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Indian Pharmaceutical Patenting Under Section 3(D): A Model for Developing Countries

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**INDIAN
PHARMACEUTICAL
PATENTING UNDER
SECTION 3(D): A
MODEL FOR
DEVELOPING
COUNTRIES**

Volume 12 | Issue 2 | Article 3

Nicholas Eitsert
2022-2023

INDIAN PHARMACEUTICAL PATENTING UNDER SECTION
3(D): A MODEL FOR DEVELOPING COUNTRIES

Nicholas Eitsert

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I. INTRODUCTION

Medical breakthroughs throughout the last century have redefined modern health. Vaccines can prevent many of the world's cruelest sicknesses, doctors can replace faulty organs, and illnesses that were once death sentences can now be treated with simple pills. Human longevity has improved as people are healthier for longer. For much of the world, however, these advances in medicine are unavailable or underutilized due to exorbitant pricing. The developing areas of Asia, Africa, and South America are perhaps most affected by high pharmaceutical prices due to fragile economies offering depressed wages. Obtained through the UN-sponsored Global Drug Facility (GDF), a six-month supply of the tuberculosis 'wonder-drug' Delamanid is priced at \$1,700 USD,¹ despite most of the countries highly affected by tuberculosis having average six-month wages of less than \$2,000 USD² and research suggesting that the drug could be produced and sold at a profit for as little as \$5 a month.³ While the GDF's \$1,700 price tag is significantly lower than the price offered to most patients in the United States, pharmaceutical companies' practice of monopolistic group pricing ensures that drugs remain just as unattainable, if not more, in the developing world. Even dated, long-established cures maintain excessive prices in many of these markets due to exploitations in patenting systems and marketing tricks. Utilizing techniques to increase the life of patent monopolies is known as "evergreening."⁴ For example, in some regions, Pfizer still maintains partial monopoly power over a remedy for depression that was patented in 1983.⁵ Public outcry concerning increasingly unaffordable pharmaceuticals have led some politicians to question the morality of long-term patent monopolies created when pharmaceutical companies incrementally patent slight modifications or processes to breakthrough drugs that offer no clinical benefits.

¹ *TB Drug Delamanid Must Be More Affordable and Made Available in More Countries*, MÉDECINS SANS FRONTIÈRES (Oct. 10, 2019), <https://www.msf.org/delamanid-must-be-more-affordable-tuberculosis>.

² *Average Income Around the World*, WORLDDATA.INFO, <https://www.worlddata.info/average-income.php>.

³ *TB Drug Delamanid Must Be More Affordable and Made Available in More Countries*, *supra* note 1.

⁴ Hazel Moir & Deborah Gleeson, *Explainer: Evergreening and How Big Pharma Keeps Drug Prices High*, THE CONVERSATION (Nov. 5, 2014, 2:27 PM), <https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623>.

⁵ *Id.*

Indian intellectual property law has long aimed to minimize the inefficiencies caused by pharmaceutical patent evergreening and to encourage affordable medication costs. To this effect, the Indian patent system aims to “clearly identify certain inventions . . . which would retard research, or industrial process, or be detrimental to the national health or well-being, and make those inventions non-patentable.”⁶ India’s hesitance to issue pharmaceutical patents containing product claims, seen as detrimental to public health, has frustrated Western intellectual property scholars for decades.⁷ Despite these experts’ concerns, India’s skepticism towards issuing and enforcing pharmaceutical patents benefits patients around the world.⁸

This paper examines the practice of pharmaceutical patent evergreening and discusses how a history of foreign exploitation influenced India’s intellectual property policy revisions after the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Drawing on existing literature and content analysis of cases, this article argues that legislation equivalent to Section 3(d) of the Indian Patent Act of 1970 should be considered by developing nations’ legislatures in the fight to prevent modern pharmaceutical patent evergreening and to ensure the availability of life-saving pharmaceuticals in the poorest regions of the world.

II. EVERGREENING: A METHOD OF PATENT TERM EXTENSION

Corporations understand the market advantages patent protection can provide. Consequently, 629,647 patent applications were filed in 2015 in the United States alone.⁹ Conducting the research and development necessary to fabricate a product worthy of patent protection is remarkably expensive, especially in certain industries. The average cost of developing a prescription drug that gains market approval is disputed¹⁰ but falls somewhere between

⁶ *Novartis Ag v. Union of India*, (2013) 6 SCC 1, 19 (emphasis omitted) (India).

⁷ Kristina Lybecker, *India’s Patent Law is No Model for the United States: Say No to No Combination Drug Patents Act*, IPWATCHDOG (June 26, 2019), <https://www.ipwatchdog.com/2019/06/26/indias-patent-law-no-model-united-states/id=110727/>.

⁸ *Indian Pharmaceuticals Industry Analysis*, INDIA BRAND EQUITY FOUND., <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>.

⁹ Pat. Tech. Monitoring Team, *U.S. Patent Statistics Chart Calendar Years 1963–2020*, USPTO, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

¹⁰ See Joseph A DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016).

\$648 million and \$2.7 billion.¹¹ The success of companies willing to take on costly development risks depends on their ability to recapture research and development expenses in sales revenue. Patent policies that allow these companies to set monopoly pricing and recoup costs over a fixed duration are thus vital for the success of the pharmaceutical industry. Despite the clear importance of protecting the intellectual property of pharmaceutical companies, the construction of patent terms is still a balancing act. Breakthrough drugs have the capability of saving millions of lives, but only when they are accessible to the masses. Exceedingly high pricing places many pharmaceuticals beyond the reach of the world's neediest. Recent public outcry has encouraged discussion over the morality of pharmaceutical patenting.¹² Some candidates in the 2020 U.S. Presidential Election even suggested seizing the patents of pharmaceutical companies who overprice their drugs.¹³

Presently, TRIPS requires that World Trade Organization (WTO) members provide patent durations of at least twenty years from issue.¹⁴ Most countries offer patent term adjustments to compensate for drug regulatory review (such as 35 U.S.C. § 156), which further postpone the introduction of generic versions of branded pharmaceuticals into the market.¹⁵ Yet, this seemingly generous period of exclusivity is not enough to satisfy some pharmaceutical companies. Whether out of financial necessity, or simple greed, pharmaceutical companies have developed numerous methods,

¹¹ Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERNAL MED. 1569, 1569 (2017).

¹² Dana Brown & Elizabeth Pfister, *Insulin: A Case Study for Why We Need a Public Option in the Pharmaceutical Industry*, STAT (Sept. 10, 2019), <https://www.statnews.com/2019/09/10/insulin-public-option-pharmaceutical-industry/>; Austin Frakt, *How Patent Law Can Block Even Lifesaving Drugs*, N.Y. TIMES (Sept. 28, 2015), <https://www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html>; Christopher Rowland, *Pfizer Had Clues Its Blockbuster Drug Could Prevent Alzheimer's. Why Didn't It Tell the World?*, WASH. POST (June 4, 2019), https://www.washingtonpost.com/business/economy/pfizer-had-clues-its-blockbuster-drug-could-prevent-alzheimers-why-didnt-it-tell-the-world/2019/06/04/9092e08a-7a61-11e9-8bb7-0fc796cf2ec0_story.html.

¹³ Donald Judd, *Pete Buttigieg Proposes Seizing Patents and Steep Taxes on Pharmaceutical Companies Who Won't Negotiate Drug Prices*, CNN (Oct. 7, 2019, 7:29 AM), <https://www.cnn.com/2019/10/07/politics/buttigieg-drug-pricing-proposal/index.html>.

¹⁴ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights art. 33, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

¹⁵ 35 U.S.C. § 156 (2018).

including evergreening, for increasing the span in which they can produce monopoly profits. Patent evergreening is the process of patenting a new invention that is really just a slight modification of something old.¹⁶ Whether an applicant's new innovation covers a required manufacturing step, an associated business step, or a slight molecular change of a previous innovation, evergreening helps patent holders extend patents covering products that are about to expire. Patent holders can accomplish patent evergreening in several ways.

First, patent holders can evergreen by building a patent thicket. Thick webs of related patents protect a patent holder's investment by preventing competitors from simply designing around a single patent.¹⁷ These thickets, however, are often used to unfairly restrict competition.¹⁸ One popular illustration of the anticompetitive effects of patent thickets involves the Humira antitrust case recently dismissed by the U.S. District Court for the Northern District of Illinois.¹⁹ In this case, AbbVie's original patent covering Humira's pharmaceutical compound expired in 2016.²⁰ Despite this expiration, pharmaceutical manufacturers hoping to enter the market with a generic version in 2017 were confronted with over 100 additional patents blocking entry into the market. According to one patent attorney, "it is not uncommon for a drug to be covered by a handful of patents. Twenty patents [are] considered a lot. One-hundred patents for a single drug is nearly unprecedented."²¹ With a web of over 100 patents, each carrying its own presumption of validity, generic pharmaceutical manufacturers are essentially powerless to challenge the Humira thicket through traditional

¹⁶ Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS'N J. 385, 386 (2013).

¹⁷ *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, I-MAK, <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

¹⁸ Susannah Luithi, *AbbVie Sued Over Humira 'Patent Thicket'*, MODERN HEALTHCARE (March 19, 2019, 12:21 PM), <https://www.modernhealthcare.com/politics-policy/abbvie-sued-over-humira-patent-thicket>.

¹⁹ *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020).

²⁰ U.S. Patent No. 6,090,382 (filed Feb. 9, 1996) (issued July 18, 2000).

²¹ Zachary Silbersher, *Why Was the Humira "Patent Thicket" Antitrust Case Against AbbVie Dismissed?*, MARKMAN ADVISORS (June 10, 2016), <https://www.markmanadvisors.com/blog/2020/6/10/why-was-the-humira-patent-thicket-antitrust-case-against-abbvie-dismissed>.

patent disputes.²² AbbVie's monopoly is currently set to expire in 2023, seven years after expiration of the original patent.

AbbVie's predatory patenting of Humira created enormous market inefficiencies. In just one year, AbbVie brought in almost \$20 billion in revenue from Humira,²³ which accounted for most of AbbVie's \$4.6 billion net income, some of which came at the expense of patients, insurance companies, and the government.²⁴ Additionally, the filing and prosecuting of patent applications is certainly not inexpensive. It has been estimated that prosecuting the Humira patents costed AbbVie \$100,000 per patent.²⁵ Finally, AbbVie surely spent millions of dollars defending its evergreening practices in court. Strict anti-evergreening laws preventing the extension of the patent monopoly might have prevented these inefficiencies.

As another form of patent evergreening, drug manufacturers sometimes subsequently patent different extended release, tablet, or capsule versions of previously patented pharmaceuticals in combination with expensive marketing campaigns used to discourage use of the old, but clinically identical, drug, thus retaining some of the generic's market. Professors Hazel Moir and Deborah Gleeson explain how this type of evergreening works with an example from the Australian pharmaceutical market:

In the case of the depression drug venlafaxine (marketed as Efexor), the original version had major side-effects. However, when provided in extended release form these side-effects were substantially reduced.

Naturally the extended release form (Efexor-XR) became preferred. Although it might seem obvious to combine venlafaxine with an extended release form to overcome the side-effect problem, the patent office granted two new patents for extended release versions of venlafaxine.

²² The dismissal of Plaintiffs' claims in *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020), was appealed. The merits of the generic manufacturer's antitrust claims will be considered by the Seventh Circuit.

²³ Matej Mikulic, *Revenue from AbbVie's Humira 2011-2020*, STATISTA (Feb. 22, 2021), <https://www.statista.com/statistics/318206/revenue-of-humira/>.

²⁴ *AbbVie Net Income 2010-2021*, MACROTRENDS, <https://www.macrotrends.net/stocks/charts/ABBV/abbvie/net-income>.

²⁵ Silbersher, *supra* note 21.

One of these was written in such a broad form that it delayed generic entry by two and a half years, while legal wrangling took place. Eventually the evergreening patent was declared invalid. But the cost to taxpayers of this delay is estimated at \$209 million.

Pfizer has a second evergreening strategy for venlafaxine. When venlafaxine is taken, the human body converts it to desvenlafaxine. In other words desvenlafaxine is a variant of the original active pharmaceutical ingredient venlafaxine. Clearly the two compounds are closely related. So it is astonishing that desvenlafaxine passed the tests for getting a patent.

Desvenlafaxine is marketed as Pristiq. Pristiq entered the market early in the two-and-a-half-year period of legal wrangling over the extended release venlafaxine (Efexor-XR) patent. Pfizer's marketing of Pristiq in February 2009 was so lavish that it attracted the attention of investigative journalists.

Pristiq has no additional benefits for patients. Despite this, during the first six months of 2014[,] half of prescriptions were written for Pristiq rather than for the clinically identical Efexor-XR.

But Pristiq costs between \$A22.32 and \$A26.50 more than Efexor-XR, depending on the dose. Based on reported prescription volumes in 2013-14, the cost to the taxpayer of doctors prescribing Pristiq rather than Efexor-XR exceeds \$21 million a year.²⁶

Pfizer's success in evergreening the patent for Efexor-XR was only possible due to a patent system that allows multiple patents over essentially the same innovation. While 35 U.S.C. § 101 and comparable Australian laws restrict inventors to one patent per eligible invention,²⁷ "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is considered to be patentable subject matter.²⁸ Since Pristiq is technically a different, unanticipated molecule than Elexor-XR, it has no problem meeting basic criteria of § 101 or other provisions of U.S. patent law, even if it is a no more effective solution than Elexor-XR. The patenting of this novel, but effectually identical, drug allowed Pfizer to retain a portion of the market for the Efexor cure.

Despite the availability of generic Efexor, doctors still prefer to prescribe Pristiq over the less expensive, clinically equivalent Efexor-XR

²⁶ Moir & Gleeson, *supra* note 4.

²⁷ MPEP § 2104 (9th ed. June 2020).

²⁸ *Id.*

generic. Professor Moir attributes this to an aggressive marketing campaign by Pfizer.²⁹ This campaign has convinced doctors to prescribe expensive Pristiq, which is under patent protection and thus cannot be produced by generic manufacturers.³⁰ Whether utilizing improper marketing, kickbacks, or simply convincing doctors that Pristiq is somehow better than its clinical equivalent, Pfizer's promotion of Pristiq imposes unnecessary costs on patients and the healthcare system. The underlying cure, Efexor, has existed since 1983; yet Pfizer has managed to extend a partial monopoly for the treatment until the Pristiq patent expires in 2023.³¹ In the meantime, hundreds of millions of dollars have been wasted.³²

Increased drug prices are far from the only source of loss contributable to evergreening. Pfizer conducted research and development, clinical trials, and marketing in the production of Pristiq at considerable expense: a cure no more effective than the existing one.³³ Clinical trials surely involved unnecessarily subjecting clinically depressed individuals to placebo medication while knowing that Pristiq never had a chance of being more effective than the Efexor-XR already on the market. Finally, Pfizer and generic manufacturers spent hundreds of millions of dollars litigating the matter in federal court.³⁴ Simply barring Pfizer's evergreening patent application would have avoided this unnecessary cost. Patent evergreening places a financial burden on the public, unnecessarily consumes court resources, and postpones the allotment of rights that should vest in the public domain following the expiration of the original patent term. When the evergreened patent is for a pharmaceutical, those who cannot afford to pay the monopoly price may decide to forgo treatment.

III. PATENT EVERGREENING PREVENTION

Pharmaceutical patent evergreening has existed for decades. In pursuit of fair competition and decreased pharmaceutical prices, nations have developed several methods of discouraging evergreening. These methods include using existing anticipation and obviousness constraints to prevent patent issuance or to invalidate evergreened patents, discouraging bad faith

²⁹ Moir & Gleeson, *supra* note 4.

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

litigation with sanctions, and creating statutory provisions to explicitly prohibit patent evergreening.

The leading patent evergreening case in the United States is *Schering Corp. v. Geneva Pharmaceuticals, Inc.*³⁵ In *Schering Corp.*, pharmaceutical company Schering sued generic manufacturer Geneva Pharmaceuticals for infringement of a pharmaceutical patent claiming the metabolite of the antihistamine loratadine, descarboethoxyloratadine. Geneva, who sought to market generic loratadine, responded by asserting that the patent in-suit was anticipated by an earlier, now expired, patent for loratadine, which was also assigned to Schering. Finding that a disclosure of descarboethoxyloratadine was inherent in the earlier loratadine patent, the U.S. Court of Appeals for the Federal Circuit held that the metabolite patent was anticipated under 35 U.S.C. § 102(b) and therefore invalid.³⁶

While the term “evergreening” is not explicitly mentioned in *Schering Corp.*, Schering’s attempt to extend its patent monopoly by subsequently patenting the metabolite of an existing drug is a clear example of evergreening. While the Court held that a disclosure of descarboethoxyloratadine was inherent in the early loratadine patent, the decision did not go so far as to preclude patent protection for metabolites of known drugs.³⁷ Further, Schering’s petition for rehearing *en banc* was hotly contested, with several judges dissenting from its denial.³⁸ Today, roughly eighty percent of the 100 top-selling drugs in the United States have obtained extended patent monopolies through evergreening.³⁹

Most countries have anticipation and obviousness bars to patent eligibility which are equivalent to 35 U.S.C. § 102 and § 103 in the United States. Australia is one of these countries. When it comes to discouraging pharmaceutical patent evergreening, Australia has developed supplementary obligations by which the plaintiff in a pharmaceutical patent infringement lawsuit (usually the name-brand drug company) must abide. Specifically, Subdivision 26C of the Therapeutic Goods Act requires that a pharmaceutical

³⁵ 339 F.3d 1373 (Fed. Cir. 2003).

³⁶ *Id.* at 1382.

³⁷ *Id.* at 1381.

³⁸ *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992 (Fed. Cir. 2003) (denying petition for rehearing *en banc*).

³⁹ Erik Komendant, *Anti-Competitive Evergreening Delays Patient Access to More Affordable Generics and Biosimilars*, ASS’N FOR ACCESSIBLE MEDS., <https://accessiblemeds.org/resources/blog/anti-competitive-evergreening-delays-patient-access-more-affordable-generics>.

company intending to sue a generic manufacturer for patent infringement after the generic manufacturer has applied for registration of the generic pharmaceutical certify that the proceedings (1) are to be commenced in good faith, (2) have reasonable prospects of success, and (3) will be conducted without unreasonable delay.⁴⁰ If the certification is found to be false, the pharmaceutical company could be fined up to AUD \$10 million.⁴¹ Subdivision 26D also prescribes extra accountability for interlocutory injunctions.⁴² If such an injunction is granted, but later found to be “vexatious or not reasonably made or pursued,”⁴³ the court may award compensation to the generic manufacturer, the federal government, and the government of the state or territory.⁴⁴ This legislation imposes a substantial burden on the plaintiff pharmaceutical company, the underlying goal being to prevent pharmaceutical companies from extending a patent monopoly with frivolous litigation.

A third approach explicitly prohibits pharmaceutical patent evergreening. Section 3(d) of the Indian Patent Act, the topic of this paper, is one example of this approach. Section 3(d) requires that new forms of existing substances have increased efficacy to be eligible for patent protection.⁴⁵ This constraint, which is discussed in detail in the next section, is uniquely beneficial to developing countries. While evergreening is a problem in the United States and other developed nations, this paper does not suggest that these countries adopt new anti-evergreening statutory provisions such as India’s section 3(d). Unlike developing nations, developed countries have adequate resources to prevent patent evergreening and negotiate pharmaceutical prices without such legislation. In countries with universal healthcare, for example, the government enjoys a massive amount of purchasing power and has a heightened negotiating platform as a result.⁴⁶ Additionally, while developing countries may fear retaliation for utilizing compulsory licensing, developed countries possess the political and

⁴⁰ *Therapeutic Goods Act 1989* pt 3-2 div 2 sub-div 26C para (3) (Austl.).

⁴¹ *Id.* pt 3-2 div 2 sub-div 26C para (5A).

⁴² *Id.* pt 3-2 div 2 sub-div 26D.

⁴³ *Id.* pt 3-2 div 2 sub-div 26D para (4).

⁴⁴ *Id.* pt 3-2 div 2 sub-div 26D para (5).

⁴⁵ The Patents Act, 1970, §3(d), (India),

https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf, amended by The Patents (Amendment) Act, 2005 (India),

https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf.

⁴⁶ *Key Design Components and Considerations for Establishing a Single-Payer Health Care System*, CONG. U.S. CONG. BUDGET OFF., at 17 (May 2019), <https://www.cbo.gov/system/files/2019-05/55150-singlepayer.pdf>.

economic pressure to prevent retributory misdealing. Finally, pharmaceutical companies typically house their headquarters and resources within developed nations,⁴⁷ giving these countries discretion over tax rates, civil or criminal prosecutions, and sanctions. It is developing countries that should rely on anti-evergreening legislation, such as India's Section 3(d), to level the playing field.

IV. EMERGENCE OF SECTION 3(D)

The patentability of pharmaceuticals has fluctuated under India's intellectual property law of the past century. Under British rule, intellectual property rights in India primarily benefited foreign corporations at the expense of Indian citizens.⁴⁸ A patent inquiry committee appointed in 1949 by the Indian government to study the consequences of British influence on the Indian patent system reported that "the Indian Patent system has failed in its main purpose, namely, to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public."⁴⁹ These failures are especially evident with respect to pharmaceutical patenting. In his 1959 *Report on the Revision of the Patents Law*, Justice N. Rajagopala Ayyangar noted that between ninety-two and ninety-six percent of the applications for patents relating to drugs and pharmaceuticals from 1947 to 1957 were owned by foreign applicants.⁵⁰ Justice Ayyangar studied the various systems of pharmaceutical patenting around the world, comparing India's failures to the success found in other countries. Justice Ayyangar observed that "even in a large number of countries in which *per se* product claims for chemical substances are allowed, the laws permit only claims for processes so far as articles of food and medicine are concerned."⁵¹ The French, Belgian, German, and Swiss systems, among others, each contained such restrictions on the patentability

⁴⁷ *What Are the Top 15 Pharmaceutical Companies in the World?*, GETRESKILLED (Apr. 2020), <https://www.getreskilled.com/pharmaceutical-companies/>.

⁴⁸ Shri Justice N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law*, INTELL. PROP. INDIA 14–15 (Sept. 1959), https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-_Justice_N_R_Ayyangar_committee_report.pdf.

⁴⁹ *Id.* at 14.

⁵⁰ *Id.* at 273.

⁵¹ *Id.* at 37.

of pharmaceuticals.⁵² Finally, Justice Ayyangar noted the success of Section 38(A)(I) of the U.K. Patent Act of 1907, which barred the issuance of patents for substances “prepared or produced by a chemical process or intended for food or medicine,” in the protection and encouragement of the British chemical and pharmaceutical industries.⁵³ In cooperation with India’s pharmaceutical industry leaders, Justice Ayyangar recommended that the Indian legislature adopt a system of permitting only process claims for pharmaceutical patents.⁵⁴ Many of Justice Ayyangar’s recommendations, including those concerning pharmaceutical patenting, were incorporated in the Indian Patent Act of 1970.

Since pharmaceutical product patents were barred under the Indian Patent Act of 1970,⁵⁵ evergreening of drug patents was a non-issue in India until TRIPS-era changes were incorporated in the 1990s and 2000s. TRIPS, which compelled India to enforce pharmaceutical product patents, set a 2005 deadline for India to expand its pharmaceutical patent protection.⁵⁶ This deadline generated conflict in Parliament, as legislators struggled to agree on a path to modernize the patent laws. An ordinance allowing pharmaceutical product patenting quickly passed through Parliament in late 2004 to avoid defaulting on India’s commitment under TRIPS.⁵⁷ Debate continued, as an amendment to the Indian Patent Act of 1970 was needed before the ordinance expired in 2005.

Two letters were written to Indian officials during this period encouraging Indian legislators to consider the potential effects of an overhauled patenting system on the global market for low cost pharmaceuticals. The first letter, authored by the HIV/AIDS Director for the World Health Organization, expressed deep concern over the availability of inexpensive antiretrovirals if India were to permit pharmaceutical product patents.⁵⁸ The director stated that delegations from Ghana, Lesotho, Malawi,

⁵² *Id.* at 36.

⁵³ *Id.* at 23.

⁵⁴ *Id.*

⁵⁵ See Sidhant Goel & Mohit Goel, *Patentability of the Medical ‘Pro’(S)—Pro-Ducr V. Pro-Cess*, SIM & SAN (Apr. 2017),

https://www.simandsan.com/intellect_patentability_of_the_medical.html (stating “substances intended for use or capable of being used . . . as medicine” are unpatentable).

⁵⁶ *Novartis Ag v. Union of India*, (2013) 6 SCC 1, 42 (India); The Patents (Amendment) Act, 2005, §1(2) (India),

https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf .

⁵⁷ *Novartis*, 6 SCC at 42.

⁵⁸ *Id.* at 44.

Namibia, China, Indonesia, and Vietnam, among others, shared this concern.⁵⁹ Anxious that the enforcement of product patents in India may reduce the supply of life-saving antiretrovirals, WHO offered technical support to promote the implementation of TRIPS policies consistent with the public health objective of ensuring access to medicines.⁶⁰ The director signed off with hope that India continue to fulfill the needs of the poorest nations that urgently need access to antiretrovirals.⁶¹

The Director of Advocacy, Communication, and Leadership for Joint United Nations Programme on HIV/AIDS (UNAIDS) also authored a letter. The director explained:

The implications [of permitting pharmaceutical product patents in India would be] devastating: the vast majority of countries hit hardest by AIDS do not have sufficient manufacturing capacity in the pharmaceutical sector and must rely upon imports from major producing countries such as India if they are to succeed in scaling up access to HIV treatment to the millions of their people in need.⁶²

UNAIDS also participated in a Global Day of Action against the amendment and encouraged India to “send out a strong message in support of both research innovation and access to affordable HIV-related pharmaceuticals and other essential medicines.”⁶³ Together, these letters attracted a strong opposition that expressed worries about pharmaceutical patent evergreening under a system allowing pharmaceutical product patenting with few limitations.

Novartis’s patent for imatinib mesylate, the very patent at issue in the *Novartis* case,⁶⁴ was specifically mentioned as a caution against allowing such patenting by a member of the opposition, who stated the following:

For example, the drug called ‘Glevic’ (sic Gleevec/Glivec), is used for the treatment of Leukaemia [sic]. 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

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.* at 46.

⁶³ *Id.*

⁶⁴ *Id.* at 2.

India. At the same time, the generic versions are available in the country which cost only Rs.8,000 to Rs.10,000.⁶⁵

Section 3(d) of the 2005 amendment to the Indian Patent Act of 1970 was developed to address the apprehensions of this opposition. Section 3(d) of the act states:

What are not inventions.—The following are not inventions within the meaning of this Act, — . . .

(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.

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[.]⁶⁶

While Section 3(d) does not go so far as to bar all product claims for chemical or pharmaceutical patents, the explanatory comment illustrates that Section 3(d) serves specifically to curb the patenting of all chemicals and pharmaceuticals that do not differ significantly from those already in the public domain with regards to efficacy. Since one pharmaceutical may have dozens of patent applications exhibiting only slight variations from each other, Section 3(d) effectively invalidates most pharmaceutical patents and abolishes pharmaceutical patent evergreening by restricting patentees to the earliest filed patent application, unless a later filed application demonstrates significantly increased efficacy. Section 3(d) immediately drew opposition from Western Intellectual Property experts but was not tested in the Indian Supreme Court until 2013.⁶⁷

⁶⁵ *Id.* at 49 (footnote omitted).

⁶⁶ The Patents (Amendment) Act, 2005, *supra* note 56, § 3 (first emphasis added; second in original).

⁶⁷ Lybecker, *supra* note 7.

V. *NOVARTIS V. UNION OF INDIA*

In 1994, the Ciba-Geigy Corporation filed a non-provisional patent application for “Pyrimidine derivatives and processes for the preparation thereof” at the U.S. Patent and Trademark Office.⁶⁸ The application described “Formula I” (imatinib), an anti-tumor drug claiming the potential to revolutionize the treatment of some cancers.⁶⁹ The application was quickly granted, and Ciba-Geigy merged with Sandoz to form Novartis AG.⁷⁰ Despite serious side effects resulting from the use of imatinib in dogs, university researchers persuaded Novartis to conduct a human trial at the University of Oregon Medical School in 1998.⁷¹ These researchers discovered beneficial therapeutic effects, and the methanesulfonic acid addition salt of imatinib, imatinib mesylate, was granted FDA approval and marketed as Gleevec just two and a half years later.⁷²

Novartis’s U.S. patent application for imatinib was filed one year before the TRIPS deadline for enforcement of pharmaceutical product patents in India, and thus Novartis could not claim the benefit of their U.S. filing date when filing for product patent protection in India. Novartis needed a more recent, post-TRIPS filing date to acquire a patent monopoly in India, and fulfilled this need on July 17, 1998, with the filing of a patent application for the beta crystalline form of imatinib mesylate in the Chennai Patent Office.⁷³ This beta crystalline form was said to be an improvement over non-crystalline imatinib mesylate thanks to enhancements in thermodynamic stability and increased bioavailability.⁷⁴ Almost immediately, Novartis’s application attracted pre-grant oppositions from generic manufacturers and the Cancer Patients Aid Association.⁷⁵ A hearing was conducted by the Assistant Controller of Patents and Designs in 2005 and Novartis’s application was rejected as anticipated by the prior Zimmermann patent application from

⁶⁸ U.S. Patent No. 5,521,184 (filed Apr. 28, 1994) (issued May 28, 1996).

⁶⁹ *Id.*

⁷⁰ Thomas Meek, *This Month in 1996: Ciba-Geigy and Sandoz Merge*, PMLIVE (Mar. 17, 2014), http://www.pmlive.com/pharma_news/this_month_in_1996_ciba-geigy_and_sandoz_merge_553502.

⁷¹ Claudia Dreifus, *Researcher Behind the Drug Gleevec*, N.Y. TIMES (Nov. 2, 2009), <https://www.nytimes.com/2009/11/03/science/03conv.html?pagewanted=all>.

⁷² *Id.*

⁷³ *Novartis Ag v. Union of India*, (2013) 6 SCC 1, 7 (India).

⁷⁴ *Id.* at 8.

⁷⁵ Varun Chhonkar, *Glivec Patent Dispute: The Case So Far*, PATENT CIRCLE (Oct. 3, 2011, 2:04 PM), <https://patentcircle.blogspot.com/2011/10/glivec-patent-dispute-case-so-far-part.html>.

1994 describing the free base form of imatinib.⁷⁶ Additionally, the court found that patentability of the invention was prohibited by section 3(d) of the Indian Patents Act of 1970.⁷⁷

Novartis appealed the decision, arguing, among other things, that its application was not anticipated by Zimmerman and that section 3(d) of the Indian Patents Act is not in compliance with TRIPS.⁷⁸ The Intellectual Property Appellate Board (IPAB) reversed the Assistant Controller's finding of anticipation and held that the application satisfied the tests of novelty and obviousness.⁷⁹ Unfortunately for Novartis, the IPAB upheld the constitutionality of Section 3(d) and concluded that Novartis's application for the beta crystalline form of imatinib mesylate is barred under Section 3(d).⁸⁰ The IPAB considered the pricing of Gleevec in their decision, observing that "a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective."⁸¹ While Novartis enjoyed exclusive marketing rights over the drug, a monthly dose of Gleevec cost several times the average Indian's yearly salary.⁸² The IPAB further stated that "Appellant's alleged invention won't be worthy of a reward of any product patent,"⁸³ suggesting that the court viewed Novartis's disclosure over the prior art (Zimmermann) not worthy of patent protection in view of the cost that would be imposed on patients. Finally, the IPAB held that Novartis could still be allowed a process patent for the preparation of imatinib mesylate in beta crystalline form, but not a product patent over the drug itself.⁸⁴

Novartis directly petitioned the Supreme Court of India to review the IPAB decision. The Supreme Court, realizing the need for judicial interpretation of Section 3(d), agreed to hear the case. After reflecting on the history of the Indian patent system and the findings of the 1957 committee led by Justice N. Rajagopala Ayyangar, the Supreme Court found a clear legislative intent to abolish pharmaceutical patent evergreening in India

⁷⁶ *Novartis*, 6 SCC at 9.

⁷⁷ *Id.*

⁷⁸ *Id.* at 10.

⁷⁹ *Id.*

⁸⁰ *Id.* at 10–11.

⁸¹ *Id.* at 11.

⁸² *Id.* See also *Pocket Book of Labour Statistics*, MINISTRY LABOUR & EMP. 29 (2017), http://labourbureau.gov.in/Report_PBLs_2017.pdf.

⁸³ *Novartis*, 6 SCC at 11.

⁸⁴ *Id.* at 11–12.

under Section 3(d).⁸⁵ The Court then turned its inquiry to facts of the case. For Section 3(d) to apply, a patent application for the beta crystalline form of imatinib mesylate must be “a new form of a known substance.”⁸⁶ In making its determination, the Court first observed that Gleevec was launched long before the issuance of the U.S. patent for the beta crystalline form of imatinib mesylate and that Gleevec was declared to be covered by the earlier Zimmerman patent in its International Drug Application.⁸⁷ Thus, Novartis “had always maintained that imatinib mesylate is fully a part of the Zimmerman patent.”⁸⁸ Next, the Court recognized the U.S. patent examiner’s original rejection of the U.S. application for the beta crystalline form of imatinib mesylate as being anticipated by the Zimmerman patent.⁸⁹ Further, the U.S. Board of Patent Appeals, reversing on appeal, stated that “[w]e may presume, therefore, that claims 21 and 22 are based on an enabling disclosure; and that the specification of the Zimmerman patent teaches any person skilled in the art how to use a compound of [imatinib], or a pharmaceutically acceptable salt thereof.”⁹⁰ The U.S. Board of Patent Appeals did, however, find the use of the beta crystalline form of imatinib mesylate to comprise a manipulative step in the method of treating tumor disease and thus patentable over the disclosure of imatinib in Zimmermann.⁹¹ The Indian Supreme Court was not tasked with determining whether this new application presents a manipulative step beyond the Zimmermann patent, but solely with determining whether this application teaches “a new form” of the known substance described in Zimmermann.⁹² Based on the points above, the Court ultimately decided that Zimmermann teaches a method for treating tumors using imatinib mesylate, and that the beta crystalline form of imatinib mesylate is merely a new form of the imatinib mesylate taught in Zimmermann.⁹³ Section 3(d), which requires that the new form of the known substance must have significantly different efficacy than the first, therefore applied to the new application.

The Court was next tasked with determining whether the beta crystalline form of imatinib mesylate offered significantly different efficacy than the imatinib mesylate taught in Zimmermann. In evaluating the

⁸⁵ *Id.* at 17.

⁸⁶ *Id.* at 21.

⁸⁷ *Id.* at 63–64.

⁸⁸ *Id.* at 71.

⁸⁹ *Id.* at 66.

⁹⁰ *Id.*

⁹¹ *Id.* at 67.

⁹² *Id.* at 53–54.

⁹³ *Id.* at 71.

specification, the Court described the new application as being a “loosely assembled, cut-and-paste job, drawing heavily upon the Zimmermann patent.”⁹⁴ Appellant’s counsel introduced affidavits describing a number of improvements present in the beta crystalline form, namely better processability, greater stability at room temperature, and greater bioavailability over free base imatinib.⁹⁵ Yet, appellant’s counsel failed to identify improvements in the beta crystalline form of imatinib mesylate over the *non-crystalline* form of *imatinib mesylate*. Since the Court held that the Zimmermann teaches imatinib mesylate, the benefits of the beta crystalline form over free base imatinib were irrelevant. Even considering beta crystalline imatinib over free base imatinib, the Court held that none of the improvements presented, not even an increase in bioavailability, demonstrated an enhancement in efficacy, as an increase in bioavailability does not intrinsically mean that the drug will produce better responses.⁹⁶ In its closing statements, the Court noted that Gleevec, the drug seeking protection under the application, appeared to have always been imatinib mesylate, not the *beta crystalline form* of imatinib mesylate.⁹⁷ Thus, the Court understood that Novartis was attempting to patent a drug that would otherwise be unpatentable in India—that is, to evergreen a drug disclosed prior to the enforcement of pharmaceutical product patents in India.

Since the application for the beta crystalline form of imatinib mesylate described a new form of a known substance that demonstrated no difference in efficacy over the known substance, the application failed the test of patentability under Indian law.

Section 3(d) of the Indian Patent Act of 1970 and the Indian Supreme Court’s decision in *Novartis* faced harsh international backlash from developed nations. One trade organization has called Section 3(d) “a significant barrier to pharmaceutical innovation and commercialisation [sic] in India” and “inconsistent with India’s international obligations.”⁹⁸ Scholars sharing this mindset ignore India’s commitment to provide low cost medications to the world’s poor and disadvantaged who would otherwise become victims of preventable or treatable illness simply due to their inability

⁹⁴ *Id.* at 85.

⁹⁵ *Id.* at 87.

⁹⁶ *Id.* at 92–93.

⁹⁷ *Id.* at 96.

⁹⁸ *Copy or Compete? How India’s Patent Law Harms Its Own Drug Industry’s Ability to Innovate*, GENEVA NETWORK 2, 4 (Nov. 2018), <https://geneva-network.com/wp-content/uploads/2019/07/WP-Copy-or-Compete-JULY-2019.pdf>.

to pay exorbitant prices demanded by pharmaceutical companies complicit in evergreening. In fact, India's enforcement of anti-evergreening legislation is vital for the success of public health initiatives in India and around the world. An analysis of the success of Cipla, a pharmaceutical company, in treating the African AIDS crisis explains just how far reaching such legislation can be.

VI. CIPLA AND THE AFRICAN AIDS CRISIS

According to the World Health Organization, Sub-Saharan Africa's share of the global disease burden was twenty-four percent in 2017, despite only containing fourteen percent of the global population during that period.⁹⁹ In 2015, roughly 1.6 million Africans died of malaria, tuberculosis, or HIV-related illnesses alone.¹⁰⁰ Each of these diseases is treatable or preventable with timely access to appropriate medicine; however, medications are often unavailable to the continent's neediest.¹⁰¹

In 2001, roughly twenty-five million Sub-Saharan Africans were HIV-positive, comprising nearly seventy percent of the infected population worldwide.¹⁰² Despite the AIDS epidemic being recognized as a public health crisis by the United Nations, fewer than 10,000 African HIV/AIDS patients reportedly received the medication required for treatment.¹⁰³ Indian pharmaceutical manufacturer Cipla entered the African HIV market by offering Médecins Sans Frontières a triple-therapy AIDS drug for \$350 per year in 2001.¹⁰⁴ A comparable drug cocktail costed approximately \$10,000 per year in the U.S.¹⁰⁵ Cipla's drug cocktail almost certainly infringed on product patents assigned to Bristol-Myers Squibb and Merck; however, India

⁹⁹ *Health in Africa: Building an African Pharmaceutical Industry*, NEWAFRICAN MAG. (Jun. 29, 2017), <https://newafricanmagazine.com/15654/#>.

¹⁰⁰ Tefo Pheage, *Dying from Lack of Medicines*, AFR. RENEWAL (Dec. 2016–Mar. 2017), <https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines>.

¹⁰¹ *Id.*

¹⁰² Charles Miller & Kenneth Goldman, *Merck, AIDS, and Africa*, NYU STERN SCH. BUS. 2 (Oct. 23, 2003), <http://pages.stern.nyu.edu/~lcabral/teaching/aids.pdf>.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Jacqui Wise, *Access to AIDS Medicines Stumbles on Trade Rules*, 84(5) BULL. WHO 342, 342 (2006).

does not enforce pharmaceutical product patents filed prior to 1995.¹⁰⁶ Thus, Cipla could produce these medications, first patented years before TRIPS, without committing infringement under Indian law. Bristol-Myers Squibb and Merck immediately announced their own price reductions on AIDS drugs sold in Africa after accusations of evergreening AIDS medication patents.¹⁰⁷ Still, these name-brand medications costed almost twice as much as Cipla's generic.¹⁰⁸ Cipla approached South Africa concerning the importation of AIDS medication and asked South Africa to grant it compulsory licenses to sell medications patented in South Africa by Bristol-Myers Squibb and Merck, among others (as these patents would otherwise bar importation under South African law). A coalition of thirty-nine Western pharmaceutical companies sued South Africa to prevent the issue of the compulsory license and, despite later dropping the case, were temporarily successful in preventing the importation of Cipla's inexpensive generic.¹⁰⁹

The Western pharmaceutical industry's legal success was short lived. Cipla continued to supply Médecins Sans Frontières and invested heavily in the African market. By 2007, sixty-three percent of antiretrovirals (ARVs) used in Sub-Saharan Africa were generics, eighty-five percent of which originated in India.¹¹⁰ Cipla's venture into the African market did not rely on compulsory licensing or patent exhaustion. Rather, it was Western pharmaceutical companies' voluntary non-enforcement of ARV patents that made this expansion possible.¹¹¹ Likely performed for publicity reasons, this voluntary non-enforcement increased the availability of low-cost, Indian ARVs in Africa.¹¹² A 2007 study of brand and generic supply of HIV/AIDS drugs in Sub-Saharan Africa explains how Cipla developed its considerable market share. While the average name brand ARV medication cost \$277 per

¹⁰⁶ See Rajeshkumar Acharya, *The Global Significance of India's Pharmaceutical Patent Laws*, AM. INTELL. PROP. L. ASS'N, <https://www.aipla.org/list/innovate-articles/the-global-significance-of-india-s-pharmaceutical-patent-laws>.

¹⁰⁷ Lori Hinnant, *Merck Lowers Price of AIDS Drugs in Africa*, DAILY LOC. NEWS (Aug. 19, 2021, 5:01 AM), <https://www.dailylocal.com/2001/03/08/merck-lowers-price-of-aids-drugs-in-africa/>.

¹⁰⁸ *Id.*

¹⁰⁹ *Pharmaceutical Companies Sue South Africa Over Patent Law*, ARIZ. DAILY WILDCAT ONLINE (Mar. 5, 2001), https://wc.arizona.edu/papers/94/112/01_91_m.html; *Drug Companies Withdraw AIDS Drug Lawsuit Against South Africa*, KHN: KHN MORNING BRIEFING (Apr. 19, 2001), <https://khn.org/morning-breakout/dr00004113/>.

¹¹⁰ See Colleen V. Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?*, 2(3) PLOS ONE 1 (2007).

¹¹¹ *Id.*

¹¹² *Id.*

year in 2007, the average generic only cost \$114 per year.¹¹³ Considering that thirty-three African nations have a GDP per capita under \$2,000 per year, the generic medication offered a substantial discount.¹¹⁴ As of 2017, Cipla has established, or plans to establish, ARV manufacturing facilities in South Africa, Uganda, Morocco, and Algeria.¹¹⁵ These facilities help Cipla provide medication to twenty million HIV patients, mostly based in Africa.¹¹⁶

The mention of Western pharma's voluntary non-enforcement of patent rights is not to suggest that Western pharma should be praised for their actions in Africa. According to Andrew O'Hehir of *Salon Magazine*, "10 million men, women and children died of AIDS in sub-Saharan Africa between 1997 and 2003, when drugs that could have saved their lives already existed and were abundant in other parts of the world."¹¹⁷ Not only was Western pharma's decision of voluntary anti-enforcement of ARV patents likely a business-focused, rather than philanthropic, but Western pharmaceutical companies and their friends in government also vigorously defended the shortage of ARVs in Africa through 2001. After the 1998 introduction of South African legislation allowing for the parallel importation of patented pharmaceuticals,¹¹⁸ the U.S. government threatened to withhold development assistance to the nation unless the provision was repealed.¹¹⁹ As explained by one British columnist, "South Africa is now the epicentre of the global [AIDS] quake The international community has been quick to respond to this catastrophe: the United States has threatened South Africa with sanctions for trying to prevent its citizens from catching the disease."¹²⁰ While Western pharmaceutical companies were suing and the U.S. government was threatening sanctions over the importation of inexpensive,

¹¹³ *Id.*

¹¹⁴ *GDP Per Capita / Africa*, TRADING ECON., <https://tradingeconomics.com/country-list/gdp-per-capita?continent=africa>.

¹¹⁵ *Cipla Announces Africa Expansion Strategy During International AIDS Conference*, CIPLA (July 18, 2016), <https://www.cipla.co.za/cipla-news/cipla-announces-africa-expansion-strategy-international-aids-conference/>.

¹¹⁶ *Id.*

¹¹⁷ Andrew O'Hehir, *Pick of the Week: Big Pharma's African Genocide*, SALON (Sept. 5, 2013, 11:01 PM),

https://www.salon.com/2013/09/05/pick_of_the_week_big_pharmas_african_genocide/.

¹¹⁸ William W. Fisher III & Cyril P. Rigamonti, *The South Africa AIDS Controversy A Case Study in Patent Law and Policy*, HARV. L. SCH. 1, 7 (Feb. 10. 2005), <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf>.

¹¹⁹ Anup Shah, *Pharmaceutical Corporations and AIDS*, GLOB. ISSUES (June 2, 2002), <http://www.globalissues.org/article/53/pharmaceutical-corporations-and-aids>.

¹²⁰ George Monbiot, *Hanging On to the Profits from Aids*, GUARDIAN.CO.UK (Aug. 5, 1999), <https://www.theguardian.com/comment/story/0,3604,280272,00.html>.

lifesaving ARVs into South Africa, pharma's supporters in Washington, D.C., sought to quell any congressional empathy. On one exceptional occasion, "a U.S. government health bureaucrat told a congressional committee that Africans lacked a Western sense of time, and did not use clocks or watches"; thus, they could not be trusted "to take medications on a regular schedule" (which is necessary for the prevention of drug-resistant mutations).¹²¹ In fact, "subsequent epidemiological research indicates that people in Africa have been *more* compliant with drug regimens than people in the West."¹²² Had Cipla not forced Western pharma's hand in 2001 by offering exceptionally low-cost ARVs, and in doing so demonstrating the economic feasibility of continent-wide treatment to the western public, these companies would not have faced the political and public pressure resulting in a reduction in drug prices and non-enforcement of patent rights.¹²³

While Section 3(d) was absent in Indian law until 2005 and *Novartis* was not decided until 2013, the principles underlying Section 3(d) and the *Novartis* decision are evident in this earlier narrative. First, there was extreme need for antiretrovirals in sub-Saharan Africa. This region was home to over a quarter of the world's HIV/AIDS patients at one point, yet few received treatment.¹²⁴ The U.S. Congress was alarmingly apathetic towards the suffering occurring, and little evidence suggests any U.S. initiative to substantially reduce the suffering in sub-Saharan Africa was in the works. It was Cipla's entry into the market that promoted considerable change, which was only possible thanks to a ban on subsequently filed patent applications evergreening on breakthrough drugs. Thus, Merck and Bristol-Myers Squibb had not been, nor could have been, awarded patent rights covering antiretrovirals in India. By producing antiretrovirals and offering them to South Africa at low cost, Cipla supplied the economic and political pressure necessary for name brand producers to reduce the price of their medications. Had exclusive rights obtained through evergreening been enforceable, the production of antiretrovirals would have been barred in India. Instead, Cipla's entry into the market for antiretrovirals likely increased the lifespan and improved the quality of life of thousands of Africans living with HIV/AIDS.

¹²¹ O'Hehir, *supra* note 117.

¹²² *Id.* (emphasis in original).

¹²³ See *supra* text accompanying notes 101–119.

¹²⁴ *UNAIDS Report Shows that 19 Million of the 35 Million People Living with HIV Today Do Not Know that They Have the Virus*, UNAIDS 1–2 (July 16, 2014), https://www.unaids.org/sites/default/files/web_story//20140716_PR_GapReport_en.pdf. See also Miller & Goldman, *supra* note 102.

VII. SECTION 3(D) AS A MODEL FOR DEVELOPING COUNTRIES

Public health initiatives in Africa, assisted by the availability of low-cost antiretrovirals, have substantially reduced AIDS's burden on the region. This has not eliminated the need for low-cost pharmaceuticals, and new public health threats are constantly emerging. Cancer, for example, poses such a threat. In 2017, Médecins Sans Frontières physician and HIV treatment pioneer Dr. Eric Goemaere stated that, “[f]or cancer [in Africa], we are where we were in the beginning of the 90s for HIV . . . [it is considered] too complex, too expensive. People don't want to look at it.”¹²⁵ Unfortunately, countries that failed to enact anti-evergreening legislation equivalent to India's Section 3(d) are experiencing the results. In an article aptly titled “Dying for intellectual property law,” South African health journalist Zukiswa Pikoli explains that “only seven of the existing 24 medications [for cancer] are available in [South Africa's] public health system because of excessive pricing.”¹²⁶ This pricing is primarily a result of South Africa's new intellectual property regime. A comparative examination of India's and South Africa's handling of patent applications for imatinib explains the problem. According to an article published by Médecins Sans Frontières in 2013,

[w]hile India avoided patenting imatinib, South Africa granted Novartis an initial patent on imatinib in 1993, which expires this month. However, *secondary patents granted by South Africa*, including one on imatinib mesylate salts, *extend Novartis' monopoly until 2022*. As a result, treating a patient with imatinib for a year in South Africa costs \$33,896 (R312,234)—259 times more expensive than the least expensive Indian generic alternative.¹²⁷

Had South Africa barred the issuance of secondary patents (evergreening), a generic imatinib could have come to market ten years sooner. Countries allowing for the importation of generic imatinib entertain prices far lower than those in South Africa. Largely thanks to Indian imports, a twelve-month supply of generic imatinib costs \$7,638 USD in Brazil and

¹²⁵ SECTION 27, *Dr Eric Goemaere—HIV/TB Unit Coordinator, Médecins Sans Frontières*, YOUTUBE (June 22, 2018), <https://www.youtube.com/watch?v=QxTfQFsOag> [<https://perma.cc/E4T8-954A>].

¹²⁶ Zukiswa Pikoli, *Dying for Intellectual Property Law*, DAILY MAVERICK (Nov. 25, 2019), <https://www.dailymaverick.co.za/article/2019-11-25-dying-for-intellectual-property-law/>.

¹²⁷ *Why the Indian Supreme Court Ruling on Novartis Matters to South Africa*, MÉDECINS SANS FRONTIÈRES (Apr. 1, 2013) (emphasis added), <https://www.msf.org.za/stories-news/press-releases/why-indian-supreme-court-ruling-novartis-matters-south-africa>.

\$2,261 USD in Latvia, for example.¹²⁸ Thus, developing countries should discourage incremental patenting that serves no purpose other than extending a patent monopoly. Instead, developing countries should encourage quickening the entry of generics and increasing the accessibility of life-saving drugs. India's Section 3(d) provides the framework that should be adopted throughout the developing world.

VIII. CONCLUSION

Profit-driven pharmaceutical companies' abuse of Western patenting systems has resulted in anti-competitive markets and increased pharmaceutical pricing. These market inefficiencies and exorbitant prices are especially detrimental to public health programs in the poorest regions of the world. Section 3(d)-style legislation and interpretation, consistent with the Indian Supreme Court decision in *Novartis AG v. Union of India*, are necessary to combat exploitive pharmaceutical companies' practice of extending exclusive monopoly rights through patent evergreening and increase the accessibility of life-saving pharmaceuticals in the poorest regions of the world.

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¹²⁸ Andrew Hill et al., *Target Prices for Mass Production of Tyrosine Kinase Inhibitors for Global Cancer Treatment*, 6 *BMJ OPEN*, Jan. 27, 2016, at 1, 6.