In short, it is better to be a rights holder subject to the risk of compulsory licenses than not to be a rights holder at all. Instead of interpreting India’s Patents Act to allow for such possibilities, the Indian High Court dashed Novartis’s hopes for establishing a precedent favorable to the pharmaceutical industry when it upheld section 3(d).

147. Press Release, Novartis, supra note 122.

148. The High Court’s decision against Novartis had exactly the effect on the pharmaceutical industry that Novartis sought to avoid. “With Novartis’s defeat, the pharmaceutical industry began to strategically review its mailbox filings, and its new filings as well, to weed out the clearly unmeritorious applications.” Baker, supra note 130, at 1. “The most recent example is further withdrawals by GlaxoSmithKline of two ARV patent applications, on Abacavir and Trizivir.” See id.; see also Novartis v. Union of India, W.P. Nos. 24759 & 24760 of 2006 (Madras H.C. June 8, 2007), available at http://judis.nic.in/chennai/jqrydisp.asp?fnm=11121 (providing an overview of both sides’ arguments before the Indian High Court).

149. Once a pharmaceutical company secures a patent in a country, it often goes out of its way to prevent the issuance of a compulsory license by negotiating with the country and lowering the price of its drug. See Brazilian President Silva Issues Compulsory License for Merck’s Antiretroviral Efavirenz, MED. NEWS TODAY, May 9, 2007, http://www.medicalnewstoday.com/articles/70154.php.
C. Examining Other WTO Members’ Patent Laws Post-Novartis

Recognizing that the Novartis decision has far-reaching implications not just for Indian patent law, but also for the equivalent laws of all WTO members, this section compares the controversial passages of India’s Patents Act to similar sections contained in other prominent WTO members’ patent laws. Since the TRIPS Agreement was developed “to narrow the gaps in the way [intellectual property] rights are protected around the world, and to bring them under common international rules,” all members are equally responsible for enforcing a uniform system of standards for intellectual property protection. India’s Patents Act has been subjected to international scrutiny regarding its compliance with the TRIPS Agreement since it was amended in 2005, and the debate intensified following the Novartis decision. The tension between the developed countries that house the pharmaceutical industry and the third world was highlighted in the Novartis decision since nearly forty countries have granted patents for the beta crystal form of Glivec, while India decided that the new form did not warrant a patent.

Although it is important to compare India’s Patents Act to the standards set forth in the TRIPS Agreement, it is equally important to compare India’s new patent regime to similar laws of its fellow WTO members whose patent laws have not faced such strict scrutiny in the international spotlight. A direct comparison between India’s “enhanced efficacy” standard regarding “new forms of a known substance” and equivalent laws of other WTO members reveals that both the language and intent behind section 3(d) of India’s Patents Act is extremely similar to the patentability requirements contained in other prominent members’ laws. Therefore, if India’s Patents Act

150. This section examines the equivalent laws of other WTO members on a purely textual level and does not address surrounding case law since it is beyond the focus of this note. Furthermore, an examination of other members’ case law would not serve as a fair comparison with India’s Patents Act since India has not had an opportunity to develop its case law as extensively as other member states.


152. See Novartis.com, Frequently Asked Questions, supra note 73.

153. See Posting of Shamnad Basheer to SPICY IP, supra note 90 (explaining that the Mashelkar Committee was in part established to compare India’s new Patents Act to similar laws of other WTO Members).

154. See supra Part II(C). This section only compares other WTO members’ laws to section 3(d) of India’s Patents Act since it was the primary subject of contention in the Novartis case.
does not satisfy TRIPS’s requirements, the patent regimes of other WTO members are equally suspect.

1. United States Patent Law

United States patentability requirements are broad and offer little qualification on their face. Specifically, the law provides that “[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, subject to the conditions and requirements of this title.” Since a patent may be granted for “new and useful improvements” to already-patented inventions, U.S. patent law clearly allows for incremental innovation; however, the exact standards for determining what constitutes a “new” or “useful improvement” are not contained in the statute itself.

The U.S. Patent and Trademark Office elaborates on U.S. patentability requirements and asserts that “[t]he subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be nonobvious to a person having ordinary skill in the area of technology related to the invention.” The office places limits on what may be patented on the grounds of “obviousness” by disallowing minor, insignificant changes in an already-patented invention. Specifically, the office explains that “the substitution of one color for another, or changes in size, are ordinarily not patentable.” In this manner, the U.S. protects the ability of patent applicants to improve upon already-existing inventions while preventing the practice of patent evergreening. Indian law attempts to strike this same balance by disallowing a
2. United Kingdom Patent Law

The United Kingdom allows patents for inventions that are “new,” involve an “inventive step,” and are “capable of industrial application.” The U.K. Intellectual Property Office explains that “a claim to a tablet of a particular shape or structure would be acceptable if this resulted in a particularly favourable release profile for the active agent.” The office does not elaborate on what qualifies as a “particularly favourable release,” but instead goes on to specify that if an alteration to an already-patented substance’s “new shape or form is merely presentational or conveys information . . . , then it represents either an aesthetic creation or a mere presentation of information,” which “are not in themselves patentable.” In other words, the U.K. has allowed for patentable incremental innovation of pharmaceutical substances while protecting against evergreening by preventing the patenting of merely “aesthetic creations.” The U.K. does not define “particularly favourable release,” much like the Indian Patents Act does not define “significantly . . . with regard to efficacy.” For clarification, one must turn to either country’s case law or other instances in which the patent offices of the countries have granted patents using their respectively broad language in order to determine what new developments in already-patented substances qualify for new patents.

3. Chinese Patent Law

In order for an invention to qualify for a patent in China, it “must possess novelty, inventiveness and practical applicability.”

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165. Id.
166. Id.
The law specifically qualifies “inventiveness” by defining a new invention as one that demonstrates “prominent substantive features and represents a notable progress.”168 The law does not specifically explain what new features of an already-patented invention satisfy the “notable progress” component of the “inventiveness” requirement.169 Similarly to the Indian Patents Act, Chinese patentability requirements remain broad and allow for examination of inventions on a case-by-case basis.

When compared to other prominent WTO Members’ patentability requirements, section 3(d) of India’s Patents Act contains similarly broad and unqualified language.170 India’s “enhanced efficacy” requirement is equally as broad as the U.S.’s “useful improvement” language, the U.K.’s “particularly favourable release” requirement, and China’s “notable progress” patentability requirement.171 Even when directly compared with the patentability requirements of India’s fellow WTO members, the Indian Patents Act is just as compliant or non-compliant with the TRIPS Agreement’s standards as other members’ laws.

III. A HEALTHY SOLUTION FOR INDIA AND OTHER DEVELOPING COUNTRIES

India should stand by section 3(d) of its Patents Act and not succumb to international pressure to recreate its patent regime according to the interests of both pharmaceutical companies and developed countries. Instead, India’s Patent Office should attempt to clarify its patentability standards by providing a more detailed Web site that would explain and give at least one example of a known substance that demonstrates an enhanced efficacy, thus meriting a patent. Additionally, India should continue to preserve its role as a valued pharmacy to the third world by carefully scrutinizing patent applications to help prevent evergreening. Finally, other developing countries should follow India’s lead by maintaining their compliance with the TRIPS Agreement’s and the Doha Declaration’s standards.

168. Id.
169. Id.
while enacting stricter patent regimes instead of relying heavily on compulsory licenses.\footnote{Some developing countries have already recognized the powerful implications of section 3(d) of India’s Patents Act and have begun modeling their laws on India’s. See Gireesh Chandra Prasad, \textit{Copycats Popping Patent Law Pill}, ECON. TIMES, Aug. 13, 2007, \texttt{http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare\_Biotech/Pharmaceuticals/Copycats_popping_patent_law_pill/articleshow/2276358.cms} (“More than 10 countries in the Asia-Pacific region are planning to adopt the much-debated provision which makes it difficult for drug makers to get patent protection for anything less than breakthroughs in pharmaceutical research. The provision describes what sort of pharmaceutical substance is worthy of a patent. The idea is to prevent companies from blocking the entry of cheaper rival products by passing off old medicines in new bottles as patent-worthy inventions.”).}

Novartis’s case against the Indian government subjected the Indian Patents Act to scrutiny from the developed world. While the broad language of section 3(d) is compliant with TRIPS’s standards when compared directly to TRIPS’s language, the Doha Declaration, and similar laws of other WTO members, it would still be prudent for the Indian government to clarify which types of innovations to already-patented inventions satisfy the “substantially enhanced efficacy” requirement. Had the Indian High Court offered some guidance on how “enhancements might be quantified, such as in terms of fewer side-effects or lower dosages,”\footnote{Novartis Patent Challenge Dismissed in India, supra note 1.} then the government would be able to better defend the language of section 3(d).

Ideally, India’s Patent Office should demystify the entire patenting process by providing guidelines and instructions on how to search for patentable substances on its Web site, much the like U.S. Patent and Trademark Office exhibits on its detailed site.\footnote{See, e.g., United States Patent and Trademark Office Home Page, \texttt{http://www.uspto.gov/main/patents.htm} (last visited Feb. 21, 2008) (indicating the type of information that could be exhibited on the Indian Patent Office’s Site). Although India has a Web site for its Patent Office, the information available on the site is limited and, as of February 21, 2008, contained no information relating to explanations or interpretations of patentability requirements. See Office of Controller General of Patents, Designs and Trademarks Home Page, \texttt{http://www.patentoffice.nic.in/} (last visited Feb. 21, 2008).} More detailed information regarding patent requirements from India’s Patent Office would be especially helpful given that India’s Patents Act is not supplemented with extensive case history or judicial interpretations like many of its fellow WTO members that have older, more established patent regimes. Although other WTO members’ laws contain similarly vague language concerning their patentability requirements, the developed countries of the world are able to reinforce their requirements with case law and numerous examples of
both approved and denied patent applications.\textsuperscript{175} As is the case with other developing countries, India’s patent regime is so new that more guidance regarding its specific requirements is needed in order to facilitate better investment and trade relations with other WTO Members.

The patentability requirements set forth in section 3(d) of the Patents Act reveal the Indian government’s clear desire to promote incremental innovation while discouraging frivolous patent evergreening.\textsuperscript{176} Unfortunately, it is difficult to distinguish between the two practices on paper since each “enhancement” to an already-patented invention must be evaluated on a case-by-case basis.\textsuperscript{177} In some respects, it is important for patent law language to remain broad so that it does not limit invention. India is on the right track with its Patents Act, but India’s Patent Office should expand upon the language of section 3(d) to include at least one example of a previously known substance that demonstrates an “enhancement of the known efficacy” of the substance. Doing so would prevent a flood of futile patent applications and clarify its laws for future applicants.

Although India is currently considering amending the controversial language of section 3(d), the government should not fold to criticism from developed WTO members. If India amends its patent law again, the action would signal major vulnerability within the Indian patent regime and could open the door to even more challenges and amendments following other denied patent applications. India’s patent law, while new, measures up to similar laws of its fellow WTO members, and the Indian government should stand behind it as such.\textsuperscript{178} While India’s hesitancy to defend its Patents Act vigorously is understandable given the country’s limited experience with product patents, now is the time for the Indian government to project confidence in its patent regime. As more case law is generated and India’s Patent Office grants more patents, the requirements of section 3(d) will become clearer. On the reverse side, pharmaceutical companies should not be discouraged from submitting more patent applications, but should instead view each application as an


\textsuperscript{176} See Ali K, \textit{supra} note 31.


\textsuperscript{178} See \textit{supra} notes 170-71 and accompanying text.
opportunity to learn specifics about the types of new or “enhanced” substances that the government deems patentable.

Although India would inspire more confidence in its new patent regime if it began granting patents on a more regular basis, one should expect the Indian Patent Office to move slowly and cautiously in granting patents as its employees accustom themselves to the new concepts and standards. India is not averse to granting pharmaceutical patents, as evidenced by the patents it has already granted for a Hepatitis C medicine and for an HIV/AIDS drug, Celzentry.\(^\text{179}\) However, the country is understandably hesitant to grant too many patents too soon given its concern with protecting its successful and critical generic market and its status as the “Pharmacy of the Third World.”\(^\text{180}\)

Novartis was adamant in asserting that its case against India was not about compulsory licenses,\(^\text{181}\) yet the company would have been in a much stronger legal position if India had granted a patent for Glivec and then attempted to issue a compulsory license for the drug. Knowing this, Novartis made it clear that it “fully supports flexibilities in the TRIPS agreement that allow governments to make exceptions to patent rights and import pharmaceuticals produced under compulsory license in case of a national emergency or a lack of supply from the patent-holders.”\(^\text{182}\) Although the WTO recognizes the need for compulsory licenses in order to combat threats to global health such as HIV/AIDS and the avian flu, it still discourages the extended use of such licenses.\(^\text{183}\)

As it is not yet clear exactly how the TRIPS Agreement and the Doha Declaration reconcile the ability of WTO members to issue


182. Id.

compulsory licenses in cases of national emergency, as defined by the state declaring the emergency. India has avoided losing a potential WTO challenge to its broad laws on the subject by not invoking them. The WTO would likely take issue with an Indian attempt to issue compulsory licenses, on the basis of price, on patented medicines for potentially limitless periods. Instead of making use of its liberal, but almost certainly challengeable compulsory licensing laws, India has chosen to limit the number of patents it grants by wording section 3(d) carefully in order to prevent evergreening. In this manner, India has successfully demonstrated a legal option for other developing countries that are unable to afford patented medicines or to produce their own generic versions of patented medications.

Instead of predominately relying on compulsory licensing to protect public health, more developing countries should follow India's example and create stricter patent laws that prevent evergreening while still adhering to the requirements and allowances of TRIPS and the Doha Declaration. After all, if a government is more discriminating in determining which substances are patentable, then fewer patents will be granted and the need to rely on compulsory licenses will decrease. Additionally, pharmaceutical companies will be further discouraged from attempting to evergreen their products at the expense of patients. Instead, drug developers will be encouraged to create substances that demonstrate true advances in effectiveness and/or previously unknown and valid second uses for existing substances.

IV. CONCLUSION

India has been wisely cautious in granting patents for pharmaceuticals. Its decision not to grant Novartis's patent for Glivec is evidence of its dedication to preserving its role as a third world medicine supplier, all the while upholding the requirements of the TRIPS Agreement. Had Novartis won its case against the Indian government, it could have opened the door to establishing a broader practice of granting patents for inventions that resulted from

184. See supra Part II(B).
185. See supra notes 141-42 and accompanying text.
186. See id.
187. See Prasad, supra note 172 (“More than 10 countries in the Asia-Pacific region are planning to adopt the much-debated provision which makes it difficult for drug makers to get patent protection for anything less than breakthroughs in pharmaceutical research.”).
188. See supra Part II.A.
evergreening.  As long as India continues to abide by TRIPS’s standards, while continuing to clarify the patentability standards contained in section 3(d) of the Patents Act, the Indian High Court’s decision should not be challenged in the WTO Dispute Settlement Body.

Although India’s Patents Act satisfies TRIPS’s requirements, the broad language of section 3(d) requires clarification. If India’s Patent Office would provide patent seekers with some minimal guidance regarding the type of previously known substance that exhibits a patent-worthy enhanced efficacy, then applicants would be able to determine the probability of their application’s success. A more transparent patenting process would increase the efficiency of the system and reinforce the legitimacy of India’s patent regime. As more patent applications are approved and denied and more case law is generated, patent seekers in India will find increasingly greater clarity regarding Indian patentability requirements. Pharmaceutical companies must be patient with India while the country’s Patent Office familiarizes itself with new legal concepts.

India’s patent process remains slow as the country attempts to navigate its way through challenging legal concepts, conflicting WTO guidance exhibited in both the TRIPS Agreement and the Doha Declaration, and international pressure to amend its patent laws. However, despite these major hurdles, India has discovered a legal method with which to preserve its role as a powerful generic drug manufacturer. Instead of relying on its vast compulsory licensing laws, which would likely face WTO challenges given the broad range of reasons that India allows for granting them, India chose to limit carefully the number of patents it grants for new forms of known substances in order to prevent patent evergreening. Although section 3(d) of India’s Patents Act may seem particularly ambiguous, it is almost identical in both wording and purpose to similar laws of other WTO Members. Thus, before other countries criticize the most controversial portion of India’s patent law, they should reevaluate the wording and reasoning behind their own equivalent laws.

189. See Bidwai, supra note 31.
190. See Novartis Patent Challenge Dismissed in India, supra note 1.
191. See Bidwai, supra note 31.
192. See supra note 175 and accompanying text.
193. See Posting of Bibek Debroy, supra note 102.
194. See id.
195. See supra notes 141-42 and accompanying text.
196. See supra Part II.C.
Other developing countries would benefit from following India’s example by espousing confidence in their own patent laws instead of relying on emergency compulsory licenses, which almost always face severe opposition from powerful companies and developed countries. India’s bold handling of the Novartis case reveals that developing countries are capable of standing up to developed countries on human rights issues while satisfying their international legal obligations. India’s legal solution turned out to be a healthy one as well.

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