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Indian Patent Law: Walking the Line

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INTRODUCTION

Every day countless lives are saved by drugs produced by pharmaceutical companies. These life-saving drugs demonstrate the incredible medical advances that can be achieved through research and development. These drugs, however, do not come cheaply. Pharmaceutical companies expect high returns from their successful drugs and rely on profits generated through patents to recoup the sunk costs of research and development.[1]

The World Trade Organization (WTO) has set an international standard for patent protection, to which all members are expected to conform. India, however, has recently come under scrutiny for imposing its own narrow interpretation of patent rights and stands accused of violating its obligations as a WTO Member.

In 2005, India denied Swiss pharmaceutical Novartis a patent for its cancer drug Glivec because it did not demonstrate "enhanced efficacy" as required by Section 3(d) of the Indian Amended Patents Act of 1970.[2] Novartis challenged this decision by appealing to both the Indian Patent Office and the Indian judicial system.

On August 6, 2007, the Indian High Court of Madras ruled against Novartis, holding that Section 3(d) of the Indian Amended Patent Act of

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[1] United Nations Conference on Trade and Development, *Debating Pharmaceutical IPRs—A Joint UNCTAD-Stockholm Network Event*, Geneva, Switz., Feb. 20, 2007, *available at* http://www.unctad.org/sections/dite_totip/docs/dite_pcbb_ias0048_en.pdf.

[2] Indian Patent Office, *In the matter of application for Patent No. 1602/MAS/98*, Jan. 25, 2006 [hereinafter IPO Decision].

1970 (Patent Act) was constitutional.[3] Additionally, the Court held that it had no authority to decide whether or not this Section was in violation of the WTO's Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS).[4] The Novartis challenge was the first case to directly confront the Amended Indian Patent Act, and its result has confirmed that Indian courts interpret patent laws quite narrowly.

The decision came as a relief to human rights organizations and a disappointment to the pharmaceutical industry.[5] Human rights organizations feared that a broad reading of the Patent Act would have a detrimental impact on a key Indian industry—generic pharmaceuticals.[6] This industry is pivotal in providing low cost drugs not only to the general Indian population, but also to developing countries that do not have the capabilities of producing drugs themselves, and whose citizens cannot afford the high price of name-brand drugs.[7]

Pharmaceutical companies worried that a narrow interpretation of Indian patent law would result in fewer patents being issued. This in turn would reduce the incentive to invest in research and development, and could potentially stifle the development of improved drugs.[8]

This comment proposes that cultural preferences have had a strong influence over the development of Indian patent law, and that these preferences influenced the court decision against Novartis. Part I will introduce TRIPS and international patent law, discuss the development of Indian patent law in the context of its colonial past and WTO membership, and explain the decisions by the Indian Patent Office and the Court of Madras in the context of Glivec's development. Part II will explore WTO attitudes and approaches to TRIPS and argue that if Switzerland were to bring India to the WTO's Dispute Settlement Board (DSB), it would be unsuccessful due to the liberal nature of TRIPS and the DSB's history of giving discretion to individual countries to interpret their TRIPS obligations. Part III will conclude by arguing that despite the Glivec decision, pharmaceutical investment in India will not be stifled, but continue to grow due to the relatively low cost of investment and highly skilled work force.

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[3] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).

[4] *Id.* para. 8.

[5] Amelia Gentleman, *Indian Law on Generic Drugs is Upheld*, INT'L HERALD TRIB., Aug. 6, 2007, *available at* http://www.iht.com/bin/print.php?id=7005552.

[6] *Id.*

[7] *Id.*

[8] *Id.* The incentive mentioned by pharmaceuticals is money obtained from the exclusive rights to their patented drugs. *Id.*

I. THE DECISIONS OF INDIA'S PATENT OFFICE AND COURT ARE NOT SURPRISING WHEN VIEWED IN CONTEXT WITH THE DEVELOPMENT OF INDIAN PATENT LAW

A. Intellectual Property Rights and TRIPS Generally

The purpose of an intellectual property right is to give social and economic recognition to people for the creations of their minds.[9] As international trade has increased over recent decades and ideas are more frequently exchanged in global arenas, the need for harmonized intellectual property laws has emerged. The push for harmonization culminated in the formation of the WTO's Trade Related Aspects of Intellectuals Property Rights Agreement (TRIPS).[10] TRIPS came into force on January 1, 1995 as a result of the 1986–1994 Uruguay Round Negotiations.[11] TRIPS recognizes seven classes of intellectual property rights: (1) copyright and related rights; (2) trademarks; (3) geographical indications; (4) industrial designs; (5) patents; (6) layout designs of integrated circuits; and (7) protection of undisclosed information.[12]

Particularly, TRIPS Article 27.1 provides that "patents shall be available for any inventions . . . provided that they are new, involve an inventive step and are capable of industrial application."[13] Article 27.2 provides that members may deny patents to the extent necessary to protect "*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment . . . ."[14] The term of exclusivity articulated by Article 33 is twenty years counted from the date of filing.[15]

Once TRIPS came into force, developing countries, such as India, were given a period of five years to harmonize their patent laws with TRIPS.[16] India took the full five years and then a five year extension before becoming fully compliant.[17] As of January 1, 2005, India amended

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[9] Praveen Dalal, *Indian Patent Law—Some Reflections*, IPFRONTLINE.COM, July 25, 2006, http://www.ipfrontline.com/depts/article.asp?id=11882&deptid=6; WTO—TRIPS—What Are Intellectual Property Rights?, http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm (last visited Feb. 2, 2009).

[10] WTO—TRIPS—What are Intellectual Property Rights?, *supra* note 9.

[11] WTO—TRIPS—Frequently Asked Questions, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Feb. 2, 2009) [hereinafter WTO FAQ].

[12] Agreement on Trade-Related Aspects on Intellectual Property Rights, Jan. 1, 1995, 33 I.L.M. 1125 (1994) [hereinafter TRIPS].

[13] *Id.* at art. 27.1.

[14] *Id.* at art. 27.2.

[15] *Id.* at art. 33.

[16] WTO FAQ, *supra* note 11.

[17] *Id.*

its Patent Act in an effort to be fully compliant with TRIPS.[18] One question raised by Novartis, and explored by this comment, is whether or not India is in fact fully compliant with TRIPS.

B. Indian Culture had a Strong Influence on the Development of Patent Law

India's strong anti-patent sentiment is clearly illustrated by Indian Prime Minister Indira Gandhi's recent assertion that "[t]he idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering for life and death."[19] Traditionally, Indian knowledge has not been protected through legal means.[20] In fact, knowledge sharing is the norm in India. For example, Indian classical music is not copyrighted, Bollywood scripts closely mimic U.S. films, and until 1995, pharmaceutical drugs could not legally be patented.[21] One result of India's cultural and legal tendencies against protecting intellectual property is the development of a thriving generic drug industry.[22] This industry uses reverse-engineering to copy patented drugs and produce them at very low cost.[23] The strong generic industry is a direct result of highly protectionist Indian patent law.

1. India's Colonial History Influenced Its Attitude Toward Patent Protection

India was an English colony until 1947.[24] Prior to its independence, India's patent laws were based on those found in England and were embodied in the Indian Patents and Design Act of 1911.[25] Under this system, eighty to ninety percent of India's patents came to be held by foreigners.[26] Concerned that foreigners would gain undue influence over India's economy, in 1948 (and again in 1957) Prime Minister Jawaharla Nehru formed a government committee to evaluate the patent system.[27]

The committee results asserted that India's patent system was allowing foreigners to "achieve monopolistic control over the market" in major

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[18] *Id.*

[19] Indira Gandi, *Address Before the World Health Assembly, Geneva (May 1982), in* INTELLECTUAL PROPERTY RIGHTS: GLOBAL CONSENSUS, GLOBAL CONFLICT? 186 (R. Michael Gadbaw & Timothy J. Richards eds., 1988).

[20] Suketa Mehta, *Owning Om*, YOGA AND JOYFUL LIVING, Dec. 2007, at 68.

[21] *Id.*; WTO FAQ, *supra* note 11.

[22] Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J., 911, 920 (2003).

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

industries such as food, chemicals, and pharmaceuticals.[28] Specifically with regard to pharmaceuticals, the committee found that the general public was unable to afford medications and the drug-price index was increasing.[29]

In response to these findings India passed the Patent Act of 1970.[30] This Act's purpose was to prevent patentees from enjoying a monopoly over a patented article, and to protect and prioritize the public interest.[31] Through this Act, India set forth a protectionist agenda aimed at promoting Indian business and establishing strong domestic industries.

The Patent Act of 1970 created a very weak system for protecting pharmaceuticals in particular. In fact, drugs could not be patented.[32] The Act only allowed for the patenting of "process claims covering methods of their manufacture."[33] This provision allowed for a robust generic pharmaceutical industry to develop.[34]

By using reverse engineering and slightly altering the production processes of patented drugs, Indian generic pharmaceuticals were able to create less expensive versions of the patented drugs that were then distributed to the greater population.[35] Additionally, patents expired after a term of five years from the date of issue or seven years from the date of filing, whichever was shorter.[36] The results of this system were impressive. At the time of independence, India's pharmaceutical industry was insignificant.[37] By the 1990's however, "Indian companies control[led] seventy percent of the domestic formulations market and eighty-five percent of the bulk drugs market."[38]

2. WTO Membership Caused a Shift in Indian Patent Law, but Not in Indian Attitudes

After India joined the WTO in 1995, it was required to bring its own patent laws up to the standard set forth by TRIPS. Because the WTO set out extended deadlines for developing countries such as India, it was able to postpone TRIPS compliance until January 1, 2005, ten years after its

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[28] Barnes, *supra* note 22, at 920.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

[34] Juan Bacalski, *Mexico's Pharmaceutical Patent Dilemma and the Lesson of India*, 23 ARIZ. J. INT'L & COMP. L. 717, 728–29, 734 (2006).

[35] *Id.* at 718.

[36] Barnes, *supra* note 22, at 921.

[37] *Id.* at 924.

[38] Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND J. TRANSNAT'L L. 507, 527 (1996).

joining.[39] Although a transition period was allowed, India assumed immediate obligations that required specific provisions be initiated to ensure patent application priority and exclusive marketing rights. India's failure to legally implement these changes lead to two WTO disputes.[40]

In 1996 and 1997, parallel complaints brought by the United States and the European Community challenged India's compliance with TRIPS under Articles 70.8 and 70.9.[41] The complaints alleged that India failed to implement both a legally sufficient "mailbox system" within the meaning of TRIPS Article 70.8, and a system of exclusive marketing rights under Article 70.9.[42]

The United States argued that "[b]ecause India had failed to establish a fully functional mailbox system that granted mailbox applications the legal status required by the TRIPS Agreement as of their priority filing date, large numbers of applications that would have been filed were currently being withheld until India established such a system."[43] India asserted that its current "mailbox system," based solely on administrative practice and which had not been formalized by Indian law, was sufficient to fulfil its TRIPS obligations. The panel held that India's "mailbox system" was inconsistent with TRIPS Article 70.8 because it did not offer a "means" by which patent applications could securely be filed. Likewise, the panel found India in violation of Article 70.9 by offering no means of exclusive marketing rights for the interim period between filing a patent application and being granted or denied a patent.

Political reaction to the panel's findings illustrates India's resistance to changes in their patent law.[44] Lawmakers agreed that no amendments would be made to Indian law without a consensus and one opponent of change stated "[w]e will see that pressure applied by external forces does not affect our independent decision."[45]

India appealed the decision of the panel and the appellate body

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[39] Prabhu Ram, *India's New "TRIPS-Compliant" Patent Regime Between Drug Patents and the Right to Health*, 5 CHI.-KENT J. INTELL. PROP. 195, 195 (2006).

[40] Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS79/R (Aug. 24, 1998); Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R (Sept. 5, 1997); Appellate Body Report, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997). Because the complaints were almost identical, this comment will refer solely to the U.S. complaint, DS50.

[41] Panel Report, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R (Sept. 5, 1997).

[42] *Id.*

[43] *Id.* para. 5.4.

[44] Vasuki Rao, *India Plans Committee on Patent Law Reform*, J. COM., Aug. 21, 1997, at A4.

[45] *Id.*

affirmed.[46] As a result of these decisions, India passed the Patents (Amendment) Act of 1999, which brought its patent law into conformity with the panel findings.[47] The political reaction and resistance to change is not surprising given India's long journey toward compliance.[48] Although India had putatively been in full compliance with the requirements set forth by TRIPS as of 2005,[49] Novartis' challenge to India's Patent Act has called India's compliance into question.

3. Section 3(d) of India's Patents Act is Raising Questions Relating to Both Indian and WTO Law

Section 3(d) is at the heart of discussions questioning India's compliance with TRIPS. Despite the controversy surrounding Section 3(d), Novartis' challenge is the only one to have been brought before the Indian courts.[50] Due to its vague, and potentially very limiting meaning, Section 3(d) was challenged by Novartis as being contrary to both local Indian law and WTO international law.

Section 3(d) provides that:

> 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 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 purpose 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

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[46] Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/7 (Dec. 19, 1997).

[47] Status Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/10/Add.3 (Mar. 9, 1999).

[48] Ram, *supra* note 39. India's Parliament insisted on a ten year transition period to TRIPS compliance. Rishi Gupta, *TRIPS Compliance: Dealing with the Consequences of Drug Patents in India*, 26 HOUS. J. INT'L L. 599, 615 (2004).

[49] WTO FAQ, *supra* note 11.

[50] Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENG. J. MED. 541, 542 (2007). Other controversial provisions of the Amended Patent Act of 1970 include the Compulsory Licensing requirement (allowing the government to grant a license to an Indian firm to produce a patented drug without the consent of the patent owner) and the Mailbox Application provisions (offering no protection to patent applications filed between 1995-2005 against infringers aside from the payment of "reasonable royalties" by the manufacturer of the generic version of the drug). The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

differ significantly in properties with regard to efficacy.[51]

According to this provision, a known drug cannot be patented unless the "known efficacy" of the substance has been enhanced. The Act provides no test or guidelines for determining enhanced efficacy.

One of the primary purposes for this provision was to prevent the evergreening of a patent.[52] The process of evergreening occurs when a company makes a change to a patented product through "incremental innovation," and thus obtains a new patent for its product.[53] Through evergreening pharmaceutical companies are able to extend the life of their patents, thereby protecting money invested in research and development.

India has used the "enhanced efficacy" concept to differentiate genuine innovation from evergreening.[54] Although the High Court stated that efficacy could be defined as "the ability of a drug to produce a desired therapeutic effect," the Court failed to define any factors to differentiate the genuine innovation from mere incremental innovation unworthy of a patent.[55]

Although proponents of human rights organizations have commended efforts to reduce evergreening, representatives of the pharmaceutical industry argue that without recognition of incremental innovation pharmaceutical companies will lose the incentive to invest in the research and development of patented drugs and "patients will be denied new and better medicines."[56] Pharmaceutical companies argue that breakthrough innovations, though important, are rare,[57] and that it is through incremental innovations that many important advances are made. Examples of incremental innovation include improved safety and effectiveness of the drug, fewer side effects, greater stability during storage and transport, and new formulations of the product aimed at specific patient groups such as children.[58] Additionally, it is argued that without strong patent protection, the Indian pharmaceutical industry will be unable to transform from a

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[51] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 3(d).

[52] *Novartis*, 2007 A.I.R. 24759; *Novartis Patent Challenge Dismissed in India*, BRIDGES WKLY. TRADE DIG. NEWS, Sept. 5, 2007, http://ictsd.net/i/news/bridgesweekly/7819/ [hereinafter *Novartis Dismissed*].

[53] Gentleman, *supra* note 5.

[54] *Novartis Dismissed, supra* note 52.

[55] *Id.*; *Novartis*, 2007 A.I.R. 24759.

[56] *Novartis Dismissed, supra* note 52.

[57] Press Release, PhRMA, Indian Court Decision Weakens Incentives for New Innovations that Benefit Patients (Aug. 6, 2007) *available at* http://www.phrma.org/news_room/press_releases/indian_court_decision_weakens_incentives_for_new_innovations_that_benefit_patients/.

[58] *Id.*

generic leader into an innovator.[59] Despite strong arguments against India's current interpretation of Section 3(d), India's treatment of patent applications is unlikely to change unless Switzerland complains successfully to the WTO.

C. Novartis Was Unsuccessful in Its Application to the Indian Patent Office and in Its Judicial Challenge

Following the development of Glivec, Novartis took steps to obtain a patent in India. Its efforts were unsuccessful and resulted in an appeal to the Indian Patent Office as well as the Indian Courts.

1. The History of Glivec

Glivec is a drug developed by the Swiss pharmaceutical company Novartis and is used to treat two specific types of cancer: chronic myeloid leukemia and gastrointestinal stromal tumors.[60] Glivec[61] is based on the molecule imatinib.[62] In 1993, Novartis obtained patents in the United States as well as the European Patent Office for synthesizing the molecule imatinib.[63] Novartis later developed "the mesylate salt of imatinib and then the beta crystal form of imatinib mesylate to make it suitable for patients to take in pill form."[64] Glivec was launched globally in 2001 and is the only form of Glivec marketed to date.[65]

When imatinib was developed in 1992, it was ineligible for a patent in India because pharmaceutical products were not offered such protection.[66] At that time India did not offer protection for drugs themselves.[67] The only protection offered was a patent for the exact process used to create the drug.[68] The "beta crystalline" form of the molecule was developed for patients to take as a pill and launched as Glivec in 2001.[69]

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[59] *Id.*

[60] Novartis, Glivec Patent Case in India: FACT vs. FICTION, http://www.novartis.com/downloads/about-novartis/facts-vs-fiction-india-glivec-patent-case.pdf (last visited Feb. 2, 2009) [hereinafter FACT vs. FICTION].

[61] Glivec is marketed as "Gleevec" in the United States. *See* Novartis Pharmaceuticals, http://www.novartis.com/products/pharmaceuticals.shtml (last visited Feb. 2, 2009).

[62] Novartis, Addressing Innovation Dilemmas in Emerging Markets: Glivec Case Advances Debate in India, http://www.novartis.com/downloads/newsroom/Dilemmas_in_emerging_markets-Glivec.pdf (last visited Feb. 2, 2009) [hereinafter Addressing Innovation].

[63] IPO Decision, *supra* note 2, at 2.

[64] FACT vs. FICTION, *supra* note 60.

[65] *Id.*

[66] *Novartis Dismissed, supra* note 52.

[67] *Id.*

[68] *Id.*

[69] *Id.*

Because of its status as a developing country, India was not required to comply fully with TRIPS until 2005.[70] In the interim period between 1995, when TRIPS came into force, and 2005, when India was required to be fully TRIPS compliant, India introduced a system of "exclusive marketing rights."[71] Novartis was granted exclusive marketing rights for Glivec, which allowed it to market and sell Glivec exclusively for five years or until its patent application was either accepted or rejected by the Indian Patent Office (IPO), whichever was earlier.[72] The attainment of exclusive marketing rights did not guarantee Novartis a patent and was strictly a function of procedure mandated by the WTO.[73]

2. Novartis Unsuccessfully Attempted to Patent Glivec in India

Once India was fully compliant with TRIPS, the IPO began considering previously filed patent applications such as Novartis' application for Glivec. Novartis' application for Glivec was denied.[74]

Cancer Patients Aid Association, India (CPAA) formally opposed the patent application.[75] Novartis' denial was based on three conclusions made by the IPO: (1) imatinib mesylate was a known substance that was disclosed as imatinib in patents issued in the United States and other countries in 1993; (2) the discovery of imatinib mesylate was "obvious"; and (3) imatinib mesylate did not meet the Section 3(d) "enhanced efficacy" requirement.[76]

Arguing that imatinib mesylate was an unknown substance, Novartis claimed that (1) the free base previously patented as "imatinib" had been changed into a salt form, and (2) a particular crystal form of the salt had been made through human intervention.[77] CPAA claimed that imatinib meyslate salt "inherently existed" in the substance patented as imatinib. Novartis countered by claiming that the 1993 patent for imatinib did not "disclose imatinib mesylate, but merely the corresponding free base."[78]

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[70] Ram, *supra* note 39.

[71] *Infra* Part I.B.ii.

[72] Intellectual Property Office India, Exclusive Marketing Rights, http://www.patentoffice.nic.in/ipr/patent/emr.htm (last visited Feb. 2, 2009); Addressing Innovation, *supra* note 62.

[73] *Infra* Part I.B.ii.

[74] IPO Decision, *supra* note 2. Novartis has appealed this decision and is awaiting a final determination by the Indian Patent Office. Addressing Innovation, *supra* note 62.

[75] *Id.* at 1. This intervention highlights the tension between those advocating liberal patent laws in India for economic reasons and those who favor a more protectionist perspective for human health reasons.

[76] *Id.* at 2–4.

[77] *Id.*

[78] *Id.*

The Patent Office rejected Novartis' argument.[79]

CPAA attacked Novartis' application on further grounds citing obviousness. CPAA claimed that once the free base was disclosed in the 1993 Patent, it would have been "obvious for a person skilled in the art to prepare corresponding pharmaceutically acceptable salts."[80] Despite Novartis' objection that the 1993 patent disclosed "only the free base, and not any salt of imatinib," the IPO agreed with CPAA that imatinib mesylate did not satisfy the non-obvious requirement.[81]

Finally, the IPO addressed Section 3(d).[82] Pursuant to Section 3(d) of the Patents Act, "any salt, polymorph or derivative of known substance is not patentable unless such . . . substance shows enhanced efficacy."[83] Novartis put forth an affidavit by an expert comparing the "relative bioavailability of the free-base with that of the B-crystal form of imatinib mesylate" and found that there was a thirty percent difference in bioavailability.[84] To support its argument that imatinib mesylate was a new product (and more than the "mere discovery of a new form of a known substance"), Novartis argued that the crystal form was not an inherent property of imatinib and that human intervention was necessary to bring about this new compound.[85] The IPO held that the patent application offered a new form of a known substance and did not demonstrate any improvement in efficacy.[86] The IPO rejected the application.

The decision by the patent officer has been appealed and a final decision is pending.

D. Novartis Unsuccessfully Appealed to the Indian Courts

In 2006, in response to the IPO's rejection of its patent application, Novartis filed two writ petitions. One petition challenging the decision of the patent board is ongoing. The second petition asked the court to declare Section 3(d) of the Indian Patent Amendment Act unconstitutional and noncompliant with TRIPS.[87]

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[79] Examining the 1993 patent, the Office found that claims 6 to 23 claimed a "pharmaceutically acceptable salt of the base compound." IPO Decision, *supra* note 2. These points were important to the Patent Office, convincing it that imatinib mesylate was a known substance from the prior applications and is in fact a normally occurring substance in the registered form of imatinib. *Id.*

[80] IPO Decision, *supra* note 2.

[81] *Id.*

[82] *Id.*

[83] *Id.* In an affidavit Novartis notes that "the proviso to the section 3(d) is unique to India and there is no analogous provision in the law of any other country of the world." *Id.*

[84] IPO Decision, *supra* note 2.

[85] *Id.*

[86] *Id.*

[87] *Novartis*, 2007 A.I.R. 24759.

Novartis challenged Section 3(d) of the Amended Patent Act of 1970 on two grounds. They first argued that Section 3(d) was not compliant with TRIPS.[88] Next, they argued that Section 3(d) was unconstitutional.[89] After much discussion regarding the compliance of Section 3(d), the court held that it did not have jurisdiction to decide whether or not Section 3(d) was TRIPS compliant.[90] It then went on to hold that Section 3(d) did not violate India's Constitution.[91]

1. TRIPS Compliance

Novartis' main contention was that Section 3(d) violates Article 27 of TRIPS. Article 27 states that products and processes that are "new, involve an inventive step and are capable of industrial application" are worthy of patents.[92] Article 1(1) of TRIPS provides that "[m]embers shall give effect to the provisions of this Agreement."[93] Novartis argued that because the introduction of Section 3(d) prevented a new form of a known substance from being patented, a right granted under TRIPS Article 27 was taken away.[94]

Defenders of Section 3(d) argued that it is indeed compliant under TRIPS. Counsel proposed that each member country is given enough "elbow room to bring in a local law in discharging their obligation under 'TRIPS' having regard to the various needs of their citizens."[95] Emphasis was placed on the fact that India is a "welfare country" and that its first obligation is to its citizens and their good health.[96] Counsel argued successfully that, even if Section 3(d) were not found compliant, the Indian courts would have no authority to offer a remedy.[97] Instead, the DSB of the WTO was the correct body to resolve this issue.

The Court held that according to Article 64 of TRIPS and the structure of the agreement, disputes were intended to go through the DSB. As stated by the Court:

> When such a comprehensive dispute settlement mechanism is provided as indicated above and when it cannot be disputed that it is binding on its member States, we see no reason at all as to why the

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[88] *Id.* para. 1.
[89] *Id.*
[90] *Id.* para. 8.
[91] *Id.* para. 10.
[92] TRIPS, *supra* note 12, at art. 27(1).
[93] *Id.* at art. 1(1).
[94] *Novartis*, 2007 A.I.R. 24759, para. 3.
[95] *Id.* para. 4.
[96] *Id.*
[97] *Id.* para. 8.

> petitioner, which itself is part of that member State, should not be directed to have the dispute resolved under the dispute settlement mechanism referred to above.[98]

In order for this question to be resolved, Novartis will need to petition the Swiss government to bring a formal complaint against India to the WTO DSB. Novartis' cause does not currently appear to be on the Swiss government's agenda, but this may change in the event of future adverse patent decisions.[99]

2. Constitutional Challenge

Novartis' constitutional attack attempted to prove that Section 3(d) offended Article 14 of the Indian Constitution.[100] In rendering its decision, the Court put great emphasis on parliamentary intent. The Court concluded that Section 3(d) was not in violation of Article 14 of the Constitution, and that the effects of Article 14 were within the scope of parliamentary intention.

Article 14 of the Indian Constitution confers the right to equality before the law.[101] It states "[t]he State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India."[102] Novartis argued that because there are no guidelines to understand "enhanced efficacy," uncontrolled discretion is given to the patent controller.[103] This "arbitrary exercise of power" is a violation of Article 14.[104] Novartis' argument was rejected by the Court.[105] The Court held that Article 14 could only be invoked when it was clear that in the exercise of discretionary power there was a possibility of "real and substantial discrimination."[106] In upholding the discretion granted to controllers by the Act, the Court stated that "[w]e cannot presume that the authorities will administer the law 'with an evil eye and an unequal hand.'"[107]

In evaluating the effect and scope of Section 3(d) the Court gave much weight to protectionist sentiments previously expressed by Parliament. The

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[98] *Id.*

[99] Andrew Jack, *Novartis to Move Indian R&D*, FIN. TIMES, Aug. 22, 2007, *available at* http://www.ft.com/cms/s/0/5d5a403c-5048-11dc-a6b0-0000779fd2ac.html.

[100] *Novartis*, 2007 A.I.R. 24759, para. 3.

[101] INDIA CONST. art. 14.

[102] *Id.*

[103] *Novartis*, 2007 A.I.R. 24759, para. 1.

[104] *Id.*

[105] *Id.* para. 17.

[106] *Id.*

[107] *Id.*

Court referred to Parliamentary debates surrounding the adoption of the Amended Patent Act of 1970.[108] Many feared that by amending patent laws to be more favorable to pharmaceutical companies, the general population could be denied access to vital medications.[109] The Court noted that in Parliament's view, the Act was designed to "safeguard the economic interests of this country . . . and must be viewed with greater latitude."[110] The Court found that Section 3(d) was an accurate reflection of Parliamentary intent to limit the number of patents available to pharmaceutical companies and a conscious effort to curb evergreening.

The Court went on to examine the efficacy requirement and its application to Glivec. The Court defined efficacy as "the ability of a drug to produce the desired therapeutic effect" and noted that in the field of pharmacology efficacy is "independent of potency of the drug."[111] The Court found that the proper test for determining enhanced efficacy is to compare the details of the new substance looking to be patented with the old substance. If upon comparison the properties differ significantly with regard to efficacy, then a patent should be granted.[112]

The decision mentioned no factors for making the relevant comparison, leading to ambiguity in the analysis. For example, according to Novartis, Glivec has a thirty percent increase in bioavailability over the

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[108] *Id.*

[109] *Novartis*, 2007 A.I.R. 24759. The Court notes that the amended Section 3(d) no doubt resulted from the debates held in Parliament and was a response to public health concerns. *Id.*

[110] *Id.* para. 18. Prior to amendment, Section 3(d) read "the mere discovery of any new property of new use of 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." The Patents Act, 1970, No. 39, Acts of Parliament, 1972, at § 3(d). The amended Section 3(d) reads:

> [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.

The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 at § 3(d). In response to Parliamentary debate, the original amendment (under Ordinance 7/2004), which arguably would have been in clear TRIPS compliance, was abandoned in favor of the section now under dispute. Surprisingly, the court implied that perhaps Section 3(d) is not in fact compliant with TRIPS. *Novartis*, 2007 A.I.R. 24759, para. 10. The court referred to the amended section as "drafted in a great hurry [] realizing that [it] is likely to be struck down on the grounds that it is incompatible with 'TRIPS' . . . ." *Id.*

[111] *Novartis*, 2007 A.I.R. 24759, para. 13.

[112] *Id.*

original form of imatinib.[113] As required by the Court, and seemingly by the Patent Office, this is a proven form of increased efficacy. This change, however, was not deemed an adequate change in efficacy as determined by the IPO.

The Court made clear that Parliamentary intent influenced its decision. The language repeated by the Court implied a desire to maintain the spirit of traditional patent law while bringing the Patent Act (arguably) into TRIPS conformity.

II. TRIPS INTERPRETATIONS ALLOW FOR FLEXIBILITY AMONG WTO MEMBER COUNTRIES

Prior to the Uruguay Round negotiations there was no specific agreement on intellectual property rights within the General Agreement on Tariffs and Trade (GATT).[114] After pressure from the United States and other countries to create a harmonized standard of intellectual property rights, TRIPS was agreed on and came into force for all WTO members as of January 1, 1995.[115] TRIPS does not require individual members to have identical intellectual property laws. Instead, TRIPS sets a minimum standard for protection of intellectual property rights to which members must conform.[116] Members are free to implement laws that are more extensive than TRIPS as long as those laws do not "contravene the provisions of the agreement."[117]

A. Textual Arguments Support the Contention that TRIPS Allows Individual Members Discretion for the Implementation of Intellectual Property Law

If Switzerland decides to bring a complaint against India to the DSB, it is unlikely that the DSB would find India in violation of TRIPS. While TRIPS sets an international minimum standard, it aims to allow members flexibility and discretion. There are three provisions within TRIPS that enhance this argument and bolster India's decision to interpret its patent obligations narrowly: (1) the preamble; (2) Article 1(1); and (3) Article 7.[118]

The preamble of TRIPS begins by recognizing "the underlying public policy objectives of national systems for the protection of intellectual

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[113] IPO Decision, *supra* note 2.

[114] WTO FAQ, *supra* note 11.

[115] *Id.* Note that the time table given to each country varied by their status as a developed, undeveloped or least developed country. Also, extensions were given to countries that needed more time, as was the case with India.

[116] *Id.*

[117] *Id.*

[118] TRIPS, *supra* note 12.

property, including developmental and technological objectives."[119] This statement acknowledges that each member will have individual needs that must be met and accounted for on a case by case basis. In regard to India, primary concerns are protecting the generic industry and the continued production of low cost drugs.

Article 1(1) notes that "[m]embers shall give effect to the provisions of this Agreement."[120] Novartis contended that by implementing a strict interpretation of "enhanced efficacy," India did not give full effect to the provisions of TRIPS and was therefore in violation of its obligation as a member. Article 1 goes on to say, however, that "[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[121] This provision again breathes discretion into TRIPS, by allowing members flexibility. India enacted a policy of being tough on patent applicants. Though this is considered a loss to pharmaceutical companies, human rights organizations applaud such efforts.[122]

Article 7 of TRIPS articulates the *objective* of TRIPS:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations.[123]

By qualifying the protection of intellectual property rights as being in "a manner conducive to social and economic welfare," TRIPS again

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[119] *Id.* at Preamble.

[120] *Id.* at art. 1(1).

[121] *Id.*

[122] Despite the negative reaction to the decision by pharmaceutical companies, many non-governmental organizations have supported the Indian court's interpretation of their patent laws. Gentleman, *supra* note 5. As a leader in the production of generic drugs, India plays a vital role in providing cheap medications—especially for AIDS—to undeveloped countries that can neither afford to pay the price for pharmaceutical drugs nor produce the drugs on their own. *Id.* The decision by the court has been called "a huge relief" by many health activists who feared that a wide view of the Indian Patent Act would halt India's production of inexpensive medicines distributed to the poor. *Novartis Dismissed, supra* note 52. In fact, nearly half a million people, including former Swiss President Ruth Dreifuss, Archbishop Desmond Tutu, and members of the European Parliament and the United States Congress, signed a Medecins Sans Frontieres (MSF) petition urging Novartis to drop the case. *Id.* MSF purchases eighty-four percent of the AIDS drugs it distributes from Indian generic producers. The organization worried that a ruling in favor of Novartis would have reduced the production of affordable medicines in India that it considers vital to the treatment of diseases throughout the developing world. *Id.*

[123] TRIPS, *supra* note 12, at art. 7.

illustrates flexibility. The defense in the Novartis case referenced Article 7 as "providing enough elbow room to a member country" to balance individual property rights with the greater social and economic needs of the country.[124]

Considering the effect of these three provisions, the DSB would likely determine that India had exercised appropriate discretion to advance its policy favoring low cost drugs at the expense of granting pharmaceutical patents.

B. The DSB Has Allowed Member Countries Latitude in Interpretating Their TRIPS Obligations

The DSB has shown two general approaches when evaluating violations of TRIPS. The first is an inflexible mandate that the explicit obligations set forth by TRIPS must be obeyed. The second approach is more flexible and allows discretion sufficient to fulfill members' interpretations of certain ambiguous TRIPS obligations. Because of the nature of the Section 3(d) controversy, if a complaint were to be filed against India in the WTO, the DSB would likely evaluate India using the more flexible approach.

When there is a clear violation of the explicit TRIPS obligations, the DSB reacts to enforce the letter of the law. In *Canada-Term of Patent Protection*,[125] the United States challenged Canada's interpretation of TRIPS Article 70.1 and 70.2, whereby Canada did not grant a full twenty year period of exclusivity for patents issued prior to TRIPS' enactment.[126] Under Canada's prior Patent Act, effective before Canada came into compliance with TRIPS, patents were granted exclusive rights for a term of seventeen years.[127] The panel noted the distinction between Article 70.1's statement that TRIPS did not trigger obligations in respect to "acts" that occurred before the date of compliance, and Article 70.2's imposition of TRIPS obligations on "rights" existing prior to the agreement.[128] The panel held that patents that existed prior to TRIPS were "rights," thus guaranteeing patent protection for twenty years.[129] Following this determination, the panel found Article 33 obligations unambiguous in defining the terms of patent protection for twenty years from the filing

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[124] *See Novartis*, 2007 A.I.R. 24759, para. 4.

[125] Panel Report, *Canada—Term of Patent Protection*, WT/DS170/R (May 5, 2000), *aff'd* Appellate Body Report, *Canada—Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000).

[126] Panel Report, *Canada—Term of Patent Protection*, paras. 6.2, 6.25, WT/DS170/R (May 5, 2000).

[127] *Id.* paras. 2.1, 2.7.

[128] *Id.* paras. 3.1–3.2.

[129] *Id.*

date.[130] This case illustrates the DSB's intolerance for explicit deviations from TRIPS obligations.

A second case brought against Canada illustrates the DSB's more lenient approach, which allows individual members latitude to interpret ambiguous provisions of TRIPS. In *Canada-Patent Protection of Pharmaceutical Products*, the European Community (EC) challenged Section 55.2(1) of Canada's Patent Act.[131] This provision allowed potential competitors of a patent owner to use a patented item (without authorization and during the term of the patent) for the purpose of obtaining regulatory permission to sell the product upon expiration of the patent.[132] Three TRIPS Articles were examined in this matter: Article 27.1, Article 30 and Article 28.1.[133]

The EC challenged that by allowing competitors to obtain government approval for products prior to the patent's expiration, Canada was in violation of Article 27.1 which states that "patents shall be available . . . without discrimination . . . ."[134] Canada argued, and the panel agreed, that it was within its right to limit the patent rights conferred.[135] Canada relied on Article 30 which provides that:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interest of third parties.[136]

The DSB found that the EC's rights were *not* unreasonably restricted and that Canada was exercising permissible discretion.[137] Following the panel's determination that Canada's actions were within its Article 30 exclusionary rights, the panel dismissed the EC's argument that Canada was failing its Article 28 obligation to confer exclusive rights to a patent owner.[138]

It is likely that, if brought in front of the DSB, India's case would be evaluated with leniency because the Section 3(d) controversy is more

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[130] *Id.* paras. 7.1–7.2.

[131] Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 12, 2000).

[132] *Id.* paras. 2.1–2.7.

[133] *Id.* paras. 3.1–3.2.

[134] *Id.* para. 3.1.

[135] *Id.* para. 3.2.

[136] TRIPS, *supra* note 12, at art. 30.

[137] Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, paras. 3.1–3.2, WT/DS114/R (Mar. 12, 2000).

[138] *Id.*

closely related to the *Canada-Pharmaceutical Patents* case than *Canada-Term of Patent Protection*. The reason for this is that Section 3(d) involves an interpretation of India's TRIPS obligations and not a strict conflict with an explicit provision. In the context of Article 27.1, the DSB could easily determine that the "enhanced efficacy" requirement is a permissible test for the "innovative step" requirement. It is also likely that the DSB would view India's choices in light of Article 27.2, which allows a member to limit patents for the purpose of protecting public health. Given the DSB's prior decisions, India would likely be found compliant with its TRIPS obligations.

III. THE NOVARTIS DECISION SHOULD NOT HAVE A LARGE EFFECT ON PHARMACEUTICAL INVESTMENT IN INDIA

Following Novartis' adverse court decision, Daniel Vasella, Chief Executive of Novartis, commented that his "concrete plans" for investment in research in India would be directed elsewhere:

> This is not an invitation to invest in Indian research and development, which we would have done. We will invest more in countries where we have protection. It's not a punishment. It's just a question of the culture for investment. Do you buy a house if you know people will break in and sleep in your bedroom?[139]

Despite these strong words, it is unlikely that the Novartis decision will curb investment in India. Firms have approached India with caution since the 1970s. After the Indian government reduced patent protection in 1970, many firms left India and invested elsewhere.[140] Although there has been increased interest in investing in India following its 2005 compliance with TRIPS, firms have been cautious.[141] The recent Novartis case justifies such cautious attitudes, but it also signals to firms the direction in which India plans to take its new patent law. Armed with this knowledge, pharmaceutical companies will be able to tailor their investments to maximize the benefit they can extract from India while minimizing their risk.

A. India is Competitive on the Global Market

Controversy over the Novartis decision has led to speculation that India will lose pharmaceutical investment opportunities to countries such as

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[139] Jack, *supra* note 99.

[140] Andrew Jack & Amy Yee, *China May Prove a Hard Pill for India to Swallow*, FIN. TIMES, Aug. 31, 2007, *available at* http://www.ft.com/cms/s/0/bb84b50c-575a-11dc-9a3a-0000779fd2ac.html.

[141] *Id.*

China.[142] Following India's long period without strong patent protection, investment in India, even prior to the Novartis decision, had been cautious.[143] Now, although it will continue to compete with countries such as China for investment, many of India's attributes, such as low production costs and an educated work force, will continue to attract companies to invest in research and development within its borders and continue to make it a competitive choice for pharmaceutical investment.[144]

Since India's new patent laws came into effect in 2005, it has been competing directly with countries such as China and Singapore[145] for pharmaceutical investment. Throughout this period, however, these two other countries have enjoyed greater investment due to their stronger patent protection regimes.[146] Still, at least a dozen companies have chosen to invest in India since it amended its patent laws in January 2005.[147] The following chart[148] serves as a snapshot of investment in India by pharmaceutical companies:[149]

Company	Area of Focus	Investment
Allegan Inc.	Inflammatory, infection, urological indications	$3–5 Million
Eisai Pharmaceuticals	API process	$120 Million (including manufacturing plants)
Dupont	Molecular biology, bio-informatics, and polymer synthesis	$23 Million
Ratiopharm GmbH	Basic processes	$36 Million (in two phases)
Teva	Basic processes	$3–4 Million
AstraZeneca	TB &NCE research, process & development	$15 Million
BMS-Syngene	Basic drug discovery	N/A
Pliva	Basic studies for generics	$1 Million

[142] *Id.*
[143] *Id.*
[144] Jack, *supra* note 99.
[145] *Id.*
[146] *Id.*
[147] P.B. Jayakumar, *MNCs Still Bullish on India R&D*, BUS. STANDARD, Aug. 27, 2007, *available at* http://www.business-standard.com/common/storypage_c.php?leftnm=10&autono=295940.
[148] *Id.*
[149] *Id.*

Nektar Therapeutics	Pre-clinical and bio-analytical development	$10 Million

Though some of these investments seem small, it has been noted that the number of partnerships with local companies outnumbers those in China and Singapore.[150] This is significant because local partnerships stimulate growth and innovation by local firms, which in turn contribute greatly to local economies.[151] The "Indian pharmaceutical industry has carved out a unique place on the global map, not only as a manufacturer of generic drugs but also of new formulations, with growing emphasis on research and development and new drug discovery . . . ."[152] In addition, the Indian pharmaceutical industry is ranked fourth globally in terms of volume, with "annual turnover of over US $ 11 billion" and an eight percent share in the world pharmaceutical market.[153]

It is important to view Indian pharmaceutical investment in the context of its past patent history. When the Indian Patent Act was amended in 1970, many foreign companies left due to the lack of patent protection.[154] Following the 2005 changes to patent law, companies are once again considering India a viable option for investment.[155] Concerns over implementation of these new laws, as illustrated by the Novartis case, have kept investors cautious, but money is beginning to flow back into the country.[156] Some drug makers have formed "research-based" partnerships with Indian companies. For example, pharmaceutical giant GlaxoSmithKline (GSK) has recently teamed up with local Indian company Ranbaxy to conduct early-stage drug development.[157] In fact, GSK has consistently increased the number of clinical studies it has conducted in India, going from three leading up to 2005 to sixteen in 2006, to

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[150] *Id.*

[151] World Business Counsel for Sustainable Development, *The Role of the Health Care Sector in Expanding Economic Opportunity*, Aug. 21, 2008, http://www.inclusivebusiness.org/2008/08/the-role-of-the.html (summarizing ADEEB MAHMUD & MARCIE PARKHURST, THE ROLE OF THE HEALTH CARE SECTOR IN EXPANDING ECONOMIC OPPORTUNITY, ECONOMIC OPPORTUNITY SERIES (Harvard University 2007) *available at* http://www.hks.harvard.edu/m-rcbg/CSRI/publications/report_21_EO%20Health%20Care%20Final.pdf).

[152] *Favourable Global Trends for Indian Pharmaceutical Industry*, INDIA CHRONICLE, Nov. 2007, at 03, http://www.sunmediaonline.com/indiachronicle/nov07/investmentupdate.html.

[153] *Id.*

[154] Jack & Yee, *supra* note 140.

[155] *Id.*

[156] *Id.*

[157] Utkarsh Palnitkar, *Drug Discovery in India—Trends and Challenges*, EXPRESS PHARMA, May 16–31, 2008, http://www.expresspharmaonline.com/20080531/research02.shtml.

approximately thirty-one in 2007.[158] Trials carried out in India are typically forty to sixty percent cheaper than in the United States and quicker because patients can be enrolled more rapidly than in the United States.[159] Though enthusiasm for investment has been tempered with caution over India's patent laws,[160] it is unlikely that this hesitation will completely detract from the many positive incentives that India can offer companies willing to invest in pharmaceutical development.

B. India's Strongest Asset is Its Workforce

The strength of India's workforce is perhaps its greatest asset in attracting foreign pharmaceutical investment.[161] Ajit Dangi, director general of the Organization of Pharmaceutical Producers of India (OPPI), noted:

> Some companies may be concerned about issues like data exclusivity, which is allowed in about 40-50 countries but not in India. Similarly, Section 3(d) of the Patent Act lacks clarity and this also may be a concern. But that need not deter them from investing in India as there are other factors involved while taking business decisions.[162]

One factor that weighs heavily in favor of India's continued receipt of foreign investment is the large number of English-speaking engineers and scientists who are willing to work for relatively low wages.[163] India, in fact, produces more university graduates than the United States, and roughly forty percent of Indian university graduates hold degrees in science or engineering.[164] A large draw for companies is the Indian Institute of Technology (IIT). This university was founded by former Prime Minister Nehru and its graduates are highly sought after.[165] IIT is one of the most selective universities in the world, accepting about 2500 of over 100,000 who take the entrance exam every year.[166] A well-educated, English-speaking population willing to work for comparatively low wages is certainly an attractive feature offered by India to investors.

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[158] P.T. Jyothi Datta, *GSK Doubles Clinical Trials*, HINDU BUS. LINE, Nov. 26, 2007, *available at* http://www.thehindubusinessline.com/2007/11/26/stories/2007112651470300.htm.

[159] Jack & Yee, *supra* note 140.

[160] *Id.*

[161] Gupta, *supra* note 48, at 615.

[162] Jayakumar, *supra* note 147.

[163] Gupta, *supra* note 48, at 626–27.

[164] *Id.* at 627.

[165] *Id.*

[166] *Id.*

Additionally, investors can look to India's thriving generics industry to provide well-educated workers with highly relevant experience. Though the primary research and development of the generics industry consists of reverse-engineering, new patent laws will encourage firms to utilize India's educated workforce. Many of the skills and much of the process knowledge required for reverse-engineering is directly applicable to the discovery process.[167]

Although concerns over India's patent laws will influence pharmaceutical investment, these sentiments are not new. Despite the fact that the Novartis case affirmed some fears regarding India's patent law, it also provided information to pharmaceutical companies that will allow them to invest in India to their advantage. The hospitable environment offered by India will continue to attract international pharmaceutical investment.

CONCLUSION

The Novartis case presented the Indian Court with an opportunity to defy the cultural and political trends toward weak patent protection. Instead of paving the way for a new era of strong patent protection, the Court maintained the Indian tradition of protectionism. The decision of India's High Court, however, is not surprising given India's traditional culture and protectionist past. Despite the controversy surrounding Section 3(d), it is unlikely that the WTO would find India in violation of TRIPS because of the wide discretion given to member countries by the language of TRIPS.

Though the Novartis case has stirred up a great deal of publicity, pharmaceutical investment in India is likely to continue at its current pace. Although the Novartis decision will not serve as a beacon to new investors, it is not an unexpected result—India's history of weak enforcement has long led foreign firms to exercise caution when investing in India. The many draws to investing in India, primarily its exceptional work force, will continue to court pharmaceutical investors and will result in continued growth in that sector.

[167] *Id.* at 630.