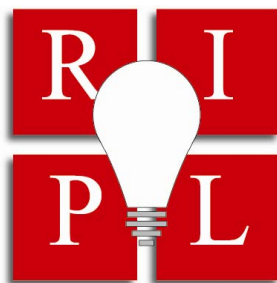


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



3(D) VIEW OF INDIA'S PATENT LAW: SOCIAL JUSTICE ASPIRATION MEETS PROPERTY RIGHTS IN
NOVARTIS V. UNION OF INDIA & OTHERS

SABY GHOSHRAY

ABSTRACT

Wherever the art of Medicine is loved, there is also a love of Humanity.

Hippocrates 400 BC

Not many constitutional decisions from developing countries find themselves at the center of global debate like the Indian Supreme Court's *Novartis* decision invalidating the Gleevec patent. The patent was invalidated under amended Section 3(d) of the Indian Patents Act, which was amended to address some of the concerns of imbalance between the maximalist and minimalist cultures in the pharmaceutical context. Section 3(d) of the Indian Patent Act introduced a new threshold of patent eligibility for pharmaceutical innovation that requires applicants to demonstrate enhanced efficacy of their products. The objective of this Article is to get beyond the reactionary reviews of the Indian patent regime and seek a nuanced view of its doctrinal trajectory. The Article achieves this by deconstructing Section 3(d) by focusing on its legislative intent, extracting its human rights dimension, and tracing its harmonizing elements. In the end, the Article serves to dispel the myth of Section 3(d)'s TRIPS incompatibility, unearths Section 3(d)'s human rights dimension, and rehabilitates India's intellectual property regime amidst a global condemnation of its minimalist viewpoint.

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I. INTRODUCTION

Pharmaceutical companies have practiced the art of extending market exclusivity for much of the twentieth century. In the name of product life cycle management, these innovators seek to extract corporate monopoly rent,¹ almost for

* © Saby Ghoshraj 2014. Dr. Saby Ghoshraj specializes in Constitutional Law, International Human Rights Law, Intellectual Property Law and Capital Jurisprudence, among others. His work has appeared in Albany Law Review, ILSLA Journal of International and Comparative Law, European Law Journal ERA-Forum, Toledo Law Review, Georgetown International Law Review, Temple Political & Civil Rights Law, Fordham International Law Journal, Santa Clara Law Review and Miami Law Review, to name a few. The author would like to thank Jennifer Schulke for her assistance in legal research and typing of the manuscript. Also, to my beautiful children, Shreyoshi and Sayantan, your simplicity, curiosity and quest for rightful living motivates and inspires me, everyday. I offer much appreciation to the members of The John Marshall Review of Intellectual Property Law Editorial Board for their thoughtful suggestions and dedication in the edit process. Finally, to every child, woman and man that labors under the blazing sun, and seeks relief from life saving medicines, I dedicate this Article. My hope, this small work can awaken the humanistic attitudes in the pharmaceutical industry, and no person, young or old, ever goes without life saving medicines. Dr. Ghoshraj can be reached at sabyghoshraj@sbcglobal.net.

¹ Saby Ghoshraj, *Interpreting Myriad: Acquiring Patent Law's Meaning Through Contemporary Jurisprudence and Humanistic Viewpoint of Common Heritage of DNA*, 10 J. MARSHALL REV. INTELL. PROP. L. 508, 511 n.15 (2011). In that I Article, I stated:

By "corporate monopoly rent-seeking," I generally draw attention to the corporate practices where the corporate entity attempts to derive economic benefits by extracting economic rent via manipulating the existing socio-political landscape. In this context, rent-seeking occurs as the corporate entity extracts additional value by various means, such as imposing barriers to entry to other competitors or developing unilateral ability to fix a higher than normal market price. The term "monopoly" is included in the description to capture a unique dimension of such uncompensated value extraction in that the corporate entity enjoys monopoly privileges under the guidance of legal or regulatory framework. Originally introduced in 1967, the concept of "rent-seeking" was formalized in 1974 and identified as distinct from the basic profit-seeking behavior of economic agents. *See generally* Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft*, 5 W. ECON. J. 225 (1967) (introducing the idea of "rent-seeking"); Anne Krueger, *The Political Economy of the Rent-Seeking Society*, 64 AM. ECON. REV. 291 (1974) (formalizing the same concept). In the present context, I draw a distinction between profit-seeking and rent-seeking behaviors of bio-technology companies, where the former engages in mutually agreeable financial transactions within an efficient market environment, but where the later [*sic*] extracts abnormal profits in a skewed market environment by foreclosing other competitors' meaningful opportunities to compete due to patent exclusivity for a significant period of time.

Id.

perpetuity, either through patent evergreening,² or to a limited extent, through patent layering.³ By marketing the hackneyed rationale of commercial incentive for innovation, these companies have been advancing their market exclusivity strategies,⁴ while obfuscating the market impact of predatory pricing to poorer segments of humanity.⁵ Impacted asymmetrically by this quintessential dichotomy, countries have walked divergent paths in formulating their respective patent systems.⁶

² Evergreening refers to the slew of business strategies and legal maneuverings to extend market exclusivity of products, and in the process continuing to extract their monopoly rent-seeking practices. See Sarah Harding, *Perpetual Property*, 61 FLA. L. REV. 285, 303–05, 315–16 (2009). In the domain of pharmaceutical products, evergreening may cover practices such as taking out new patents by simply changing form and method of administering dosage of a particular medicine without changing the active ingredients, or taking out new patents on a mixture of delivery mechanism and non-substantive mixture in the originally patent drug, thereby delaying the patent of the original patent. See Thomas Faunce, *The Awful Truth About Evergreening*, THE AGE (Aug. 7, 2004), <http://www.theage.com.au/articles/2004/08/06/1091732084185.html>. Thus, neither recognized in judicial opinions, nor codified within statutes, the phenomenon of evergreening can be seen as a maneuver utilized by patent holders to use existing legal and regulatory loopholes to extend patent exclusivity of their products. See Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades*, 31 HEALTH AFFAIRS 2286, 2286–87 (2012) (explaining this concept by showing how pharmaceutical companies engage in evergreening by sequentially seeking patent protections, either via incremental improvement to a single drug, or patenting multiple characteristics of a single drug. NAT'L INST. FOR HEALTH CARE MGMT. RESEARCH AND EDUC. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 1 (2002) [hereinafter NIHCM STUDY] (examining the effects of manufacturers modifying products that are branded and approaching patent expiration in order to delay competition posed by generic brands).

³ Often used interchangeably in the literature, there is a fine line of distinction between patent evergreening and patent layering. *Evergreening*, EUR. GENERIC MED. ASS'N, <http://www.egagenerics.com/gen-evergrn.htm> (last visited May 3, 2014); see also Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management after KSR v. Teleflex*, 63 FOOD DRUG L.J. 275, 276 (2008); Edson Beas Rodrigues, Jr. & Bryan Murphy, *Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines*, 16 ALB. L.J. SCI. & TECH. 423, 431 (2006) (noting that a strategy commonly described as “evergreening” is aimed at extending the commercial life of patent protection through new medical use patents). Patent layering can be seen as different from patent evergreening, when multiple characteristics of a single drug is used to obtain market exclusivity, without altering the active ingredients of the drug itself. Patent layering can also be seen as a subset within the broader connotation of patent evergreening, which conveys the meaning of market exclusivity extending strategy in general. While patent evergreening can be seen as a continuation mechanism to perpetuate or evergreen a prior proprietary status, patent layering can be seen as creating a portfolio from a single source, by utilizing various inherent characteristics of the source. Developing such a portfolio allows the benefit of multiple sequential temporal segments such that the portfolio acts as an extension of the source, thereby extending the original temporal segment into a bigger temporal segment.

⁴ See WENDY H. SCHACHT & JOHN R. THOMAS, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 (THE HATCH-WAXMAN ACT) 2–3 (2005).

⁵ See Greg Martin, Corinna Sorenson & Thomas Faunce, *Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines*, GLOBALIZATION AND HEALTH (June 12, 2007), <http://www.globalizationandhealth.com/content/3/1/4>.

⁶ Here I draw attention to the maximalist versus minimalist debate in intellectual property law. The term “maximalist” is used to describe a position/theme and emphasis is placed on the

The better part of the twentieth century witnessed two diametrically discordant patent regimes in the world. Riding a maximalist rights culture,⁷ pharmaceutical patents exploded in the developed nations.⁸ At the same time, concern for wider access to medicine prompted the developing countries to allow the low priced generic drug industries to thrive.⁹ Failure to balance the rights of both the innovator and those of the end users has allowed pharmaceutical giants to reap financial bonanza, while a lack of access to life saving drugs has caused millions of people to perish.¹⁰ The arrival of the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) in 1995¹¹ and its progeny, International Intellectual Property

inclusion of all factors possible associated with the position. Whereas, the term “minimalist” is used to describe a position/theme and emphasis is placed on eliminating any extra factors and reducing down to only the necessary elements. By the time developing countries arrived at the world stage as independent nations by shedding their colonial shackles, developed countries have already forged ahead in technology and have fenced their industrial interests with a maximalist, property rights based intellectual property paradigm. Seeking their new international economic order, developing countries relied on a minimalist vision of intellectual property framework that focused on wider access and less on corporate monopoly—thus, initiating two diverging paths through which the intellectual property regimes in the developing and the developed nations began its maturation process. See James Boyle, *Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 97, 107–08 (F. Scott Kieff ed., 2003) (examining the tension between maximalist and minimalist perspectives within the context of gene patenting).

⁷ See *id.*

⁸ See, e.g., PATENT TECH. MONITORING TEAM, U.S. PAT. & TRADEMARK OFF., U.S. PATENT STATISTICS CHART CALENDAR YEARS 1969–2013 (2014), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm. Between 1979 and 2008, the number of patents granted in the U.S. almost quadrupled, from 52,000 in 1979 to 182,000 in 2008. *Id.* Similar explosions have been observed in the EU, almost tripling between 1985 and 2005.

⁹ See Martin Khor, *Generics under Threat: Can India Still Supply Cheap Medicines for the World?*, 259 THIRD WORLD RESURGENCE 4, 4–5 (2012).

¹⁰ *Id.* at 5.

¹¹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS] (setting forth obligations for patent protection). Despite the WTO granting developing countries (“DC”) and least developed countries (“LDC”) transitional periods to comply with all the provisions of TRIPS:

[t]o the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, . . . it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

See TRIPS, art. 65.4. TRIPS is very pejorative in its implications for both these groups of countries. The TRIPS Agreement’s explicit requirement to harmonize patent terms for a minimum of twenty years and to grant patents in all fields of technology has raised concerns about its effects on both DC and LDCs. Moreover, as the TRIPS Agreement mandates all member States to develop patentability criteria on standards drawn from U.S. law, concerns have also been raised that TRIPS may be lacking both the DC and LDC countries’ unique interests. See Karin Timmermans & Togi Hutadjulu, *The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals*, WORLD HEALTH ORG. 14, 20–21 (May 2–4, 2000) (examining significant divergence amongst the jurisdictions in existing concepts surrounding knowledge accumulation, processing, and applying).

Agreements (“IIPA”),¹² have consolidated the patent protection landscape in favor of the pharmaceutical giants. This has directly impacted the developing nations’ fight against evergreening and patent layering, as one hundred and fifty-nine members of the World Trade Organization (“WTO”) became obligated to relax their patentability standards.¹³ Under the threat of TRIPS, Indian patent law also needed a facelift.

Following its TRIPS obligation, Indian legislators rose up to the challenge of recalibrating its patent regime. Indian lawmakers introduced an amendment to the Indian Patents Act in 2005, carrying the aspirations of billions of impoverished citizens, inside India and abroad.¹⁴ The lawmakers amended Section 3(d), which quickly gained worldwide notoriety.¹⁵ This notoriety has grown even more since the Swiss Pharmaceutical giant Novartis failed at its § 3(d) challenge in the Indian Supreme Court.¹⁶ Novartis’ legal battle in India started in 2005, when the Indian Patent Office rejected its Gleevec patent application,¹⁷ which the company challenged, citing § 3(d)’s unconstitutionality and incompatibility with TRIPS.¹⁸ By the time Novartis’ appeal trekked its way through the Madras High Court and eventually in front of the Supreme Court, more than seven years passed.¹⁹ Despite the delays, the Supreme Court upheld both the Patent Office’s and the High Court’s core findings.²⁰ Mixed reactions have greeted the ruling since then. Legal scholars have both defended and condemned the decision.²¹ Pharmaceutical companies have

¹² See United Nations Conference on Trade and Development, N.Y.C., U.S. & Geneva, Switz., *International Investment Arrangement: Trends and Emerging Issues*, 44, UNCTAD/ITE/IIT/2005/11 (2006).

¹³ See generally *Understanding the WTO: The Organization Members and Observers*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited May 3, 2014) [hereinafter *Understanding WTO*].

¹⁴ See The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2005), § 3(d) [hereinafter Amendment Act of 2005].

¹⁵ See George Best & Photon Rao, *Drug Patenting in India: Potentially Lucrative, but a Difficult Task*, 8 PHARM. L. & INDUS. REP. 46, 46 (2010).

¹⁶ See Gardiner Harris & Katie Thomas, *Low Cost Drugs in Poor Countries Get a Lift in Indian Court*, N.Y. TIMES, Apr. 1, 2013, <http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartisdrug-patent.html?partner%3Drss%26emc%3Drss>.

¹⁷ Novartis AG v. Union of India, Misc. Petition Nos. 1-5 of 2007 in TAII- 5/2007/PT/CH & Misc. Petition No. 33 of 2008 in TA/1/2007/PT/CH & TA/1-5/2007/PT/CH, at 153, 157, 161 (Intellectual Property Appellate Board June 26, 2009), available at <http://www.imak.org/storage/Gleevec%20IPAB%20decision%2026%20June%202009.pdf> [hereinafter *Novartis IPAB Order*]; Novartis Ag v. Union Of India & Ors., (April 1, 2013) ___ S.C.R. ___, Civil Appeal Nos. 2706-2716, 2728, and 2717-2727, ¶ 172 (India), available at <https://www.yumpu.com/en/document/view/11889318/gleevec> [hereinafter *Novartis Supreme Court Decision*].

¹⁸ *Novartis Supreme Court Decision*, *supra* note 17, ¶ 172.

¹⁹ *Id.*; Novartis AG v. Union of India & Ors. [2007] 2007 A.I.R. 24759, 4 MLJ 1153 (India Madras H.C.) [hereinafter *Novartis Madras H.C. Decision*].

²⁰ *Id.*

²¹ See Dhanalakshmi Iyer, *Analysis of Section 3(d) of Indian Patent Act*, IP FRONTLINE (Apr. 9, 2012), <http://www.ipfrontline.com/depts/printabletemplate.aspx?id=26756> (stating that “section 3(d) encourages sequential developments of existing products or technologies that help bring in improved products” into the marketplace); Manoj Pillai et al., *Patent Procurement in India*, INTELL. PROP. OWNERS ASS’N 1, 25 (2007) (noting that Indian Patent Law is more restrictive when examining

threatened to pull out of their Indian businesses.²² Countries have threatened to impose trade sanctions on India.²³ Taking a retrospective look, these reactions have been either reactionary²⁴ or purpose-driven.²⁵ The analyses are either narrowly tailored,²⁶ or have missed the decision's broader themes.²⁷ The multinational pharmaceutical companies and the patent attorneys backing them have been plainly biased in their respective agendas.²⁸ This Article seeks to deconstruct such false narratives surrounding § 3(d).

Not many constitutional decisions from developing countries find themselves at the center of global debate, especially not in the manner of a constitutional invalidation, like that of Novartis' Gleevec patent.²⁹ These debates include the quintessential tension between maximalist rights paradigm versus minimalist patent framework,³⁰ innovation suppression versus wider access to medicine,³¹ and

pharmaceutical patent applications and will "likely require evidence of significantly higher efficacy in order to be granted.")

²² See Tracy Staton, *Pharma giants arm-twist U.S. government for IP action in India*, FIERCE PHARMA (Feb. 6, 2014), <http://www.fiercepharma.com/search/site/story%20pharma%20giants%20arm%20twist%20us%20govern>.

²³ See Sachin Parashar, *India-US Ties are Under Stress Again, this Time Over Trade and Investment*, TIMES OF INDIA (Feb. 23, 2014), <http://timesofindia.indiatimes.com/business/india-business/India-US-ties-are-under-stress-again-this-time-over-trade-and-investment/articleshow/30915237.cms> (explaining that India is a priority foreign country ("PFC") and a PFC tag "can allow the US to impose unilateral sanctions against India for domestic laws which deny benefits to the US under any trade agreement.").

²⁴ See Staton, *supra* note 22.

²⁵ See Lisa Kilday, *Global IP Reaction to India's Rejection of the Novartis Drug Patent*, IPWATCHDOG (May 28, 2013, 7:30 AM), <http://www.ipwatchdog.com/2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent/id=40778/>.

²⁶ See Iyer, *supra* note 21.

²⁷ *Id.*

²⁸ A misplaced notion of potential revenue loss from reduced prosecution and due diligence activities from scope reduction in the patentability criteria may have been one of the catalysts for opposing the *Novartis* decision. Although *Novartis* relied on Section 3(d) as this Article has established, *Novartis* is also about preferring a minimalist regime over its maximalist counterpart. Yet, an adequate understanding of the minimalist paradigm's scope can hardly justify the pervasive condemnation by professionals and pharmaceutical companies in erecting a harder stance against minimalist patent regimes. See Boyle, *supra* note 6 (discussing scope of minimalist paradigm in gene patenting).

²⁹ For an in-depth review of Gleevec's chemical composition, bond structures, reactivity, see Rajshree Chandra, *The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Case in India*, in INCENTIVES FOR GLOBAL PUB. HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MED. 381, 391 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein, eds., 2010).

³⁰ See Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1053 (2009), available at http://lawcommons.luc.edu/cgi/viewcontent.cgi?article=1011&context=facpubs&sei-redir=1&referer=http%3A%2F%2Fscholar.google.com%2Fscholar%3Fq%3Drelated%3AukDTSBAB2CAJ%3Ascholar.google.com%2F%26hl%3Den%26as_sdt%3D0%2C47#search=%22related%3AukDTSBAB2CAJ%3Ascholar.google.com%2F%22.

³¹ See *id.* The basic premise of a patent is that the innovator should be compensated for proprietary ideas conceived and formulated in the innovation. Taken to its logical extension, the proposition holds that, if the commercial impetus is taken away, the frequency of innovation will decrease. If the frequency of innovation is decreased, the ideas may not arrive at the market place, which in turn might stymie discovery of life saving drugs. On the contrarian theme, it is argued

corporate monopoly rent-seeking practices versus the collective utility of social welfare.³² This Article captures these issues through the Novartis legal saga in India. The objective of this work is to get beyond the reactionary reviews of the Indian patent regime and seek a nuanced view of its doctrinal trajectory. The Article achieves this by deconstructing § 3(d) by focusing on its legislative intent, extracting its human rights dimension, and tracing its harmonizing elements. Section 3(d) of the Indian Patent Act introduced a new threshold of patent eligibility for pharmaceutical innovation that requires applicants to demonstrate enhanced efficacy of their products.³³ Failing to satisfy this § 3(d) threshold, first at the Patent Office and later before the Madras High Court on appeal, Novartis' suit arrived at the Indian Supreme Court.³⁴ Centered on two distinct threads, Novartis argued for invalidating § 3(d)'s heightened threshold on account of its TRIPS incompatibility and unconstitutionality under the Indian Constitution.³⁵ This Article addresses the merits of both of these challenges and seeks to rehabilitate § 3(d) within the global intellectual property landscape by shedding revelatory light on its genesis and implications. Amidst a flawed condemnation of Indian intellectual property regime, this work further recasts the patentability debate by tracing the TRIPS' colonialist root within the quintessential maximalist vs. minimalist debate. This debate has thus far ignored the harmonization requirement of global patent law.³⁶

In Part II of this Article, I delve into a background analysis of the *Novartis* case. Here, Gleevec's patent history and chemical composition, in conjunction with a chronology of Novartis' legal journey through the India legal landscape, provides a context for the core issues before the Supreme Court. From the anatomy of the case, I move on to deconstructing the contentious Section 3(d) in two parts in Part III. Analyzing the text, motivation, and legislative development of the amendments in § 3(d) allows me to decode the efficacy standard and its implication for

that, shared heritage of humanity and our civilization's human rights commitment makes it incumbent upon us to ensure medicine can be widely accessed by all individuals regardless of their ability to pay, which in turn would argue for reducing the scope of patent to relax the exclusivity enjoyed by the pharmaceutical companies. Within this protectionist paradigm, it is argued, resides the driving force for continued innovation in science and technology. This is a flawed argument, as it is the spirit of cooperation and mutual learning that has advanced human construct incrementally towards acquiring more meaning from existing process and objects. Moreover, most of today's scientists work in the academia under the paradigm of publish-or-perish. Therefore, the search for a new product for the benefit of mankind cannot stop if the number of patents gets reduced, or the scope of patenting becomes restrictive, rather too much power at the hands of a corporation that develops a predatory practice that excludes the majority of the end user from enjoying the fruits of labor, especially if the products are pharmaceutical or biological in nature.

³² By its monopoly rent-seeking behavior, holders of patent extracts additional value by various means, imposing barriers to entry to other competitors, while foreclosing wider access to patented product. Thus, by such deterministic principles of patentability, exclusivity is fostered within society, economic incentive remains restricted to a limited few, and the majority is deprived of the fruits of labor, such as access to medicine.

³³ See Amendment Act of 2005, *supra* note 14, § 3(d).

³⁴ *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 15, 18, 190.

³⁵ *Id.* ¶ 15.

³⁶ The emerging connectivity of our existences and the shared evolution of our ways of life make it difficult to navigate within individual jurisdictional idiosyncrasies, which invites us to examine the need for harmonization in law across the different jurisdictions.

pharmaceutical scope reduction. I then examine § 3(d) TRIPS' compatibility in Part IV. Reviewing the genesis of TRIPS and its contentious history provides a backdrop to view India's intellectual property aspirations within its patent amendment. This leads me to examine *Novartis'* expanded meaning and future implications in Part V. The Article concludes in Part VI, by establishing the main objectives of the work—which are to dispel the myth of § 3(d)'s TRIPS incompatibility, to unearth § 3(d)'s human rights dimension, and to rehabilitate India's intellectual property regime amidst a global condemnation of its minimalist viewpoint.

II. PATH TO THE INDIAN SUPREME COURT

Evaluating *Novartis'* position requires contextualizing 3(d)'s genesis with patent history of Gleevec. In the late 1990s, the team of Ciba-Geigy scientists, led by Nicholas Lydon, Elisabeth Buchdunger, and Jurg Zimmerman, invented imatinib.³⁷ The first series of patents covering imatinib and its various salts were filed in Switzerland in 1992 and in the EU, U.S., and other countries in 1993.³⁸ Upon formation of *Novartis*, out of Ciba-Geigy's merger with Sandoz in 1996,³⁹ a new patent application on a specific polymorphic form, a beta-crystalline version of imatinib, was filed in Switzerland. This beta crystalline form of imatinib mesylate forms the active ingredient of the anti-cancer drug Gleevec, also known as Glivec.⁴⁰ Between the years of 1997 and 1998, *Novartis* filed more patents covering this beta crystalline form in various countries.⁴¹ The company received FDA approval and its U.S. patent in 2003.⁴²

Despite having been granted patents protection in many countries between 1993 and 1998, *Novartis* did not get the opportunity to file a patent in India. Instead, it filed a "mailbox application" for patent in 1998.⁴³ Prior to 2005, Indian patent regime did not allow patent filing for pharmaceutical drugs.⁴⁴ Interestingly, the expansion

³⁷ See Elisabeth Buchdunger & Juerg Zimmerman, *The Story of Gleevec*, INNOVATION.ORG, http://www.innovation.org/index.cfm/StoriesofInnovation/InnovatorStories/The_Story_of_Gleevec (last visited May 3, 2014).

³⁸ See *Family List: US5521184 (A)—1996-05-28*, ESPACENET PAT. SEARCH, http://worldwide.espacenet.com/publicationDetails/inpadocPatentFamily?page=0&FT=D&CC=US&locale=en_EP&D B=&NR=5521184A&date=19960528&ND=&KC=A (last visited May 3, 2014).

³⁹ See Lawrence M. Fisher, *Post-Merger Integration: How Novartis Became No. 1*, STRATEGY+BUS. (Apr. 1, 1998), <http://www.strategy-business.com/article/16383?gko=28081> (stating that the "\$30.09 billion merger of Sandoz and Ciba-Geigy, which was announced in early 1996, came amid a flurry of big deals in the pharmaceutical industry").

⁴⁰ Srividhya Ragavan, *The Patent Failure of Novartis with Gleevec*, LAIPLA 1, 1 (2013) <http://www.laipla.net/wp-content/uploads/2013/04/RagavanNovartisNoteApril2.pdf>; see also *Novartis AG v. Natco Pharma & Others*, Controller of Patents and Designs, Application No. 1602/MAS/1998 (2005) (India), available at <http://indiankanoon.org/doc/1352538/>.

⁴¹ Ragavan, *supra* note 40, at 1 (cataloguing that *Novartis* had over 35 patents covering the polymorphic form of Gleevec in various countries).

⁴² *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/Scripts/cder/ob/docs/obdetail.cfm?Appl_No=021588&TABLE1=OB_Rx (last updated May 3, 2014).

⁴³ Ragavan, *supra* note 40, at 1.

⁴⁴ The Patents Act, No. 39 of 1970, INDIA CODE (1970), § 5 [hereinafter The 1970 Act].

of patent protection for Gleevec coincided with a transformation within Indian patent regime. As a precondition to joining the WTO,⁴⁵ India was required to amend its Patent Law to allow pharmaceutical patents,⁴⁶ which prompted the need to reformat its patent regime in compliance with the intellectual property norms under TRIPS.⁴⁷ Meanwhile, all patent applications were held in a mailbox waiting to be processed once the amendments came into force in 2005.⁴⁸ In the interim, the patent applicants were granted Exclusive Marketing Rights (“EMR”).⁴⁹ This allowed them to sell their products, while preventing competitors from producing and selling generic version of the drugs.⁵⁰ Novartis received its EMR in 2003.⁵¹

Under the terms of the EMR, the applicant was to automatically lose its exclusive marketing privilege if its pending patent application was rejected.⁵² The legal battle began soon after Novartis was granted its EMR. Novartis filed infringement suit against the generic companies that were producing Gleevec’s generic versions in India prior to 2003.⁵³ The injunction against the generic companies saw the price of Gleevec skyrocketing in India.⁵⁴ Against price increases of 1000 percent, the generic drug makers, cancer patient advocacy groups, and legal rights organizations brought pre-grant motions opposing the Gleevec patent.⁵⁵ In

⁴⁵ See *Understanding WTO*, *supra* note 13 (noting that by July 2008, 153 countries were Member States in the WTO, including, in addition to the United States, Canada, and the European Union, many developed and developing countries in Asia, Africa, Central and South America, and the Middle East (e.g., China, India, Brazil, Rwanda, and UAE)).

⁴⁶ TRIPS, *supra* note 11, art. 27.1.

⁴⁷ *Id.* art. 65.4.

⁴⁸ *Id.* art. 70.8(a)–(c). The amendments added were (a)–(c). *Id.*

⁴⁹ *Id.* art. 70.9.

⁵⁰ World Trade Org., *TRIPS and Pharmaceutical Patents: Developing Countries’ Transition Periods*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm. “Mailbox” is an interim administrative filing process for the efficient date stamping and processing of new patent applications until the member country’s laws could harmonize to the standards set up as conditions for their being part of the agreement. *Id.* Once the countries are caught up to the standards, mailbox applications were to be processed according to their priority receipt date. *Id.* Article 70 also imposed requirement on transitional members to grant Exclusive Marketing Rights (“EMR”) for pharmaceuticals for which a patent and marketing approval had already been procured in another member state and for which a patent application processing is pending with the appropriate authority in that transitional member state. *Id.* EMR is to be granted by the transitional member “for a period of five years after obtaining marketing approval in that Member [state] or until a product patent is granted or rejected in that Member [state], whichever period is shorter.” *Id.* TRIPS Agreement, Article 70.8(a) required India to “provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed . . .” *Id.* Thus, India had provided patent applicants with “mailbox” facility where all the patent applications for pharmaceutical products filed during the transition period had to be accepted and stored for examination beginning in 2005. *Id.*

⁵¹ See *Novartis Gets EMR for Gleevec*, THE ECON. TIMES, (Dec. 24, 2003, 9:24 PM), available at http://articles.economictimes.indiatimes.com/2003-12-24/news/27545132_1_gipap-emr-novartis-india.

⁵² TRIPS, *supra* note 11, art. 70.9.

⁵³ See Shammad Basheer, *First Mailbox Opposition (Gleevec) Decided in India*, SPICY IP (Mar. 11, 2006), <http://spicyip.com/2006/03/first-mailbox-opposition-gleevec.html>.

⁵⁴ *Id.*

⁵⁵ See *Novartis Case: Background and Update—Supreme Court of India to Recommence Hearing*, LAWYERS COLLECTIVE (Sept. 6, 2011), available at <http://www.lawyerscollective.org/>

support of their position, these stakeholders cited Gleevec's (i) lack of novelty under anticipation, (ii) lack of added "efficacy" under Section 3(d), (iii) obviousness and (iv) wrongful priority.⁵⁶ Three years later, Novartis' patent application was rejected by the Chennai Patent Examiner's Office on multiple grounds, chiefly relying on Section 3(d) of the newly amended Indian Patent Act.⁵⁷ Thus, conceived out of India's TRIPS obligation to allow instances of Gleevec patents to be filed, Section 3(d) became instrumental in rejecting Novartis' right of market exclusivity in India.⁵⁸

Contextualizing 3(d)'s place in the Gleevec's patent denial calls for reviewing two important issues: (1) how 3(d)'s efficacy requirement presents a higher threshold than what the patent applicants were accustomed to, and (2) specifics surrounding the chemistry of Gleevec. Knowing the chemical composition, reactivity, and characteristics of Gleevec aids our understanding of how the functionality of "efficacy" can be linked to evaluating patent eligibility of the pharmaceutical product in question under the newly minted Section 3(d) of Indian Patent Act.⁵⁹ It is important to note that, for patent eligibility review, structural differences exist amongst the various versions of imatinib. Of particular importance is the difference between imatinib's free base form and its beta crystalline form imatinib mesylate.⁶⁰ With patent protection on thirty-five different forms of imatinib under its belt, Novartis had filed its Indian patent application for a particular polymorphic version, which is a methanesulfonic acid salt of imatinib.⁶¹ The task before the Indian patent system was to determine whether the methanesulfonic acid version of imatinib conveys a significant inventive step to warrant patent protection. Guided by the Section 3(d)'s enhanced efficacy standard, the issue for the patent examiner was to adjudicate whether the applied product contains significantly enhanced efficacy compared its prior variants.⁶²

Upon rejection of its patent application by the assistant controller of Patents,⁶³ Novartis AG, along with its Indian subsidiary, Novartis India, filed two writ petitions in the Madras High Court.⁶⁴ The petitioners sought a reversal of the Assistant Controller's order by finding Section 3(d) invalid.⁶⁵ Petitioners based their contention

[news/archived-news-a-articles/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html](https://www.indiankanoon.com/doc/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html).

⁵⁶ N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues*, in INTELLECTUAL PROP., PHARM.& PUB. HEALTH: ACCESS TO DEVELOPING COUNTRIES 225, 238–39 (Kenneth Shadlen, Samira Guennif, Alenka Guzman, & N. Lalitha, eds., 2011); *see also* Chandra, *supra* note 29, at 390–91.

⁵⁷ Amendment Act of 2005, *supra* note 14, § 3(d).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Ragavan, *supra* note 40, at 2.

⁶¹ *Id.* at 1–2.

⁶² Amendment Act of 2005, *supra* note 14, § 3(d).

⁶³ *See generally* Novartis Madras H.C. Decision, *supra* note 19. Novartis' contention that Gleevec was a new substance was rejected by the Assistant Controller of Patents and Designs. *Id.* ¶ 3. Observing that, although the new beta drug can be more effectively absorbed into the bloodstream, this bioavailability did not meet the improvement in efficacy as required by Section 3(d), and as a result, the patent application did not present a new substance. *Id.*

⁶⁴ *See id.* ¶ 1.

⁶⁵ *Id.*

on two grounds: unconstitutionality on grounds of arbitrariness on part of the patent examiner⁶⁶ and lack of merit in violation of India's TRIPS obligations.⁶⁷ In 2007, before the High Court could form its opinion, Novartis' first petition was transferred to the Intellectual Property Appellate Board ("IPAB")⁶⁸—a specialist tribunal set up to deal with appeals from the various intellectual property offices across the country pursuant to the Section 117G of the Indian Patent Act.⁶⁹ In 2009, the IPAB amended the decision of the Assistant Controller of Patents and Design in part by holding that the product in question did not violate the novelty and non-obviousness criteria,⁷⁰ but failed the test of enhanced efficacy under 3(d).⁷¹ Empowered by the Special Leave Petition ("SLP") under Article 136 of the Indian Constitution,⁷² Novartis was able to challenge directly to the Supreme Court in 2009,⁷³ which eventually led to the landmark decision of *Novartis v. Union of India and Others* on April 1, 2013 ("*Novartis*").⁷⁴

The legal battle over the Gleevec patent was fought over ten years, covering issues from constitutionality of the amendments to the patent regime's TRIPS compatibility.⁷⁵ However, as the case found its way from the IPAB to the Supreme Court, the relevance of Section 3(d) gained primacy.⁷⁶ It is time now to take a comprehensive look at the Section 3(d) of the Indian Patent Act.

⁶⁶ *Id.* ¶ 1.

⁶⁷ *Id.*

⁶⁸ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 15.

⁶⁹ The 1970 Act, *supra* note 44, § 117G. See also Linda L. Lee, *Trials and TRIPS-ulations: India Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 287–88 (2008) (noting that the Indian judicial system comprises a specialized tribunal entitled the Intellectual Property Appellate Board ("IPAB") established on September 15, 2003 to hear appeals from Registrar of Trademarks and Geographic Indications and from the Controller of Patents).

⁷⁰ *Novartis* IPAB Order, *supra* note 17, at 186.

⁷¹ *Id.* at 189 (finding that the Appellant has failed to satisfy the efficacy requirement for its beta crystalline form of imatinib mesylate pursuant to section 3(d) of the Act).

⁷² INDIA CONST. art. 136, *amended by* The Constitution (Ninety-sixth Amendment) Act, 2011 (stating that the "Supreme Court may, in its discretion, grant special leave to appeal from any judgment, decree, determination, sentence or order in any cause or matter passed or made by any court or tribunal in the territory of India").

⁷³ See *Novartis AG v. Union of India and Others, SLP (Civil) Nos. 20539-20549 of 2009*, LAWYERS COLLECTIVE (Nov. 23, 2010), <http://www.lawyerscollective.org/access-to-medicine/atm-current-cases.html> [hereinafter *Novartis*, LAWYERS COLLECTIVE]; *Novartis* Supreme Court Decision, *supra* note 17.

⁷⁴ *Novartis* Supreme Court Decision, *supra* note 17, at ¶¶ 193–94. Here I draw attention to the long drawn saga of Novartis' fight with the Indian patent regime, which "eventually" was decided against Novartis, after appealing all the way to the Indian Supreme Court regarding the composition of the panel. *Id.*

⁷⁵ See generally *Timeline of Key Events in Novartis's Attack on the Pharmacy of the Developing World*, DOCTORS WITHOUT BORDERS (last visited May 3, 2014), available at <http://www.msf.ie/timeline-key-events-novartiss-attack-pharmacy-developing-world> [hereinafter *Novartis Timeline*].

⁷⁶ Sarah Boseley, *Novartis Denied Cancer Drug Patent in Landmark Indian Case*, GUARDIAN (Apr. 1, 2013 9:10 AM), <http://www.theguardian.com/world/2013/apr/01/novartis-denied-cancer-drug-patent-india>; see also *Novartis Timeline*, *supra* note 75.

III. CONTEXTUALIZING SECTION 3(D): THROUGH MOTIVATION AND LEGISLATIVE HISTORY

Much before the 2013 decision by the Indian Supreme Court, Section 3(d) had already been subjected to a mixed review.⁷⁷ Pharmaceutical companies condemned its higher threshold of patentability for fear of losing their extended market exclusivity.⁷⁸ Scholars lauded its mechanism for preventing pharmaceutical companies from extending their market exclusivity strategies.⁷⁹ 3(d)'s legislative history of formulation is quite extensive. It reveals the lawmakers' motivations, which are both shaped by the Indian Constitution's commitment to health and colored by the aspirations of the millions relying on India as the *only* source of life saving drugs.⁸⁰ It is important, therefore, to review 3(d)'s development history, in which the legislators had to grapple with the quintessential schism between the twin strands of patentability—a western-centric maximalist property view, and the developing countries' public utilitarian minimalist perspective.⁸¹

⁷⁷ See Iyer, *supra* note 21 (noting that India strictly limits the patenting of known medicines); Manoj Pillai et al., *supra* note 21, at 24, 25 (emphasizing that Indian Patent Law is more restrictive in the pharmaceutical context because section 3(d) was introduced to prevent “evergreening of patents” and made pharmaceutical patents a focal point of international debate). The response to 3(d) has been mixed. Advancing a western centric viewpoint, some commentators criticized the higher threshold of patentability implied in 3(d).

⁷⁸ See Adam Taylor, *Here's The Patent Law That Is Allowing India To Smack Down Big Pharma*, THE BUSINESS INSIDER (Apr. 1, 2013), available at <http://www.businessinsider.com/novartis-loses-india-patent-case-2013-4> (“Novartis and other big drug companies say the ruling will hurt innovation in India, and Novartis has threatened to stop supplying India with its drugs following the ruling.”); Dwijen Rangnekar, *Calling Big Pharma's Bluff*, THE HINDU (Apr. 3, 2013) available at <http://www.thehindu.com/todays-paper/tp-opinion/calling-big-pharmas-bluff/article4575235.ece>.

⁷⁹ See NIHCM Study, *supra* note 2, at 4; Cynthia M. Ho & Ann Weilbaeher, *An Introduction—Patents versus Patients: Must We Choose*, 18 ANNALS OF HEALTH 1, 4 (2009), available at <http://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1110&context=annals>.

⁸⁰ See Randeep Ramesh, *Cheap Indian Drugs Under Threat*, THE GUARDIAN U.K. (Mar. 23, 2005), available at <http://www.guardian.co.uk/world/2005/mar/23/india.aids1> (stating that millions of patients around the world rely on inexpensive treatment from India); *Indian Court Ruling in Novartis Case Protects India as the 'Pharmacy of the Developing World'*, DOCTORS WITHOUT BORDERS (Aug. 6, 2007), available at <http://www.msf.org.au/media-room/press-releases/press-release/article/indian-court-ruling-in-novartis-case-protects-india-as-the-pharmacy-of-the-developing-world.html> (emphasizing that “millions of patients and doctors in developing countries” rely on affordable medicines from India); Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495 (2007). The amendment to § 3(d) was viewed by Lok Sabha member Suresh Kurup as vital for preventing pharmaceutical companies from obtaining several patents on one medication. See Transcript of Combined Discussion on the Statutory Resolution Re: Disapproval of Patents (Amendment) Ordinance, 2004 (No. 7 of 2004) and the Patents (Amendment) Bill, 2005 (Resolution negated and Bill Passed) at *41–42, LOK SABHA (Mar. 22, 2005), available at <http://164.100.47.132/LssNew/psearch/result14.aspx?dbsl=1866>.

⁸¹ See Ho, *supra* note 30, at 1049.

A. Motivation and Context of Section 3(d)

The latter part of the twentieth century witnessed pharmaceutical giants becoming successful in extending market exclusivity of their products in the developing countries predominantly via two pathways. In the first, a strict property rights paradigm took root within the various international trade agreements like TRIPS.⁸² In the second, a narrative of commercial impetus for incremental innovation as a precondition for wider access to life saving drugs has allowed companies to dictate patentability dialogues.⁸³ This allowed pharmaceutical companies to shape patent regimes favoring market exclusivity extension mechanisms in many developing countries.⁸⁴ The reality of life-saving drugs drifting out of reach for the poor has not gained much traction in these discussions.⁸⁵ Dangling the carrot of membership to global trade organization was enough incentive for developing countries to acquiesce into asymmetric bargaining power through TRIPS. This in turn has allowed the imposition of strict property rights based on patentability regimes, where each incremental innovation has become subject to patent protection for the continuation of corporate monopoly rent-seeking. As such, evergreening and patent layering has now become the norm in patentability frameworks.

Evergreening is a term for corporate maneuvering where a product manufacturer continues to extract patent protection on an originally patented product for successive designated periods on more than one attribute, even though

⁸² See Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 370–79, 383 (2006) (“[I]t is no surprise that less developed countries have been concerned about the heightened protection required by the TRIPs Agreement and its deleterious impact in the areas of agriculture, health, environment, education, and culture.”). While the U.S. and the U.K. led the neo-liberal movement that imposed western strict constructionist view of property rights into the various free trade agreements, U.S. laws eventually shaped the TRIPS agreements by imposing its norms into the framework through the WTO mechanism. This view is corroborated by scholars who see TRIPS as a product of unequal bargaining between developed and developing countries, where instead of exchange of norms, asymmetric modalities have been coerced upon the developing countries in the name of global harmonization. Therefore, instead of being left out, developing countries accepted the requirement of the imposition of strong intellectual property rights within their domestic legal regimes in order to enjoy the benefits of international trade.

⁸³ *Id.* at 390.

⁸⁴ Maximalist viewpoint of patent protection has allowed pharmaceutical companies in the United States to utilize various market exclusivity extension strategies to maintain their patent protections. The National Institute of Health Care Management Research and Education Foundation conducted a study in May 2002 and found that, between 1989 and 2000, only 35% out of the 1035 new drugs approved by the USFDA entailed a new active principle. See NIHCM Study, *supra* note 2, at 3. In other words, pharmaceutical companies were able to extend the lives of nearly two-thirds of their already-patented drugs by making alterations to the drugs’ methods of production, forms, or uses.

⁸⁵ Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development*, ¶¶ 13–14 Human Rights Council, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (stating that over “100 million people fall into poverty annually” because of healthcare costs and that approximately “2 billion people lack access to essential medicines”).

such attributes can be linked to a single product.⁸⁶ The U.S. National Institute of Health Care and Medicines took notice of this strategy as there was a concerted effort by some companies to patent even minor modifications of an original product: “[d]rug manufacturers patent a wide range of inventions connected with incremental modifications of their products, including minor features such as inert ingredients and the form, color, and scoring of tablets.”⁸⁷ Section 3(d) was designed to prevent this, as the following discussion of the text and explanation of the statute would reveal. Section 3(d) reads as follows:⁸⁸

(d) *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*⁸⁹

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, *unless they differ significantly in properties with regard to efficacy.*⁹⁰

Thus, 3(d) establishes an extra layer of deterministic criteria in the patent eligibility framework. This specific layer stipulates that, only those pharmaceutical derivatives that can be demonstrated to exhibit significantly enhanced efficacy are eligible for patent protection.⁹¹ This added layer would be a step towards real innovation as opposed to claiming innovation on minor enhancement. Therefore, this extra layer requiring enhanced efficacy would help in preventing fraudulent or superfluous patent applications that are routinely sought through evergreening or patent layering.⁹²

Developments in both organic and inorganic chemistry, along with advancement in quantitative techniques, opened much larger possibilities of product formation via chemical reactions. By slight alteration of chemical bonds, or simple

⁸⁶ Robert Chalmers, *Evergreen or Deciduous? Australian Trends in Relation to the 'Evergreening' of Patents*, 20 MELBOURNE U. L. REV. 29, 29 (2006) (stating that the term “evergreening” refers to “the strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies”).

⁸⁷ NIHCM Study, *supra* note 2, at 16.

⁸⁸ Amendment Act of 2005, *supra* note 14, § 3(d).

⁸⁹ *Id.*

⁹⁰ *Id.* (emphasis added).

⁹¹ *Id.* See also *Novartis* Supreme Court Decision, *supra* note 17, ¶ 103 (conducting a thorough review of prior, existing and emerging patent landscape of India and taking stock of the legislative history of the 2005 law, the Indian Supreme Court observed that Section 3(d) was meant to create a “second tier of qualifying standards” for chemical substances to combat “any attempt at repetitive patenting or extension of the patent term on spurious grounds”).

⁹² See *infra* Part IV.

modification in starting reactions, a range of derivative products can be obtained from an original product. Under a maximalist patent regime, pharmaceutical companies can obtain market exclusivity on a wide range of related products, from the original compound to its derivatives, which may arrive in varied chemical structures, such as salts, polymorphs, and isomers.⁹³ Maximalist patent regimes allow pharmaceutical companies to develop derivatives of original patented product, while also bestowing upon these companies patent exclusivity for years to come.⁹⁴ Section 3(d) recognizes this.⁹⁵ As each subsequent variant of a compound is structurally equivalent to the original, either in their naturally existing forms, or as known pharmaceutical substances,⁹⁶ it is more likely than not that these structurally similar substances are functionally equivalent. Therefore, 3(d)'s requirement of enhanced efficacy of the derivative is more effectively shown by observing its chemical interaction with other chemical compounds that offer the most significant reactivity.⁹⁷

The statute for 3(d) calls for a patent eligible product to be “efficacious,”⁹⁸ or have the attribute of enhanced efficacy over a prior known form, regardless of whether the invention is incremental or groundbreaking. Here, 3(d) creates a “floor” in demonstrating “efficacy,” while charting a layered patentability framework for pharmaceutical products.⁹⁹ Therefore, in order to claim patent, the onus of proving enhancement—that of improved and enhanced functionality—would fall on the patent applicant.¹⁰⁰ Thus, imposition of this simple demonstrability barrier for claiming a patent should be recognized as a process or instrumentality of bringing improved chemical compounds to the market to make significant contributions as pharmaceutical agents. This efficacy step certainly can distinguish between patent applicants that arrive via evergreening and those that contain a rigorous inventive step. Therefore, by making it mandatory for derivatives of known substances to exhibit added efficacy, 3(d) encourages sequential development of improved products to address significant public health needs.¹⁰¹

⁹³ See Chandra, *supra* note 29, at 391.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ See *infra* Part IV.

⁹⁸ See Shamnad Basheer & Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing Out the Creases in Section 3(d)*, 5 SCRIPTED 232, 234 (2008), available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf>.

⁹⁹ *Id.* at 238–39.

¹⁰⁰ Amendment Act of 2005, *supra* note 14, § 3(d); Basheer & Reddy, *supra* note 98, at 239.

¹⁰¹ See Basheer & Reddy, *supra* note 98 at 239. See, e.g., Soutik Biswas, *Novartis India Case: Campaigners Hail Patent Rejection*, BBC NEWS (Apr. 1, 2013), <http://www.bbc.com/news/business-21992724>; *Indian Supreme Court Decision on Novartis Case a Victory for Access to Medicines in Developing Countries*, DOCTORS WITHOUT BORDERS (Apr. 1, 2013), <http://www.doctorswithoutborders.org/press/release.cfm?id=6707&cat=press-release>.

B. A Chemical Composition Analysis

From the chemistry of the products, Novartis' Gleevec represents a transition from the discovery of the original free base to a polymorphic salt that is identified as a useful drug.¹⁰² To contextualize Gleevec's chemical characteristics in light of 3(d)'s requirement, let us briefly review the highlighted steps in its U.S. Patent.¹⁰³

1. The product in question focuses on a derivative obtained via synthesis of the imatinib free base, a compound that was patented in the U.S., EU and several other countries between 1993 and 1998.¹⁰⁴ As India did not provide product patents for pharmaceutical substances at that time, this could not be patented in India.¹⁰⁵
2. Imatinib mesylate was developed by adding methanesulfonic acid to the imatinib free base, which converted the drug from a free base to a salt.¹⁰⁶
3. The polymorphic form of imatinib, a beta crystalline variant of imatinib mesylate, has been recognized as the most stable form of the salt. Novartis filed its patent application for this particular product and it is this application that has been the focus of dispute in this patent saga.¹⁰⁷
4. The anti-cancer drug Gleevec is based upon the above beta crystalline form of imatinib mesylate.¹⁰⁸

The 3(d) framework would require Novartis to demonstrate that Gleevec—the beta crystalline form of imatinib mesylate—has an enhanced effectiveness over the original imatinib free base.¹⁰⁹ However, doing so under the 3(d) criteria would require the applicant to first identify an appropriate benchmark to claim such effectiveness.¹¹⁰ In its application, Novartis submitted that the new beta crystalline form can be absorbed more easily into the blood stream,¹¹¹ and this superior bioavailability can be used as a benchmark to measure enhanced efficacy.¹¹² This

¹⁰² See Chandra, *supra* note 29, at 391.

¹⁰³ U.S. Patent No. 5,521,184 (filed Apr. 28, 1994); see also E.P. Patent No. 0,564,409 (filed Mar. 25, 1993).

¹⁰⁴ '184 Patent, at [22], [30], [45].

¹⁰⁵ Basheer & Reddy, *supra* note 98, at 239.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ See Chandra, *supra* note 29, at 387 (stating that the “new Act's section 3(d) limits patents only to chemical entities that employ at least one new reactant”).

¹¹⁰ Basheer & Reddy, *supra* note 98, at 238–39.

¹¹¹ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 188.

¹¹² Here bioavailability refers to the absorption—a physical process where molecules of the original compound enters the spaces between the molecules of the solvent. It does not refer to a more transformative binding stage of the drug in question. Thus, it cannot be used as a benchmark for measuring efficacy of a drug. *Id.* ¶ 184; see also Lalitha, *supra* note 56, at 239.

line of argumentation lacks structural merit, as the heightened absorption—easier accumulation into the blood stream—does not meet the necessary criteria of increased efficacy under Section 3(d).¹¹³ This was duly noted by the Supreme Court in rejecting Novartis' claim.¹¹⁴

Let us impart additional color to the efficacy discussion. To achieve enhancement in a characteristic, the first step is to identify an appropriate benchmark. Therefore, to obtain an effective benchmark, in going from a prior product to a newer product, the applicant must address the difference between the original target outcome and the new intended target outcome. We present a hypothetical scenario to illustrate the point.

A pharmaceutical company PC, having enjoyed the exclusivity of patent protection for 18 years for its blood pressure medication BPR1, introduces in the market a new product BPR2. BPR2 is a derivative of BPR1 with the following results in random clinical trials prior to patent application: (i) the average decrease of blood pressure in switching from BPR1 to BPR2 has *not* been statistically significant; (ii) the average reduction of side effect from muscle pain in BPR2 is statistically more significant in comparison to BPR1. Could this be a demonstration of BPR2's enhanced efficacy over BPR1 and thus, patent eligible?

To capture the essence of above illustration, it must be noted that, the idea of efficacy must revolve around improving the target condition for which the original drug obtained its patent. Thus, in the case of the beta crystalline form of Gleevec, merely showing an enhanced hygroscopic attribute of easier absorption cannot be determined as a criterion for enhanced efficacy. Similarly, a mere reduction of a side effect must not be construed as satisfying the heightened standard of 3(d).¹¹⁵ This was the position held by the patent office and was subsequently upheld by the Supreme Court.¹¹⁶ However, the issue of efficacy is a loaded term that warrants further evaluation, as a series of questions can be raised.

For example, under what framework can we authenticate that the beta crystalline form lacked efficacy? What does the term efficacy mean? Can “therapeutic efficacy” be functionally equated with efficacy under Section 3(d)?¹¹⁷ What are some of the ways to construct benchmarks to measure efficacy for new inventions in pharmaceutical products space? Although the *Novartis* decision by the Supreme Court presented one view, the argument surrounding efficacy is *not* over yet. Efficacy was a vehicle that the lawmakers introduced to fulfill their objective of creating balance between a maximalist property rights framework and a wider utilitarian theme. Now is the time to retrace some of the legislative history and public sentiments that embodies Section 3(d).

¹¹³ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 187.

¹¹⁴ *Id.* ¶¶ 187–88, 190, 191.

¹¹⁵ *Id.* ¶¶ 189, 195.

¹¹⁶ *Id.* ¶ 195.

¹¹⁷ *Id.* ¶ 180 (stating that efficacy means “that ability to produce a desired or intended result”).

C. Legislative History of Section 3(d)

Reviewing the landscape of the Indian Patent Act reveals that Section 3(d) is not a sudden trajectory reversal, nor has it been a reactionary response to an altered socio-political landscape. Rather, 3(d) should be seen more as an organic enhancement within the corpus of patentability within the broader Indian intellectual property movement. Several other sections and chapters within Indian Patent law have been the precursor of Section 3(d).

Multi-layer patent eligibility criteria are nothing new within the Indian patentability framework, as has already been enshrined in the statutory provisions within Section 2 of the Indian Patent Act.¹¹⁸ Section 3 instead provides clear guidance to delineate amongst inventions, patentable inventions, and patentability for incremental inventions.¹¹⁹ The Indian Supreme Court duly corroborated this in noting that, "Section 3 of the Patent Act, which provided for exclusions from

¹¹⁸ The 1970 Act, *supra* note 44, §§ 2(1)(j)(i–iii), 2(1)(l)(i–v), 3(a–i). Section 2 contained the definition and interpretation clauses. It also defined the terms "invention" and "medicine" in clauses (j) and (l) respectively as under subsection 1. Invention means any new and useful:

- (i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; (iii) substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.

Id. § 2(1)(j). Medicine or drug includes:

- (i) all medicines for internal or external use of human beings or animals, (ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals, (iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals, (iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants; (v) all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the, medicines or substances above referred to.

Id. § 2(1)(l). Sections 1 and 2 comprised Chapter I, following which Chapter II was headed Inventions not patentable. Chapter II had three sections which, as originally framed, are as under Section 3:

What are not inventions. The following are not inventions within the meaning of this Act,—(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws ; (b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health; (c) the mere discovery of a scientific principle or the formulation of an abstract theory; (d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant

Id. § 3.

¹¹⁹ *See id.*

patentability, was recast.”¹²⁰ Furthermore, examination of the relationship between the current version of Section 3(d) and Section 83 of Chapter 16 (“hereinafter Section 83”), reveals a commitment for commercial incentive for innovation, which is punctuated with distinctions among classes of innovations along a patent eligibility framework.¹²¹ In general, Section 3 of the Patent Act provides various exclusionary provisions.¹²² Section 83 specifically addresses how patent law can be made consistent with a nation’s social justice obligations in encompassing a utilitarian theme by specifically adopting public welfare objectives.¹²³ Unfortunately, this minimalist paradigm is in sharp contrast to the property rights-focused maximalist patent framework that came to embody the reformatting needs of developing countries under TRIPS in the 1990s.¹²⁴

Therefore, the condemnation of 3(d) has to be evaluated through multiple competing dimensions. First, 3(d) symbolizes a utilitarian themed patent paradigm that is inconsistent with the western viewpoint on intellectual property protection.¹²⁵ Second, the neo-liberal drive to incorporate western property rights ideals within TRIPS’ process instrumentalities does not comport with the social justice-centric equality paradigm of 3(d).¹²⁶ Yet the Indian lawmakers ensured that the social justice component remained an integral part and that corporate monopoly rent-seeking practices do not supersede broader public utility in their amendment to the Indian Patent Act.

Keeping in view Section 3(d)’s shared ancestry with Section 83, further reviewing its implications and objectives would not be out of place. Section 83 balances both fundamentals—India’s treaty obligations and India’s commitment to social and economic welfare for the masses.¹²⁷ Section 83, therefore, provides for

¹²⁰ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 73.

¹²¹ The Patents (Amendment) Act, No. 38 of 2002, INDIA CODE (2013), § 83, available at <http://indiacode.nic.in/> [hereinafter Amendment Act of 2002].

¹²² See Basheer & Reddy, *supra* note 98, at 238.

¹²³ Amendment Act of 2002, *supra* note 121, § 83(d)–(g). Section 83 of Chapter 16, through items (d) through (g) stipulates the following:

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socioeconomic and technological development of India; (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health; (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

Id.

¹²⁴ See Yu, *supra* note 82, at 370–80.

¹²⁵ See *infra* Part IV.

¹²⁶ *Id.*

¹²⁷ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 68.3. The Statement of Objects and Reasons for the Amendment Act of 2002 observes the following:

commercial impetus through a layered patentability criterion, where in specific subsections, it erects barriers for flawed extension of market exclusivity.¹²⁸ This then ensures that the rights and obligations of all stakeholders are recognized within the patent regime.¹²⁹ More specifically, the Section prohibits patents that would otherwise impede advancement in public health and nutrition.¹³⁰

Section 83 is very thorough in charting specific exclusionary guidelines in bringing to light an intellectual property regime committed to social justice in ensuring equality of all stakeholders. Thus, it refuses to provide a patentability umbrella for a range of products that includes: (i) product patents that might interfere with the federal government's actions in protecting public health,¹³¹ and (ii) product patents that might pose significant barrier towards making necessary drugs available to the low income people at reasonably affordable prices.¹³² Such social justice threads of Section 83 are the intellectual precursor to Section 3(d). Clearly, therefore, with the necessary ground already established, 3(d) has simply followed a predictable trajectory.

Now, to further contextualize Section 3(d), its relationship with the main Chapter 2¹³³ is worth recognizing. Within the Indian Patent Act, Chapters 2 and 3, taken in conjunction, create a framework that neatly delineates between inventions that are not patentable with those that are patentable.¹³⁴ With the overall objective of Section 3 to provide guidelines for what are not inventions,¹³⁵ additional clarity is introduced in 3(d). Both Chapters 2 and 3 also provide a nuanced linkage between inventions and patentable elements.¹³⁶ When two dichotomous elements have been juxtaposed, they are granulated by distinguishing between (i) a class that recognizes

[w]hile considering amendment to the Act, efforts have been made to make the law not only TRIPS complaint [sic] but also to provide therein necessary and adequate safeguards for protection of public interest, national security, bio-diversity, traditional knowledge, etc. Opportunity is also proposed to be availed of for harmonising the procedure for grant of patents in accordance with international practices and to make the system more user friendly.

Id.

¹²⁸ See Amendment Act of 2002, *supra* note 123, § 83.

¹²⁹ Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 3 (2001) (noting that TRIPS type intellectual property regimes can have such pronounced impact on access to medicines revolving around "life-or-death consequences").

¹³⁰ *Id.* at 4.

¹³¹ See Amendment Act of 2002, *supra* note 123; *Novartis* Supreme Court Decision, *supra* note 17, ¶ 17 ("We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens.").

¹³² *Novartis* Supreme Court Decision, *supra* note 17, ¶ 42.

¹³³ *Id.* ¶¶ 45–46.

¹³⁴ The 1970 Act, *supra* note 44 (stating under Chapter II what inventions are not patentable, whereas Chapter III discusses how to apply for patents under the Act).

¹³⁵ *Novartis* IPAB Order, *supra* note 17, at 186.

¹³⁶ *Id.* at 179 (stating that the "patentability of an alleged invention is basically determined by establishment of novelty (anticipation), inventive step and industrial applicability of a product or a process [section 2(1)(j), and 2 (1) (l) of the Act] to the exclusion of inventions which are not patentable listed in section 3 and 4 of the Act.").

that certain products may not be deemed inventions, and (ii) the other class that indicates that despite being inventions, certain products may not be granted patents based on other considerations, such as lacking a specifically articulated criterion.¹³⁷ Clearly, the exclusionary criterion enshrined in 3(d)'s efficacy test has its origin within the meaning of these sections of the Indian Patent Act. Combining this linkage with the legislative history behind 3(d) provides us with an important baseline through which to evaluate the historical viability, and thus, the constitutionality of Section 3(d) within the Indian constitutional framework.

The genesis of 3(d) is linked to Indian patent regime's obligation to the developing world. In the eyes of the developing and the least developed nations, India is a messianic figure that provides for life saving drugs to the millions of poor and uninsured. In recognizing India's status as the *pharmacy for the world's poor*, the legislators paid careful attention to the growing apprehension that abuse of product patent in medicine might lead to widespread deprivation of life saving medicine.¹³⁸ Thus, prompted by their fear in extending excessive monopolies to pharmaceutical companies, the lawmakers debated over words and explanations that

¹³⁷ The 1970 Act, *supra* note 44, § 10(4)(a)–(b); Cynthia M. Ho, *Global Access to Medicine: The Influence of Competing Patent Perspectives*, *FORDHAM 35 INT'L L.J.* 1, 48–49 (2011).

¹³⁸ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 76. Commenting on the legislative process prior to the enactment of 3(d) in its Patent Law, the Indian Supreme Court observed:

Parliament had an absolutely unenviable task on its hands. It was required to forge, within a very limited time, an Act that would be TRIPS compliant without, in any way, compromising on public health considerations. It is seen above that the TRIPS Agreement had aroused grave concerns about its impact on public health. India had learnt from experience the inverse relationship between product patents and the indigenous pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices. It is also seen above that after the patent system in India barred the grant of patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country scaled great heights and became the major supplier of drugs at cheap prices to a number of developing and under developed countries. Hence, the reintroduction of product patents in the Indian patent system through the TRIPS Agreement became a cause of alarm not only in this country but also for some international agencies.

Id. This sentiment was corroborated by the following excerpts from a letter from the HIV/AIDS Director of the World Health Organization ("WHO"), dated December 17, 2004, to the Minister of Health and Family Welfare, Government of India:

We would like to bring to your attention that several of our Member States have expressed their concern that in the future, generic antiretroviral drugs from India may no longer be available to them. Among other places, these concerns were expressed by the delegations of Ghana, Lesotho, Malawi, and Namibia at our recent Procurement & Supply Management (PSM) Workshop in Nairobi, Kenya (2–9 December, 2004), and by Bangladesh, Cambodia, China, Indonesia, Korea, Laos, Thailand, Papua New Guinea, and Vietnam at the Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines held in Kuala Lumpur, Malaysia (28–30 November 2004).

Id.

can carry lasting and impactful meaning for the amended Section 3(d).¹³⁹ Thus, when the phrase “[t]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance”¹⁴⁰ was added to the original Section, the focus was on life saving medicines and drugs, which also have constitutional imprimatur within the Indian context.¹⁴¹

¹³⁹ *Id.* ¶ 80. During the debate surrounding the passage of the bill in the Indian Parliament, one law maker observed:

India has benefited from the low cost generic industry to dominate 30 per cent of the low cost drugs in the world . . . Secondly, it (the bill) is vague about the evergreening effect in which companies extend their patent rights by switching from capsules to tablets, for instance. This extends monopolies. Parliament must make sure that it protects the rights of India to make these generic drugs. We should remove the provision that allows this evergreening . . . What should and what should not be patentable has also been left open to interpretation. Earlier, the new use for a substance could not be patented. Now this has been qualified to allow it by putting “mere new use” instead of “new use.”

Id. Similar sentiment was echoed by another lawmaker:

Sir, a company which obtains a patent by changing their chemicals, before the expiry of the patent, they will again apply for a patent and again get a patent. So, in this way, they will continue to get a patent for the same medicine. For example, the drug called ‘Glevic’ (sic Gleevec/Glivec), is used for the treatment of Leukaemia. It is patented by Novartis. This was originally patented in 1993. The cost of the drug for the treatment of this disease comes to about Rs.1,20,000 per month in India. At the same time, the generic versions are available in the country which cost only Rs.8,000 to Rs.10,000.

Id. ¶ 82.

¹⁴⁰ *Id.* ¶ 83. Unique in its statutory implication and unparalleled as a patentability criteria, Section 3(d) incorporates the widely used patent eligibility criteria of “innovativeness” by borrowing the drug regulatory term “efficacy” as a bright line rule for determining the patentability of pharmaceutical inventions. On the surface, the procedural instrumentality seems straightforward, but the application leaves open the possibility of interpretation due to the requirement of selecting measurement benchmark. “Efficacy” has been borrowed from the European Union Directive on drug regulation, which states:

a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

Id. ¶ 185 n.1.

¹⁴¹ THE CONSTITUTION OF INDIA, Nov. 26, 1949, Part IV, art. 47. Any development within the Indian legal system, India’s international treaty obligations must have to be balanced with its constitutional adherence to the promotion of health and human rights. Thus, reformatting its

The above provides a snapshot of legislators' extensive due diligence and prolonged discussions in enacting 3(d).¹⁴² It also opens a window into the burdens legislators had to carry in structuring this amendment.¹⁴³ Revealed in various letters and pleas, the amendments to Indian patent law carried with it the hopes of many developing countries, where purchasing life saving drugs at the world market prices continue to be beyond reach of the majority.¹⁴⁴ Prompted by their responsibility to ensure a semblance of equality in public access to medicine, these lawmakers evaluated every word within the amended Section.¹⁴⁵ By duly incorporating additional words, such as, "the mere discovery,"¹⁴⁶ the legislators attempted to narrow the scope of patentability for highly specialized drugs, with a clear agenda to ensure that they never go beyond the reach of the poor.

The amended version of 3(d) is a product of legislative intent.¹⁴⁷ And if the legislators are the representatives of the people of the country, the language of 3(d) represents the collective intent of its citizens. TRIPS incompatibility or asymmetric trajectory relative to the global corporate viewpoint should certainly be subservient to these sentiments.¹⁴⁸

D. Preventing Evergreening—The Primary Objective

Thrust upon the world scene with an objective of leveling the playing field for pursuing access to life saving drugs, Section 3(d) had an eventful arrival.¹⁴⁹ Challenged by a very powerful pharmaceutical giant in its introductory invocation, 3(d) has already travelled a contentious road, a road rarely travelled by the maximalist patent paradigms.¹⁵⁰ Yet, if Indian patent regime were to rise up to its obligation to its utilitarian fundamentals, the amendment must embody opposition to

patent regime required balancing its TRIPS obligation with its constitutional mandate towards the protection of public health. For anecdotal examples of how the right to health has been a strong constitutional force in Indian courts, see generally Saby Ghoshray, *Searching For Human Rights To Water Amidst Corporate Privatization In India: Coca-Cola V. Perumatty Grama Panchayat*, 39 GEO. INT'L ENVTL. L. REV. 643 (2007). Against this constitutional landscape, Article 47 and 39 (e)–(f)'s duty to improve public health must be taken into consideration to properly evaluate the genesis of Section 3(d) within India's Patent law. See the "Directive Principles of State Policy" found in Part IV, that states, "The State shall regard . . . the improvement of public health as among its primary duties . . ." CONST. INDIA art. 47; see also CONST. INDIA art. 37, 39(e)–(f). However, the Supreme Court of India has declared, "it is now settled law that right to health is integral to right to life." *Punjab v. Chawla*, A.I.R. 1997 S.C. 1225. With almost uncanny similarity to the United States' Due Process clause, the relevant Section notes, "No person shall be deprived of his life or personal liberty except according to procedure established by law." CONST. INDIA art. 21.

¹⁴² See *supra* notes 138–141.

¹⁴³ See *supra* note 138 and accompanying text.

¹⁴⁴ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 76.

¹⁴⁵ See *supra* notes 138–141 and accompanying text.

¹⁴⁶ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 83.

¹⁴⁷ See *supra* notes 138–141.

¹⁴⁸ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 76.

¹⁴⁹ See *id.* ¶ 15.

¹⁵⁰ *Id.*

evergreening and patent layering.¹⁵¹ Section 3(d) presents such opposition; yet, it allows meaningful inventions to have commercial success. However, developing a robust definitional paradigm for meaningful innovation that is not contradictory to social justice principles is a challenge. And the answer to that challenge was introducing “efficacy.”¹⁵² Unfortunately, however, the requirement and significance of efficacy in the context of 3(d) has not been adequately evaluated.¹⁵³

Maximalist patent framework does not typically endorse an additional preventive layer of efficacy or a meaningful inventive step such that a broad range of innovations could be subject to patentability.¹⁵⁴ A trifling change or minimal modification in the existing product could become subject to new patent claim.¹⁵⁵ In this paradigm, a new coverage is envisaged by crafting simply a newer invention and the patentee could garner exclusive rights over such minor modification of the original.¹⁵⁶ And the process can continue forever, as Figure 1 illustrates.

¹⁵¹ *See id.*

¹⁵² *Novartis* Madras H.C. Decision, *supra* note 19, ¶ 3.

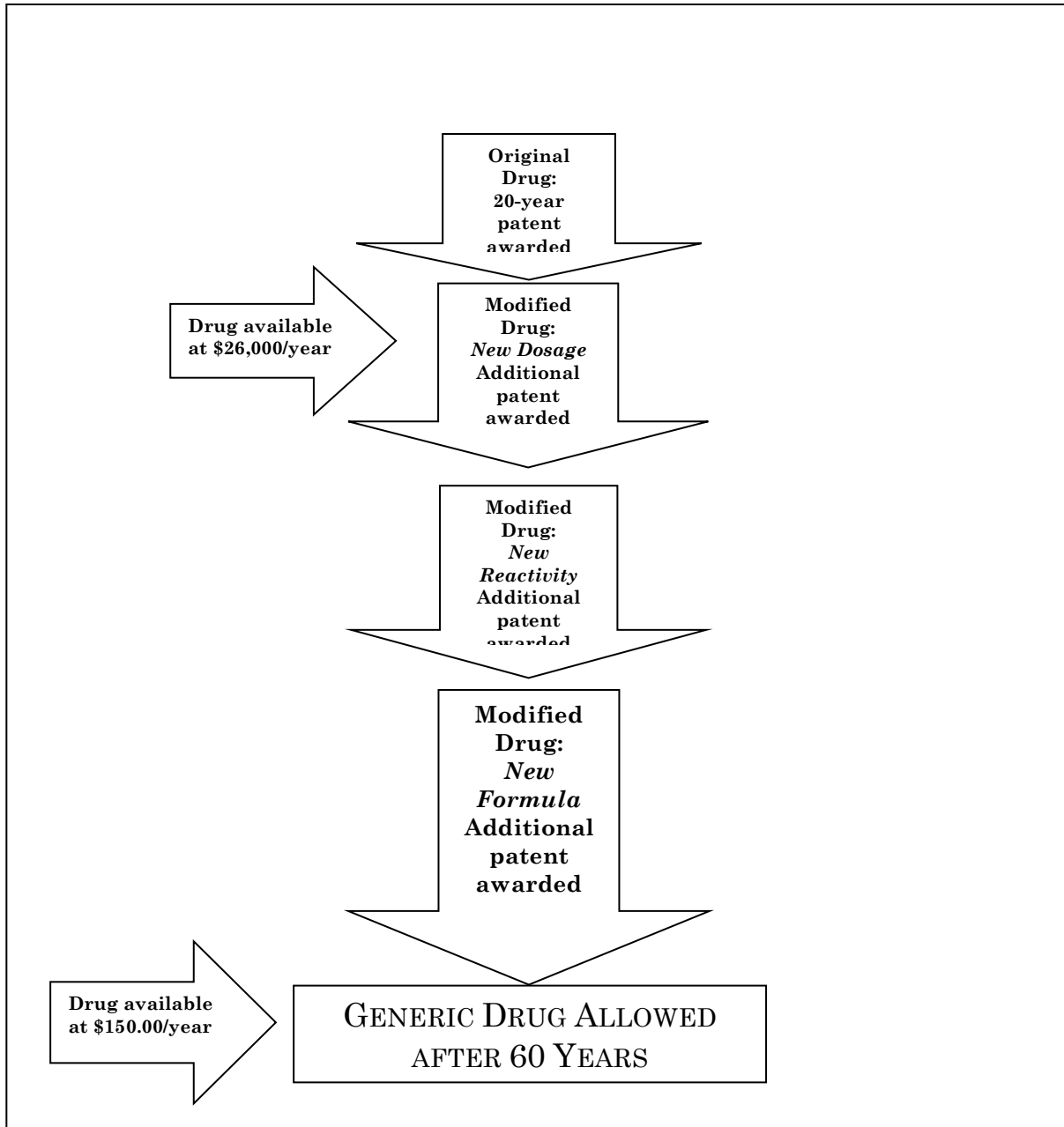
¹⁵³ *Id.*

¹⁵⁴ Alan Devlin, *Patent Law's Parsimony Principle*, 25 BERKELEY TECH. L.J. 1693, 1709 (2010) (stating generally that a maximalist approach provides patentees with the greatest level of protection for their innovation).

¹⁵⁵ Burcu Kilic & Luigi Palombi, *The Question of Patent Eligible Subject Matter and Evergreening Practices*, INFOJUSTICE.ORG (July 27, 2013), <http://infojustice.org/archives/30314>. (noting that in India “patent eligible subject matter may exclude certain trivial innovations from the broad category of ‘inventions’”).

¹⁵⁶ *See id.*

FIGURE 1: EVERGREENING DELAYING WIDER ACCESS TO MEDICINE



The scenario above could stymie competition, while the original patentee continues on extracting monopoly rent.¹⁵⁷ This could also decimate the interests of other stakeholders within the framework.¹⁵⁸ Therefore, in order to obtain a patent under the Indian patent regime, an applicant having an existing patent who may have incorporated a insignificant change or a minute enhancement is confronted with a second layer of eligibility criteria.¹⁵⁹ Section 3(d) specifically mentions, “a mere discovery of a new form of a known substance”¹⁶⁰ is unable to ever meet the threshold of novelty and inventive step, pursuant to clauses j¹⁶¹ and j(a)¹⁶² of Section 2(l)¹⁶³ of the Indian Patent Act.

Residing within the deeper meaning of discovery is a spirit of heightened novelty threshold. The clauses j and j(a) of the Indian Patent Act have responded to this by requiring a specific inventive step. Because j and j(a) were incorporated prior to 3(d), the development of 3(d) should be seen within a continuum with these two clauses. Thus, 3(d)'s imposition of an extra layer of qualifying standard of patentability in the form of efficacy should be recognized as coming from continuity, not via arbitrary imposition.¹⁶⁴

Arbitrariness was featured in Novartis' challenge and therefore, requires further evaluation.¹⁶⁵ Novartis invoked arbitrariness to invalidate 3(d) by arguing its contradiction with the fundamental right of equality.¹⁶⁶ Novartis submitted that efficacy has not been defined in the original patent act and thus, is subject to

¹⁵⁷ See Discussion, *supra* Part III.

¹⁵⁸ See Discussion, *supra* Part III.

¹⁵⁹ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 103. The court stated:

The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.

.Id.

¹⁶⁰ *Id.* ¶ 100.

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ See *id.*

¹⁶⁴ *Novartis* Madras H.C. Decision, *supra* note 19, ¶ 13 (stressing that under 3(d), patent applicants have to show increased efficacy especially if the discovery is only a derivative of a known substance); see also *Novartis* Supreme Court Decision, *supra* note 17, ¶ 104.

¹⁶⁵ See *Novartis* Supreme Court Decision, *supra* note 17, ¶ 18; *Madras High Court Dismisses Novartis' Petitions*, THE HINDU, Aug. 7, 2007, <http://www.thehindu.com/todays-paper/tp-national/madras-high-court-dismisses-novartis-petitions/article1887489.ece> [hereinafter *High Court Dismisses*].

¹⁶⁶ *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 16, 17; see also *High Court Dismisses*, *supra* note 165.

capricious invocation by the patent controller.¹⁶⁷ Clearly, the appellant has ignored the statutory history of how the extra layer has come to be codified within Indian law, and by which efficacy came to encapsulate the legislative intention of that development.

Section 3(d) simply puts a second layer of qualifying standards for pharmaceutical products.¹⁶⁸ Yet it does not foreclose genuine inventions.¹⁶⁹ This allows for true inventions to get the necessary patent protection, while rejecting any attempt at repeatedly patenting or extending the patent term on spurious grounds. Moreover, 3(d) sits at the intersection of patentability and invention.¹⁷⁰ For example, if the clause (d) is decoupled from the remainder of Section 3,¹⁷¹ and the original legislative history of the Patent Act of 1970¹⁷² is forgotten, then Section 3(d) can be seen as an extension of the definition of invention. In such case, if the clauses j and j(a) of the Section 2(1) are combined with Section 3(d), on the superficial level, it might appear that the Act creates multiple layers with diverging standards for inventions for different product classes.¹⁷³ However, if Section 3(d) is read in conjunction with the entire legislative history of the original Act,¹⁷⁴ its 2005 amendment,¹⁷⁵ and the relevant clauses of Section of 2(l),¹⁷⁶ Section 3(d) is revealed in its cogent implications and robust applications.¹⁷⁷

E. Deconstructing Efficacy of 3(d)

The word efficacy appears within both the text and explanation of 3(d).¹⁷⁸ Linguistically, efficacy means, “the ability to produce a desired or intended result.”¹⁷⁹

¹⁶⁷ *Novartis* Madras H.C. Decision, *supra* note 19, ¶ 14; *High Court Dismisses*, *supra* note 165.

¹⁶⁸ *Id.* ¶ 104.

¹⁶⁹ Jitesh Kumar, *The Glivec Case: Getting Beyond Efficacy*, LIFE SCIENCES INTELL. PROP. REV. (Feb. 19, 2014), <http://www.lifesciencesipreview.com/article/the-glivec-case-getting-beyond-eficacy>.

¹⁷⁰ *See infra*, Part IV.

¹⁷¹ *See Novartis* Supreme Court Decision, *supra* note 17, ¶ 104.

¹⁷² *Id.*; *see also* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15, 18 (2005), *available at* http://www.nls.ac.in/students/IJLT/resources/1_Indian_JL&Tech_15.pdf (citing N.R. AYYANGAR, COMMITTEE REPORT ON THE REVISION OF PATENTS LAW (1959)).

¹⁷³ *See infra*, Part IV.

¹⁷⁴ *See Novartis* Supreme Court Decision, *supra* note 17, ¶ 104.

¹⁷⁵ *See id.* ¶¶ 102, 103.

¹⁷⁶ *Id.*

¹⁷⁷ *See id.* ¶¶ 102, 103.

¹⁷⁸ Amendment Act of 2005, *supra* note 14, § 3(d).

¹⁷⁹ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 180. From the beginning, the Indian court system, construed the meaning of efficacy within a narrow spectrum to mean therapeutic efficacy. *Id.* Beginning with Madras High Court, which examined the scope of § 3(d) and interpreted “efficacy” to convey only “therapeutic efficacy.” *Id.* In this construction, the Court relied on the Dorland’s Medical Dictionary that defines efficacy as “the ability of a drug to produce the desired therapeutic effect.” *Id.* ¶ 183. The Court further reasoned that the efficacy of a drug is independent of the potency of the drug. *Id.* ¶ 180. Thus, by resorting to a narrow interpretation on the meaning of the expression “therapeutic,” the High Court observed that the patent applicant

Reading efficacy superficially might invite a wide range of possibilities for various products. If we are to take efficacy by itself and without designating a class of product, it might make for a perplexing regime. Implementation of efficacy, therefore, would depend on a slew of factors: the function, the utility, and the objective of the product under consideration. Could there be a robust way of measuring efficacy? This newly introduced term, “efficacy,” within such a narrow statutory construct, certainly leaves the door open for capricious determination by a patent examiner. Therefore, it would be instructive here to provide a nuanced analysis.

We can better appreciate the Supreme Court’s interpretation of efficacy by adopting a product-specific analysis. Here the Supreme Court applied efficacy specifically for pharmaceutical products. By introducing a new term, “therapeutic efficacy” to qualify the term, the Court developed a more robust framework surrounding the term “efficacy.”¹⁸⁰ Arguing that the function of a medicine is to cure a disease, the Court reasoned that the testing for efficacy can be adequately performed by measuring therapeutic efficacy.¹⁸¹ Yet, the Court had recognized the difficulty of not having a standard or a consistent framework to measure therapeutic efficacy.¹⁸² This therefore, invites us to introspect on a series of questions: What shall the appropriate parameter for therapeutic efficacy be? What are the characteristics, advantages and benefits that can be brought forward for a substantive determination of the enhancement of therapeutic efficacy? Duly recognizing these procedural uncertainties, the Court introduced a nuanced framework for applying 3(d). This certainly has the desired effect of rescuing the somewhat tenuous trajectory of 3(d) from its statutory uncertainty by steering it toward a more robust application for pharmaceutical products.¹⁸³ Thus, by embarking into a new procedural framework, the Court has recast the original efficacy into therapeutic efficacy. Introducing therapeutic efficacy still leaves open the issue of its appropriate measurement for consistent application to determine patentability for a wide-ranging product types.

From a definitional paradigm, efficacy gave life to 3(d), yet there is a missing element that the Court attempted to provide, which leads me to explore whether this automatically lends to judging therapeutic efficacy of a medicinal product strictly and narrowly? Given that the introduction of 3(d) into the patent act has already raised the bar much higher than before, does the argument for narrow and stricter interpretation of therapeutic efficacy hold water?

To determine whether pharmaceutical substances and medicinal products must receive a narrow and strict interpretation for their patent eligibility, a variety of factors must be evaluated. Looking at the language of the statute, the 2005 Amendment introduced the condition of “enhancement of the known efficacy.”¹⁸⁴

would have to demonstrate how effective the new discovery would be in either healing of a disease or producing a good effect on the body. *See supra* Part IV.

¹⁸⁰ *See Novartis* Madras H.C. Decision, *supra* note 19, ¶ 13.

¹⁸¹ *Novartis* Supreme Court Decision, *supra* note 17, ¶ 180.

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.* at ¶ 180.

This was further explained in the attendant explanation, which would require that, the derivative products “differ significantly in properties *with regard to efficacy*.”¹⁸⁵ Although complex, the explanations can be distilled into specific observations. First, we must recognize that not all advantages or beneficial properties are relevant. Second, properties that can be identified for measuring efficacy must be carefully isolated. In the case of medicinal products, such characteristics should form the measurable parameters to demonstrate the therapeutic efficacy.

For the Novartis patent in question, various different products in many forms have been submitted in the application.¹⁸⁶ Each of these different forms is associated with a subset of properties that are strictly inherent to that form.¹⁸⁷ For example, solubility is a strictly inherent property of a salt,¹⁸⁸ like hygroscopic is characteristic to a polymorphous compound.¹⁸⁹ From its chemical composition, a salt and its polymorphous equivalent, when manufactured, can be claimed as different discoveries from the perspective of patent application. Yet, following the patentability standard of the current Indian regime would prompt us to apply the higher threshold of 3(d).¹⁹⁰ This in turn would require us to test whether there has been enhancement of therapeutic efficacy in achieving the cycle of discovery from the salt to the polymorphous compound.¹⁹¹

Application of the threshold test in this example, therefore, would require us to find an applicable property of the claimed product which has a measurable criterion for testing.¹⁹² This would help determine whether the quantum of efficacy has increased from the prior patented product to the newly claimed product. In selecting an applicable property, however, great care must be taken to identify only those properties that can be both (i) measure effectively to demonstrate efficacy and, (ii) are significantly different with respect to the specific efficacy being sought. Here, unless the efficacy is shown to have increased significantly, a patent is rejected.¹⁹³ A mere change of form or inconsequential differences in form, from one type of property to another, must not qualify as showing increased efficacy. Therefore, therapeutic

¹⁸⁵ *Id.* (emphasis in original).

¹⁸⁶ *Id.* ¶ 8 n.1.

¹⁸⁷ *Id.* ¶ 181.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* ¶ 180 n.1 (citing Oxford Dictionary of English). The Court in *Novartis* has construed the operational meaning of efficacy “the ability to produce a desired or intended result.” *Id.* This led the Court to conclude that, for pharmaceutical drugs, the desired result is to cure a disease, and thus “not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.” *Id.* ¶ 180. Thus, when evaluating the efficacy of different compounds, say, between the alpha and the beta form of Gleevec, a slew of characteristics could be available for observation, such as, thermodynamic stability, lower hygroscopicity, enhanced bioavailability, etc. In the pre-3(d) patent regime, an applicant could get away with showing any properties, ranging from hygroscopicity, stability, bioavailability, for the purpose of patentability. Section 3(d), however, instituted an added layer—an enhanced threshold through which to examine patentability. Thus, in the opinion of the Court, the furnished properties did not meet the threshold to establish therapeutic efficacy. *Id.* ¶¶ 187–89.

¹⁹¹ *Id.* ¶ 180.

¹⁹² *Id.* ¶¶ 187, 192.

¹⁹³ *Id.* ¶ 180; see also Amendment Act of 2005, *supra* note 14, § 3(d).

efficacy has to be interpreted within a narrower spectrum and via a stricter procedural analysis. Yet, implementing such procedures comes with the sophistication rigor that any complex chemical measurement calls for.

IV. SECTION 3(D) AND THE TRIPS COMPATIBILITY

The twin threads of Novartis' challenge centered on 3(d)'s lack of constitutionality and TRIPS incompatibility.¹⁹⁴ TRIPS incompatibility has garnered significant coverage, an area on which the Madras High Court has refrained from ruling, citing jurisdictional grounds.¹⁹⁵ It is time to evaluate the issue of TRIPS compatibility within the broader rubric of Indian intellectual property regime.

The TRIPS framework sought to align global patentability regimes in line with predominantly U.S. standards, and the feasibility of achieving this was recognized early on.¹⁹⁶ The resulting framework did not clearly define patentability criteria, nor did it articulate a bright line of distinction between invention and patentability. In many ways, the TRIPS agreement created a multi-layer exception paradigm that has taken into account the different starting points from which member States began their journey towards industrialization. Therefore, the only hurdle Section 3(d) might face is if under a broader WTO panel evaluation the efficacy barrier is eventually found to be in direct contravention of TRIPS.¹⁹⁷ Here, the deterministic benchmark would be to evaluate whether a required demonstration of efficacy invites one of the two outcomes—either imposing an undue burden on the innovator, or the

¹⁹⁴ *Novartis* Madras H.C. Decision, *supra* note 19, ¶ 1. Novartis' constitutionality argument focused on challenging 3(d)'s imposition of efficacy allowed patent examiner unfettered power of arbitrariness. *Id.* ¶ 3 (arguing this to be in violation of Article 14 of the Constitution, INDIA CONST. art. 14: "The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India"). Novartis sought to invalidate 3(d)'s efficacy threshold. The Court found "a broad distinction between discretion which has to be exercised with regard to a fundamental right guaranteed by the Constitution and some other right which is given by the statute." *Id.* ¶ 34. Concluding that the statutory patent rights in question fall into the latter category, the Court in essence, foreclosed the issue of constitutionality in the case. In addition, I have shown elsewhere in this Article, *see supra* Part III, the deeper constitutional adherence given to the protection of public health within the policy objective certainly closes the book on any issue of unequal protection, as argued by Novartis.

¹⁹⁵ *Novartis* Madras H.C. Decision, *supra* note 19, ¶ 4.

¹⁹⁶ See Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 7 (2004).

¹⁹⁷ As discussed thus far in this Article, I have articulated the need for balancing pharmaceutical companies' right to obtain market exclusivity for their innovation with the widespread apprehension about price of life saving drugs going outside the means of the millions. This sentiment is found in the TRIPS agreement, as Article 7 mandates member States to work towards a "balance of rights and obligations" that is "to the mutual advantage of producers and users of technological knowledge and . . . conducive to social and economic welfare." TRIPS, *supra* note 11, art. 7 ("Objectives"). India's legislative debates and subsequent introduction of Section 3(d) is a testament to countries' difficulties in crafting the right balance between two competing interests, while ensuring both innovation and wider access to the drugs. In this context, the international agreements clearly favor the pharmaceutical giants, as when and if, drug companies perceive existential danger within patent law in India, they are free to both file challenges through the WTO and withdraw from the Indian market.

patentability framework in the target jurisdiction is subject to arbitrary determination. However, given its clear articulation,¹⁹⁸ well established legislative history,¹⁹⁹ associated due diligence in its crafting,²⁰⁰ and a highly nuanced judicial deterministic paradigm,²⁰¹ Indian patent regime's efficacy framework can no longer be recognized as narrowly construed for TRIPS violation. Rather, it is of significant value to trace the flexibility guidelines provided within TRIPS in formulation of 3(d).

Article 27 of TRIPS²⁰² asserts that, "patents shall be available for any inventions, provided that they are new, involve an inventive step and are capable of industrial application."²⁰³ Lack of precise language leaves the door open for member States to fill the gaps left in the guidance. Here, neither the term "inventive step" nor, the term "capable of industrial application" has been clearly defined in the TRIPS documents. This would prompt member States to define their own patentability criteria pursuant to their specific national interests. From a comparative perspective, the term "inventive step"²⁰⁴ can be recognized as synonymous with the term non-obvious.²⁰⁵ And, the term "capable of industrial application"²⁰⁶ can be seen as conveying the meaning useful.²⁰⁷

TRIPS' language reveals aspects of interconnectedness and diversity that the agreement sought to embody within member States' patent regimes.²⁰⁸ As countries progressed through the cycle of civilization and arrived at respective industrial development phases, they arrived at different times.²⁰⁹ In this diverging chronology, technology posed differing advantages and challenges to the States.²¹⁰ Responding to specificities of situations impacting them, member States have historically crafted their patentability criteria, both by responding to their unique challenges and by utilizing their specific advantages.²¹¹ Uniqueness has been more pronounced in certain fields, necessitating accommodation of bespoke and case specific concerns.²¹² The language of TRIPS recognizes this and therefore, allows member States the flexibility to define patentability criteria in a manner that suits their specific national interests.²¹³ Western countries have periodically utilized such flexibility.

¹⁹⁸ See *supra* Part III; Amendment Act of 2005, *supra* note 14, § 3(d).

¹⁹⁹ See *supra* Part III.C; Amendment Act of 2002, *supra* note 123, § 83.

²⁰⁰ See *supra* Part III.C.

²⁰¹ *Id.*; see *Novartis* Supreme Court Decision, *supra* note 17, ¶ 104.

²⁰² TRIPS, *supra* note 11, art. 27.1.

²⁰³ *Id.*

²⁰⁴ *Id.* art 27.1 n.5.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*; Alessandra Arcuri & Rosa Castro, *How Innovative is Innovative Enough? Reflections on the Interpretation of Article 27 TRIPS from Novartis v. Union of India*, at 9 (SOC'Y OF INT'L ECON. LAW, Working Paper No. 52/08), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1159821.

²⁰⁸ See *id.*

²⁰⁹ See *id.*

²¹⁰ *Id.* at 10–11 (inferring that the scope of patentability differs amongst WTO members due to a number of variables); see also TRIPS, *supra* note 11.

²¹¹ Arcuri & Castro, *supra* note 207, at 10–11.

²¹² See *id.*

²¹³ *Id.* at 11; TRIPS, *supra* note 11, art. 8.

For example, in 2001 the U.S. Patent and Trade Office (“USPTO”) revised its utility guidelines for biotechnology.²¹⁴ Similarly, Germany recently introduced a provision to restrict patent monopolies on a gene sequence.²¹⁵ Therefore, if Section 3(d) follows a trajectory similar to its U.S. and German counterparts and introduces refinement, why must there be differing responses? Moreover, taking an expansive meaning of the term, enhanced therapeutic efficacy could be recognized as synonymous to non-obviousness in Section 103 of the U.S. Patent Act.²¹⁶ The robustness of 3(d)’s nuanced approach can be recognized through its premise, which presumes most forms of existing pharmaceutical substances are deemed obvious unless they exhibit enhanced and substantive therapeutic efficacy.²¹⁷

Article 27 of TRIPS endows a member State with the option to exclude certain inventions from patentability, if their commercial exploitation is contrary to the national interest or inconsistent with the settled law of the land.²¹⁸ This exception allows flexibility to member States in crafting their patentability framework to be in line with their own interests. Moreover, members are also allowed to exclude various method patents that are consistent with providing essential health and human services to its citizens.²¹⁹ Thus, the TRIPS agreement embodies a commitment to public health and societal welfare. This commitment has also found resonance in various WTO agreements and conferences. Most importantly, in the 4th WTO Ministerial Conference in Doha on November 14, 2001,²²⁰ the following was adopted:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

²¹⁴ Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092 (Jan. 5, 2001), available at <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>. Such types of requirement are also being applied by the EPO. *Decision of the Opposition Division*, EUROPEAN PAT. OFFICE 308 (June 2002).

²¹⁵ In 2004, the German Parliament introduced legislative amendment to limit patent protection on human gene sequences to “disclosed functions” at the time of the patent application. As a result, any patent application on a human DNA sequence used for a specific function would not be eligible to cover a second function discovered later by another researcher using the same DNA sequence. See Ned Stafford, *German Biopatent Law Passed*, THE SCIENTIST (Dec. 9, 2004), <http://www.seedquest.com/News/releases/2004/december/10737.htm>; Ghoshray, *supra* note 1, at 517–18.

²¹⁶ 35 U.S.C. § 103 (2012).

²¹⁷ See *supra* Part III.

²¹⁸ See TRIPS, *supra* note 11, § 27.

²¹⁹ *Id.*

²²⁰ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002). This is also when they decided to extend exemptions for pharmaceutical patent protection for LDN until 2016.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.²²¹

Furthermore, TRIPS provide the following flexibility to its member States:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

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

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.²²²

In evaluating TRIPS compatibility of a member State's legal jurisdiction, we must bear in mind the fundamental precept—a member State has flexibility to create an individual paradigm that is resonant with its internal aspirations.²²³ The TRIPS agreement has empowered its member States to craft their own patentability regimes that reflect their diverging starting points from an agrarian way of life towards industrialization. Thus, while TRIPS ensures that innovators have commercial impetus, nowhere in the agreements does it advocate the granting of unfettered right

²²¹ World Trade Organization, Declaration on the TRIPS agreement and public health, WT/MIN(01)/DEC/2, ¶ 1–4 (Nov. 20, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter WTO Declaration on TRIPS Agreement].

²²² *Id.* ¶ 5(a)–(d).

²²³ *Id.* ¶ 4.

of evergreening to pharmaceutical companies.²²⁴ Rather, despite its history of origin being steeped in discontent among member States, its robust framework reveals a commitment towards allowing member States to effectively combat corporate monopoly rent-seeking behavior.²²⁵

Under the emerging rubric of Section 3(d), pharmaceuticals can no longer shape the market exclusivity in their favor, nor, can they subsume broader public interest within the predatory property rights framework.²²⁶ This is consistent with the various flexibilities offered to the member States by the Articles 7,²²⁷ 8,²²⁸ and 27 of the TRIPS agreement, in conjunction with paragraphs 4,²²⁹ 5,²³⁰ and 6²³¹ of the Doha Declaration. As member States are allowed to control their patent regimes in a manner consonant with their broader national objectives, 3(d) encapsulates India's social justice goals, while giving primacy to public health.²³² This is also in line with the United Nations' primary objective in structuring various conferences and protocols to ensure any development towards adverse impact on public health is effectively prevented. Thus, the Union of India is within its rights under the TRIPS agreement to adjust its patentability criteria and set higher standards for patent protection. And it is therefore TRIPS compliant. It is important to note that Indian law must be judged and interpreted not by the colonialist prescription imposed by the western world, but through the lens of its treaty obligation that allows it to set its own goals and aspirations.

V. BROADER DIMENSIONS AND FUTURE IMPLICATIONS OF *NOVARTIS*

The chief contribution of the *Novartis* decision is to introduce a new law—Section 3(d) of the Indian Patent (Amendment) Act. By unleashing 3(d) on to the global intellectual property landscape, *Novartis* signaled an effective provision against market exclusivity extension mechanisms of pharmaceutical giants,²³³ while declaring war against strict property rights based intellectual property frameworks. Despite becoming a subject of sharp criticism for venturing into the uncharted territory of structural revision in patentability,²³⁴ *Novartis* is laudable as one of the path-breaking cases to arrive in 2013. It's laudable for introducing a model for

²²⁴ Molly M. Chen, *Reconsidering the U.S. Patent System: Lessons from Generics*, 45 VAND. TRANSNAT'L L. 1249, 1257 (2012).

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ See TRIPS, *supra* note 11, art. 7.

²²⁸ *Id.* art. 8.

²²⁹ See WTO Declaration on TRIPS Agreement, *supra* note 221.

²³⁰ *Id.*

²³¹ *Id.*

²³² See Ellen F.M. 'T Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in *ECONOMICS OF AIDS AND ACCESS TO HIV/AIDS CARE IN DEVELOPING COUNTRIES: ISSUES AND CHALLENGES* 39 (2003).

²³³ See *India's Novartis Decision*, N.Y. TIMES (Apr. 5, 2013) (noting that "India decided to prevent drug companies from getting monopoly protection on updated drugs that did not represent a major advance over previous versions—a practice often referred to as 'evergreening'").

²³⁴ *Id.*

erecting a bulwark against corporate monopoly rent-seeking practices. It's path-breaking for its long-standing implications on at least four areas.

First, retrenching from novelty and non-obviousness line of reasoning, *Novartis* reduced the scope for pharmaceutical products, while staying within applicable patentability framework for pharmaceuticals. This is a new development. Prior to 2005, pharmaceutical products could not be patented in India.²³⁵ This Amendment has brought pharmaceuticals under patent eligibility, but developed a layered deterministic paradigm to reduce the scope of pharmaceutical patents.

Second, by rejecting the seductive urge for conformity with western laws, *Novartis* blazed a divergent path in formulating 3(d) that resonated with the social justice and utilitarian themes of equality. By reconciling India's treaty obligations with its human rights imperatives, 3(d) imposed a human rights component into the market-driven intellectual property framework.²³⁶ Responding to the aspirations of billions that rely on India's generic drug market for survival,²³⁷ *Novartis* sought to level the playing field in the procurement of humanity's basic survival needs.²³⁸

Third, recognizing TRIPS' contentious origin and long simmering discontent of the developing regimes,²³⁹ 3(d) can be recognized as a model of patentability for developing nations to follow. If evaluated without bias, 3(d) can be utilized as a much needed hybrid framework that can bridge the schism between the maximalist and minimalist paradigms of patentability.

Fourth, *Novartis* signals a judiciary interest in seeing harmonization of patent regimes across the globe. While the contours of such harmonization might not be as clear-cut, viewing *Novartis* in conjunction with some of the earlier cases, we can certainly conceptualize a future where laws of Nations may be showing tendencies to merge. Next, I discuss these four threads in detail.

A. Scope Reduction of Patentability via 3(d)

Novartis narrowed the scope of patents by reasoning that novelty and non-obviousness considerations should not form the core necessary requirement in determining patentability.²⁴⁰ The Court needed a new requirement, a layer of proving therapeutic efficacy, for going beyond the novelty and non-obvious considerations.²⁴¹ Therapeutic efficacy can be seen as having the same impact on patentability of pharmaceuticals that the "markedly different characteristics"²⁴² of *Diamond vs. Chakrabarty*²⁴³ had on the patentability of biological products when that

²³⁵ See Amendment Act of 2005, *supra* note 14, § 2(h).

²³⁶ *Id.* § 3(d).

²³⁷ See James Love, *The Production of Generic Drugs in India*, BRIT. MED. J. (Mar. 22, 2011), <http://www.bmj.com/content/342/bmj.d1694>.

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ See *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 102–04.

²⁴¹ *Id.*

²⁴² See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

²⁴³ *Id.* at 309–10 (upholding the patentability of man-made bacteria that devours oil droplets in the ocean).

seminal case arrived on the scene. With the introduction of 3(d), the novelty and non-obviousness characteristics can neither hold primacy nor stand alone in their deterministic objective, thereby attenuating the force of their requirement in the framework. Thus, by enhancing the force of therapeutic properties of the invention in determining patentability, the Court may have signaled that the novelty and non-obviousness characteristics have lesser patentability value than the newly introduced efficacy requirement.²⁴⁴

A discussion of some aspect of the comparative nuances of the two patent regimes might be helpful in adequately contextualizing the 3(d) consequences. Despite their similarities on many aspects, the Indian patent regime and the U.S. patent regime differ significantly. The U.S. patent office could consider the validity of a patent if the invention contained some of the desired therapeutic properties, even if they lacked markedly different distinguishable characteristics, although the paradigm has shifted somewhat in the post-*Myriad* landscape.²⁴⁵ Within the U.S. context however, in a competition between the *markedly different characteristics* and the therapeutic properties, the latter could win even if the *markedly different characteristic* is conspicuous by its absence in the invention.²⁴⁶ As if by following the cue from the post-*Myriad* framework in the U.S., the Indian Supreme Court has narrowed the older paradigm's expansive limits. By specifically observing the framework to be unnecessarily encompassing, the Court prevented patentability criteria to be vaguely amenable to all kinds of claims.²⁴⁷ The fundamental question is therefore whether therapeutic efficacy can be used as a patentability threshold to measure the diagnostic utility of the drug in question and whether this diagnostic aspect in of itself invokes similar transformative idea as contained in *markedly different characteristics* paradigm. Thus, 3(d)'s synonymous application of the *markedly different characteristics* seems to have the potential to invalidate patentability of many pharmaceutical products with just incremental changes and less therapeutic value.

B. Dissecting Novartis' Human Rights Dimension

The scope restriction in *Novartis* should be recognized as the judiciary's attempt to introduce functional efficiency in the patentability doctrine.²⁴⁸ Technology's advancement has allowed pharmaceuticals companies to make constant changes in the original product in an effort to claim inventions for perpetuity. Within a decidedly maximalist paradigm, this could mean pharmaceutical companies could prolong their control of market exclusivity for decades, leaving access to life saving drugs out of reach for most. Looking at the explosion of patents in the last three decades under an overtly inclusive patent paradigm, the right to health for all humanity has, therefore, become a fleeting afterthought. Lost in this frenzy are the

²⁴⁴ See *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 102–04.

²⁴⁵ See Ghoshray, *supra* note 1, at 523–24.

²⁴⁶ *Id.*

²⁴⁷ See *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 102–04, 191–92.

²⁴⁸ See Basheer & Reddy, *supra* note 98, at 239.

interests of various stakeholders. Section 3(d) recalibrated such contour of patentability by encapsulating diverging stakeholder interests: the multi-national companies, the domestic pharmaceutical industry, and the consumers. Here, 3(d) elevates the “floor” by limiting patent protection to new chemical entities and their derivatives on condition of substantive enhancement of therapeutic efficacy, which in turn allows the rights of more individuals to be recognized within the patent discourse.²⁴⁹

Western patent paradigms provide a dynamic lens through which to see the interplay between bounty and suffering. This paradox has to be evaluated through its inherent dichotomy within the global patent landscape. Patentability doctrines have evolved through the quintessential tension between the two frameworks, one predicated on the idea of state supervision and the other premised on monopoly rent based corporate ownership of natural resources. Maximalist patent paradigms are antithetical to the human rights dimensions of various UN declarations that promote fundamental rights to health and longevity.²⁵⁰ Woven within the real life background of *Novartis* is the narrative of human sufferings borne out of delayed medical care and lack of access to drugs.²⁵¹ The Court’s ruling, therefore, invites us to take a retrospective inquest at searching for patent law’s legal lineage under mankind’s common heritage. More than 150 years ago, the U.S. Supreme Court recognized the abstract fundamentals of human invention by tracing its roots in a shared humanity in observing that:

The Supreme Court has recognized that scientific principles and laws of nature, even when for the first time discovered, have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the subject of exclusive rights to any one person.²⁵²

Therefore, *Novartis*’ scope reduction must appropriately be seen through a human rights lens. 3(d)’s imposition of a new patentability layer imposes a human rights obligation on the part of the State to ensure human rights concerns are carefully balanced with the innovator’s right to extract commercial incentive for innovation. This is especially significant, as technology’s advancement has allowed pharmaceutical companies to engage in excessive experimentation of random isolation and purification of chemical compounds. Either by data mining or by using computer algorithms, pharmaceutical companies can generate a wide range of products, most of which can be subject to patent application. By making simple changes in the original drug, companies can strive for patent eligibility for eternity, in the process preventing the access to essential drugs for the masses. *Novartis*

²⁴⁹ See *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 104, 191–92.

²⁵⁰ See Ghoshray, *supra* note 1, at 525.

²⁵¹ See *Novartis*, LAWYERS COLLECTIVE, *supra* note 73.

²⁵² *In re Meyer*, 688 F.2d 789, 795 (C.C.P.A. 1982).

foreclosed this human rights abuse within the Indian context, a model that certainly can be followed by other developing countries.²⁵³

C. Rebalancing TRIPS Discontent in The Shadow of Patentability Schism

To comprehend *Novartis* is to review the genesis of 3(d) within the context of developing nations' obligation to reformat their patent regime. While elucidating the virtues of the TRIPS agreement in comporting to the flexible needs of its member States,²⁵⁴ we certainly cannot overlook its predatory genesis.²⁵⁵ Despite its U.S.-led property rights-centric origin and TRIPS' contentious history of discontents and disagreements has been subsumed under a coercive imposition of western-centric perspectives. Section 3(d)'s layered imposition of heightened patentability is a path forward towards restoring balance in the international patent regime.²⁵⁶ Thus, viewed through such an evolutionary response lens,²⁵⁷ 3(d) can be seen as a legitimate evolution of developing countries' aspirations towards equality and social justice. The innovative force of Section 3(d) not only helps realign patent framework's asymmetric contour, it also extricates global intellectual property norm from the inertia of old world order.

Section 3(d) sits at the confluence of two conflicting priorities. On one side is the asymmetry in income and economic viability calling for intervention towards making access to essential drugs a universal reality. On the other side, seduction to industrialization prompting developing countries to become obligated to join WTO, despite their discontents.²⁵⁸ With its explicit provision to align the interest of all stakeholders, 3(d) can be used as a prototype for the emerging economies of the world. In an era where developing countries are finding it difficult to incorporate anti-evergreening or anti-patent layering within their patent regimes, 3(d) could act as a benchmark for others to follow. Moreover, as developed countries continue to forge coalition against patent regimes with such evergreening laws,²⁵⁹ following India's lead might help in building a coalition of patent regimes with human rights sentiments.²⁶⁰ Not only will this help in making a level playing field in a deeply

²⁵³ See, e.g., Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 *FORDHAM L. REV.* 1133, 1137 (2002) (concluding that the high cost of HIV/AIDS drugs due to patent protection is a human rights violation).

²⁵⁴ See TRIPS, *supra* note 11.

²⁵⁵ Peter Drahos, *Developing Countries and International Intellectual Property Standard-setting*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 29, http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf (last visited May 10, 2014).

²⁵⁶ See generally *Novartis* Supreme Court Decision, *supra* note 17, ¶¶ 102–04, 180.

²⁵⁷ *Id.*

²⁵⁸ See generally WORLD TRADE ORG., 2007 WTO PUBLIC FORUM: HOW CAN THE WTO HELP HARNESS GLOBALISATION? 135 (2008), available at http://www.wto.org/english/res_e/booksp_e/public_forum07_e.pdf.

²⁵⁹ *The Complete Text of the U.S. Proposal for the TPP IPR Chapter*, KNOWLEDGE ECOLOGY INT'L (Feb. 10, 2011), available at <http://keionline.org/node/1091>.

²⁶⁰ See e.g., Ryan Abbott, *Of Evergreening and Efficacy, Part III*, HARVARD LAW PETRIE-FLOM CTR. (April. 16, 2013), <https://blogs.law.harvard.edu/billofhealth/2013/04/16/of-evergreening-and->

divisive intellectual property landscape, it might rebalance the original discontent countries felt at the asymmetric imposition of TRIPS on their respective intellectual property regimes.

D. Examining Novartis' Harmonizing Dimension

An expanded meaning of *Novartis* opens up some illuminating aspects. Viewing *Novartis* within a broader corpus made of select opinions from diverging regimes may signal an undercurrent of harmonization. There is a paradox in law at play here. Strictly speaking, the global intellectual property landscape is divided between a maximalist and a minimalist paradigm. Yet, globalization calls for conformity and convergence in Nations' laws. It is not ideal for a maximalist framework to be the model for others to follow, simply because it lacks a human rights dimension and is predominantly based on a strict property rights dimension. Therefore, any variants of minimalist patent paradigm could be used as models for harmonizing global patent law.

Evaluating *Novartis* in light of some other cases from the U.S. and the U.K., we might be witnessing a newer thought process percolating amongst the judiciary. Although *Novartis* falls within a continuum in the annals of Indian constitutional decision, the Indian Supreme Court's opinion in *Novartis* acquires a superior interpretative gloss if further dissected through the patentability thresholds established in *Monsanto Tech. LLC v. Cefetra BV* ("*Cefetra*")²⁶¹ and *Eli Lilly & Co. v. Human Genome Sciences* ("*Eli Lilly*").²⁶² A newer patentability threshold for the DNA sequence in *Cefetra* was established by requiring a direct connection between the invention and the function it was designed for.²⁶³ In *Eli Lilly*, the patentability threshold was pegged at responding to a two-step inventive step—whether the patentable sequence should disclose its function, and whether this function has concrete and immediate benefit.²⁶⁴ Similarly, by examining the questions raised by Judge Sweet in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office* ("*Myriad*"),²⁶⁵ a patentability threshold was set at determining whether the claimed invention is fundamentally different.²⁶⁶ By placing *Novartis*' new threshold of

efficacy-part-iii/ (stating countries such as Argentina and the Philippines have incorporated provisions similar to Section 3(d) of India's provision and predicting that "[i]n the aftermath of [the *Novartis*] case, it is more likely other countries will follow India's lead" that [the *Novartis* case] "may be a signal regarding changing political attitudes toward the demands of multinational corporations") (referring to *Novartis* Madras H.C. Decision, *supra* note 19).

²⁶¹ Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.J. EUR-Lex LEXIS 396 [hereinafter *Cefetra*].

²⁶² [2008] EWHC (Pat) 1903, [2008] R.P.C. 29, *aff'd*, [2010] EWCA Civ 33, [2010] R.P.C. 29 (Eng.) [hereinafter *Eli Lilly*].

²⁶³ See *Cefetra*, *supra* note 261 at ¶ 79.

²⁶⁴ See *Eli Lilly*, *supra* note 262, at 99.

²⁶⁵ *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office*, 702 F. Supp. 2d 181, 226 (S.D.N.Y. 2010), *aff'd-in-part, rev'd-in-part sub nom.* 653 F.3d 1329 (Fed. Cir. 2011), *aff'd-in-part, rev'd-in-part* 689 F.3d 1303 (Fed. Cir. 2012), *aff'd-in-part, rev'd-in-part sub nom.* 133 S. Ct. 2107 (2013).

²⁶⁶ *Id.* at 226.

determining whether the compound demonstrate enhanced efficacy within the corpus of these three cases, it can be argued that there may be a convergence of thought process developing among the judiciaries. The similarity underscores a growing consensus towards restricting the scope of patentability for biological and pharmaceutical products that have implications for human health and longevity.²⁶⁷ This indeed is a broader indication of the emergence of a newer minimalistic patent paradigm. As *Novartis* embarks on a decidedly minimalist patent paradigm, its shared ideals with patent cases from other jurisdiction are an encouraging indication for both the shared heritage of humanity and their human rights sentiments.

VI. CONCLUSION

This Article opens a window into the maximalist-minimalist schism of patentability centering on the Indian Supreme Court's *Novartis* case. Viewing *Novartis*' reduced scope of patentability for pharmaceutical innovation through the prism of the amended Section 3(d), Indian intellectual property paradigm's misplaced condemnation is re-examined. Deconstructing the criticism surrounding 3(d) required an evaluation of its genesis, which proceeded in three major segments.

First, understanding the context and prevailing landscape of criticism further corroborated global patent paradigm's deep schism and maximalist framework's decoupling from social justice values. Second, contextualizing 3(d) through its roots and development allowed for an adequate and comprehensive appreciation of its constitutionality and TRIPS compatibility. Third, going beyond rehabilitating 3(d), this Article sought an expanded meaning of *Novartis*, which is not only laudatory but, also path-breaking.

Contemporary wisdom placed Indian intellectual property regime in a wide-ranging criticism from troubled to inefficient to inadequate. Riding the similar wave of condemnation, the *Novartis* decision has been criticized for its reliance on Section 3(d).²⁶⁸ Evaluating the logic behind the court's conclusion, this Article basks in the excitement of *Novartis*' arrival on the global patent landscape, while rehabilitating Section 3(d) in multiple steps.

By charting through its legislative history and its placement in the continuum of India's constitutional jurisprudence, 3(d) is seen both as a natural progression in law and a revitalization of human rights element in the global stage. Moreover, 3(d)'s nuanced framework in delivering a multi-layer approach to patentability is evaluated with rigor to place it on firmer footing. Finally, 3(d)'s TRIPS compatibility is reviewed and found to be robust.

Going beyond the patentability discussion, this Article sought the expanded meaning of *Novartis* and identified four broader themes.²⁶⁹ First, retrenching from the novelty and non-obviousness line of reasoning, *Novartis* reduced the scope for

²⁶⁷ Amy Kapczynski, *Harmonization and Its Discontents*, 97 CALIF. L. REV. 1571, 1616 (2009).

²⁶⁸ See e.g., Frederick M. Abbott, *Inside Views: The Judgment In Novartis v. India: What The Supreme Court Of India Said* (Apr. 4, 2013, 4:33 PM), <http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/>.

²⁶⁹ See *supra* Part V.

pharmaceutical products, while staying within applicable patentability framework for pharmaceuticals.²⁷⁰ Second, by rejecting the seductive urge for conformity within western laws, *Novartis* blazed a divergent path in formulating 3(d) that resonated with the social justice and utilitarian themes of equality.²⁷¹ Third, recognizing TRIPS' contentious origin and long simmering discontent among the developing regimes, 3(d) can be recognized as a model of patentability framework for other Nations.²⁷² Fourth, *Novartis* signals a judiciary interest in seeing harmonization in patent regimes across the globe.²⁷³

Finally, this Article is about recalibration, it is about deconstructing a false narrative. It is about challenging the myth percolating through the corporate dominated patent paradigm that has become the driving force in the western patent framework. Despite corporate reluctance, perhaps in the not so distant future, the path to patentability may begin to straddle some of the humanistic contours identified here. In such traversal, our ethical compass must be guided by the realm of sacred, a sacred borne out of our longing for human rights of all mankind and fundamentals of distributive justice.

²⁷⁰ See *supra* note 14 and accompanying text.

²⁷¹ See *supra* note 237 and accompanying text.

²⁷² See *Novartis* Supreme Court Decision, *supra* note 17.

²⁷³ See *supra* Part V.