

Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act

Jodie Liu*

During the last quarter of the twentieth century, India was known as the “Pharmacy of the Developing World,” a critical source of inexpensive, life-saving drugs for the world’s most impoverished populations. But when India joined the World Trade Organization in 1995, it became subject to the Agreement on Trade Related Aspects of Intellectual Property (“TRIPS”), which required it, among other things, to restore product patents on drugs by a certain date. India’s 2005 Amendments to the Patents Act did just that, but also included a number of provisions—called “TRIPS flexibilities”—intended to lessen the blow regarding access to medicines. Two critical TRIPS flexibilities were (1) a compulsory licensing provision, which stipulated that public interest needs could compel brand-name pharmaceuticals to agree to license their patented drugs; and (2) an anti-evergreening provision which raised the bar for what pharmaceutical companies had to show to obtain a drug patent in the first place. The Amendments emphasized the purposes of these provisions: the compulsory licensing provision aimed at ensuring public health interests were satisfied, while the anti-evergreening provision intended to eliminate wasteful efforts to maintain weak patents.

*In the two most important decisions interpreting the 2005 Amendments to the Patents Act to date, the Intellectual Property Appellate Board in *Bayer v. Natco* and the Supreme Court of India in *Novartis AG v. Union of India* sought to reinforce the fundamental rationale of these two key TRIPS flexibilities. Ultimately, however, *Bayer* and *Novartis* interpreted the two flexibilities in ways that may have weakened the principles they set out to bolster.*

INTRODUCTION

The annual cost of a certain life-saving liver cancer drug in India is more than thirty times that of the average Indian’s annual income.¹ Local companies can produce and sell the same drug for a small fraction of the brand-name sticker price, but the drug’s foreign inventors want to prevent those low-cost, life-saving drugs from ever reaching the Indian market. The inventors harbor no ill intentions. But they have invested hundreds of millions in developing the drug and depend upon charging higher prices, as afforded under patent protection, to recoup the staggering costs. Against this backdrop, patent rights in India have given rise to impassioned international debate.

* Harvard Law School, J.D. 2015. This piece benefited greatly from the thoughtful comments of Professor William Alford and the staff of the *Harvard International Law Journal*.

1. Ravinder Gabble & Jillian Clare Kohler, *To Patent or Not to Patent? The Case of Novartis’ Cancer Drug Glivec in India*, 10 *GLOBALIZATION & HEALTH* 3, 5 (2014).

Since India dramatically transformed its patent law in the 1970s, the country's generic medicine industry has flourished, both domestically and abroad. Currently, India exports roughly \$10 billion worth of generics every year,² and has become so effective in supplying medicines to developing countries in particular that it has earned the moniker "Pharmacy of the Developing World."³ This mammoth generics industry, however, came under threat in 1995 when India joined the World Trade Organization (WTO) and became bound by the Agreement on Trade Related Aspects of Intellectual Property (TRIPS),⁴ which imposed stronger intellectual property rights regimes on all WTO member countries. Responding to those access to medicine concerns, India in 2005 adopted amendments that managed to comply with the stricter requirements imposed by TRIPS while also containing a number of provisions called "TRIPS flexibilities" that would make it easier to challenge patents.

For brand-name pharmaceuticals, these impending changes prompted substantial anxiety that extended well beyond India's borders. Perhaps most importantly, generic products could seep into high-income countries where brand-name drug companies operated their primary markets. In middle- and low-income countries, India's exports of generic medicines could not only provide cheaper alternatives to brand-name counterparts but also, through competition, indirectly lower prices of other medicines.⁵ Moreover, the Indian model could spread.⁶ As India demonstrated, WTO membership and TRIPS compliance did not necessarily preclude adoption of patent laws that favor public health outcomes. Rather, following India's example, WTO members could employ TRIPS flexibilities to enact relatively weak IP regimes that are nonetheless TRIPS-compliant.⁷

2. Gardiner Harris & Katie Thomas, *Top Court in India Rejects Novartis Drug Patent*, N.Y. TIMES, (Apr. 1, 2013), http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?pagewanted=all&_r=1&.

3. See Médecins Sans Frontières, *Examples of the Importance of India as the "Pharmacy of the Developing World"* (2007), available at <http://www.msfaccess.org/content/examples-importance-india-pharmacy-developing-world>. See generally Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Public Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INT'L L. 785 (2011).

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS].

5. See, e.g., Tamara Hafner & David Popp, *China and India as Suppliers of Affordable Medicines to Developing Countries* (Nat'l Bureau of Econ. Research, Working Paper No. 17249, 2011), available at <http://www.nber.org/papers/w17249>.

6. Elliot Hannon, *How an Indian Patent Case Could Shape the Future of Generic Drugs*, TIME, Aug. 21, 2012, available at <http://world.time.com/2012/08/21/how-an-indian-patent-case-could-shape-the-future-of-generic-drugs/>; see also Juan Bacalski, *Mexico's Pharmaceutical Patent Dilemma and the Lesson of India*, 23 ARIZ. J. INT'L & COMP. L. 717, 720 (2006) (arguing that the "more mature Indian pharmaceutical industry" may serve as "a model to which Mexico's industry may be compared and from which important lessons may be drawn").

7. See generally Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571 (2009).

This paper analyzes the implementation of two key TRIPS flexibilities in India through two landmark cases: (1) *Bayer v. Natco*,⁸ interpreting the compulsory licensing provision in section 84 of the Patents Act, 1970 (“Patents Act”); and (2) *Novartis AG v. Union of India*,⁹ interpreting the anti-evergreening patentable subject matter provision in section 3(d) of the Patents Act. Whatever the role of legislative purpose ought to be in statutory interpretation, it was clearly a key player in *Bayer* and *Novartis*, where the courts relied heavily on the legislature’s reasons for adopting sections 84 and 3(d) to inform their interpretations of the language. By way of illustration, the *Bayer* court referred at least seventy-eight times to the “public interest” or “public health” stakes underpinning the compulsory licensing procedure. In *Novartis*, the court devoted forty out of the opinion’s ninety-six pages toward the history leading up to section 3(d) and the innovation-promoting goal section 3(d) sought to ensure.¹⁰

Evaluating whether the decisions remained faithful to the clear motivations behind the sections 84 and 3(d) flexibilities, this article argues that *Bayer* and *Novartis* are ultimately difficult to reconcile with their professed aims. With respect to the compulsory licensing regime, the Intellectual Property Appellate Board (IPAB) in *Bayer* effectively read out of section 84 several key public interest considerations for which the provision explicitly provided. Meanwhile, the supreme court in *Novartis* undermined section 3(d)’s anti-evergreening rationale by comparing the subject patent compound to a very early, and arguably quite far-removed, form of the compound that lacked potential to be actually administered as a drug. In doing so, the supreme court belied its surface argument that the anti-evergreening purpose behind section 3(d) was doing the heavy lifting in invalidating the brand-name pharmaceutical’s patent.

Setting aside the controversial question of whether India’s access-promoting IP policy is fair in light of its profit-curtailing effects on brand-name pharmaceuticals in the global north, this article offers a theory as to how the courts’ interpretations in *Bayer* and *Novartis* may actually be problematic from the perspective of India and other countries in the global south. Ultimately, the courts in both *Bayer* and *Novartis* found against the foreign brand-name drug companies, and global health experts have championed the two decisions as the most significant victories for access to medicines since India joined the WTO. If the two outcomes clearly advance an important public health interest, why should the Indian courts care about potentially problematic interpretations of sections 3(d) and 84? As for the compulsory licensing provision, *Bayer*’s reading of section 84 renders India more susceptible to a challenge in the WTO’s dispute settlement body, where a more

8. *Bayer Corp. v. Natco Pharma. Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai, 2013).

9. *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (2013) (Madras H.C.).

10. *Id.* paras. 29–102.

natural reading of the section probably would be accepted. While the *Novartis* reading of section 3(d) may not implicate serious WTO ramifications, the supreme court's decision may discourage Indian innovation in the development of treatments for diseases primarily affecting the global south.

The article proceeds as follows. Part I provides brief background on the Indian patent regime and the changes thereto instigated by India's entrance into the WTO. Part II examines the compulsory licensing regime established by section 84 of the Patents Act and the IPAB's interpretation of the provision in *Bayer*. This Part argues that, despite the IPAB's continual emphasis on the "public interest" purposes behind section 84, the IPAB articulated a less than natural reading of the provision that all but eliminated certain considerations clearly implicating the "public interest." Part III then examines the heightened patentable subject matter bar established by section 3(d) of the Patents Act and the Supreme Court of India's interpretation of the provision in *Novartis*. This Part argues that, despite the court's careful presentation of the historical anti-evergreening motivations giving rise to section 3(d), the court's analysis of the provision tends not to speak to those anti-evergreening concerns at all. Part IV concludes.

I. INDIA'S PATENT REGIME

A. 1970–1995: *Development of a Generic Drug Industry*

India's original patent regime was promulgated in the colonial era and modeled after British patent laws.¹¹ Like the British system, the early Indian patent regime provided strong protections that made the Indian market attractive to multinational corporations.¹² By 1970, foreign pharmaceuticals controlled nearly 70% of the domestic market and charged among the highest drug prices in the world.¹³

Incomes, however, had not kept pace with prices.¹⁴ In response to growing public health concerns, the Indian government passed the Patents Act, 1970, which in one fell swoop eliminated all product patents on drugs.¹⁵ Section 5 of the Act barred pharmaceuticals from obtaining product patents on their drugs, meaning that pharmaceuticals could seek only process patents that are generally easy for challenging companies to design around.¹⁶

11. P. NARAYANAN, PATENT LAW 5 (4th ed. 2006).

12. *Id.*

13. See Zoe Lynn Turrill, *Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard*, 44 GEO. J. INT'L L. 1556, 1558–59 (2013).

14. See Janice M. Mueller, *The Tiger Awakens*, 68 U. PITT. L. REV. 491, 510 (2007) (discussing the unaffordability of brand-name drugs).

15. Section 5 excludes patents on "substances intended for use, or capable of being used, as food or as medicine or drug." The Patents Act § 5, No. 39 of 1970, INDIA CODE (1970) [hereinafter The Patents Act].

16. "No patent shall be granted in respect of a claim for the substances themselves, but the claims for the methods or processes of manufacture shall be patentable." *Id.*

Even if a company obtained a process patent on the manufacturing method of a drug, other pharmaceuticals could reverse engineer the drug and produce it by a method other than that specified in the process patent.¹⁷ Further, the Act reduced the number of years of protection granted by process patents from fourteen years to seven—far less time than is usually required for research, testing, and development of many drugs.¹⁸ Because process patents afforded such minimal protection, pharmaceuticals seldom sought them out.¹⁹

Over the next three decades, the number of drug patents granted plummeted to effectively nil, creating substantial room for local pharmaceuticals that were growing more technically sophisticated.²⁰ Over a relatively short period of time, India developed one of the most robust generic pharmaceutical industries in the world, and national Indian firms captured a large swath of the domestic market share formerly held by foreign firms.²¹

B. 1995–2005: *Transition Period*

In 1995, India joined the WTO, bolstering its reputation as a reliable trade partner in the global economy. The benefits of WTO membership, however, came with costs: in particular, acceptance of TRIPS. TRIPS was the culmination of developed countries' efforts to obtain stronger IP protection abroad, especially in developing countries.²² It sought to increase harmonization of IP regimes worldwide by imposing minimum standards upon all WTO member nations.²³ WTO member nations could officially charge other member nations with violating the terms of TRIPS by bringing an action against them in the WTO's Dispute Settlement Body (DSB).²⁴ Although the TRIPS obligations clearly favored information-exporting developed countries, developing countries like India had no choice but to accept the terms of the agreement if they wanted to be welcome at the WTO. Still, developing countries were afforded transition periods to bring themselves into TRIPS compliance, and the least developed countries were afforded even more time to bring themselves into compliance.²⁵

17. See William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market 2–3* (U.S. Int'l Trade Comm'n, Working Paper No. 2007-05-A, 2007), available at http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf.

18. The Patents Act, *supra* note 15, § 53.

19. Kapczynski, *supra* note 7, at 1577.

20. Kapczynski, *supra* note 7, at 1577–78.

21. Mueller, *supra* note 14, at 515.

22. See WEI SHI, *INTELLECTUAL PROPERTY IN THE GLOBAL TRADING SYSTEM: EU-CHINA PERSPECTIVE* 66 (2008).

23. Kapczynski, *supra* note 7, at 1571.

24. TRIPS, *supra* note 4, art. 64.

25. *Id.* art. 65–66.

C. TRIPS Requirements and Flexibilities

TRIPS imposes certain unambiguous requirements. Patents have to be granted for inventions in “*all* fields of technology,” subject only to limited exceptions,²⁶ and have to last at least twenty years.²⁷ Several other requirements are vaguely defined, however, and countries have had some flexibility in defining the precise contours of the TRIPS requirements. In the 2005 Amendments to the Patents Act (“2005 Amendments”),²⁸ India introduced product patents on pharmaceuticals by simply deleting section 5 of the Patents Act. But the 2005 Amendments also contained numerous access-friendly policy levers, or “TRIPS flexibilities,”²⁹ that the Indian generics industry could invoke to invalidate brand-name patents and bring generics to the market, despite the re-introduction of product patents. Some of the measures were obvious—compulsory licensing, for instance, had already received much attention as a key tool for promoting access—but others made creative use of procedural rules in the patent approval process.³⁰ For instance, the 2005 Amendments provided for expansive procedural opportunities to challenge patents and restrictions on obtaining injunctive relief for patent infringement. They also included prohibitions on a series of terms that patent-based companies might otherwise seek to impose on licenses.

Nearly a decade later, two TRIPS flexibility provisions have emerged as major legal battlegrounds. As expected, Indian pharmaceuticals have invoked compulsory licensing, a practice by which the government allows a party to use a patent without the patentee’s permission,³¹ and the Comptroller General issued India’s first compulsory license in 2012.³² But the TRIPS flexibility that has garnered even more international attention is the anti-evergreening provision section 3(d), explained in greater detail below, which excludes from patentable subject matter any new form of a known substance, if the new form does not feature an “efficacy” above and beyond that of the known substance.³³ In light of the two 2013 decisive court victories for the Indian generics industry—one upholding the first compulsory license granted in India and the other vindicating the first major anti-evergreening challenge to a foreign pharmaceutical’s product patent—compulsory licens-

26. *Id.* art. 27.1–3 (emphasis added).

27. *Id.* art. 33.

28. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India) [hereinafter 2005 Amendments] (emphasis added), available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

29. See generally Kapczynski, *supra* note 7.

30. *Id.* at 1589.

31. Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 945 (2000); see also TRIPS, *supra* note 4, art. 31 (allowing WTO members to allow for the “use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government”).

32. See Rachna Bakhru, *India Grants First Compulsory Licence Under Patents Act*, 3 INTEL. PROP. MAG. 46, 46 (2012).

33. 2005 Amendments, *supra* note 28.

ing and anti-evergreening will likely become the predominant mechanisms by which India advances its access to medicine interests.

II. COMPULSORY LICENSING AND *BAYER V. NATCO*

A. *Section 84 of the Patents Act*

A compulsory license is a license granted by the government that allows a party to use a patent without the patentee's permission,³⁴ usually in exchange for a royalty.³⁵ The rationale for granting compulsory licenses is clear: the public welfare benefit of a license in some instances outweighs the incursion into the patentee's monopoly and the attendant negative effects of that incursion.³⁶ TRIPS allows WTO members to issue compulsory licenses for "public health" purposes but directs members to grant licenses only on an individualized basis³⁷ and on terms tailored to meet the purpose for which the licenses are issued.³⁸

As developing countries were coming into the WTO fold in the late 1990s, many commentators conceived of compulsory licensing as perhaps the primary mechanism for ensuring that TRIPS obligations would not significantly hamper access to medicines.³⁹ However, following concerns that the TRIPS guarantees were not sufficiently explicit to afford adequate protection to countries of the global south, the Doha Ministerial Declaration on TRIPS and Public Health ("Doha Declaration") sought to clarify any ambiguities relating to the compulsory licensing scheme under TRIPS.⁴⁰ Namely, the Doha Declaration addressed the scope of "public health" and the ability of WTO members to grant compulsory licenses to third parties when the members themselves lack manufacturing capabilities.⁴¹

Pursuant to TRIPS and the Doha Declaration, the 2005 Amendments specified three conditions under which compulsory licenses ought to be granted. Under section 84, the Controller of Patents may issue a compulsory

34. Ford, *supra* note 31, at 945; *see also* TRIPS, *supra* note 4, art. 31.

35. Kapczynski, *supra* note 7, at 1586 n.80.

36. *See, e.g.*, Sara Germano, *Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries*, 76 *UMKC L. REV.* 273, 279–80 (2007).

37. TRIPS, *supra* note 4, art. 31(a) ("[A]uthorization of such use shall be considered on its individual merits.").

38. *Id.*, *supra* note 4, art. 31(c) ("[T]he scope and duration of such use shall be limited to the purpose for which it was authorized.").

39. *See, e.g.*, Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 1 *J.L. MED. & ETHICS* 247, 248–49 (2009) (describing how the Doha Declaration expressly confirmed the right of WTO members to grant compulsory licenses in light of questions by originator pharmaceutical companies as to whether TRIPS ensured such a right).

40. *See* World Trade Organization, Ministerial Declaration of 20 November 2001, *WT/MIN(01)1/DEC/2* (2001).

41. *See generally* Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 *AM. U. INT'L L. REV.* 1299, 1332–33 (2002).

license “on such terms as he may deem fit”⁴² any time three years after the issuance of a patent⁴³ if (1) the “reasonable requirements of the public . . . have not been satisfied”; (2) the “patented invention is not available to the public . . . at a reasonable price”; or (3) the “patented invention is not worked in . . . India.”⁴⁴ However, there is also an emergency kicker: under section 92, the government may bypass the discretion of the Controller of Patents and order compulsory licensing in “circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use.”⁴⁵ Consistent with TRIPS, patentees should in all circumstances receive “reasonable” remuneration.⁴⁶

B. *The Bayer v. Natco Decision*

The controversy in India over Nexavar, a drug developed by Bayer to treat late-stage liver cancer, began when Bayer filed an action against Indian pharmaceutical Natco alleging that Natco was producing a generic version of Nexavar in violation of Bayer’s Indian patent on the drug.⁴⁷ Rather than arguing non-infringement, Natco filed a compulsory license application with the Controller General of Patents (Controller), alleging that all three conditions of section 84(1) were independently met so as to permit a compulsory license: (1) Nexavar was not available to the public at a reasonably affordable price; (2) the reasonable requirements of the public for Nexavar had not been met; and (3) Nexavar was not being worked in India.⁴⁸

On March 9, 2012, the Controller granted Natco the first ever compulsory license in India and awarded Bayer a royalty of 6% of Natco’s sales.⁴⁹ Bayer appealed. On March 4, 2013, the IPAB upheld the Controller’s grant

42. The Patents Act, *supra* note 15, § 84(4).

43. *Id.* § 84(7).

44. *Id.* § 84(1). In full, § 84(1) provides as follows:

84. *Compulsory licenses* — (1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

45. *Id.* § 92.

46. *Id.* § 90(1)(i) (having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors). Section 90(1)(i) complies with TRIPS article 31(h), which requires “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

47. Bakhru, *supra* note 32.

48. *Id.* at 46.

49. Natco Pharma. Ltd. v. Bayer Corp., Compulsory License Application No. 1/2011 (Controller of Patents, Mumbai, Mar. 9, 2012), *available at* http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf.

of the compulsory license,⁵⁰ but increased the royalty to 7%.⁵¹ In its decision, the IPAB reiterated time and again that the sole concern of the compulsory license procedure—and the key to interpreting section 84—is whether the “public interest” has been satisfied.⁵²

1. “Reasonably Affordable”

The IPAB first considered the section 84(1)(b) issue: whether the compulsory license could be granted on the grounds that the drug was not “available to the public at a reasonably affordable price.”⁵³ When determining the level at which to price the drug in India, Bayer had considered the “huge amounts” of money and time it had incurred during R&D, and the company argued this was a permissible consideration in determining what was “reasonably affordable.”⁵⁴ Implicit in Bayer’s argument was the notion that the legislature’s addition of “reasonably” implied that affordability permitted consideration of multiple factors, including affordability to the inventor.

The IPAB, however, flatly rejected Bayer’s argument.⁵⁵ When assessing whether a compulsory license ought to be granted under the reasonable affordability prong of section 84(1), the only pertinent inquiry was whether the price was reasonably affordable “with reference to the public.”⁵⁶ Whether the price was reasonably affordable with reference to the inventor was irrelevant.⁵⁷ Not only was this interpretation clearly buttressed by the access to medicine purpose of section 84(1), the IPAB reasoned that it was required by the plain meaning of “afford,” which naturally refers to the buyer rather than the seller of a product.⁵⁸ Applying this interpretation to the facts, the IPAB concluded that the Controller of Patents had permissibly found that the 280,000 rupees per month Bayer had charged for Nexavar was “alone relevant” in determining that the drug was not reasonably affordable under section 84(1).⁵⁹

50. Bayer Corp. v. Natco Pharma. Ltd., Order No. 45/2013, para. 57 (Intellectual Property Appellate Board, Chennai, 2013).

51. *Id.* para. 54.

52. *See, e.g., id.* para. 43 (“After all, the compulsory licence procedure itself is only in public interest.”); *id.* para. 43 (“Here we are not concerned with the interest of the compulsory licence applicant, but only the public interest.”); *id.* para. 42 (“Section 84 . . . is only concerned with the price at which the drug is made available to the public.”).

53. The Patents Act, *supra* note 15, § 84(1)(b).

54. Bayer Corp., Order No. 45/2013 para. 38. Bayer had a point: if Section 84(1)(b) had in mind *nothing* but affordability to the public, it could have said simply “affordable” rather than “*reasonably* affordable.”

55. *Id.* para. 40.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.* para. 44.

2. “Reasonable Requirements of the Public”

Next, the IPAB considered the section 84(1)(a) issue: whether the compulsory license could be granted on the grounds that the “reasonable requirements of the public” had not been met. To give meaning to the “reasonable requirements of the public,” section 84(7) lists several circumstances under which “the reasonable requirements of the public shall be deemed not to have been satisfied.”⁶⁰ At issue in *Bayer* was one particular deeming circumstance: when “the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent.”⁶¹ Bayer had contended that its implementation in India of a patient assistance program, which helped provide Nexavar at little to no cost for a host of low-income cancer patients, had met the reasonable requirements of the public. However, Natco relied on the deeming provision to contend that Nexavar was not being worked in India on a commercial scale because Bayer had no manufacturing facilities for Nexavar in India.⁶² Rather, Bayer’s patient assistance program in India depended solely upon imports of the drug into the country.⁶³ The “reasonable requirements of the public” analysis thus boiled down to whether Bayer’s importing of the drug through the patient assistance program amounted to sufficient working of the drug on a commercial scale so as not to trigger grant of compulsory license.

The IPAB concluded it did not suffice. In rejecting the contention that Bayer’s patient assistance program precluded the triggering of section 84(1)(a), the IPAB focused on the word “commercial” in the deeming provision, section 84(7)(d). Whether the drug had been worked on a “commercial” scale had to do with the “market price” of the drug, the IPAB reasoned, which implied that a prohibitively costly drug could not be commercially viable.⁶⁴ As a consequence, it was of little relevance to section 84(1)(a) whether importing might qualify as “working”—which was the key interpretational issue in the subsequent section 84(1)(c) analysis—or whether Bayer undertook the patient assistance program before or after Natco applied for a compulsory license. To the extent that Bayer’s patient assistance program bore at all on the “reasonable requirements of the public,” the program’s imports had to be “on a commercial scale to an adequate extent and [be] sold at a reasonably affordable price.”⁶⁵ So long as the drug’s price was too high to be commercial, the drug satisfied section 84(7)(d), which in turn deemed that section 84(1)(a) had been triggered.

60. The Patents Act, *supra* note 15, § 84(7).

61. *Id.* § 84(7)(d).

62. Bayer Corp. v. Natco Pharma. Ltd., Order No. 45/2013, para. 50 (Intellectual Property Appellate Board, Chennai, 2013).

63. *Id.* para. 35.

64. *Id.* para. 41.

65. *Id.*

3. “Working”

Finally, the IPAB considered the section 84(1)(c) issue: whether the compulsory license could be granted on the grounds that the drug was “not [being] worked in the territory of India.” Bayer again raised the argument that importing could satisfy the working requirement, and that “working” therefore did not require local manufacturing in India.⁶⁶ In fact, Bayer contended, “working” might actually *require* importing under certain circumstances, such as in the present case, where “the quantity [of the drug] required in India does not economically justify the setting up [of] a manufacturing facility in India.”⁶⁷ The IPAB rejected Bayer’s argument that “working” did not require local manufacturing but left entirely open what “working” did require.⁶⁸ Indeed, the IPAB held that “worked” under section 84(1)(c) “must be decided on a case to case basis,” such that “‘working’ [in some cases] could mean local manufacture entirely and ‘working’ in [other] cases could mean only importation.”⁶⁹

C. Ramifications of the IPAB Interpretation

For all of its repeated emphasis that the section 84 “compulsory licence procedure . . . is *only* in the public interest,”⁷⁰ the IPAB did not seem concerned about several public interest considerations explicitly mentioned in the provision. Rather, the IPAB gave the provision a meaning that may well undercut the very public interest purpose it seeks to advance, and perhaps one that even violates India’s international obligations under TRIPS.

The effect of *Bayer* is that the “reasonably affordable” condition in section 84(1)(b) now does essentially all of the work of the compulsory licensing scheme, as the other two conditions have been either defined away or made so ambiguous as to have little practical effect. Under the IPAB’s reasoning, the “reasonable requirements of the public” condition in section 84(1)(a) cannot be avoided by handing out the product for free to those who are unable to afford it, because such assistance programs do not actually lower the market price of the drug. Rather, to assert that the “reasonable requirements of the public” have been met, a pharmaceutical may need to lower the drug’s price for all. Meanwhile, the “working” condition of section 84(1)(c) carries little weight, at least *ex ante*, since the IPAB reserves full discretion to determine on a case-by-case basis whether “working” might require local importing of the drug. From a pharmaceutical’s perspective, the “working” condition is likely too poorly defined to provide workable guidance. Ultimately, the IPAB’s interpretation zeroes in on one factor alone—market

66. *Id.* para. 50.

67. *Id.*

68. *See id.* paras. 52–54.

69. *Id.* para. 52.

70. *Id.* para. 43 (emphasis added).

price—as the linchpin of the compulsory license regime, regardless of whether the public interest purpose behind the compulsory licensing regime is otherwise satisfied.

On the one hand, the IPAB's reading is not necessarily detrimental to access purposes. The singular focus on price has an obvious intuitive appeal, as the approach would tend to force brand-name pharmaceuticals seeking to avoid compulsory license measures to ensure the market price of its product remains low. Presumably, pharmaceuticals themselves are in the best position to weigh the costs of a potential compulsory license against the costs of charging a lower price. On the other hand, however, economic realities make this calculus far from straightforward. An exclusive focus on price may be less than socially optimal, as it reduces the number of options available to brand-name pharmaceuticals in making the drug available. Gone is the incentive to set up programs like Bayer's patient assistance program, and gone too is the incentive to set up local manufacturing facilities in India, which would have the natural effect of expanding local access. Price differentiation, a method whereby companies charge different prices to different groups of people depending on their respective abilities to afford the product, could perhaps still have been available under the IPAB's interpretation of the compulsory licensing scheme; although the Controller strongly hinted that such strategies would be sufficient to avoid compulsory licensing,⁷¹ the IPAB declined to pursue the option.

In addition to perhaps undermining the very purpose the compulsory licensing provision seeks to promote, the IPAB's interpretation makes India more vulnerable to WTO challenges. As noted above, the IPAB largely interpreted away the "working" condition in section 84(1)(c) as a "flexible" provision that may, depending on the case, require local manufacture.⁷² This interpretation runs up against principles in the TRIPS Agreement. Specifically, article 27.1 of TRIPS stipulates, "patents shall be available and patent rights enjoyable without discrimination as to . . . whether products are imported or locally produced."⁷³ This principle of non-discrimination with respect to place of manufacture would seem to foreclose *requiring* pharmaceuticals to manufacture locally if they want to avoid compulsory licensing.

The IPAB defended its interpretation by arguing that Bayer's patent on Nexavar had indeed been "granted" with "no discrimination . . . on the ground of absence of local manufacture."⁷⁴ Implicit in the IPAB's defense

71. *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory License Application No. 1/201135, 53 (Controller of Patents, Mumbai, Mar. 9, 2012).

72. *Bayer Corp. v. Natco Pharma Ltd.*, Order No. 45/2013, para. 52 (Intellectual Property Appellate Board, Chennai, 2013).

73. TRIPS, *supra* note 4, art. 27.1 (providing that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced").

74. *Bayer Corp.*, Order No. 45/2013 para. 52 (Intellectual Property Appellate Board, Chennai, 2013).

was the assertion that the non-discrimination principle affected only the patent itself and not the compulsory license. As long as lack of local manufacture did not bar the granting of a patent in the first place or lead to the revocation of the patent later it *could* determine the granting of the compulsory license. However, this argument ignores the language in article 27.1 of TRIPS stipulating that “patent *rights* [shall be] *enjoyable*” —not merely that “*patents* shall be *granted*” —without discrimination as to the place of a product’s manufacture.⁷⁵ While compulsory licenses have no effect on whether patents will be granted, since by their very nature they come after the fact, they can all but vitiate a patent holder’s enjoyment of patent rights if, for instance, the party granted the compulsory license overtakes the entirety of the patent holder’s market share.

III. ANTI-EVERGREENING AND *NOVARTIS AG v. UNION OF INDIA*

A. Section 3(d) of the Patents Act

In its 2005 Amendments, India inserted several patentable subject matter exclusions that had “no parallel anywhere else in the world.”⁷⁶ The most discussed of these exclusions arose in section 3(d), which forbids patents on “new forms of known substances”—such as new salt, ester, polymorphic, or isomeric forms of known compounds—if “they differ significantly in properties with regard to efficacy.”⁷⁷

Although not explicitly directed toward the pharmaceutical industry, section 3(d) had the most far-reaching consequences in the field of drugs. In 2007, patent applications for modifications of existing drugs comprised, according to estimates, more than three-fourths of the 9,000 patent applications awaiting review by the Indian Patent Office.⁷⁸ Moreover, records of heated debates in the Indian Parliament over section 3(d) indicate that the provision was aimed at preventing a particular practice in the pharmaceuti-

75. *Id.* art. 27.1 (emphasis added).

76. Shamnad Basheer & Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing Out the Creases in Section 3(d)*, 5 *SCRIPTED* 232, 234 (2008); see also Shamnad Basheer, *India’s Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 *INDIAN J.L. & TECH.* 15, 24 (2005).

77. 2005 AMENDMENTS, *supra* note 28, § 3(d). In full, section 3(d) reads as follows:

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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

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

78. Sara Beth Myers, *A Healthy Solution for Patients and Patents: How India’s Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights*, 10 *VAND. J. ENT. & TECH. L.* 763, 774 (2009).

cal industry: evergreening.⁷⁹ Drug companies engage in evergreening when they “extend the market exclusivity of a drug beyond the life of its original patent by obtaining multiple patents that cover different aspects of that drug, including the active ingredient, formulations, methods of manufacturing, chemical intermediates, mechanisms of actions, packaging, screening methods, and biological targets.”⁸⁰

However, immediately upon passage of section 3(d), debate arose as to what evergreening truly encompassed. There is a crucial—albeit murky—distinction between “evergreening,” which is generally agreed to be useless and not worthy of patent protection, and “incremental innovation,” the patent protection worthiness of which has been debated by scholars.⁸¹ On paper, evergreening and incremental innovation could appear like very similar actions, but incremental innovation usually could be distinguished as an important stepping stone in the development of a breakthrough drug where evergreening could not.⁸² A pharmaceutical is almost certainly evergreening if it merely modifies the tablet color or the inert ingredients of a drug and seeks a patent on the modification.⁸³ A more difficult case, however, is when a modification increases a drug’s bioavailability, a type of absorptivity defined as “the degree to which a drug or other substance is absorbed or reaches a target site in the body.”⁸⁴ While increased bioavailability necessarily addresses a new problem, it can produce significant improvements in drug delivery and allow more people to benefit from the drug’s effects.⁸⁵ The question then is whether this type of improvement is an incremental innovation worthy of patent protection.

B. *The Novartis AG v. Union of India Decision*

On April 1, 2013, the Supreme Court of India upheld the rejection of Novartis’s patent application on Gleevec, a groundbreaking drug used in the

79. During the parliamentary debates over section 3(d), the Minister of Commerce and Industry Sri Kamal Nath and Parliamentarian Suresh Kurup stressed that the purpose of section 3(d) was to prevent evergreening and “me too” drugs. See Transcript of Parliamentary Debate (Lok Sabha Debates) (Mar. 22, 2005), available at <http://164.100.47.132/LssNew/debates/DebateArchive.aspx>.

80. Joanna T. Brougher, *Evergreening Patents: The Indian Supreme Court Rejects Patenting of Incremental Improvements*, 19 J. COMM. BIOTECHNOLOGY 54, 55 (2013).

81. Compare Albert I. Wertheimer & Thomas M. Santella, *Pharmacoevolution: The Benefits of Incremental Innovation*, 8 (IPN Working Paper on Intellectual Property, Innovation and Health, 2005) with Kapczynski, *supra* note 7, at 1577.

82. See Wertheimer & Santella, *supra* note 81, at 6–7.

83. NAT’L INST. FOR HEALTH CARE MGMT., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION (2002), available at <http://www.ifpma.org/innovation/ip-rights/incremental-innovation.html>.

84. OXFORD ENGLISH DICTIONARY ONLINE, <http://www.oed.com/view/Entry/273773?redirectedFrom=bioavailability&> (last visited Nov. 2, 2014).

85. Wertheimer & Santella, *supra* note 81, at 8; see also INT’L FED’N OF PHARM. MFRS., INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS (2013), http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf (“Incremental innovation advances medicines by expanding therapeutic classes, increasing the number of available dosing options, discovering new physiological interactions of known medicines, and improving other properties of existing medicines.”).

treatment of chronic myeloid leukemia, on the grounds that the patent failed to meet section 3(d) requirements. In pronouncing its decision, the court took great pains to lay out “in . . . detail the ‘why’ and the ‘how’ of the law,”⁸⁶ devoting more than ninety paragraphs to the parliament’s concerns when drafting section 3(d) about pharmaceuticals “artificially extend[ing] the period of patent to keep competitors out and keep the prices of . . . patented product[s] high.”⁸⁷ The court then made clear it would interpret “what the law is in light of its ‘why’ and ‘how.’”⁸⁸

The section 3(d) issue in *Novartis* centered around three forms of the compound imatinib: imatinib free base, imatinib mesylate non-crystalline, and imatinib mesylate beta crystalline. In 1993, Novartis sought and obtained patent protection on the compound imatinib in its free base form in the United States and several other countries⁸⁹—but not in India, given the Patent Act’s prohibition on product patents.⁹⁰ At the time, there was no identified use for the compound. In fact, imatinib in its free base form was not administrable to humans.⁹¹

Novartis, therefore, looked into ways of improving upon the free base compound: first, by converting it to imatinib mesylate, a specific salt form of the imatinib compound that was not mentioned in any of the 1993 applications; and second, by identifying particular polymorphic forms of the salt that were particularly stable, including the beta crystalline form of imatinib mesylate⁹² eventually used to produce Gleevec.⁹³ In 1998, after India joined the WTO and the country’s TRIPS compliance became an inevitability, Novartis filed a patent application in India on the beta crystalline form of imatinib mesylate, specifying in its application the use of beta crystalline imatinib mesylate in Gleevec and other aspects of the drug’s solid form.⁹⁴ After the passage of the 2005 Amendments, which provided product patent protection for the first time since 1970, the Assistant Controller of Patents reviewed Novartis’s application and rejected the patent on grounds of failure of novelty and non-obviousness.⁹⁵ On appeal, the IPAB reversed with respect to the novelty and non-obviousness issues, holding that the Gleevec patent in fact satisfied both those requirements, but nonetheless found that

86. *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (2013) (Madras H.C.) para. 87.

87. *Id.* para. 79.

88. *Id.* para. 87.

89. Basheer & Prashant, *supra* note 76, at 239; *see also, e.g.*, Pyrimidine Derivatives & Processes for the Preparation Thereof, U.S. Patent No. 5,521,184 (filed Apr. 28, 1993) (issued May 28, 1996).

90. *Id.* at 239.

91. *Id.*

92. *Id.* at 235–36.

93. Saby Ghosray, *3(d) View of India’s Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others*, 13 J. MARSHALL REV. INTELL. PROP. L. 719, 727 (2014).

94. The drug’s solid form refers to the “way the individual molecules are packed together into a solid when the drug itself is manufactured.” Novartis’s 1993 patent applications dealt solely with free base imatinib and did not specify particular attributes of the yet-to-be-formulated Gleevec. *Id.*

95. Shamnad Basheer, *First Mailbox Opposition (Gleevec) Decided in India*, SPICYIP (Mar. 11, 2006, 10:48 AM), <http://spicyip.com/2006/03/first-mailbox-opposition-gleevec.html>.

the patent failed under section 3(d).⁹⁶ Novartis appealed the decision to the Supreme Court of India.⁹⁷

In upholding the rejection of Novartis's patent under section 3(d), the court held that the substance Novartis sought to patent, imatinib mesylate beta crystalline, was indeed a new form of the known compound imatinib free base, but that Novartis did not present sufficient evidence of an enhancement in therapeutic efficacy in the imatinib mesylate beta crystalline as compared to imatinib free base.⁹⁸ The court therefore addressed two key issues of interpretation posed by section 3(d): first, what constitutes the known substance to which one compares the form sought to be patented; and second, what "enhanced efficacy" as compared to the known compound is necessary to overcome a section 3(d) challenge.⁹⁹

1. "Known Compound"

In addressing the "known compound" question, the court sidestepped articulating a clear test and even evaded resolution of what the "known compound" actually was in the case. Although it appeared to define what constituted a "known compound" under section 3(d), the court did not elaborate upon the application of the test and effectively concluded that even if such a test applied, it was not determinative of the case.¹⁰⁰ First, the court noted that the evidence suggested that the beta crystalline form of imatinib mesylate was "two stages removed" from imatinib free base, which in turn pointed to imatinib mesylate non-crystalline being the "substance immediately preceding" the subject of the patent rather than imatinib free base.¹⁰¹ If the "known compound" was the "substance immediately preceding" the subject patent, and the "substance immediately preceding" was one stage rather than "two stages removed" from the substance in the subject patent, then the natural subsequent inquiry would have been how to determine one versus two or more stages removed. On this point, however, the court was silent. And despite hinting that the proper "known substance" under a section 3(d) analysis might be imatinib mesylate non-crystalline, the court stopped short of declaring so outright. Instead, the court skipped directly to a comparison between the efficacies of the imatinib mesylate beta crystalline and imatinib free base, on the grounds that the comparison formed the basis

96. *Id.*

97. *See* Novartis AG v. Union of India, 2007 A.I.R. 24759 (2013) (Madras H.C.).

98. *Id.* para. 175.

99. *Id.* para. 174.

100. *Novartis AG*, 2007 A.I.R. paras. 171, 175 (first noting that the applicant ought to have "show[n] the enhanced efficacy of the beta crystalline form of Imatinib Mesylate over Imatinib Mesylate (non-crystalline)" but then going on to evaluate the "enhanced efficacy of the beta crystalline form of Imatinib Mesylate vis-à-vis Imatinib in free base" instead).

101. *See id.* para. 170 (noting that the evidence suggested, and even Novartis had admitted before the Court, "that the subject product, in terms of invention, [was] two stages removed from Imatinib in free base").

of Novartis' argument "as made out in the subject application and the supporting affidavits."¹⁰²

2. "Enhancement of Known Efficacy"

Apparently accepting Novartis' position that the "known compound" point of comparison was imatinib free base, the court then addressed the main source of debate in the case: just how high of a bar is set by "enhancement of known efficacy" in section 3(d).¹⁰³ The court held that imatinib mesylate beta crystalline did not meet that bar.¹⁰⁴ To hold that the beta crystalline form of imatinib lacked sufficient "efficacy" over a known compound, the court had to narrow substantially the otherwise vague term "efficacy." It did so in a two-step analysis.

The first task before the court was defining "efficacy" in section 3(d) as "therapeutic efficacy." The court employed the dictionary definition of "efficacy"—"the ability to produce a desired or intended result"—but specified that the term necessarily possessed different meanings "depending upon the result the product under consideration is . . . intended to produce."¹⁰⁵ And in the case of a drug "that claims to cure a disease," "the test of efficacy can only be therapeutic efficacy."¹⁰⁶ Second, the court examined the scope of "therapeutic efficacy." It ruled out various types of modifications, the effects of which they determined would not enhance the "therapeutic efficacy" of a drug, but eschewed defining the contours of "therapeutic efficacy."¹⁰⁷ The only real question, the court claimed, was whether increased bioavailability, or the fraction of the drug that can be absorbed or taken up by the body, could constitute "therapeutic efficacy."¹⁰⁸ However, the court concluded simply that whether or not increased bioavailability could constitute "therapeutic efficacy," Novartis failed to demonstrate the bioavailabilities of imatinib mesylate beta crystalline and imatinib free base via "established . . . research data."¹⁰⁹

C. Ramifications of the Supreme Court of India's Interpretation

Despite the decision's professed faithfulness to the innovation-promoting, anti-evergreening rationale behind section 3(d), the court's vague application of the law hardly advanced an anti-evergreening understanding of section 3(d) and may have even undermined the provision's purpose. In

102. See *id.* para. 175.

103. See *id.* ("Let us now consider the case of the appellant as made out in the subject application and the supporting affidavits, and examine the issue of enhanced efficacy of the beta crystalline form of Imatinib Mesylate vis-à-vis Imatinib in free base form.")

104. See *id.* para. 182.

105. *Id.* para. 180.

106. *Id.*

107. See *id.* para. 187.

108. See *id.* para. 188.

109. See *id.* para. 189.

comparing imatinib mesylate beta crystalline to the very early and quite far-removed form of imatinib free base, which lacked meaningful evergreening potential, the court applied its section 3(d) analysis to a question that had little bearing on the problem section 3(d) had set out to rectify. And in answering that question, the court reached the somewhat disingenuous conclusion that Novartis's patent on Gleevec was seeking to keep evergreen a compound that had never been, and could never be, administered as a drug. Such an interpretation of section 3(d) could, oddly enough, negatively impact access to medicines in the developing south by discouraging Indian development of drugs for neglected diseases.

Although the court's reasons for rejecting Novartis's patent may have been strong from an access to medicines perspective, the court left entirely open the "known compound" issue. In dicta, the court surmised that imatinib mesylate *might* be the proper "known compound," because imatinib mesylate beta crystalline was "two stages removed" from imatinib free base.¹¹⁰ However, the court did not pursue that inquiry and failed to explain how it had determined that imatinib free base was "two stages removed."

The court had at least two important alternative standards for defining "stages removed." First, the number of "stages removed" could depend solely upon how the development of the drug actually played out. Adopting such a standard would place the burden of proof on drug companies to show how much effort was involved in getting from one stage to the next. Alternatively, the number of "stages removed" might be a more mechanical analysis requiring reviewing bodies to inspect a compound's physical structure and to ask how many changes in chemical positions it would take to get from compound A to compound B.¹¹¹ This latter approach appealed to the New Delhi High Court in *Hoffmann-La Roche v. Cipla*,¹¹² in which Indian generic manufacturer Cipla challenged the validity of Hoffmann-La Roche's patent on its pancreatic cancer drug Tarceva. However, the former standard better comports with a purposive understanding of section 3(d). If courts interpret "known compound" with a goal toward ferreting out those patents where a company quickly and cheaply identified a minor change simply to keep its previous patent evergreen, then it should matter how the development of the various compounds actually occurred rather than how many mechanical steps were involved in that process.

The court's indeterminate position on what constitutes a "known compound" is particularly vexing in light of two considerations. First, the court equivocated as to whether section 3(d) set forth a patentable subject matter requirement—suggesting a more categorical approach to all similar cases—or a patentability requirement—suggesting a more individualized assessment of each case. The ruling thus leaves next-to-no guidance for the patent

110. *Id.* para. 165.

111. *Id.* paras. 87–89.

112. CS (OS) No. 89/2008, C.C. 52/2008 (2012) (Delhi H.C.) paras. 74–77, 112–14.

offices and lower courts to interpret subsequent disputes over the proper “known compound” point of comparison. Second, what constitutes a “known compound” is an especially consequential question in the drug industry, as drug development often is so predicated upon similar previous compounds¹¹³ that it is difficult to imagine a section 3(d) challenge to a drug patent that would not invite significant debate as to the proper “known compound” to which the subject patent’s efficacy ought to be compared.

More importantly, it is difficult to reconcile the court’s move in interpreting “known compound” with section 3(d)’s stated aim of preventing patent evergreening. By failing to articulate an implementable standard for determining the “known compound” and then comparing the efficacy of imatinib mesylate beta crystalline only to imatinib free base, the court left the strong impression that imatinib free base was the relevant “known compound.” This interpretation of section 3(d) undercuts the provision’s anti-evergreening rationale. Despite accepting that “free base form [i]matinib has very little or no solubility” and is “therefore not capable of being administered as a drug to human beings,” the court evaluated imatinib free base as the “known compound” in a section 3(d) analysis.¹¹⁴ But if section 3(d) is aimed at preventing evergreening, the “known compound” ought to be capable of being kept evergreen in the first place.

The court’s treatment of “therapeutic efficacy” is similarly troublesome. Novartis had argued, and the court did not explicitly reject, that imatinib free base had *no* therapeutic efficacy whatsoever, as it would simply “sit in the stomach like a brick and . . . pass out with no therapeutic effect”¹¹⁵ when administered to humans in solid form. Indeed, for the scientists developing the drug, oral bioavailability had been a tremendous hurdle, as the compound was useless without sufficient bioavailability.¹¹⁶ Since the court entertained Novartis’ submission that imatinib free base had no effect, it ought to have confronted the argument that the “therapeutic efficacy” of imatinib mesylate beta crystalline rested in the fact that it could actually bring about a therapeutic effect in patients where imatinib free base could not. Instead, the court ducked the glaring issue by holding simply that Novartis had failed to present “established . . . research data” to prove its assertion.¹¹⁷ As it stands, *Novartis* suggests that evergreening may encompass the transformation of an entirely inert substance into one that actually produces an effect on the human body, which is perhaps vastly overinclusive of the evergreening activity that section 3(d) sought to prevent.

113. Whertheimer & Santella, *supra* note 81, at 10.

114. *Novartis AG v. Union of India*, 2007 A.I.R. 24759 (2013) (Madras H.C.) paras. 171, 175.

115. *Id.* para. 175.

116. Ghoshray, *supra* note 93, at 727.

117. *Novartis AG*, 2007 A.I.R. paras. 171, 175.

Although the exceptionally high bar *Novartis* set for section 3(d) may appear to be a victory for access to medicine efforts in the short run, it could in the long run diminish Indian research and development in the area of diseases specific to the global south. Foreign pharmaceuticals typically have little incentive to research neglected diseases regardless of patent protection strength, but the reinstatement of product patents with the 2005 Amendments had prompted Indian pharmaceuticals to ratchet up R&D on such diseases. Over the period of 2000 to 2011, the study identified fourteen newly approved drug and vaccine products for neglected diseases as attributable to India; only two of these were approved before 2005.¹¹⁸ The other twelve were approved in 2008–2010, with a bevy of approvals occurring in 2008 alone: just as one might expect would be the case if companies began engaging in R&D once patent protection became reasonably assured.¹¹⁹ If transforming a non-administrable compound into an administrable one is insufficient to overcome the section 3(d) hurdle, as *Novartis* suggests, then patent protection may no longer be reasonably assured and any progress made toward the treatment of neglected diseases may come to a grinding halt.

IV. CONCLUSION

In the two most important decisions interpreting the 2005 Amendments to date, the IPAB in *Bayer v. Natco* and the Supreme Court of India in *Novartis AG v. Union of India* sought to reinforce the fundamental rationale of two key TRIPS flexibilities. The compulsory licensing provision of section 84 strove to ensure public health interests were satisfied, while the anti-evergreening provision of section 3(d) aimed to eliminate wasteful efforts to keep patents evergreen and instead encourage meaningful innovation.

Yet, *Bayer* and *Novartis* interpreted the two flexibilities in ways that may have actually weakened the purposes the courts set out to bolster. In *Bayer*, the IPAB greatly reduced the incentive to brand-name pharmaceuticals to undertake certain public interest measures explicitly provided for in section 84, such as local manufacturing facilities and low-cost programs. In doing so, IPAB also inadvertently made India more vulnerable to a WTO challenge, as its interpretation of the “working” condition in section 84 runs into conflict with the non-discrimination dictate in article 27.1 of TRIPS. Meanwhile, in *Novartis*, the court effectively deemed the brand-name patent an attempt to keep evergreen a much earlier compound that could not even be administered in the human body. In molding section 3(d) into a particularly tough standard that likely captures a much broader swath of activity

118. Belen Pedrique et al., *The Drug and Vaccine Landscape for Neglected Diseases (2000–11): A Systematic Assessment*, 1 LANCET GLOBAL HEALTH 371, 373–74 (2013).

119. *Id.*

than the provision sought to prevent, *Novartis* may have lamentable long-run implications for budding domestic efforts to develop cures for neglected diseases.

