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Novartis Ag v. Union of India: "Evergreening," Trips, and "Enhanced Efficacy" Under Section 3(d)

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**NOVARTIS AG V. UNION OF INDIA:
"EVERGREENING," TRIPS, AND "ENHANCED
EFFICACY" UNDER SECTION 3(d)**

*Dorothy Du**

TABLE OF CONTENTS

I.	INTRODUCTION	225
II.	BACKGROUND AND PROCEDURAL HISTORY OF <i>NOVARTIS AG</i>	227
A.	LEGAL BACKGROUND—INDIA'S PHARMACEUTICAL PATENT LAWS.....	227
B.	DRUG PATENTS AND DRUG PRICES.....	229
C.	TRIPS ARTICLE 27.1.....	231
D.	PROCEDURAL HISTORY OF <i>NOVARTIS AG</i>	234
III.	DOES EVERGREENING OCCUR IN INDIA?	238
A.	UNSOUND THEORIES OF EVERGREENING	239
B.	EVERGREENING AS IT OCCURS IN INDIA	241
IV.	WHAT IS ENHANCED EFFICACY?	242
A.	INVENTIVE STEP OR INDUSTRIAL APPLICATION REQUIREMENT	242

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224	J. INTELL. PROP. L.	[Vol. 21:223
B.	MORE THAN INVENTIVE STEP AND INDUSTRIAL APPLICATION.....	245
1.	<i>Noncompliance With TRIPS</i>	245
2.	<i>Analysis of an Additional Enhanced Efficacy Requirement Generally</i>	250
3.	<i>Narrowing the Interpretation of Efficacy to Therapeutic Efficacy Only</i>	252
4.	<i>Lack of Theoretical Transparency About Therapeutic Efficacy Interpretation</i>	255
V.	NOVARTIS AG: PATENTABILITY DEPENDS ON INTERPRETATION OF ENHANCED EFFICACY	258
A.	IPAB’S INTERPRETATION OF ENHANCED EFFICACY	258
B.	REINTERPRETATION OF ENHANCED EFFICACY ON APPEAL	260
VI.	CONCLUSION	262

I. INTRODUCTION

A decision in *Novartis AG v. Union of India*,¹ an Indian Supreme Court case, was announced on April 1, 2013.² The Supreme Court heard the final arguments from both sides in September 2012. The much anticipated decision has the potential to shake up the landscape of the pharmaceutical industry and public health in India because it concerns the application of a controversial provision of the Indian Patents Act of 2005, Section 3(d). The Supreme Court has interpreted Section 3(d) in a manner that may significantly limit the ability of pharmaceutical companies to obtain "secondary patents" on life-saving drugs. So-called secondary patents, or "patents that cover alternative structural forms of the base molecule," have frequently been referenced in the debate about Section 3(d).³

Controversy surrounds Section 3(d) in three major respects. First, Section 3(d) is an unusual provision among different countries' patent laws because it imposes a requirement of "enhanced efficacy" over the prior art before a patent on a reformulation or modification of an original pharmaceutical compound can be obtained. Second, Section 3(d) applies only to pharmaceutical product patents, not patents in any other field of technology. Third, the lower courts in *Novartis AG* have defined "efficacy" in Section 3(d) narrowly to mean "therapeutic efficacy" only. This narrow interpretation drew umbrage from petitioner Novartis as unsupported by the text of the statute and damaging to incentives for pharmaceutical innovation.

This Article represents the culmination of several months of research consisting of analysis of primary documents, review of the literature, and interviews. It advances the following propositions: (1) Under the Indian Supreme Court's interpretation of Section 3(d) of the 2005 Amendment of the

¹ *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311 (India), available at <http://supremecourtsofindia.nic.in/outtoday/patent.pdf>.

² This Article was originally written between January 2013 and March 31, 2013. The decision in the case was handed down on April 1, 2013, the day after the Article was originally written. See Nirmala George, *India's Top Court to Deliver Novartis Judgment*, YAHOO! NEWS (Mar. 31, 2013, 3:55 AM), <http://news.yahoo.com/indias-top-court-delivers-novartis-judgment-074548556.html>; Kaustubh Kulkarni, *Big Pharma Waits Nervously On Glivec Patent Verdict*, REUTERS INDIA (Mar. 27, 2013, 8:10 PM), <http://in.reuters.com/article/2013/03/27/india-drugs-patent-novartis-glivec-idINDEE92Q02E20130327>; E. Kumar Sharma, *SC Verdict On Novartis' Glivec Case Expected On April 1*, BUS. TODAY INDIA (Mar. 28, 2013, 11:48 AM), <http://businesstoday.intoday.in/story/sc-verdict-on-novartis-glivec-case-expected-on-april-1/1/193667.html>; Indo Asian News Service, *SC Verdict on Novartis AG's Patent Claim April 1*, YAHOO! NEWS, Mar. 29, 2013, <http://india.nydailynews.com/business/782d17a2316f7221bb1881ef2ef47d57/sc-verdict-on-novartis-ags-patent-claim-april-1#ixzz2P972KmUF>.

³ See, e.g., Bhaven N. Sampat, Kenneth C. Shadlen & Tahir M. Amin, *Challenges to India's Pharmaceutical Patent Laws*, 337 SCIENCE 414, 414–15 (2012).

Indian Patents Act as requiring enhanced efficacy in a manner not coextensive with the inventive step and utility requirements for patentability, Section 3(d) is not compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the World Trade Organization's (WTO) minimum standards for intellectual property protection.⁴

(2) Notwithstanding TRIPS compliance, a requirement of efficacy for secondary patents under Section 3(d) may benefit India by striking a better balance between pharmaceutical innovation and India's public health concerns than strict TRIPS compliance would.

(3) A broad interpretation of Section 3(d)'s enhanced efficacy requirement would be the interpretation most consistent with the claimed purpose of Section 3(d) to block patenting of unimportant, minor modifications of prior art, although it does so imperfectly.

(4) A construction of efficacy as therapeutic efficacy creates an unprincipled distinction between "therapeutic" and other "efficacy" that does not accord with patent law theory, although it may nevertheless further India's public health aims. Insofar as India's underlying motivation for Section 3(d) is inconsistent with patent law theory, India should make explicit the true purpose of Section 3(d) and argue that it should not have been required to comply fully with TRIPS by 2005.

(5) *Novartis AG* provides an example of a pharmaceutical product that would fulfill a broader requirement of enhanced efficacy, but would fail a narrower requirement of "enhanced therapeutic efficacy" despite embodying a significant achievement over the prior art.

Part II of this Article describes the legal background and procedural history of the *Novartis AG* case leading up to the Supreme Court decision. Part III will explore what "evergreening" means and will argue that it does not occur in the way it has frequently been argued in India. Part IV sets out the three possible interpretations of Section 3(d)'s enhanced efficacy requirement from which the Indian Supreme Court chose and the legal and policy consequences of each. It will address important considerations of each, including TRIPS compliance, public health concerns, and incentives for innovation. Part V returns to *Novartis AG* and argues that Novartis's patent application for the cancer drug Glivec should not have been rejected on Section 3(d) grounds under a broad interpretation of enhanced efficacy. Part VI concludes.

⁴ Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 281 (2008).

II. BACKGROUND AND PROCEDURAL HISTORY OF *NOVARTIS AG*

A. LEGAL BACKGROUND—INDIA'S PHARMACEUTICAL PATENT LAWS

India's current patent laws are inextricably tied to its desire, following independence from Britain, to establish a patent system that prioritizes its country-specific goals, rather than Western goals. The Indian Patents Act of 1970 (1970 Act) explicitly prohibited patents on pharmaceutical *products*, although it allowed patents on *processes* for making pharmaceutical compounds.⁵ The 1970 Act was a "deliberate choice to stimulate the lagging Indian economy by promoting domestic drug manufacturing."⁶ The law had also been influenced by the Ayyangar Committee Report, a report commissioned by the Indian government in 1959, that had recommended that "underdeveloped" countries like India enact patent law provisions that would protect them from exploitation by developed countries.⁷ Without product patents, Indian companies were free to make, sell, and use, at highly competitive prices, drugs invented elsewhere. India's generic drug industry boomed over the next three decades, capitalizing on innovation by multinational companies (MNCs) that could not obtain patents under Indian law. India earned the nickname "pharmacy of the world" for its flourishing generic pharmaceutical industry and export of generics.⁸

Things took a turn in 1995, however, when India sought to become one of the inaugural members of the WTO. Although it fought a treaty mandating comprehensive intellectual property rights and insisted that patent protection be tailored to a country's level of economic development, it eventually submitted to signing TRIPS as a condition of joining the WTO,⁹ "fear[ing] restrictions on its exports" if it refused.¹⁰ India did, however, negotiate a transition period in which it did not have to bring its patent laws into full compliance with TRIPS until January 1, 2005.¹¹

⁵ *Id.* at 290–91.

⁶ *Id.* at 291.

⁷ N. RAJAGOPALA AYYANGAR, GOVERNMENT OF INDIA, REPORT ON THE REVISION OF THE PATENT LAW 19–20 (1959).

⁸ Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495, 536–37 (2007) ("India has been a net exporter of drugs since 1988–89 . . ."); *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 2 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>.

⁹ Lee, *supra* note 4, at 293.

¹⁰ Mueller, *supra* note 8, at 517.

¹¹ Lee, *supra* note 4, at 293.

In 2005, India enacted the Patents (Amendment) Act of 2005 (2005 Amendment),¹² which aimed to bring India into compliance with TRIPS.¹³ The 2005 Amendment, *inter alia*, enabled the patenting of pharmaceutical products.¹⁴ Section 3(d), however, limited the expansion of pharmaceutical patents by precluding patenting of:

The mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance . . . For the purposes of this clause, salts, esters, . . . combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.¹⁵

The purpose of this provision, as has been expounded *ad nauseum* in the literature, is to limit “evergreening.”¹⁶ Evergreening is a term, used primarily by detractors of the alleged practice, to describe the acquisition of secondary patents on reformulations or minor modifications of pharmaceutical products in order to unfairly extend the monopoly over the drug beyond the life of the initial patent.¹⁷

When asked whether evergreening as described by its opponents occurs in India, practitioners interviewed in this study were equivocal. Many stated that it depends on “who you’re talking to,” or that it occurs insofar as pharmaceutical companies frequently obtain secondary patents, but that whether they do so in contravention of patent law or with “malicious intention” is less certain.¹⁸ This Article will explore this question in detail below.

What people do agree on is that Section 3(d) creates a barrier to obtaining pharmaceutical patents and that the enhanced efficacy requirement is unclear for two reasons. First, it is unclear what is meant by “efficacy.” Second, it is

¹² The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=128116.

¹³ *Id.*

¹⁴ Lee, *supra* note 4, at 294.

¹⁵ *Id.* at 294–95.

¹⁶ Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 304–05 (2010), available at <http://www.mtlr.org/volseventeen/ouellette.pdf>; Sampat, Shadlen & Amin, *supra* note 3, at 414.

¹⁷ Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law’s Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 (2008).

¹⁸ Interview with Adheesh Nargolkar and Fiona DeSouza (Jan. 15, 2013). See also Interview of A.C. (Jan. 9, 2013). A.C., a patent attorney who has requested anonymity, stated in response to the question, “Does ‘evergreening’ occur in India?”: “It depends on how you define it. Evergreening happens if having a secondary patent is evergreening.”

unclear "what kind of data will be required to establish 'efficacy'" to the satisfaction of Section 3(d).¹⁹ India's Patent Rules, comparable to Title 37 of the Code of Federal Regulations (C.F.R.), and the Indian Manual of Patent Office Practice and Procedure, comparable to the U.S. Manual of Patent Examining Procedure (MPEP), contain no guidance on what would satisfy the enhanced efficacy requirement, leaving it unclear to inventors and practitioners how much they must invest in research and development (R&D) before they can obtain a patent.²⁰

B. DRUG PATENTS AND DRUG PRICES

The chairman of Cipla, a major Indian generics manufacturer, stated that the 1970 Act was "the dawn of a Golden Age" for the Indian pharmaceutical industry, while the introduction of pharmaceutical product patents in 2005 was "one of the greatest predictable tragedies the world has witnessed."²¹ Indeed, Section 3(d) has been touted by many generic drug companies, patients' associations, and such non-government organizations (NGOs) as Lawyers Collective and Médecins Sans Frontières (MSF) as crucial to curbing the detrimental effect of the 2005 Amendment on patients' access to affordable generic medicines.

These generic companies and public health activists often cite the fact that most Indians are not able to afford life-saving on-patent branded drugs like Glivec, which treats leukemia.²² Glivec costs a patient about \$70,000 per year in the United States or \$26,160 per year in India; generic versions in India only cost about \$2,500 year.²³ These prices are prohibitive in India, a country that lacks a social safety net for its poor.²⁴ In 2005, India's per capita expenditure on health care was only about \$28 per year, with \$3 per capita spent on pharmaceuticals, compared to \$5,635 per capita health care spending in the U.S.²⁵ According to the Organisation of Pharmaceutical Producers of India

¹⁹ Mueller, *supra* note 8, at 553.

²⁰ See *id.* at 554; THE OFFICE OF CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADEMARKS, MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE §§ 2(1)(j), 3(d), 3(e) (2011).

²¹ Mueller, *supra* note 8, at 539–40.

²² See Sierra Dean, *India's Controversial New Patent Regime: The End of Affordable Generics?*, 40 INT'L LAW. 725, 732 (2006); *An Open Letter to the CEO and President of Novartis*, DOCTORS WITHOUT BORDERS (Aug. 21, 2012), <http://www.doctorswithoutborders.org/article/open-letter-Ceo-and-president-novartis>.

²³ Vikas Bajaj & Andrew Pollack, *India's Supreme Court to Hear Dispute on Drug Patents*, N.Y. TIMES (Mar. 6, 2012), http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&_r=0.

²⁴ Mueller, *supra* note 8, at 542.

²⁵ *Id.* at 543.

(OPPI), less than 4% of the population has health insurance.²⁶ Thus, most drug purchases are paid for out-of-pocket.²⁷ In January 2013, Mr. Tapan Ray, the Director General of OPPI, stated that only 1% of the Indian Gross Domestic Product (GDP) is government spending on health care, out of 4.5% total of the GDP spent on health care in India generally.²⁸

Section 3(d) ensures that generic manufacturers are free to sell subsequent versions of a drug once the original patent on the active pharmaceutical ingredient expires.²⁹ In *Novartis AG*, since Novartis never obtained a first patent in India on imatinib free base to begin with, generics manufacturers are already free to produce generic Glivec.³⁰ Generic companies are able to sell the drug at much lower prices than Novartis can because they did not have to incur hefty research and development costs developing the drug and getting it approved.

However, Section 3(d) is only a part of the equation for increasing access to generic medicines. Since drugs like Glivec are by prescription only, access to the drugs is mediated by a health professional and access to diagnostic tests. A tunnel-like focus on the price of medicines ignores these threshold conditions to access to medicine and the overall availability of treatment to poor patients. Mr. Tapan Ray highlighted this problem in his interview. In his view, “it is important to think of healthcare as a three-stage process. First, you need to have access to a doctor, who can examine you. Second, you need to undergo tests, such as MRIs, to obtain a diagnosis. Only when a doctor prescribes medicine, can the price of medicine matter.”³¹ Yet, he pointed out, the Indian government does not control the price of doctors’ fees and diagnostic tests, focusing only on the price of medicines.³²

In addition, the Indian government has alternative means to control drug prices. Mr. Ray suggests that insurance companies and the Indian government procure medicines directly, negotiate volume discounts, and provide the medicines for free or at reduced prices to the needy.³³ India also has a system of compulsory licenses in which generic companies can apply to the Controller of Patents to force patent holders to give licenses to the generic manufacturers

²⁶ *Id.*

²⁷ *Id.*

²⁸ Interview with Tapan Ray, Dir. Gen., Org. of Pharm. Producers of India (Jan. 25, 2013).

²⁹ See The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=128116.

³⁰ See discussion *infra* Part II.D.

³¹ Interview with Tapan Ray, *supra* note 28.

³² *Id.*

³³ *Id.*

in limited situations.³⁴ Although only one compulsory license has been granted, to Natco Pharma for Nexavar, Bayer's cancer drug,³⁵ more seem to be coming down the pipeline, perhaps spurred by this watershed event.³⁶

C. TRIPS ARTICLE 27.1

India has argued since Section 3(d) has been enacted that it does not violate TRIPS, but rather takes advantage of "flexibilities" for developing countries offered by TRIPS.³⁷ In order to determine what TRIPS demands and clarify TRIPS's role in the debate about Section 3(d), I devote this section to exploring the language and meaning of the relevant section of TRIPS. The text of TRIPS Article 27.1 can be divided into two components. The first states that: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."³⁸ This section lays out the basic premise that patents must be available for "*all* fields of technology" subject to the three basic requirements of novelty, utility, and non-obviousness.³⁹ No other requirements are named, giving rise to a possible negative inference that no other patentability requirements are permitted. The second component states "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."⁴⁰ This component is known as the "non-

³⁴ See Mueller, *supra* note 8, at 544, 583; NISHITH DESAI ASSOCIATES, INTELLECTUAL PROPERTY LAW IN INDIA 29 (2013), available at http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20papers/Intellectual_Property_Law_in_India.pdf.

³⁵ Kiran Kabtta Somvanshi, *Natco Pharma Awarded the Compulsory Licence to Manufacture Bayer's Cancer Drug Nexavar*, ECON. TIMES (Mar. 8, 2013), http://articles.economictimes.indiatimes.com/2013-03-08/news/37561874_1_compulsory-license-nexavar-cancer-drug.

³⁶ Tracy Staton, *India to Hit Roche, BMS with Compulsory Licenses on 3 Cancer Drugs*, FIERCEPHARMA (Jan. 13, 2013), <http://www.fiercepharma.com/story/india-hit-roche-bms-compulsory-licenses-3-cancer-drugs/2013-01-13>.

³⁷ See, e.g., WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR SOUTH-EAST ASIA, INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES 11-12, 63-64 (2010), available at <http://apps.who.int/medicinedocs/en/d/Js1752/en/> [hereinafter WHO REGIONAL OFFICE FOR SOUTH-EAST ASIA] (explaining that TRIPS's failure to lay down standards for applying the "novelty" and "inventive step" requirements of patent eligibility opened the door for India to carve out certain subject matter eligible for patent protection).

³⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS] (setting forth obligations for patent protection).

³⁹ *Id.* (emphasis added); *infra* note 121.

⁴⁰ TRIPS, *supra* note 38.

discrimination clause” of TRIPS because it appears on its face to contemplate non-discrimination among different fields of technology.⁴¹

Dissecting the meaning of the language of TRIPS Article 27.1 given the dearth of case law from the WTO Dispute Settlement Body (DSB) is more of an art than a science.⁴² Nevertheless, some guidance can be found in case law from other jurisdictions and literature. First, numerous scholars have stated that TRIPS reflects a Western conception of intellectual property rights.⁴³ Several scholars state that TRIPS is intended to be a set of “minimum standards” for intellectual property protection.⁴⁴ Under this interpretation, the first component of Article 27.1 can be seen as establishing a floor of intellectual property rights, such that intellectual property rights should not be denied for lack of additionally imposed requirements.

Still, one of the few pharmaceutical patent cases tried before the WTO DSB, *United States v. India* (DS50), seems to support “the residual power of states to forge their own intellectual property laws and policies” when the black letter rules of TRIPS do not clearly circumscribe them.⁴⁵ In that case, which concerned TRIPS Article 70.8, the government of India tried to postpone implementation of the “mailbox” rule⁴⁶ applicable to patents, leading the U.S. to file suit before the DSB.⁴⁷ Although India lost, the Appellate Body emphasized that Article 1.1 of the TRIPS Agreement states that members “shall be free to

⁴¹ Maria Victoria Stout, *Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1*, 14 B.U. J. SCI. & TECH. L. 177, 179–80 (2008).

⁴² *WTO Dispute Settlement: One-Page Case Summaries 1995–2011*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/res_e/booksp_e/dispu_summary95_11_e.pdf (showing that only four distinct disputes, *European Communities v. Canada* (DS114), *United States v. India* (DS50), *European Communities v. India* (DS79), *United States v. Canada* (DS170), over pharmaceutical patents have been adjudicated through the WTO’s DSB from 1995 to 2011).

⁴³ E.g., Mueller, *supra* note 8, at 545 (stating that WTO TRIPS Agreement requires “[a] ‘westernized’ patent system”); Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After U.S. v India*, 1 J. INT’L ECON. L. 585, 586 (1998) (explaining that it was the goal of developed countries “to impose a comprehensive set of intellectual property standards on the rest of the world” through TRIPS).

⁴⁴ E.g., Rajnish Kumar Rai, *Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India’s Patent Law in Light of India’s Obligations Under the TRIPS Agreement and Options for India*, 8 CHI-KENT J. INTELL. PROP. 41, 57–61 (2008); WHO REGIONAL OFFICE FOR SOUTH-EAST ASIA, *supra* note 37, at 3. *But see* Reichman, *supra* note 43, at 586 (“As ultimately enacted, these were not ‘minimum’ standards on intellectual property protection in the classical sense of the term: rather, they collectively expressed most of the standards of protection on which the developed countries could agree among themselves.”).

⁴⁵ Reichman, *supra* note 43, at 596.

⁴⁶ *See infra* text accompanying notes 60–62.

⁴⁷ Reichman, *supra* note 43, at 593.

determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."⁴⁸

In light of the tension between freedom and obligation that TRIPS creates, I turn to the non-discrimination clause of Article 27.1, which would be particularly relevant in a hypothetical suit between the Swiss government and Indian government. The Swiss government would be responsible for making a claim before the WTO DSB on behalf of Novartis AG because Novartis AG is a Swiss company.⁴⁹ The Swiss government could allege that Section 3(d) contravenes the non-discrimination clause by imposing additional barriers to patenting pharmaceutical products compared to other fields of technology.

Most commentators reject the most restrictive interpretation of the non-discrimination provision, finding that "Article 27.1 does not strictly require a 'single level of IP protection for all technologies or industries.'"⁵⁰ In *Canada Pharmaceuticals*,⁵¹ the WTO panel rejected a restrictive reading of Article 27.1 as forbidding any different treatment of the various fields of technology.⁵² Rather, unfair discrimination must be distinguished from differential treatment for legitimate reasons.⁵³

In *Canada Pharmaceuticals*, the European Union claimed that the Canadian Patent Act violated Article 27.1's non-discrimination clause because "it treated drug patents less favorably than patents for inventions in other fields."⁵⁴ Canada's patent statute contained a "Stockpiling Exception" which stated that it is not patent infringement to make, instruct, use, or sell a patented invention during a period set by regulation for the purpose of preparing a stockpile of products to sell *after* the patent expires.⁵⁵ The only regulations promulgated under the exception, however, applied to medicines, enabling generic manufacturers to stockpile identical generic versions of a drug beginning from six months before the drug patent expired.⁵⁶ The dispute panel of the WTO found that a law that differentiates between different fields of technology is not necessarily in violation of Article 27.1 as long as it is supported by a *bona fide* reason to differentiate.⁵⁷ The TRIPS compliance question in *Novartis AG* then,

⁴⁸ *Id.* at 596.

⁴⁹ Novartis is headquartered in Basel, Switzerland. *About Novartis*, NOVARTIS, <http://www.novartis.com/about-novartis/locations/index.shtml> (last visited May 24, 2014).

⁵⁰ Stout, *supra* note 41, at 181.

⁵¹ Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

⁵² Stout, *supra* note 41, at 181.

⁵³ *Id.* at 182.

⁵⁴ *Id.* at 184.

⁵⁵ *Id.* at 183.

⁵⁶ *Id.*

⁵⁷ *Id.* at 185.

is whether Section 3(d) legitimately differentiates between non-pharmaceutical and pharmaceutical patents.

D. PROCEDURAL HISTORY OF NOVARTIS AG

With TRIPS and India's legal and socioeconomic milieu in mind, I turn to the facts and procedural posture of *Novartis AG*. In the early 1990s, Novartis scientists made the breakthrough discovery that imatinib, the free base molecule on which Glivec is based, had startling anticancer properties.⁵⁸ In 1993, Novartis AG filed patents for imatinib free base worldwide.⁵⁹ Novartis received patents in countries including the U.S.,⁶⁰ but did not apply for a patent in India because at the time, the 1970 Act banned pharmaceutical product patents.⁶¹ In 1998, however, Novartis submitted a "mailbox" patent application in India for imatinib mesylate, a beta-crystalline form of imatinib that is used in Glivec.⁶² The patent claimed priority from a similar patent application filed in 1997 in Switzerland.⁶³ Under the "mailbox" system, patent applicants could submit applications ahead of time, which the Indian patent office would review when India became TRIPS compliant in 2005.⁶⁴

In January 2006, the Chennai Patent Office examined the imatinib mesylate patent and rejected it on grounds of (1) lack of novelty and inventive step because the 1993 patents had already claimed "all pharmaceutical salt forms of imatinib," and (2) Section 3(d), because the new product did not demonstrate enhanced efficacy despite having a 30% increase in bioavailability over the prior art.⁶⁵

⁵⁸ Leslie A. Pray, *Gleevec: The Breakthrough in Cancer Treatment*, NATURE EDUCATION (2008), <http://www.nature.com/scitable/topicpage/gleevec-the-breakthrough-in-cancer-treatment-565>.

⁵⁹ Lee, *supra* note 4, at 297–98.

⁶⁰ U.S. Patent No. 5,521,184 (filed Apr. 28, 1994), available at <http://www.ipface.org/casestudy/doc/US5521184A.pdf> (continuation-in-part of U.S. Patent Application Serial No. 42,322 (filed Apr. 2, 1993)).

⁶¹ Lee, *supra* note 4, at 297.

⁶² *The Orange Pill, Now in 3D: Rewriting Patent History?*, ACCESS (Lawyers Collective HIV/AIDS Unit, Mumbai, India), Mar. 2012, at 4 [hereinafter *Access March*].

⁶³ *Id.*; *Written Submissions on Behalf of the Intervenor*, SPICY IP, <http://www.spicyip.com/docs/petition-tenth-pdf.pdf> (last visited May 24, 2014) [hereinafter *Written Submissions*] (noting that July 1997 was the patent's priority date); see also Raghul Sudheesh, *Novartis Case Profession Shammad Basheers Academic Intervention Before the Supreme Court*, BAR & BENCH (Nov. 22, 2012, 10:20 AM), <http://barandbench.com/content/novartis-case-professor-shammad-basheers-academic-intervention-supreme-court#.UVjziVcQOf0> (explaining Professor Basheer's intervention and arguments before the Indian Supreme Court).

⁶⁴ Lee, *supra* note 4, at 293.

⁶⁵ *Id.* at 298–99; Helen Pidd, *Indian Court to Hear Crucial Novartis Patent Case on Cut-Price Generic Drugs*, THE GUARDIAN (Aug. 21, 2012, 10:27 AM), <http://www.guardian.co.uk/business/2012/aug/21/novartis-court-battle-glivec-patent>.

Novartis appealed the rejection to the Madras High Court in May 2006, opposed by the Indian Government, several generic drug companies, and an Indian NGO, the Cancer Patients Aid Association.⁶⁶ Novartis argued, *inter alia*, that the Patent Controller erred under Section 3(d), that Section 3(d) was not compliant with Article 27 of TRIPS, and that Section 3(d) was unconstitutional.⁶⁷ The case was bifurcated between the Madras High Court and the Intellectual Property Appellate Board (IPAB).⁶⁸

The Madras High Court took up the issues of TRIPS compliance and constitutionality, issuing an opinion against Novartis on August 8, 2007.⁶⁹ First, the court held that it lacked jurisdiction to review whether Section 3(d) is TRIPS compliant.⁷⁰ It concluded that it lacked authority to decide whether a domestic Indian law is compliant with an international treaty because the Indian government had not "domesticated" TRIPS.⁷¹ In other words, India had not officially made the treaty binding law domestically.⁷² It found that Article 64 of TRIPS provides for dispute resolution through the WTO DSB and recommended that the Swiss government take its case there.⁷³ The high court also considered whether it could provide declaratory relief that Section 3(d) is not TRIPS compliant.⁷⁴ It concluded that it could provide such relief under the Indian Constitution, but decided not to in this instance because it would "serve no useful purpose to the petitioner," as the court could not compel the Indian parliament to change the law to comply with TRIPS.⁷⁵ Thus, the court did not reach the question of whether Section 3(d) is compliant with TRIPS Article 27.

Second, the court decided that Section 3(d), particularly the term enhanced efficacy, does not violate Article 14 of the Constitution of India.⁷⁶ The court rejected Novartis' arguments that the provision is "vague" or "arbitrary" and

⁶⁶ Prashant Reddy, *Full Text of the Letter Asking for Justice Bhandari's Recusal from the Novartis Glivec Dispute*, SPICY IP (Sept. 8, 2011), <http://spicyipindia.blogspot.com/2011/09/full-text-of-letter-asking-for-justice.html>.

⁶⁷ Lee, *supra* note 4, at 299–300.

⁶⁸ *Id.* at 299.

⁶⁹ *Id.*; Novartis AG v. Union of India, 2007 A-I-R 24759 (Madras H.C.).

⁷⁰ Lee, *supra* note 4, at 300.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*; Gopakumar K.M., *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 LAW & DEV. REV. 325, 336 (2010). See Shanunad Basheer & Prashant Reddy, "Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d), 20 NAT'L L. SCH. INDIA REV. 131, 140–43 (2008) (critiquing of the grounds on which the Madras High Court made its decision in *Novartis AG* and providing an alternate approach to reaching the conclusion that Indian courts lack jurisdiction to decide whether a law complies with TRIPS).

⁷⁴ Lee, *supra* note 4, at 300–01.

⁷⁵ *Id.* at 301.

⁷⁶ NISHITH DESAI ASSOCIATES, *supra* note 34, at 26.

conferred uncontrolled discretion to the Patent Controller.⁷⁷ Instead, similar to the U.S. Supreme Court requiring a mere “intelligible principle” to overcome a non-delegation doctrine challenge,⁷⁸ it found that the legislature routinely uses more general terms for courts to interpret on the facts of a particular case.⁷⁹ In any case, it found Novartis a sophisticated party capable of interpreting technical language.⁸⁰

The IPAB, a special tribunal established in 2003 to hear challenges to rejections of patent applications, took up the issue of the patent office’s rejection of the Glivec patent on the merits.⁸¹ The proceedings were disrupted by the fact that the government at first appointed S. Chandrasekharan, former Controller of the Chennai Patent Office, to be the “technical member” of the Chennai-based IPAB.⁸² Although he had not been directly involved with the rejection of Novartis’s application, his filing an affidavit defending the rejection in later litigation raised serious questions about his impartiality.⁸³ The IPAB dismissed Novartis’s objection to S. Chandrasekharan’s participation before the Madras High Court.⁸⁴ After litigation back and forth over this matter,⁸⁵ Novartis’s appeal of the patent rejection on the merits was finally heard by a special bench of the IPAB, comprising Justice Negi and Dr. P.C. Chakraborty, the latter acting as “Technical Member,” in November and December 2008.⁸⁶

In June 26, 2009, the IPAB issued a decision overturning the Patent Controller’s rejection of the application based on lack of novelty and inventive step, but upholding its findings as to Section 3(d).⁸⁷ The IPAB held that “a person skilled in the art just can not predict the polymorphism and prepare the subject compound from the available disclosure,” and therefore, the patent was

⁷⁷ Lee, *supra* note 4, at 301–02.

⁷⁸ *Whitman v. American Trucking Ass’ns*, 531 U.S. 457, 472, 474 (2001), available at <http://supreme.justia.com/cases/federal/us/531/457/case.pdf>.

⁷⁹ *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (Madras H.C.) 14 (finding “[us]ing general expressions in a Statute, leaving the court to understand it’s meaning, would not be a ground to declare a section or an Act ultra vires”).

⁸⁰ Lee, *supra* note 4, at 302.

⁸¹ *Id.* at 299–300.

⁸² Shamnad Basheer, *Allegations of Bias in the Novartis Patent Litigation*, SPICY IP BLOG (June 20, 2007, 2:32 PM), <http://spicyip.com/2007/06/allegations-of-bias-in-novartis-patent.html>.

⁸³ *Id.*

⁸⁴ Lee, *supra* note 4, at 303; Shamnad Basheer, *Novartis Case at IPAB Stayed . . .*, SPICY IP BLOG (Aug. 10, 2007, 1:53 PM), <http://spicyip.com/2007/08/Novartis-case-at-ipab-stayed.html>.

⁸⁵ Lee, *supra* note 4, at 303; Basheer, *supra* note 84.

⁸⁶ Lawyers Collective HIV/AIDS Unit, *Novartis Case: Background and Update – Supreme Court of India to Recommence Hearing*, LAWYERS COLLECTIVE (Sept. 5, 2011), <http://www.lawyerscollective.org/new/s/archived-news-a-articles/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html>.

⁸⁷ *Id.*

not anticipated.⁸⁸ The U.S. FDA's orange book data for imatinib mesylate were based on Novartis's 1993 patent for imatinib in the United States, but because these data were published after 2005, they did not predate the priority date of the contested application.⁸⁹ Moreover, because not just any process for converting imatinib to imatinib mesylate would inevitably lead to the beta form, which was claimed in Novartis's rejected application, the molecule was not inherently anticipated⁹⁰ under the American case *Schering Corp. v. Geneva Pharmaceuticals, Inc.*⁹¹

On the inventive step question, IPAB held that because appellant Novartis made a technical advance beyond existing knowledge by isolating the polymorphism imatinib mesylate and identifying properties of the beta crystal form that made it suitable for use in "the making of oral solid drug formulation for curing cancer," the invention was not obvious.⁹² IPAB rejected respondent's argument that since the mesylate form of imatinib falls within the ambit of broad prior art patents, imatinib mesylate as claimed was obvious.⁹³ Under the prior art, there were "multiple choices of free base including imatinib and their salts" and "[n]o one [salt was] specially identified as important."⁹⁴ Therefore, an "uninventive man ha[d] no [reason] to choose mesylate."⁹⁵

On Section 3(d), IPAB held that Novartis's patent application did not satisfy the provision's requirement of enhanced efficacy, and therefore, upheld the Patent Office's decision.⁹⁶ First, IPAB found that Section 3(d) applied because the invention fell under "drugs/pharmaceuticals/pharmacology."⁹⁷ Next, the board stated that it agreed with the definition of efficacy set forth by the Madras High Court as requiring a "therapeutic effect in healing a disease or having a good effect on the body."⁹⁸ It found it impossible to "quantify this term by any general formula" because what Section 3(d) requires could "vary from case to case as per [the] situation."⁹⁹ However, IPAB held that (1) "bio-

⁸⁸ Novartis AG v. Union of India (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ 339 F.3d 1373 (Fed. Cir. 2003).

⁹² Novartis AG v. Union of India (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*; Lawyers Collective HIV/AIDS Unit, *supra* note 86.

⁹⁷ Novartis AG v. Union of India (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>; NISHITH DESAI ASSOCIATES, *supra* note 34, at 21–22.

⁹⁸ Novartis AG v. Union of India (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

⁹⁹ *Id.*

availability is not the same as therapeutic efficacy” and (2) Appellant cannot create its own meaning of efficacy.¹⁰⁰ Since imatinib mesylate merely claimed a 30% increase in bio-availability over the prior art, IPAB held that Novartis had failed to establish enhanced efficacy.¹⁰¹

Following IPAB’s order, Novartis appealed to the Indian Supreme Court by filing a special leave petition challenging IPAB’s interpretation of Section 3(d) and its application in this case.¹⁰² Respondents filed cross-petitions challenging IPAB’s holdings on novelty and inventive step.¹⁰³ The Supreme Court began hearing final arguments on August 9, 2011.¹⁰⁴ A decision was expected since November 2012 and finally came out on April 1, 2013.¹⁰⁵

III. DOES EVERGREENING OCCUR IN INDIA?

As the stated purpose of Section 3(d) is to prevent evergreening, a dissection of different theories of evergreening and exposition of whether evergreening occurs in India are key to analyzing Section 3(d). The meaning of evergreening is extremely fraught. Evergreening has been explained to the lay public by groups like MSF as a way for MNCs to disguise a drug that has already received a patent in order to receive a “secondary patent” on an allegedly new drug that restarts the twenty year period of exclusivity anew.¹⁰⁶ Through videos and infographics, evergreening is portrayed as an artifice to patent a so-called “improvement” on a drug, even though that improvement is minimal.¹⁰⁷ The truth, however, is much more complicated, and inaccurate statements on the subject are surprisingly common.

Thus, this part of the Article answers the question: Does evergreening, the intended target of Section 3(d), occur as it is frequently articulated—that is, as a persistent, pernicious practice bordering on defrauding the public? If not, then what occurs in reality?

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² Lawyers Collective HIV/AIDS Unit, *supra* note 86.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ See *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311 (India), available at <http://supremecourtofindia.nic.in/outtoday/patent.pdf>; George, *supra* note 2; Kulkarni, *supra* note 2; Sharma, *supra* note 2.

¹⁰⁶ *How Does Evergreening Restrict Access to Medicines?*, MEDECINS SANS FRONTIERES, <http://aids2012.msf.org/2012/the-trans-pacific-partnership-agreement-evergreening/> (last visited May 24, 2014); *‘Evergreening’ Drugs: An Attack on Access to Medicines*, MEDECINS SANS FRONTIERES (Mar. 20, 2012), <http://www.msfaccess.org/content/evergreening-drugs-attack-access-medicines>.

¹⁰⁷ *How Does Evergreening Restrict Access to Medicines?*, *supra* note 106; *‘Evergreening’ Drugs: An Attack on Access to Medicines*, *supra* note 106.

The short answer is that what pharmaceutical companies do that could conceivably be called evergreening is not necessarily harmful to society. While pharmaceutical patents are used to extend monopolies over drugs, secondary patents, like the one sought for imatinib mesylate, frequently cover the only pharmaceutically usable form of the drug known—the very innovation that the patent system means to incentivize.¹⁰⁸ An interpretation of Section 3(d) that chills such incremental, but critical innovation, may do more harm than good.

A. UNSOUND THEORIES OF EVERGREENING

Where evergreening has been described as re-patenting identical subject matter during the life of a preexisting patent, evergreening does not occur. The Indian Patent Office prohibits such patents by requiring an “inventive step” and “novelty” for all new patents.¹⁰⁹ Gowree Gokhale, the head of the Intellectual Property group at Nishith Desai Associates, stated simply that “If a second drug had *identical* properties and claims, *it would be obvious*, and the patent office would not grant a patent on it. There would be no controversy. The question is whether certain additional improvements are enough to get another patent.”¹¹⁰

Indian patent law also precludes patenting a reformulation of a drug that would permit the extension of the term of the original patent.¹¹¹ Once a patent is expired, a generic version may be produced. Tapan Ray stated in an interview that “Patent expiration is a legal process. There is no way that a drug company can simply ignore it or override it, so of course a generic entity may [begin producing it].”¹¹² Articles stating that “[e]ver-greening would . . . allow[] a patent holder, nearing the end of the 20-year life of a patent, to renew the

¹⁰⁸ See *infra* note 118 (citing *Valeant Int'l (Barbados) SRL v. Watson Pharms., Inc.*, No. 10-10526-CIV-MORENO, 2011 U.S. Dist. LEXIS 128742, at *4–5, *33 (S.D. Fla. Nov. 7, 2011), *aff'd sub nom.* *Valeant Int'l Berm. v. Actavis, Inc.*, 534 Fed. App'x 999 (Fed. Cir. 2013) (upholding patents covering Aplenzin®, a second-generation successor to Wellbutrin®, because of the drug's unexpected increase in stability and shelf-life); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1080–81 (Fed. Cir. 2008) (upholding validity of patent for Plavix® claiming isomer of prior art compound because of unexpected improvements as to favorable antiplatelet activity and the unfavorable neurotoxicity)).

¹⁰⁹ Indian Supreme Court opinion at p. 40 (quoting Patents (Amendment) Act, 2002 (Act No. 38 of 2002), Section 2(l)(j)) (“invention” means “a new product or process involving an inventive step and capable of industrial application”).

¹¹⁰ Interview with Gowree Gokhale, Intell. Prop. Attorney (Jan. 17, 2013) (emphasis added).

¹¹¹ See D.P.S. Parmar, *Legislative Framework of IP Administration*, OFFICE OF THE CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADE MARKS, at 10–11, http://www.wipo.int/edocs/mdocs/cs/sme/en/wipo_smes_del_08/wi_po_smes_del_08_www_116733-part2.ppt.

¹¹² Interview with Tapan Ray, *supra* note 28.

patent for a fresh 20-year period”¹¹³ are not just misleading, but incorrect. Even if evergreening is occurring in some sense, it is not occurring through the renewal of a preexisting patent.

A third, more plausible, theory of evergreening is that by deliberately staggering patent applications, pharmaceutical companies can patent different aspects of a single drug to preclude the production of the drug after the expiration of the original patent. Several scholars have cited this definition of evergreening, using vague examples without demonstrating how this is done.¹¹⁴ In fact, a later patent on the packaging of a particular patented drug would not prevent generic companies from selling the drug in different packaging after the expiration of the patent on the drug itself. Even if some aspect of the commercial drug itself, such as the capsule, were patented, generic companies would be free to create a different capsule for a generic version after the drug patent expired. Furthermore, a drug company cannot simply postpone obtaining a patent on a new aspect of the drug, dose, or packaging if it has already been using that drug, dose or packaging commercially. Under Indian patent law, as under U.S. patent law, inventors cannot patent an invention that “was publicly known or publicly used in India before the priority date of that claim.”¹¹⁵ If the drug company claims an earlier priority date to prevent its earlier invention from being considered prior art, it cannot also obtain an expiry on the term of the patent later than the earlier invention’s. Simply stated, the term of a patent is based on the priority date.

A last theory of evergreening is that pharmaceutical companies patent a new commercial embodiment of a drug, say, “version 2.0,” when it is no better than the original commercial embodiment of the drug, “version 1.0,” with the intention of forcing patients to pay on-patent prices beyond the life of the first patent. However, this theory, too, lacks merit. If version 2.0 were no better than version 1.0, there would be no reason for patients to demand version 2.0 when version 1.0 goes off-patent. In fact, not only should the demand for version 2.0 be no higher than for version 1.0, but after version 1.0’s patent expires, demand for version 1.0 should be *much higher* due to the entrance of generic competitors into the market. Continued high demand for a newer

¹¹³ Mueller, *supra* note 8, at 550 n.356 (quoting *Better Now, But . . .*, BUS. STANDARD (Mar. 24, 2005), http://www.business-standard.com/article/opinion/letters-now-but-105032401068_1.html).

¹¹⁴ Basheer & Reddy, *supra* note 73, at 136 n.17; Mueller, *supra* note 8, at 551 n.357; Timothy Bazzle, Note, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India’s Patent System and Essential Medicines*, 42 GEO. J. INT’L L. 785, 802 (2011) (describing the “pernicious practice of ‘evergreening’ pharmaceutical patents, a process whereby drug companies artificially extend their period of patent exclusivity by patenting trivial secondary elements of their patented drug when the underlying patent is set to expire”).

¹¹⁵ The Patents Act, 1970 § 25(1)(d), No. 39 of 1970, INDIA CODE (1993), available at <http://Indiacode.nic.in>.

iteration in spite of the availability of the old version at an off-patent price is probative of the new version's enhanced efficacy, in a broad sense of the term.

It is true that high demand for a reformulation of a drug does not necessarily prove enhanced efficacy. If it is less expensive for a drug company to generate hype for a new version of a drug that lacks enhanced efficacy than it is to develop a genuine innovation over the prior art, the company has strong incentives to patent the new version and deceive health care providers and patients into buying it at on-patent prices. The commercial success of "me-too drugs" that are no better than drugs already on the market is well-documented in the United States context.¹¹⁶ Still, this seems less likely to occur in India because the average Indian consumer is much more price-sensitive than the average consumer in a developed country when it comes to on-patent drugs.¹¹⁷ As described in Part II, most patients in India must pay out of pocket for drugs. There is the possibility that patients would be more willing to pay for drugs that they believe will be more effective for treating life-threatening diseases like AIDS or cancer. However, this would probably only comprise a small set of cases, and the parties currently opposing Novartis are not making the argument that Glivec is not more effective than other leukemia drugs and should not be sold at all.

B. EVERGREENING AS IT OCCURS IN INDIA

In contrast to the misbegotten theories described above, what *does* happen in pharmaceutical patenting is that a drug company can obtain a secondary patent on a later iteration of the drug, including the commercial formulation of the drug, after patenting the raw active molecule at an earlier stage of drug development.¹¹⁸ As explained above, such a secondary patent will not prevent generic drug companies from using the earlier iteration of the drug, including the active molecule if that is what was patented, when that iteration's patent

¹¹⁶ Scott Hensley, *Should FDA Hold 'Me-Too' Drugs to a Higher Standard?*, NPR SHOTS (Feb. 15, 2011, 5:25 PM), <http://www.npr.org/blogs/health/2011/02/17/133784085/should-fda-hold-me-too-drugs-to-a-higher-standard/>. But see Thomas H. Lee, "Me-too" Products—Friend or Foe?, 350 NEW ENG. J. MED. 211, 211–12 (2004) (arguing that so-called "me-too" products actually enhance competition and offer better value alternatives in the market for a particular class of drug).

¹¹⁷ See Bazzle, *supra* note 114, at 808–09.

¹¹⁸ See, e.g., Valeant Int'l (Barbados) SRL v. Watson Pharms., Inc., No. 10-20526-CIV-MORENO, 2011 U.S. Dist. LEXIS 128742, at *4–5, *29, *32 (S.D. Fla. Nov. 7, 2011), *aff'd sub nom.* Valeant Int'l Berm v. Actavis, Inc., 534 F. App'x 999 (Fed. Cir. 2013) (upholding a patent on bupropion hydrobromide as valid over the prior art, including bupropion hydrochloride and a prior patent on bupropion).

expires.¹¹⁹ Thus if the newer version for the drug is not a true improvement over the version originally patented, it is in the interest of generic companies to manufacture and sell the older version because patients should be indifferent between the inexpensive expired and expensive on-patent versions. The one time secondary patents would evergreen, or delay the entrance of important generics into the market is, ironically, when the modified version is *better* than the original, as demonstrated by high patient demand.

IV. WHAT IS ENHANCED EFFICACY?

The meaning of enhanced efficacy is the central issue in *Novartis AG*.¹²⁰ As explained below, the Indian Supreme Court in *Novartis AG* chose among three different interpretations of enhanced efficacy. The first interpretation is that enhanced efficacy is subsumed completely within India's "inventive step" and "industrial application" requirements. In India, as well as the EU, inventive step roughly approximates non-obviousness in the United States; and industrial application, utility in the United States.¹²¹ The second interpretation is that enhanced efficacy refers broadly to any improvements on the functioning of a pharmaceutical as a treatment. The third is that enhanced efficacy means therapeutic efficacy only, as narrowly defined by the Madras High Court and the IPAB. Each interpretation has its own attendant consequences for evergreening, public health, and innovation, and there are tradeoffs to each.

A. INVENTIVE STEP OR INDUSTRIAL APPLICATION REQUIREMENT

One interpretation of Section 3(d)'s enhanced efficacy requirement is that it is merely a rearticulation of the inventive step or industrial application requirement in the context of pharmaceutical product patents.

Section 3(d) would be least likely to contravene TRIPS Article 27.1 under this interpretation of enhanced efficacy. Inventive step and industrial

¹¹⁹ As a simple example, a patent on cell phones would not extend the protection of U.S. Patent No. 174,465, Alexander Graham Bell's expired patent on phones. The cell phone patent would only prevent people from making or using phones if the phones were cell phones.

¹²⁰ *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 56 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf> (explaining that "[w]e are clearly of the view that the importance of . . . 3(d) . . . cannot be under-estimated," and discussing whether the claimed subject matter fulfills the "enhanced efficacy" requirement at length).

¹²¹ See *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 29 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf> ("For the purposes of this Article, 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.").

application are already required in India as a result of TRIPS Article 27.1.¹²² According to Section 2(1)(j) of the 1970 Act, an "invention" is by definition a new product or process that involves an inventive step and is capable of industrial application.¹²³

Most of the practitioners interviewed for this Article believe Section 3(d) to be no more than an explanation of the inventive step or industrial application requirement in the field of pharmaceutical products. Thus, Section 3(d) is essentially not an enhanced efficacy requirement and does not add any additional barrier to patentability. For example, one interviewee, Aditi Jha, stated that she sees Section 3(d) as "just another form of saying that something is non-obvious in a more concrete way."¹²⁴ In her view, "the patent office could just demand higher efficacy [to obtain a secondary patent] even without Section 3(d). *I don't think Section 3(d) really makes a difference.*"¹²⁵ In other words, the inventive step and industrial application requirements themselves require some level of increased efficacy above the prior art in order to obtain a patent. According to Jha, Section 3(d) was written into the 2005 Amendment for primarily political reasons—the legislature was eager to mollify a constituency skeptical of the new provisions of the 2005 Amendment permitting pharmaceutical product patents.¹²⁶ Generic manufacturers and some patient groups feared that the 2005 Amendment, without a qualifying provision, would give rise to an onslaught of patents that would destroy Indian generic manufacturers' business model of reverse engineering innovative drugs.¹²⁷

Another interviewee, Leena Menghaney of Doctors Without Borders, shared a similar view that Section 3(d) is part and parcel of India's inventive step or non-obviousness standard. She believed, however, that Section 3(d) does real work by ensuring non-obviousness is strictly enforced on pharmaceutical product patent applications.¹²⁸ According to Menghaney, "A lot of the developing countries blindly grant whatever developed countries grant. They don't look closely enough at the prior art to examine what is obvious."¹²⁹ However, she too does not believe that Section 3(d) imposes an *additional*

¹²² See *supra* text accompanying notes 38–40.

¹²³ Ranjan Matthew, Lakshmikumaran & Sridharan, *Patentability Requirements in India* (2011), http://www.lakshmisri.com/Uploads/MediaTypes/Documents/L&SWebsite_IPR_Featured_Ranjan.pdf.

¹²⁴ Interview with Aditi Jha, Patent Attorney (Jan. 8, 2013).

¹²⁵ *Id.* (emphasis added).

¹²⁶ *Id.*

¹²⁷ See Rai, *supra* note 44, at 77–78 (noting that the local Indian pharmaceutical industry has not yet reached the stage where it can discover or develop new chemical entities).

¹²⁸ Interview of Leena Menghaney, Advocate from Doctors Without Borders in New Delhi (Jan. 24, 2013) ("Patent offices in India should consider this a clear signal that the law should be strictly applied, and frivolous patent applications should be rejected.").

¹²⁹ *Id.*

barrier unique to pharmaceutical products.¹³⁰ Rather, Section 3(d) merely ensures that India's overextended patent examiners¹³¹ do not cursorily gloss over the inventive step requirement for complex chemical inventions.¹³²

What Jha, Menghaney, and other practitioners may be implying is that Section 3(d) creates a doctrine analogous to the United States' "obvious to try" doctrine that has experienced recent revival in cases like *KSR v. Teleflex*, *Ex parte Kubin*, and *Pfizer v. Apotex*.¹³³ If we assume that U.S. patent law is consistent with TRIPS, which I recognize is itself an assumption for the sake of argument,¹³⁴ then Section 3(d) can be construed as consistent with TRIPS by analogy. Although *KSR* was about a mechanical and electronic device, not a pharmaceutical, it nevertheless shifted the overall tone of the courts towards using "obvious to try" to supplement the "teaching, suggestion, or motivation test."¹³⁵ In *KSR*, the U.S. Supreme Court commented that the Federal Circuit had "conclude[d] in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try.'"¹³⁶ Following *KSR*, the court in *Pfizer v. Apotex* found a patent obvious because the prior art had already narrowed down the potential combinations for an effective drug to fifty-three besylates.¹³⁷ Further, in *Ex parte Kubin*, a biotechnology case, the Patent Board reaffirmed the use of obvious to try, citing *KSR*.¹³⁸ Under the "obvious to try" test, if the prior art narrows down a finite set of particular and predictable combinations that are obvious for a person of ordinary skill in the art to try, then those combinations fail the non-obviousness requirement.¹³⁹ Section 3(d) could merely embody a legislative judgment that a reformulation or "slight" modification of a chemical compound is per se obvious to try.¹⁴⁰

¹³⁰ *Id.*

¹³¹ See INNOVACCER, OPERATIONAL ISSUES AT IP INDIA OFFICE: A BRIEF REPORT 2-4 (2011), http://dipp.nic.in/English/Discuss_paper/feedback31_CGPDTM_Innovaccer_16December2011.pdf.

¹³² *Id.* at 186.

¹³³ Andrew V. Trask, "Obvious To Try": A Proper Patentability Standard in the Pharmaceutical Arts?, 76 FORDHAM L. REV. 2625 (2008), available at <http://ir.lawnet.fordham.edu/flr/vol76/iss5/9>.

¹³⁴ Linda Lee made a similar assumption in her article: "Assuming that the patent laws of other countries are TRIPS-compliant and absent WTO ruling on the contrary, Novartis has likely overstated the noncompliance of Section 3(d)." Lee, *supra* note 4, at 309.

¹³⁵ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

¹³⁶ Trask, *supra* note 133, at 2647 (alteration in original) (quoting *KSR*, 550 U.S. at 421).

¹³⁷ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364-69 (Fed. Cir. 2007).

¹³⁸ Trask, *supra* note 133, at 2658.

¹³⁹ See *id.* at 2658-59.

¹⁴⁰ If Section 3(d) is a per se obvious to try rule, I believe that it is grossly overinclusive and creates a danger of too many Type I errors. While there were only fifty-three reasonably possible pharmaceutically-acceptable salts in *Pfizer*, there could be hundreds or thousands in other cases, with no suggestion in the prior art of which would be therapeutically effective.

As for Section 3(d) being an elaboration of industrial application in the pharmaceutical sphere, Aditi Jha thinks Section 3(d) "is meant to prevent the patenting of stereoisomers that were accidentally discovered."¹⁴¹ In her view, "the provision simply requires that the isomer actually *does something*."¹⁴² In other words, Section 3(d) is India's answer to the specific utility or substantial utility requirement that constitutes one requirement of Section 101 in the United States.¹⁴³ Like specific utility or substantial utility in the United States, Section 3(d) may simply require that patent applicants state a sufficiently well-defined use for the new drug or demonstrate a real-world benefit to the public at the time of filing, respectively.

B. MORE THAN INVENTIVE STEP AND INDUSTRIAL APPLICATION

Alternatively, the Indian Supreme Court in *Novartis AG* could have found, as the lower courts did, that Section 3(d)'s enhanced efficacy requirement demands more than on inventive step and industrial application to obtain a pharmaceutical product patent. I first argue that under any such interpretation of enhanced efficacy, Section 3(d) is not TRIPS compliant. I then present arguments for and against an additional enhanced efficacy requirement, generally. Next, I argue for and against a further restriction of the enhanced efficacy requirement to a narrow therapeutic efficacy requirement. Finally, I critique India's use of patent law theory to justify actions much more consistent with a "social welfare" theory, which I will explain.

1. *Noncompliance With TRIPS.* The Indian Supreme Court has interpreted enhanced efficacy in Section 3(d) to mean medically significant efficacy that is fundamentally different from the inventive step and industrial application requirements.¹⁴⁴ This interpretation departs from U.S. conceptions of pharmaceutical patent protection.¹⁴⁵ If the U.S. is assumed to be a good benchmark of compliance with TRIPS,¹⁴⁶ then by creating an additional barrier

¹⁴¹ Interview with Aditi Jha, *supra* note 124.

¹⁴² *Id.*

¹⁴³ See 35 U.S.C. § 101 ("useful"); MPEP Section 2107, available at <http://www.uspto.gov/web/offices/pac/mpep/s2107.html> ("A claimed invention must have a specific and substantial utility. This requirement excludes 'throw-away,' 'insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. § 101."); see also *supra* note 121.

¹⁴⁴ *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 11 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf> (finding that "section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products" and "no force in [Novartis's] submission that section 3(d) is a provision *ex majore cautela*").

¹⁴⁵ See *infra* text accompanying notes 155–72.

¹⁴⁶ See *supra* text accompanying note 133.

to patenting drugs, Section 3(d) contravenes TRIPS. This conclusion is based on past TRIPS adjudications, the plain language of Article 27.1, WTO jurisprudence, interviews, and the literature.

The plain language of Article 27.1 is ambiguous, but if anything, it suggests that inventive step, industrial application, and novelty are to be the only requirements for patentability.¹⁴⁷ As stated above, the first part of TRIPS Article 27.1 says that patents shall be available in “all fields” of technology if they are “new, involve an inventive step and are capable of industrial application.”¹⁴⁸ According to a well-known semantic canon of statutory construction, *expressio unius est exclusio alterius*, the explicit mention of items in a list gives rise to an inference that all other items are excluded.¹⁴⁹ Logical reasoning about the nature and purpose of TRIPS leads to the same conclusion. If TRIPS was meant to guarantee Intellectual Property Rights (IPRs) or at least minimum IPRs in all members of the WTO, especially developing countries that lacked such rights, then to allow such countries to append additional requirements onto the list of requirements set forth by TRIPS would render the provision a nullity. A developing country could circumvent the spirit of TRIPS by simply erecting extra barriers to patenting wherever it believed it would benefit. The second part of Article 27.1, the non-discrimination clause, only strengthens the argument that Section 3(d) violates TRIPS by clarifying that the named requirements should not be applied differently to different fields of technology.¹⁵⁰

WTO jurisprudence does not settle the question of compliance in *Novartis AG. Canada Pharmaceuticals*, the key non-discrimination case described in Part II.C, can be distinguished from *Novartis AG*. Whereas Canada’s stockpiling exception applied by statute to patents of all types and not necessarily merely to pharmaceutical patents,¹⁵¹ Section 3(d) clearly singles out pharmaceutical patents for special treatment on its face. It is hard to argue that Section 3(d) does not sanction *de jure* discrimination against such patents. Moreover, although the decision found that some discrimination may be permitted for *bona fide* reasons, the dispute resolution panel was careful to suggest that facts more extreme than those in that case could cross the non-discrimination line. The

¹⁴⁷ U.S. industry adopts this view. See Dean, *supra* note 22, at 735; Sampat, Shadlen & Amin, *supra* note 3, at 414.

¹⁴⁸ See *supra* text accompanying note 38 (quoting TRIPS Article 27.1).

¹⁴⁹ See, e.g., *People v. Smith*, 393 Mich. 432, 436, 225 N.W.2d 165, 166 (1975); *Bowsher v. Synar*, 478 U.S. 714, 723, 726 (1986) (finding that explicit grant of power to Congress to remove an officer of the United States by impeachment gives rise to negative implication that Congress cannot remove such an officer by other methods).

¹⁵⁰ See *supra* text accompanying note 38 (quoting TRIPS Article 27.1).

¹⁵¹ Stout, *supra* note 41, at 187.

panel emphasized the importance of ensuring that member governments do not abuse the "bona fide reason" loophole to "limit exceptions to areas where right holders tend to be foreign producers."¹⁵²

Throughout *Novartis AG*, the courts on every level have invoked the importance of the generic drug industry to India's economy, which raised the question of whether Section 3(d) is being used prejudicially against pharmaceutical patent holders, which tend to be foreign MNCs.¹⁵³ Interviewee Khushboo Baxi explained that her law firm's research suggests that the courts in *Novartis AG* have "listened more to the Indian drug market than to the other side" and that "NGOs, legal aid societies put pressure on the courts" to consider "the survival of the generics industry."¹⁵⁴ On these facts, Section 3(d) may violate the spirit of Article 27.1 to promote free and fair trade if it is interpreted so strictly as to preclude the patenting of a large portion of pharmaceutical drugs that foreign companies apply for, to the benefit of generic drug manufacturers.

In addition, Section 3(d)'s enhanced efficacy requirement for pharmaceutical patents is fundamentally different than limitations found in U.S. jurisprudence, yet popularly cited papers have drawn analogies to U.S. jurisprudence to defend Section 3(d). For example, while Linda Lee concedes that the efficacy requirement "has no explicit parallel in any other patent regime in the world,"¹⁵⁵ she argues that "because other countries have taken more indirect routes to achieve similar objectives, Section 3(d) is not a radical departure from international practices."¹⁵⁶ In other words, she believes that Section 3(d) creates no more of a loophole to TRIPS compliance than other countries' patent doctrines. The examples from the United States that she uses, however, do not support her thesis, particularly after the IPAB decision, which addressed some of them directly.

One doctrine Lee points to is the doctrine of inherent anticipation, which U.S. courts have used to invalidate a patent on derivatives of known substances

¹⁵² *Id.* at 186.

¹⁵³ Early in its decision, the Supreme Court of the India refers to sections of the IPAB and Madras High Court decisions in *Novartis* focusing on "the object which [section 3(d)] wanted to achieve namely . . . to provide easy access to the citizens of the country to life saving drugs" and "the pricing of the drug Gleevee by the appellant." *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 11 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>. The Court further states after extensive analysis of the history and purposes of Section 3(d) that it "expressed its bewilderment over the price of the drug." *Id.* at 49 n.1. See generally *More Foreigners than Indians Receiving Patents in India*, ECON. TIMES (May 22, 2011, 12:45 PM), http://articles.economictimes.india.com/2011-05-22/news/29571273_1_patents-act-patent-protection-utility-models.

¹⁵⁴ Interview with Khushboo Baxi, Intell. Prop. Attorney (Jan. 23, 2013).

¹⁵⁵ Lee, *supra* note 4, at 305.

¹⁵⁶ *Id.* at 304.

in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*¹⁵⁷ In that case, however, the claimed metabolite was “necessarily and inevitably” formed by the human body upon ingestion of a prior art substance.¹⁵⁸ The IPAB in *Novartis AG* specifically addressed the respondents’ inherent anticipation argument and found that there are no prior art documents describing a method that inevitably and inherently produces the beta form of imatinib in even trace amounts.¹⁵⁹ Moreover, the imatinib mesylate claimed in the rejected application is of the purified compound, not a mixture in which the beta form is present in trace amounts.¹⁶⁰

Lee also argued that U.S. courts have rejected the patenting of derivatives under the double patenting doctrine, which prohibits patentees from ownership of more than one patent with claims to the same invention or obvious modifications of the invention.¹⁶¹ The doctrine has both a statutory and a common law basis. Statutory double patenting comes from the language of 35 U.S.C. § 101, which says that an inventor may obtain “a” patent for his or her invention¹⁶²—not multiple patents. Statutory double patenting is inapposite to an ordinary Section 3(d) case, such as *Novartis AG*, because it requires conflicting claims to be exactly coextensive in scope.¹⁶³ An application attempting to patent a particular acid addition salt of a previously patented free base, in this case imatinib mesylate, is not claiming the same exact subject matter.

Non-statutory double patenting is also distinguishable from Section 3(d), even though that doctrine, like Section 3(d), was designed with the public policy purpose to prevent “an improper extension of the patent rights due to the unexpired second patent.”¹⁶⁴ Nonstatutory double patenting prevents a patent owner from obtaining a second patent with claims ‘not patentably distinct’ from the claims of an earlier patent, whether because the later claims are obvious over or anticipated by the earlier claim.¹⁶⁵ Obviousness type double patenting (OTDP) basically applies ordinary 35 U.S.C. § 103 non-obviousness analysis except that the court compares the patentee’s later claims with its earlier claims,

¹⁵⁷ 339 F.3d 1373 (Fed. Cir. 2003).

¹⁵⁸ Lee, *supra* note 4, at 306.

¹⁵⁹ *Novartis AG v. Union of India* (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

¹⁶⁰ *Id.*

¹⁶¹ Lee, *supra* note 4, at 306.

¹⁶² *Id.* at 306 n.191.

¹⁶³ Arnold B. Silverman, *Double Patenting—One Patent per Invention*, 48 JOM 67, 67 (1996), available at <http://www.tms.org/pubs/journals/JOM/matters/matters-9606.html>.

¹⁶⁴ *Id.* See also *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012); *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

¹⁶⁵ *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008). See also *Otsuka*, 678 F.3d at 1297.

rather than with all relevant prior art.¹⁶⁶ Since the IPAB found that Novartis's claims were not obvious in light of the prior art, including Novartis's own prior patents, analysis under OTDP would result in no different an outcome on the patentability of the beta crystalline form of imatinib mesylate.¹⁶⁷ Additionally, there was no argument before the IPAB that Novartis was attempting to use a new secondary patent to prevent the production of other forms of imatinib claimed in the older patent.¹⁶⁸

These illustrative examples addressing Lee's analysis demonstrate that U.S. patent law does not require anything quite like Section 3(d) does. The fact that Novartis was able to obtain a patent on Gleevec¹⁶⁹ in the United States shows that reasonable governments applying the same laws could reach disparate results. The point is that "U.S. law does not require evidence of advantageous properties of a selection invention to be presented in the application."¹⁷⁰ Although the Federal Circuit had recently raised the bar on patent applicants to demonstrate non-obviousness with cases like *Pfizer*, those cases are really about demanding the patentee to present something that (1) was new and (2) was not reasonably expected to succeed at the time of invention.¹⁷¹ In other words, the claimed invention needs to have been produced by the inventor and be materially *different* from, but not necessarily *better* than, the prior art. The U.S.

¹⁶⁶ *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1377–79 (Fed. Cir. 2012); Courtenay C. Brinkerhoff, Foley & Lardner LLP, *A Look At the U.S. Doctrine of Obviousness-Type Double Patenting*, KLUWER PATENT BLOG (June 13, 2012), <http://kluwerpatentblog.com/2012/06/13/a-look-at-the-u-s-doctrine-of-obviousness-type-double-patenting/>.

¹⁶⁷ See *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 338 (S.D.N.Y. 2006) (finding OTDP inquiry "subsumed by the broader statutory inquiry pursuant to 35 U.S.C. § 103" where OTDP prior patent is part of the prior art).

¹⁶⁸ See Brinkerhoff, *supra* note 166 (explaining the application of OTDP to prevent patents that preempt the public use of previously claimed inventions).

¹⁶⁹ "Gleevec" is the commercial name of Glivec in the United States, <http://www.gleevec.com/index.jsp> (for U.S. residents only); FDA Orange Book online's page for patent and market exclusivity information for Gleevec, http://www.accessdata.fda.gov/scripts/cder/ob/docs/pat_exclnew.cfm?Appl_No=021588&Product_No=001&table1=OB_Rx. One of the U.S. patent applications covering Gleevec that the Indian Supreme Court points as similar to the Indian patent application at issue is U.S. Patent App. No. 09/463,097, issued as U.S. Patent No. 6,894,051.

¹⁷⁰ *Selection Inventions – the Inventive Step Requirement, Other Patentability Criteria and Scope of Protection*, AIPPI (Feb. 16, 2009), <http://www.aippi-us.org/images/GR209usa.pdf>.

¹⁷¹ See *Allergan, Inc. v. Apotex Inc.*, 2014 U.S. App. LEXIS 10710, at *30–31 (Fed. Cir. June 10, 2014) ("A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference."); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1374 (Fed. Cir. 2007) ("[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability . . . so long as there was a reasonable probability of success.").

patent system made the per se judgment that the USPTO is not the correct forum for deciding whether a patent is *beneficial* over a decade ago.¹⁷²

The Swiss government has publicly stated that it does not intend to bring the case before the WTO DSB against India if Novartis loses its appeal.¹⁷³ Some interviewees, including Aditi Nadkarni and Dr. Milind Antani, speculated that this suggests that the government itself views Novartis's case as weak.¹⁷⁴ Still, this Article provides analysis that demonstrates that the Swiss government would have a colorable case against India in the DSB under the Supreme Court's interpretation of Section 3(d) as demanding more than ordinary inventive step and industrial application.

2. *Analysis of an Additional Enhanced Efficacy Requirement Generally.* Despite non-compliance with TRIPS, the Supreme Court has adopted an interpretation of Section 3(d) that demands more than inventive step and industrial application. The main benefit of requiring enhanced efficacy is straightforward—although it would have no effect on promoting access to generic medicines for the reasons described in Part III, Section 3(d) would keep out patents on useless and relatively harmless products.¹⁷⁵ Alternatively, to the extent that the theory of evergreening as patenting and creating demand for a useless version 2.0 of a drug on the market happens in some cases, Section 3(d) could have some measurable effect on promoting access to generic medicines by preventing the practice.

However, an enhanced efficacy requirement does create the possibility of blocking the patenting of genuine innovation. Gowree Gokhale sums up the problem: “The issue the pharmaceutical industry is currently facing is that it is difficult to demonstrate ‘enhanced efficacy’ at the time of patenting, even if the reformulated products in fact possess enhanced efficacy.”¹⁷⁶ The Madras High Court's opinion seems to assume that it would be easy to procure efficacy data, if enhanced efficacy exists.¹⁷⁷ If the patent office and courts decide, post-Supreme Court decision, that Section 3(d) demands proof of efficacy in the regulatory sense—that is, statistically significant clinical trials demonstrating efficacy—at the time of patenting, then many efficacious drugs may fail under

¹⁷² *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999) (holding that the “beneficial utility” requirement has become obsolete).

¹⁷³ Basheer & Reddy, *supra* note 73, at 138 n.25 (citing *Swiss Govt Not to Take Novartis Case to WTO*, BUS. STANDARD (Aug. 8, 2007), http://www.business-standard.com/article/economy-policy/swiss-govt-not-to-take-novartis-case-to-wto-107080801003_1.html).

¹⁷⁴ Interview with Aditi Nadkarni, Attorney (Jan. 17, 2013); Interview with Dr. Milind Antani, Intell. Prop. Attorney (Jan. 8, 2013).

¹⁷⁵ *But see supra* Part III.B.

¹⁷⁶ Interview with Gowree Gokhale, *supra* note 110.

¹⁷⁷ See Shamnad Basheer & T. Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232, 255 (2008).

Section 3(d).¹⁷⁸ Pharmaceutical companies typically seek patents up to several years before they are able to sell a commercially viable drug.¹⁷⁹ A patent provides the incentive to perform the clinical trials to get efficacy data by (1) guaranteeing the drug company a right to exclude others from exploiting the eventual fruits of its labor¹⁸⁰ and (2) protecting companies from having their own clinical data used as prior art against their future patent applications.¹⁸¹ If the Supreme Court requires a high level of proof of efficacy too early in the long and arduous¹⁸² process of drug development, it might put the cart before the horse.¹⁸³

Still, the potential for incidental exclusion of secondary products with enhanced efficacy would not be impossible to cure. Patent attorney A.C. suggested in his interview that Section 59 of the 1970 Act as Substituted by Act 38 of 2002, provides for amending an incomplete specification, such that the specification as amended can contain additional statistics and information about a pharmaceutical compound claimed in the original application.¹⁸⁴ This suggests that applicants lacking sufficient proof of efficacy at the time of filing could subsequently amend their applications to include the supporting data, while claiming the benefit of the priority date. There would be no danger of such an amendment enlarging the scope of the claims, because what is claimed would unambiguously remain the chemical compound as originally claimed.¹⁸⁵

¹⁷⁸ See *Written Submissions*, *supra* note 63, at 15–16 (citing Basheer & Reddy, *supra* note 177, at 255–56).

¹⁷⁹ See Basheer & Reddy, *supra* note 177, at 255–56.

¹⁸⁰ See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276 (1977) (“[T]he patent owner has an incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors.”); *How Drugs Are Developed and Approved*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/> (last visited May 24, 2014) (“New drugs, like other new products, are frequently under patent protection during development. The patent protects the salmon calcitonin sponsor’s investment in the drug’s development by giving them the sole right to sell the drug while the patent is in effect.”).

¹⁸¹ See Basheer & Reddy, *supra* note 177, at 256.

¹⁸² Jane Larkindale, *Why Does It Take So Long To Go from Mouse to Man?*, QUEST (Jan. 1, 2012, 3:11 PM), available at <http://quest.mda.org/article/why-does-it-take-so-long-go-mouse-man> (“On average, it takes a drug about 12 years to get from discovery to market, and it costs about \$1.8 billion per drug that works. Only about one drug in 10,000 actually makes it. However, due to the rigorous processes of preclinical research, about one in five drugs that get an IND [investigational drug application] eventually make it through trials.”).

¹⁸³ See Basheer & Reddy, *supra* note 177, at 256 (presenting an alternative proposal based on the U.S. model for proof of efficacy that would not unduly burden pharmaceutical companies, where, all that would be required is “a reasonable correlation between the activity and the asserted use”).

¹⁸⁴ Interview with A.C., *supra* note 18.

¹⁸⁵ For example, Novartis’s claim over the beta crystalline form of imatinib mesylate would not change with the addition of efficacy data.

3. *Narrowing the Interpretation of Efficacy to Therapeutic Efficacy Only.* If the true purpose of Section 3(d) is to separate minor modifications from genuine innovation, as proponents of Section 3(d) claim, the Supreme Court should have selected a broad interpretation of enhanced efficacy that blocks secondary patents on treatments that do not improve patient outcomes while permitting the patenting of valuable new iterations of drugs. A narrow interpretation of enhanced efficacy would not reward innovation in accordance with patent law theory, as generic manufacturers would be able to free-ride on innovations created as a result of patent incentives only provided in other countries.¹⁸⁶

There are frequently countless ways to try to turn an active drug molecule into a pharmaceutically-accepted formulation, and the different ways can have very different properties.¹⁸⁷ The “secondary” product may be more stable, more potent, less toxic, easier to administer, or cause fewer side effects, and may even be the only commercially viable form of the drug, as in Glivec’s case.¹⁸⁸ Nevertheless, the Supreme Court reaffirmed the Madras High Court and the IPAB’s construction of efficacy as therapeutic efficacy only, rendering some of these genuine improvements over prior art pharmaceuticals unpatentable under Section 3(d).¹⁸⁹ Modifications that improve therapeutic efficacy by having a unique therapeutic effect on the body fulfill Section 3(d)’s demands, while modifications improving drugs in other ways would not.¹⁹⁰

¹⁸⁶ ROGER E. SCHECHTER & JOHN R. THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS* 288–89 (2003) (explaining that under the instrumental theory of patent law, “the patent system encourages individuals to invent” and that absent a patent system, “too few inventions [would be] made”).

¹⁸⁷ See J. Keith Guillory, *Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids*, in *POLYMORPHISM IN PHARMACEUTICAL SOLIDS* 64 (Harry G. Brittain ed., 1999) (as of 1990, more than 350 patents on crystal forms granted on the basis of an advantage in terms of stability, formulation, solubility, bioavailability, recovery, or prevention of precipitation).

¹⁸⁸ See, e.g., *Valeant Int’l (Barbados) SRL v. Watson Pharms., Inc.*, No. 10-10526-CIV-MORENO, 2011 U.S. Dist. LEXIS 128742, at *4–5, *33 (S.D. Fla. Nov. 7, 2011), *aff’d sub nom.* *Valeant Int’l Berm. v. Actavis, Inc.*, 534 F. App’x 999 (Fed. Cir. 2013) (upholding patents covering Aplenzin®, a second-generation successor to Wellbutrin®, because of the drug’s unexpected increase in stability and shelf-life); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1080–81 (Fed. Cir. 2008) (upholding validity of patent for Plavix® claiming isomer of prior art compound because of unexpected improvements as to favorable antiplatelet activity and the unfavorable neurotoxicity).

¹⁸⁹ *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 17–18, 98–100 (India), *available at* <http://supremecourtindia.nic.in/outtoday/patent.pdf> (“[T]he test of efficacy can only be ‘therapeutic efficacy’ . . . we have no doubt that the ‘therapeutic efficacy’ of a medicine must be judged strictly and narrowly.”).

¹⁹⁰ *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 90–92 (India), *available at* <http://supremecourtindia.nic.in/outtoday/patent.pdf> (submitting that “efficacy is that property intrinsic to a particular drug that determines how good an agonist the drug is” and finding that “a mere change of form with properties inherent to that form would not” fulfill Section 3(d)’s “enhanced efficacy” demand).

Since this narrow interpretation of efficacy would render many tangible improvements to drugs unpatentable, it cannot be justified on the principle of preventing pharmaceutical companies from extending monopoly protection on their drugs without producing valuable changes to drugs.

A different theory that justifies the distinction created between "therapeutic" and other types of "efficacy" would be required. The theory could simply be that India should limit pharmaceutical patenting whenever it benefits India to do so, balancing increased access to affordable medicines and loss of incentives to innovate, rather than the nature and extent of innovation in a patent application. The straightforward benefit of disallowing secondary patents under this social welfare-oriented theory is that it undeniably allows India's large population of poor patients to access generic drugs sooner.¹⁹¹

India could have altruistic social welfare reasons to block the patenting of even genuine improvements on drugs. A patent, however innovative the product, is still a monopoly. If the *only* commercially approved version of the drug is the one on which the pharmaceutical company seeks a secondary patent, granting the patent would indeed block generic companies from producing the commercially approved drug until the secondary patent expires.¹⁹² The generic companies would still be welcome to come up with an alternative commercially viable option utilizing the off-patent molecule, but as interviewee Leena Menghaney of MSF stated, "generic companies face high regulatory barriers for making a second tablet with the same active compound inside. The moment you do a different form to avoid the secondary patent, you are facing regulatory barriers because now you have to show bioequivalence [to the MNC's approved drug]."¹⁹³ Considering Indian pharmaceutical companies' current model of reverse engineering rather than doing original research and development, few domestic companies would be up to the challenge.¹⁹⁴ In the meantime, India's large population of poor patients would be denied access to relatively inexpensive generics.

Moreover, limiting patenting protection in India would probably have little impact on incentives for innovation globally. Some interviewees opined that India is too small a market for brand-name pharmaceuticals relative to the world for India's patent policies are unlikely to have a real effect on innovation worldwide. According to Adheesh Nargolkar, "The incentive concern won't

¹⁹¹ See *supra* Part II.B.

¹⁹² If a patent covers the commercialized product, the patentee can legally prevent others from "making, using, offering for sale, selling or importing for those purposes that product in India." The Patents Act, 1970 § 48(a), No. 39 of 1970, INDIA CODE (1993), available at <http://Indiacode.nic.in>.

¹⁹³ Interview with Leena Menghaney, *supra* note 128.

¹⁹⁴ Mueller, *supra* note 8, at 516, 536–39.

become a problem because the other countries are supporting the MNCs. The MNCs make most of their money in developed countries.”¹⁹⁵ Aditi Nadkarni adds that concerns that the United States and EU MNCs will stop manufacturing drugs in India if Section 3(d) allows India to reverse engineer genuine improvements are unfounded because maintaining a relationship with Indian pharmaceutical companies is mutually beneficial.¹⁹⁶ For MNCs, the cost of manufacturing in India is much lower than in developed countries.¹⁹⁷ Generic companies in partnerships with MNCs, in return, have an incentive not to manufacture generic versions of drugs they are licensed to produce for MNCs because they could be sued for breach of contract or develop a bad reputation that could discourage repeat business. Thus, India has the opportunity to free-ride on the innovation produced as a result of incentives provided by other countries.

Nevertheless, limited patent protection for pharmaceuticals can pose problems in the long run. First, other developing countries, inspired by India’s free-riding, could copy the same model.¹⁹⁸ In the aggregate, the lack of robust patent systems around the world could disincentivize innovation. Second, other interviewees, such as Gowree Gokhale and Dr. Antani, suggest that a narrow interpretation of enhanced efficacy would have a negative effect on foreign investment in India.¹⁹⁹ Even if they continue to innovate, MNCs would view India as a less attractive trading partner or target for foreign direct investment (FDI). A survey of MNCs and Indian pharmaceutical companies confirms that the pharmaceutical industry in India perceives a positive relationship between a robust IPR regime and FDI.²⁰⁰ Thus, investment of foreign capital required to spur India’s economy into the twenty-first century, would suffer.

Third, and relatedly, segments of India’s domestic pharmaceutical industry could be hurt by the narrow interpretation. If more efficacious drugs cannot be patented, then innovative domestic pharmaceutical companies’ incentive to create them will naturally diminish. After all, the conventional premise of patent law

¹⁹⁵ Interview with Adheesh Nargolkar, *supra* note 18.

¹⁹⁶ Interview with Aditi Nadkarni, *supra* note 174.

¹⁹⁷ David Keeling et al., McKinsey Report, Outlook on Pharma Operations, at 7, *available at* file:///C:/Users/ddu/Downloads/Outlook_on_pharma_operations.pdf (prices are 85% to 90% lower in India than in the United States, and some Indian companies produce tablets at a cost of \$2 per thousand, compared to \$60 that MNCs spend on average).

¹⁹⁸ Sharma, *supra* note 2 (“[T]he judgement[sic] could be a signal to many other countries, especially emerging economies, on the provisions they can have in their own patent law.”).

¹⁹⁹ Interview with Gowree Gokhale, *supra* note 110; Interview with Dr. Milind Antani, *supra* note 174.

²⁰⁰ Rajnish Kumar Rai, *Effect of the TRIPS-Mandated Intellectual Property Rights on Foreign Direct Investment in Developing Countries: A Case Study of the Indian Pharmaceutical Industry*, 11 J. WORLD INTELL. PROP. 404, 419–20 (2008).

theory is that a patent system incentivizes innovation.²⁰¹ Because the patent on the active ingredient is typically obtained years before the commercially viable version is ready,²⁰² drug companies may not have enough time to recoup their costs if they rely only on the original patent for market exclusivity. Moreover, their ability to recoup costs would depend arbitrarily on the amount of time it takes for them to develop the active ingredient into an administrable drug. In fact, perversely, the greater the time and effort needed to develop the active ingredient into the commercial drug, the shorter the time the innovating company will have to recoup its costs.²⁰³ In India, home-grown pharmaceutical companies have just begun to develop advanced drug discovery and development capabilities.²⁰⁴ These companies would likely be disproportionately disadvantaged compared to MNCs if India's patent system disincentivizes secondary patents in particular because the investment required to develop subsequent or "follow-on" innovations is likely to be smaller²⁰⁵ and would be precisely the type of innovation these companies would likely be attempting to produce.

4. *Lack of Theoretical Transparency About Therapeutic Efficacy Interpretation.* Despite its flaws, a narrow interpretation of enhanced efficacy under the social welfare theory does the most to advance India's public policy goal of increasing access to cheap generic drugs compared to the other two interpretations. In weighing the benefits against the costs described above, the Indian government could find that this option is superior to both finding enhanced efficacy subsumed under inventive step and industrial application or a broad interpretation of enhanced efficacy.

Yet the problem remains that if the underlying purpose of Section 3(d) is to allow India to free-ride off of follow-on innovation without instituting a system that protects that innovation, India is not just violating TRIPS, but is also being

²⁰¹ Kitch, *supra* note 180, at 266 ("The conventional view of the patent system [is] as a device that enables an inventor to capture the returns from his investment in the invention . . . called the reward theory.").

²⁰² *Id.* at 271 ("A review of the invention case studies . . . shows that the first patentable invention frequently occurs years before the first significant commercial product.").

²⁰³ *Id.*

²⁰⁴ See Mueller, *supra* note 8, at 532, 536–37 (explaining that India's traditionally generic pharmaceutical companies, such as Ranbaxy Laboratories Ltd., are "developing significant independent R&D capabilities"). See, e.g., *Innovating India's Pharmaceutical Industry*, WIPO, <http://www.wipo.int/ipadvantage/en/details.jsp?id=2659> (last visited May 24, 2014) (explaining how Dr. Reddy's became "the first private Indian pharmaceutical company to launch New Chemical Entity (NCE) research and development" and "transform[ed] itself from a generics supplier to a pharmaceutical innovator" by "rely[ing] on IPRs").

²⁰⁵ See Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and Patent Law*, 5 J. ECON. PERSP. 29, 34 n.9 (1991) (citing Jerry R. Green & Suzanne Scotchmer, *Antitrust Policy, the Breadth of Patent Protection and the Incentive to Develop New Products*, Goldman School of Pub. Policy, Univ. of Cal., Berkeley, Working Paper No. 171, 1990).

intellectually disingenuous by not openly professing to preclude patents on genuine innovations. Section 3(d) has been touted as a patentability limitation intended to prevent the patenting of “minor modifications” that do not genuinely improve the ability of a drug to treat a disease. The provision has not been openly justified under the social welfare theory as a way to block the patenting of genuine improvements because the benefits to India outweigh the costs of free-riding.

The evidence points to the social welfare theory as the true underlying theory. As explained above, the evergreening theory cannot be the underlying theory because it does not explain the distinction between therapeutic efficacy and other types of improvements to drugs. Moreover, both the Indian legislature and the courts in *Novartis AG* have made it clear that section 3(d)’s central purpose is to promote access to important, life-saving generic drugs, accords more with the social welfare theory, rather the evergreening theory,²⁰⁶ considering that medicines are unlikely to be both too important to the public to patent and not important enough to patent.

The fact that Section 3(d) is limited to secondary patents, despite the fact that the arguments supporting the social welfare theory apply to all pharmaceutical patents, raises the possibility that India is purposefully containing Section 3(d)’s scope in order to achieve its policy goals less transparently than by banning pharmaceutical patents outright for political reasons. Novartis’s detractors may realize that openly acknowledging this explanation would be too blatant a defiance of TRIPS and would be politically or diplomatically damaging compared to the more appealing evergreening theory.

I argue that India should reconcile the narrow enhanced efficacy interpretation with the social welfare theory, if it is the true theory, by making explicit its understanding of the social and economic costs and benefits of pharmaceutical patents. Section 3(d)’s proponents should argue that India should not have been required to comply with TRIPS by 2005. Mueller writes that despite India’s ten-year grace period to implement pharmaceutical product protection, “the implementation was viewed by many as far too hasty.”²⁰⁷ Fiona DSouza of Khaitan Co. echoed this sentiment, stating “Like countries should be treated alike, but India is not alike. It is still a developing country. Even 50 years ago, it would be considered an underdeveloped country. Now, it

²⁰⁶ See *supra* note 153 and accompanying text. Not only did the Supreme Court in *Novartis AG* discuss the Ayyangar report cited in *supra* note 7 in detail, it even included tables contrasting the number of patents applied for and owned by Indians versus foreigners from the report as an appendix to the Court’s decision. *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311 (India), available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>.

²⁰⁷ Mueller, *supra* note 8, at 545.

is still developing [rather than developed]."²⁰⁸ Despite the ten-year grace period, about one third of India's population is still living in poverty, and improvements in public health conditions have been marked by great disparities between the rich and poor.²⁰⁹

Some regions are particularly affected by inequality [H]ealth inequities have been most marked in the countries where economic growth has been particularly inequitable. For example, in India, where the annual per capita growth rate has hovered around 8% for the last decade, use of antenatal care services increased by 12% from 1996 to 2008, but only 0.1% among the poor. At the same time, 37% of the population is living in poverty (in some states, over 50% of the population). The conclusion can only be that economic growth may be necessary, but not sufficient for improving the health of all.²¹⁰

The result of this has been to create a greater disparity between those lifted 'above the poverty line' and those left behind (8).²¹¹

Still, Reichman states that "[D]ifferent countries at different stages of economic development must accordingly strike their own balance between incentives to create and the benefits of free competition, while respecting the normative guidelines established by the TRIPS Agreement."²¹²

India made the decision to sign onto TRIPS in order to join the WTO.²¹³ Presumably it performed some cost-benefit analysis, weighing the public health needs of its population and the importance of the generics industry to its economy against the free trade benefits it would gain by joining the WTO. If India's agreement to TRIPS was freely made, then India should either comply with TRIPS or attempt to renegotiate the terms.

²⁰⁸ Interview with Fiona DSouza, Patent Attorney (Jan. 15, 2013).

²⁰⁹ Sarah Thomsen et al., *Bringing Evidence to Policy to Achieve Health-Related MDGs for All: Justification and Design of the EPI-4 Project in China, India, Indonesia, and Vietnam*, PMC UN NATIONAL LIBRARY OF MEDICINE NATIONAL INSTITUTES OF HEALTH 2, 7 (2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3597775/pdf/GHA-6-19650.pdf> (for the approximately one third of India's population living in poverty, the country's achievement of public health goals has been marked by persistent and even growing inequality).

²¹⁰ *Id.* at 2.

²¹¹ *Id.*

²¹² J.H. Reichman, *Enforcing the Enforcement Procedures of the TRIPS Agreement*, 37 VA. J. INT'L L. 335, 337 (1997).

²¹³ See *supra* note 10.

V. NOVARTIS AG: PATENTABILITY DEPENDS ON INTERPRETATION OF ENHANCED EFFICACY

A. IPAB'S INTERPRETATION OF ENHANCED EFFICACY

IPAB arrived at its conclusion that the imatinib mesylate application failed Section 3(d) based on three weak arguments that I will rebut in turn. First, rather than looking into the legislative intent and history behind the use of the term efficacy, IPAB overly relied on the definition of efficacy found in Dorland's Illustrated Medical Dictionary (Dorland's), which respondents offered as evidence.²¹⁴ Dorland's states that efficacy is "the ability of a drug to produce the desired therapeutic effect . . . independent of potency."²¹⁵ On this basis, the board concluded that enhanced efficacy cannot merely be a change in the amount or dosage needed to treat the illness, but rather, requires something they call therapeutic efficacy, which they left undefined.²¹⁶ In this way, the board read the qualifier "therapeutic" into the statute. Nowhere does the plain language of the statute suggest a narrowing of the term "efficacy" from its ordinary meaning.

Second, IPAB treated its conclusion that "bio-availability and therapeutic efficacy are not the same"²¹⁷ as determinative of whether the increased bio-availability offered by the beta crystalline form of imatinib mesylate fulfills the requirement of therapeutic efficacy. However, its conclusion relies on too simplistic a conception of the relationship between bio-availability and therapeutic effect. Whether the two are the "same thing" is irrelevant. Although increased bio-availability alone is not always sufficient to lead to increased therapeutic effect, it can be a contributing cause towards achieving increased therapeutic effect. In other words, changes in bioavailability can have clinical significance. If a substance already has therapeutic effect, increasing its bio-availability would of course enhance its therapeutic effect if all else is held equal. Enhanced therapeutic efficacy can follow naturally from enhanced bio-availability. In fact, many potential drug candidates have failed to be developed as a result of problems with bioavailability.²¹⁸ In such cases, an increase in bio-

²¹⁴ Novartis AG v. Union of India (IPAB June 26, 2009), *available at* <http://www.ipal.tn.nic.in/Orders/100-2009.htm>.

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ The program announcement for an NIH grant: Factors That Determine Therapeutic Drug Bioavailability, NIH GUIDE, Volume 23, Number 35, September 30, 1994, PA-95-001, *available at* <https://grants.nih.gov/grants/guide/pa-files/PA-95-001.html> ("Many potential drug candidates have failed as a result of difficulties in penetrating barriers or not arriving or remaining in active form at the site of action."). See, e.g., C. Godugu et al., Approaches to Improve the Oral Bioavailability

availability that enables the compound to be used pharmaceutically undeniably enhances therapeutic efficacy. Thus, IPAB's dismissal of bio-availability as evidence of enhanced therapeutic efficacy was too facile.

Third, IPAB's order seems to stem from its fear that an inventor could use a broad definition of efficacy in order to patent different dosages of the same essential drug by claiming that using a higher dose causes the drug to have enhanced efficacy.²¹⁹ Yet, the facts of the instant case are far from this imagined stratagem.

Here, Novartis is effectively claiming that a *lower* amount of the drug would have the same therapeutic effect.²²⁰ The patent application does not claim that the beta crystalline form of imatinib mesylate is more effective than imatinib free base because it contains a higher concentration of the active molecule; the patent claims a salt, not an amount or concentration.²²¹ Rather, the claimed salt is stated to be more effective because the active molecule has been chemically altered through its reaction with methansulfonic acid and a subsequent crystallization process to be more thermodynamically stable, less hygroscopic, and possess superior flow properties.²²²

Moreover, the polymorph of imatinib claimed in the patent is actually the only form that is *usable* in a form administrable to patients. As counsel Tehmtan R. Andhyarujina argued on behalf of Novartis, it is only the beta crystalline form of imatinib mesylate that is used in Glivec.²²³ If a drug cannot be administered, its chemical potency in vitro arguably has no therapeutic effect. In that respect, imatinib free base or even imatinib mesylate in general

and Effects of Novel Anticancer Drugs Berberine and Betulinic Acid, PLOS ONE, Mar. 10, 2014, Vol. 9 Issue 3, at 1, *available at* <http://www.plosone.org/article/info%3Adoi%2F10.1371/journal.pone.0091111>.

²¹⁹ *Id.*

²²⁰ See e.g., Godugu et al., *supra* note 218 (explaining that as a result of "poor bioavailability," "large doses" of anticancer drug candidates berberine and betulinic acid are currently required to achieve pharmacologically desired activity).

²²¹ Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, at 7 (India), *available at* <http://supremecourtofindia.nic.in/outtoday/patent.pdf>. Cf. International Patent Application WO 99/03854, page 22, *available at* <file:///C:/Users/ddu/Desktop/personal/09006361800b35af.pdf> or <http://patentscope.wipo.int/search/en/detail.jsf?docId=WO1999003854&recNum=1&maxRec=1&office=&prevFilter=&sortOption=Pub+Date+Desc&queryString=FP%3A%2899%2F03854%29&tab=PCTDescription>.

²²² Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, at 85, 88, 94 (India), *available at* <http://supremecourtofindia.nic.in/outtoday/patent.pdf>. Cf. International Patent Application WO 99/03854, pages 3, 8, *available at* <file:///C:/Users/ddu/Desktop/Personal/09006361800b35af.pdf> or <http://patentscope.wipo.int/search/en/detail.jsf?docId=WO1999003854&recNum=1&maxRec=1&office=&prevFilter=&sortOption=Pub+Date+Desc&queryString=FP%3A%2899%2F03854%29&tab=PCTDescription>.

²²³ Lawyers Collective HIV/AIDS Unit, *supra* note 86; *Gleevec*, DRUGS.COM, <http://www.drugs.com/pro/gleevec.html> (last visited May 24, 2014).

lacks therapeutic effect; it is only the beta-crystalline form of imatinib mesylate that has any therapeutic effect.

B. REINTERPRETATION OF ENHANCED EFFICACY ON APPEAL

On appeal, Novartis lost for the essential reason that the Supreme Court of India affirmed the IPAB's interpretation of efficacy as therapeutic efficacy, using the IPAB's definition of the term. If the Supreme Court had instead construed enhanced efficacy to require some type of improved efficacy, but interpreted efficacy broadly, Novartis' application would have fulfilled Section 3(d)'s demands. Finally, if the Court had decided to read enhanced efficacy into the inventive step and industrial application requirements, *a fortiori*, Novartis's patent application would have survived Section 3(d). The differing outcomes under these three interpretations exemplify the problem Section 3(d) poses to the future of pharmaceutical innovation and operations in India. Below, I argue that the Supreme Court's interpretation of Section 3(d) wrongfully precludes the patenting of a pharmaceutical like Glivec in *Novartis AG*.

First, if there exist cases in which a drug company deceives the public into demanding the latest version of a drug though the new version works no better than the old, such is not the case in *Novartis AG*. Novartis was not trying to deceive patients into demanding imatinib mesylate, when imatinib free base or some other salt was just as effective. Whereas other salts and forms of imatinib were not stable enough to be encapsulated and administered as a cancer treatment, the beta crystalline form of imatinib mesylate claimed in Novartis's rejected application was.²²⁴ Glivec, which uses this form of imatinib mesylate, has been widely recognized as a breakthrough drug for treating chronic myeloid leukemia (CML) by both Novartis's supporters and detractors.²²⁵

Second, demand for Glivec by generics and NGOs like Lawyers Collective has been extremely high.²²⁶ Considering that Indians are more price sensitive and many cannot afford branded versions of expensive drugs, the fact that Glivec has been commercially successful and patients prefer Glivec suggests that Glivec has enhanced efficacy above the prior art. That is, imatinib mesylate

²²⁴ *Novartis AG v. Union of India* (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm> ("Because of the advantageous properties, beta-crystal form is superior to the alpha form with respect to the manufacture of pharmaceutical preparations in solid dosages."). Claim 11 of the rejected application was "[a] pharmaceutical composition, comprising a form of the methanesulfonic acid addition salt of a compound of formula 1" *Novartis AG*.

²²⁵ Pray, *supra* note 58; *Access March*, *supra* note 62, at 1 (describing Glivec as "a runaway blockbuster raking in millions of dollars in *Its* first year").

²²⁶ Basheer & Reddy, *supra* note 73, at 134 (explaining that several generic drug companies and an NGO, the Cancer Patients Aid Association (CPAA), opposed the Novartis application for imatinib mesylate).

in beta crystalline form and not imatinib free base is what saves lives. Those who do not believe the innovative leap from imatinib to imatinib mesylate in beta crystalline form qualifies Novartis for a new patent have yet to identify an alternative salt or polymorph of imatinib that could be used in a commercial drug.

Third, the secondary patent demanded *would* in this case preclude the sale of generic Glivec after the expiration of a hypothetical patent on imatinib free base,²²⁷ but this is due to the nature of the secondary patent as the specific usable form in this case. It is not because the secondary patent would extend patent protection over the original invention, which it would not. Novartis's 1993 patent on imatinib did not disclose or enable the use of a usable anticancer drug.²²⁸ Rather, the invention of the beta crystalline form of imatinib mesylate and the discovery of its anticancer properties and amenability to storage in solid dosage required much additional research, which the IPAB opinion recognized.²²⁹ IPAB further conceded that Glivec satisfies the other requirements for patentability, including inventive step and industrial application.²³⁰ It is inconsistent to argue, then, that the invention of Glivec took little effort and ingenuity above the prior art.

Last and relatedly, it is the invention of imatinib mesylate, not imatinib free base, that society should aim to incentivize with its patent laws. A patent on imatinib alone could still incentivize the development of a commercial drug that

²²⁷ As explained above, however, in the particular case of *Novartis AG*, this is not a concern because Novartis did not get an original patent on imatinib in India.

²²⁸ It is a well-established under U.S. patent law that a patent on a "genus" of compounds does not necessarily preclude a patent on a particular "species" within that "genus." See, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 384 (S.D.N.Y. 2007), *aff'd*, 550 F.3d 1075 (Fed. Cir. 2008) ("In essence, patentability is not precluded by the fact that an inventor identified or selected a single compound with particularly desirable qualities from a large class of previously patented compounds."); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) (a prior art reference that discloses a genus does not necessarily disclose every species that is a member of that broad genus). Counsel for Novartis proffered to the Supreme Court that while the prior patent on imatinib free base covers imatinib mesylate, it does not enable or disclose it, as would be required for anticipation. *Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311, at 73–75 (India), available at <http://supremecourtsofindia.nic.in/outtoday/patent.pdf>. However, the Supreme Court rather bizarrely rejected the notion as "negat[ing] the fundamental rule underlying the grant of patents." *Id.* at 75.

²²⁹ *Novartis AG v. Union of India* (IPAB June 26, 2009), available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm> ("What 1993 patent disclosed was the possibility of making various salt forms of the imatinib free base which could run into hundreds. . . . [I]t could not have been concluded by any stretch of imagination that the particular beta crystalline form of imatinib mesylate would have advantageous properties which would be efficacious in the treatment of cancer. It was only after years of painstaking and expensive research that imatinib mesylate salt in a particular crystal form . . . was discovered by the Appellant." (emphasis added)).

²³⁰ *Id.*

utilizes it, since there would be no way to profit from imatinib unless and until a commercially viable drug was developed.²³¹ However, that incentive would be more incidental than targeted towards the true invention. As explained in Part IV.B.3, the effective length of the patent term—the period over which a pharmaceutical company has market exclusivity and thus can recoup its costs—would be based arbitrarily on how long it takes to get the commercially viable drug to market. In contrast, a patent on the commercially viable product would incentivize the development of the product directly and eliminate the arbitrariness of effectively different patent terms.

Perhaps India's true objection to pharmaceutical patents is that patent protection for pharmaceutical products is too strong and the term too long, considering that many Indian patients cannot afford the sticker price for life-saving drugs like Glivec. If that is the case, it may be legitimate under a social welfare theory. However, as noted in Part IV.B.4, these arguments should be made explicit so that the international dialogue and related litigation can focus on what the debate is truly about—the fact that India wants an exceptional patent provision because it believes its social and economic conditions are exceptional. Until India acknowledges its social welfare theory of patent protection, it cannot expect TRIPS and other international treaties to be modified according to its needs.

VI. CONCLUSION

The Indian Supreme Court's decision in *Novartis AG* is about much more than Novartis's application to patent the beta crystalline form of imatinib mesylate. Rather, the decision will, over time, settle many important questions whose answers will shape the future of the pharmaceutical sector in India: What does Section 3(d) demand for obtaining a secondary patent on a known substance when it requires enhanced efficacy? Which interpretation of enhanced efficacy will be applied in future cases?

This Article argued that the Supreme Court's construction of enhanced efficacy, an additional requirement to patent pharmaceutical products, above and beyond industrial application and inventive step, violates TRIPS Article 27.1. Moreover, it argued that the Supreme Court, IPAB, and High Court's decision to pursue the narrowest interpretation of enhanced efficacy in *Novartis AG* is most consistent with a general desire to curb pharmaceutical patenting, although the courts have declined to embrace this rationale. Instead, they have

²³¹ See Scotchmer, *supra* note 205, at 30 (“[I]ncentives to find fundamental technologies may require that the first patent holder earn profit from the second generation products that follow. There will be no such profit if no second-generation products follow.”).

based their decisions on an evergreening rationale that is theoretically incoherent. If Section 3(d) achieves its stated goal of preventing evergreening in the sense of patenting useless, minor modifications of drugs, then by definition, Section 3(d) makes little or no difference in access to generic medicines. On the other hand, if Section 3(d) actually promotes earlier access to generic medicines, then it must do so by precluding the patenting of genuine innovations and free-riding on innovations incentivized by stronger patent regimes. Thus, even if the results have been consistent with India's underlying social welfare goals, the reasoning behind these decisions has been flawed.

Whether India wishes to interpret enhanced efficacy (1) to require no more than inventive step and industrial application, (2) to mean improved efficacy in a broad sense, or (3) to mean therapeutic efficacy, depends on which legal and policy rationales it finds most appealing and legally sustainable going forward. The Author hopes that India succeeds in reconciling the Supreme Court's decision to choose (3) with both the theoretical underpinnings and practical realities of pharmaceutical patenting and innovation in India.

