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## *Novartis AG v. Union of India: Why the Court's Narrow Interpretation of Enhanced Efficacy Threatens Domestic and Foreign Drug Development*

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# ***NOVARTIS AG v. UNION OF INDIA: WHY THE COURT'S NARROW INTERPRETATION OF ENHANCED EFFICACY THREATENS DOMESTIC AND FOREIGN DRUG DEVELOPMENT***

KEVIN TARSA\*

**Abstract:** Through the Patents (Amendment) Act of 2005, the Indian Parliament revised the Patents Act of 1970 to permit the grant of patents for pharmaceutical products. A core provision in the 2005 Amendment was Section 3(d), which prohibited granting patents to a new form of a known substance that did not enhance the efficacy of that substance. In *Novartis AG v. Union of India*, the Supreme Court of India applied this new provision to Novartis's patent application for the final form of its drug Gleevec. The court engaged in an unreasonably narrow analysis of enhanced efficacy, potentially stifling secondary patents on important drugs and creating significant uncertainty for pharmaceutical companies going forward. *Novartis AG* evinces the ongoing tension between maintaining India's status as the "pharmacy of the world" and promoting scientific innovation in South Asia.

## INTRODUCTION

In April 2013, the Supreme Court of India upheld the Indian Patent Office's rejection of Novartis's patent application for the final form of its therapeutic drug Gleevec.<sup>1</sup> Gleevec, which comprises the beta crystalline form of a chemical compound called imatinib mesylate, is a drug that treats chronic myeloid leukemia and certain tumors.<sup>2</sup> In deciding whether to grant Novartis a patent, the Supreme Court of India faced tremendous pressure to satisfy competing interests: encouraging scientific innovation and making life-saving drugs available to the world's neediest citizens.<sup>3</sup> On the one hand, the court was urged to promote scientific research and development by affording monopolistic protection to the producers of novel drugs, in keeping with India's

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<sup>1</sup> *Novartis AG v. Union of India*, AIR 2013 SC, App. No. 2706-2716 of 2013, ¶¶ 3, 14, 195, <http://supremecourtindia.nic.in/outtoday/patent.pdf> [<https://perma.cc/53RA-2LDX>].

<sup>2</sup> *Id.* ¶ 3.

<sup>3</sup> *See id.* ¶ 4.

obligations under international treaties.<sup>4</sup> On the other hand, non-governmental organizations and legal-aid societies implored the court to protect India's generic drug producers and thus maintain India's status as the "pharmacy of the world."<sup>5</sup>

*Novartis AG v. Union of India* is significant because it tests the ambit and purpose of the Indian Patents (Amendment) Act of 2005 (2005 Amendment).<sup>6</sup> One of the core issues of the case is whether, under Section 3(d) of the 2005 Amendment, the final version of Gleevec enhances the "known efficacy" of the previous form of the drug.<sup>7</sup> Novartis contended that Section 3(d) was immaterial to the case, but the court did not find this argument persuasive.<sup>8</sup> It ruled that Section 3(d) serves as an additional bar for drugs to clear in order to prevent "evergreening," the practice of making trivial changes to an existing product simply to extend the patentee's exclusive rights over the product.<sup>9</sup>

Part I of this Comment provides background on the facts of *Novartis AG*, the history of Indian patent law, and procedural history of the legal proceedings in India. Part II discusses the statutory provisions at issue in the case, the court's analysis of these issues, and its holding. Part III critiques the court's narrow interpretation of enhanced efficacy, analyzes the court's poor understanding of evergreening, and explains why *Novartis AG* has created uncertainty for drug producers seeking secondary patents in the future.

## I. BACKGROUND

### *A. Novartis Obtains Patent for Gleevec in the United States*

On May 28, 1996, a medicinal chemist named Jürg Zimmermann received a U.S. patent for a number of chemical derivatives (the "Zimmermann patent")—including the compound imatinib, which can be used to create anti-tumoral drugs.<sup>10</sup> Nearly five years later, the U.S. Food and Drug Administration (FDA) approved Gleevec in the form of 50- and 100-milligram capsules,

<sup>4</sup> *See id.*

<sup>5</sup> *Id.*; see Dorothy Du, *Novartis AG v. Union of India: "Evergreening," Trips, and Enhanced Efficacy Under Section 3(d)*, 21 J. INTELL. PROP. L. 223, 247 (2014).

<sup>6</sup> *See* AIR 2013 SC ¶ 103.

<sup>7</sup> The Patents (Amendment) Act, 2005 § 3(d), No. 15 of 2005, INDIA CODE (2005), <http://indiacode.nic.in> [<https://perma.cc/2RGC-QEZH>] [hereinafter 2005 Amendment]; *see Novartis AG*, AIR 2013 SC ¶¶ 3, 158.

<sup>8</sup> *See Novartis AG*, AIR 2013 SC ¶¶ 99–100, 102.

<sup>9</sup> *See id.* ¶¶ 100, 103.

<sup>10</sup> *Novartis AG v. Union of India*, AIR 2013 SC, App. No. 2706-2716 of 2013, ¶ 5, <http://supremecourtindia.nic.in/outtoday/patent.pdf> [<https://perma.cc/53RA-2LDX>]; *New Treatment for Chronic Myelogenous Leukaemia (CML): European Inventor of the Year 2009 in the Category "Industry,"* EUR. PAT. OFF., <https://www.epo.org/learning-events/european-inventor/finalists/2009/zimmermann.html> [<https://perma.cc/Y46S-K3PM>] (last visited Apr. 27, 2016).

which used imatinib mesylate as their active ingredient.<sup>11</sup> Shortly thereafter, Gleevec hit the market on the basis of the Zimmermann patent.<sup>12</sup>

On January 18, 2000, Novartis applied for a U.S. patent for the beta crystalline form of imatinib mesylate.<sup>13</sup> The patent examiner initially rejected Novartis's application, but, on appeal, the Board of Patent Appeals and Interferences reversed the patent examiner's decision.<sup>14</sup> The board determined that although the Zimmermann patent teaches any person skilled in the art how to use imatinib in a pharmaceutical product to treat tumors, it does not explain how to use the beta crystalline form to do so.<sup>15</sup> Thus, Novartis's development of the beta crystalline form in a pharmaceutical composition constituted a "manipulative step"<sup>16</sup> in the treatment of tumor disease.<sup>17</sup> Consequently, the U.S. patent board granted Novartis a patent for the beta crystalline form on May 17, 2005.<sup>18</sup>

### *B. Novartis Seeks Patent for Gleevec in India*

Novartis filed a patent application for the beta crystalline form of imatinib mesylate on July 17, 1998, in the Chennai Patent Office.<sup>19</sup> Novartis claimed that its product was superior to imatinib mesylate in its free-base form for a variety of reasons, including that it stored better and was easier to process.<sup>20</sup> When Novartis filed its application, the patent law in India was in a transitional stage, and, as a result, its application was put on hold.<sup>21</sup> Before its application was considered, several amendments were introduced to the Indian Patents Act of 1970 that fundamentally shifted the nation's patent law.<sup>22</sup> Most importantly, the 2005 Amendment strengthened India's intellectual property laws by permitting the grant of patents for pharmaceutical products.<sup>23</sup> When the Assistant Controller of Patents and Designs finally reviewed No-

<sup>11</sup> *Novartis AG*, AIR 2013 SC ¶¶ 119, 121.

<sup>12</sup> *See id.* ¶¶ 115, 119.

<sup>13</sup> *Id.* ¶ 115. Novartis derived the beta-crystalline form of imatinib mesylate in a two-stage process. *Id.* ¶ 6. Beginning with imatinib in free-base form, it produced its methanesulfonic addition salt, imatinib mesylate, and then developed the beta-crystalline form of the salt. *Id.*

<sup>14</sup> *Id.* ¶ 123.

<sup>15</sup> *Id.* ¶ 124.

<sup>16</sup> "A 'manipulative step' may or may not be an 'inventive step,'" which is required under Indian law. *Id.* at 67 n.1. An inventive step is "a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention *not obvious* to a person skilled in the art." *Id.* ¶ 89.

<sup>17</sup> *See id.* ¶ 124.

<sup>18</sup> *See id.* ¶ 115.

<sup>19</sup> *Id.* ¶ 8.

<sup>20</sup> *See id.* ¶¶ 8, 175.

<sup>21</sup> *Id.* ¶ 12.

<sup>22</sup> *Id.* ¶ 10.

<sup>23</sup> *See id.* ¶¶ 74–75.

vartis's application on December 15, 2005, it rejected it because the beta crystalline form was anticipated by the Zimmermann patent, was "obvious to a person skilled in the art" given the information disclosed in the Zimmermann patent, and was disallowed by Section 3(d) of the 2005 Amendment.<sup>24</sup>

### C. Procedural History

At the time of the Assistant Controller's rejection of Novartis's patent application, the appellate authority under the 2005 Amendment had not yet become functional; thus, Novartis filed writ petitions directly before the Madras High Court challenging the patent application's rejection.<sup>25</sup> Novartis filed two additional writ petitions seeking a declaration that Section 3(d) of the 2005 Amendment was unconstitutional because it violated Article 14 of the Indian Constitution and was not in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>26</sup> Following the formation of the Intellectual Property Appellate Board (IPAB), the writ petitions were transferred from the High Court to the IPAB on April 4, 2007.<sup>27</sup> On August 6, 2007, the High Court dismissed the two writ petitions challenging the validity of Section 3(d).<sup>28</sup> Almost two years later, on June 26, 2009, the IPAB dismissed Novartis's appeals against the orders of the Assistant Controller.<sup>29</sup> Although the IPAB reversed the findings of the Assistant Controller on the issues of novelty and obviousness, it affirmed the Assistant Controller's ruling that Section 3(d) precluded Novartis from receiving a product patent.<sup>30</sup> The IPAB nevertheless ruled that Novartis could receive a process patent for preparing imatinib mesylate in beta crystalline form.<sup>31</sup> Novartis subsequently petitioned the Supreme Court of India under Article 136 of the Indian Constitution.<sup>32</sup> Although Novartis's prescribed remedy was to challenge the judgment of the IPAB before the Madras High Court, the Supreme Court of India agreed to hear the case because it involved a number of seminal patent-law issues and was likely to reach the Supreme Court of India eventually.<sup>33</sup>

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<sup>24</sup> *Id.* ¶ 14.

<sup>25</sup> *Id.* ¶ 15.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* ¶ 16.

<sup>30</sup> *See id.* ¶¶ 17, 20.

<sup>31</sup> *Id.* ¶ 20.

<sup>32</sup> *Id.* ¶ 21.

<sup>33</sup> *Id.*

### D. History of Indian Patent Law

The *Novartis AG* litigation took place during a transitional period in Indian patent law—between an era that prohibited granting patents for drugs and an era that permitted it.<sup>34</sup> When Novartis submitted its application for an Indian patent in 1998, the patent legislation then in effect, the Patents Act of 1970, forbade patents for “substances intended for use, or capable of being used, as . . . medicine or drug, or prepared or produced by chemical processes.”<sup>35</sup> In the late 1950’s, Justice N. Rajagopala Ayyangar observed that India’s first patent legislation, the Patents and Designs Act of 1911, had failed to achieve its principal goal: “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.”<sup>36</sup> India’s patent regime was so deficient that between 1930 and 1937, India granted foreigners nine times as many patents as it did to Indian citizens—even though it established several institutions for post-graduate training and numerous laboratories after independence.<sup>37</sup> Moreover, the few inventions that Indians did produce were of little economic or scientific value in comparison to the patents held by foreigners.<sup>38</sup>

In an effort to make India’s patent system more favorable to domestic inventors, Justice Ayyangar looked at patent laws abroad.<sup>39</sup> Through his research, Justice Ayyangar discovered that many of the world’s developed countries—including Japan, Germany, and the U.S.S.R.—permitted the grant of patents for chemical processes but not for chemical products.<sup>40</sup> Furthermore, notwithstanding the United States, few countries openly granted patents for medical products.<sup>41</sup> Justice Ayyangar found this state of law compelling because it was based on a rationale that prioritized public health over monopolistic protection.<sup>42</sup> By barring the grant of pharmaceutical product patents, competition among drug producers would increase, and important drugs would be made available to the general public at the lowest possible cost.<sup>43</sup> To that end, Justice Ayyangar submitted a comprehensive report in which he recommended that the Indian government pass legislation to bar the

<sup>34</sup> See *id.* ¶ 24.

<sup>35</sup> The Patents Act, 1970 § 5, No. 39 of 1970, INDIA CODE (1970); *Novartis AG*, AIR 2013 SC ¶ 24.

<sup>36</sup> *Novartis AG*, AIR 2013 SC ¶¶ 34, 37.

<sup>37</sup> See *id.* ¶ 35.

<sup>38</sup> See *id.*

<sup>39</sup> See *id.* ¶¶ 34, 37, 41.

<sup>40</sup> *Id.* ¶ 41.

<sup>41</sup> See *id.* ¶ 42.

<sup>42</sup> See *id.* ¶¶ 42, 45.

<sup>43</sup> *Id.* ¶ 42.

grant of patents for pharmaceutical products.<sup>44</sup> The Indian government followed his recommendations by enacting the Patents Act of 1970.<sup>45</sup>

The enactment of the Patents Act of 1970 shifted power in the Indian pharmaceutical market to indigenous producers, leading to a dramatic increase in the production of bulk drugs.<sup>46</sup> Between 1970 and the early 2000s, India exported substantially more pharmaceutical products than in years past, and it gained worldwide recognition as a preeminent producer of affordable, high-quality bulk drugs.<sup>47</sup>

As India's domestic pharmaceutical industry grew stronger, however, changes at the international level profoundly affected India's patent law.<sup>48</sup> In 1995, TRIPS was enacted, which required all World Trade Organization (WTO) member nations to grant patent protection for pharmaceutical products.<sup>49</sup> To comply with its international obligations, the Indian parliament contentiously passed the 2005 Amendment, which brought India's intellectual property law into harmony with other WTO nations.<sup>50</sup> Although the 2005 Amendment authorized the patenting of pharmaceutical products, it did not do so without imposing restrictions on the grant of such patents—specifically, through the implementation of Section 3(d).<sup>51</sup>

## II. DISCUSSION

The statutory provisions at issue in *Novartis AG v. Union of India* are clauses (j) and (ja) of Section 2(1) of the Patents (Amendment) Act of 2002 and Section 3(d) of the 2005 Amendment.<sup>52</sup> The drug for which Novartis sought a patent was not something entirely new; rather, it emerged from the Zimmermann patent.<sup>53</sup> Because Novartis's product contained a polymorph of a preexisting substance—namely, imatinib mesylate—Novartis did not merely have to satisfy the traditional patent requirements of novelty, non-obviousness, and usefulness.<sup>54</sup> It also had to clear a second bar in Section 3(d),

<sup>44</sup> See *id.* ¶¶ 42–43.

<sup>45</sup> See *id.* ¶ 43.

<sup>46</sup> See *id.* ¶¶ 54–56.

<sup>47</sup> See *id.* ¶¶ 57–58.

<sup>48</sup> *Id.* ¶ 59.

<sup>49</sup> See *id.*

<sup>50</sup> See *id.* ¶¶ 74, 85.

<sup>51</sup> See *id.* ¶ 94.

<sup>52</sup> See AIR 2013 SC, App. No. 2706-2716 of 2013, ¶ 3, <http://supremecourtindia.nic.in/outtoday/patent.pdf> [<https://perma.cc/53RA-2LDX>].

<sup>53</sup> See *Novartis AG*, AIR 2013 SC ¶ 108.

<sup>54</sup> See The Patents (Amendment) Act, 2002 § 2(1)(j), No. 38 of 2002, India Code (2002), <http://indiacode.nic.in> [<https://perma.cc/2RGC-QEZH>] [hereinafter 2002 Amendment]; *Novartis AG*, AIR 2013 SC ¶ 158. Section 2(1) uses the term “inventive step” instead of non-obviousness and the term “capable of industrial application” instead of useful. 2002 Amendment § 2(1); see *Novartis AG*, AIR 2013 SC ¶ 89; see also *Novartis AG*, AIR 2013 SC at 29, n.1 (explaining that

which provides that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” does not qualify as an invention.<sup>55</sup>

The threshold issue for the Supreme Court of India was whether Novartis’s product satisfied the definition of “invention” in Section 2(1).<sup>56</sup> Section 2(1)(j) provides that an invention is a “new product or process involving an inventive step and capable of industrial application.”<sup>57</sup> An inventive step is a “feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.”<sup>58</sup>

Novartis argued that it produced imatinib mesylate in beta crystalline form through two inventions.<sup>59</sup> First, Novartis derived imatinib mesylate from imatinib in free-base form by selecting example 21 of the thirty-seven compounds provided in the Zimmermann patent and then adding methanesulfonic acid to that particular compound.<sup>60</sup> Because the Zimmermann patent did not instruct a person to select example 21 instead of the others—much less instruct a person how to produce imatinib mesylate from example 21—Novartis argued that its derivation constituted an invention.<sup>61</sup> Second, seeking to produce a form of the compound that could be ingested orally by humans, Novartis synthesized a beta crystalline form of imatinib mesylate through further independent research.<sup>62</sup>

The court addressed each of Novartis’s claimed inventions separately.<sup>63</sup> First, the court rejected Novartis’s argument that its production of imatinib mesylate constituted an invention.<sup>64</sup> Specifically, the court stated that because imatinib mesylate was a known substance from the Zimmermann patent and because a journal, *Cancer Research*, had published an article in 1996 that focused on the anti-tumoral properties of the compound, it did not qualify as a

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the terms used in Section 2(1)(j) of the 2002 Amendment and in TRIPS correlate with the traditional requirements of non-obviousness and usefulness).

<sup>55</sup> 2005 Amendment § 3(d); see *Novartis AG*, AIR 2013 SC ¶¶ 17, 158. Section 3(d) makes unpatentable in India some drugs that would be patentable in other countries. *Novartis AG*, AIR 2013 SC ¶ 17. Through Section 3(d), the Indian Parliament sought to prevent evergreening and to ensure that the citizens of India had access to life-saving drugs. See *id.* ¶ 18.

<sup>56</sup> See *Novartis AG*, AIR 2013 SC ¶ 3.

<sup>57</sup> *Id.* ¶ 71.

<sup>58</sup> 2002 Amendment § 2(1)(ja).

<sup>59</sup> *Novartis AG*, AIR 2013 SC ¶ 105.

<sup>60</sup> See *id.* ¶ 106.

<sup>61</sup> See *id.*

<sup>62</sup> See *id.* ¶ 107.

<sup>63</sup> See *id.* ¶¶ 157–158.

<sup>64</sup> See *id.* ¶ 157.



new product.<sup>65</sup> Second, in analyzing whether the beta crystalline form of imatinib mesylate qualified as an invention, the court reasoned that Section 3(d) of the 2005 Amendment applied directly to the question because the beta crystalline form was a polymorph of a known substance.<sup>66</sup> Novartis argued that Section 3(d) was not applicable to this issue for two reasons—both of which the court rejected.<sup>67</sup> First, the court rejected Novartis’s argument that as long as Novartis’s product satisfies Sections 2(1)(j) and 2(1)(ja), it need not satisfy Section 3(d) because 3(d) is a provision *ex majore cautela*.<sup>68</sup> Citing the Parliamentary debate that preceded Section 3(d)’s enactment, the court observed that the section was not inessential; rather, it was specifically designed to address patents for pharmaceutical products.<sup>69</sup> Additionally, the court rejected Novartis’s argument that Section 3(d) did not apply because imatinib mesylate was not a *known* substance with *known* efficacy.<sup>70</sup> The court ruled that imatinib mesylate was a known substance with known efficacy because the Zimmermann patent protected it and because the New Drug Application that Novartis submitted to the U.S. FDA explicitly stated that the drug had undergone “extensive preclinical, technical and clinical research.”<sup>71</sup>

On the issue of whether the beta crystalline form enhanced the efficacy of a known substance with known efficacy, the court first had to determine what substance immediately preceded the subject compound.<sup>72</sup> Because Novartis argued in court that imatinib mesylate was the immediate precursor to the beta crystalline form, the court required Novartis to prove that the beta

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<sup>65</sup> See *id.* ¶¶ 127, 157. Although Novartis conceded that the Zimmermann patent *covered* imatinib mesylate, it argued that the patent did not *disclose* the compound so as to enable a person skilled in the art to prepare it. See *id.* ¶ 134. The court, however, rejected this distinction:

We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the *coverage* and the *disclosure* under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its *claims* by skillful lawyers . . . .

See *id.* ¶¶ 156–157.

<sup>66</sup> See *id.* ¶ 158.

<sup>67</sup> See *id.* ¶¶ 102–103, 160.

<sup>68</sup> *Id.* ¶¶ 99, 100, 102. *Ex majore cautela* means “[o]ut of abundant caution.” *Id.* at 55, n.2.

<sup>69</sup> See *id.* ¶¶ 102–103 (“[S]ection 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable.”).

<sup>70</sup> See *id.* ¶¶ 158–160.

<sup>71</sup> See *id.* ¶¶ 160–161 (explaining that the clinical studies featured both tolerability and efficacy components and included 1234 patients with chronic myeloid leukemia and other Ph+ leukemias as participants).

<sup>72</sup> See 2005 Amendment § 3(d); *Novartis AG*, AIR 2013 SC ¶ 165. During the hearing, Novartis emphasized that imatinib mesylate immediately preceded the beta-crystalline form; however, Novartis’s patent application and supporting affidavits suggested that imatinib in free-base form immediately preceded the beta-crystalline form. See *Novartis AG*, AIR 2013 SC ¶¶ 165, 170.

crystalline form had enhanced efficacy in comparison to imatinib mesylate.<sup>73</sup> However, because the court found nothing in Novartis's application or in its supporting affidavits that enabled the court to compare the efficacy of the beta crystalline form of imatinib mesylate to imatinib mesylate, the court focused on whether the beta crystalline enhanced the efficacy of imatinib in free-base form.<sup>74</sup> The court invoked the definition of efficacy provided in *The New Oxford Dictionary of English*: "the ability to produce a desired or intended result."<sup>75</sup> Reasoning that efficacy with respect to drugs refers to therapeutic efficacy, the court opined that Section 3(d) should be applied narrowly: simply because a property is beneficial or advantageous does not mean that the property relates to the efficacy of the drug.<sup>76</sup> After considering the testimony of two expert witnesses, the court ruled that the claimed improvements of the beta crystalline form—more beneficial flow properties, better thermodynamic stability, lower hygroscopicity, and increased bioavailability—though valuable, did not enhance the therapeutic efficacy of imatinib mesylate.<sup>77</sup> Therefore, the court ruled that Novartis' beta crystalline form was not patentable under clauses (j) and (ja) of Section 2(1) and Section 3(d), and dismissed Novartis's appeal with costs.<sup>78</sup>

### III. ANALYSIS

*Novartis AG v. Union of India* is not the only recent case that has frustrated multinational pharmaceutical companies' attempts to break into India's expanding drug market.<sup>79</sup> In November 2012, the IPAB denied patent protection to Roche Holding AG's hepatitis C drug Pegasys, holding that the drug was "obvious" and thus did not satisfy India's inventiveness requirement.<sup>80</sup> Only several months later, in March 2013, the Indian Patents Office granted a compulsory license to Natco Pharma, permitting it to sell a generic version of Bayer AG's cancer drug Nexavar at a fraction of the price for which Bayer sells its own drug.<sup>81</sup> These cases illustrate the difficulties that modern changes

<sup>73</sup> See *Novartis AG*, AIR 2013 SC ¶¶ 170–171.

<sup>74</sup> See *id.* ¶¶ 171, 175.

<sup>75</sup> See *id.* ¶ 180.

<sup>76</sup> See *id.*

<sup>77</sup> See *id.* ¶¶ 183–190.

<sup>78</sup> See *id.* ¶ 195.

<sup>79</sup> See R. Jai Krishna & Jeanne Whalen, *Novartis Loses Glivec Patent Battle in India*, WALL ST. J. (Apr. 1, 2013), <http://www.wsj.com/articles/SB10001424127887323296504578395672582230106> [<https://perma.cc/S9PB-W3KN>] (noting India's drug market is expected to grow to \$48.8 billion by 2020 according to PricewaterhouseCoopers LLP).

<sup>80</sup> See Rumman Ahmed, *India Revokes Roche Patent*, WALL ST. J. (Nov. 3, 2012), <http://www.wsj.com/articles/SB10001424052970204846304578096483954249650> [<https://perma.cc/YLB3-MBCJ>].

<sup>81</sup> See Anupama Chandrasekaran, *India Board Rules Against Bayer in Cancer Drug Patent Case*, REUTERS (Mar. 4, 2013), <http://www.reuters.com/article/2013/03/04/us-india-bayer-idUSBRE9230LC20130304> [<https://perma.cc/8HP2-9Y4X>].

to Indian patent law have created for multinational drug companies trying to enter India's pharmaceutical marketplace.<sup>82</sup> Moreover, they raise the question whether India's patent regime has become overly protective of public health at the expense of important drug development.<sup>83</sup>

### A. Why Therapeutic Efficacy Is Too Narrow

By limiting "enhancement of . . . known efficacy" in Section 3(d) to therapeutic efficacy, the Supreme Court of India engaged in an unreasonably narrow analysis of the issue, potentially stifling veritable innovation by drug producers.<sup>84</sup> The court's restrictive interpretation of efficacy excludes many important improvements on a drug—including increased bioavailability,<sup>85</sup> increased heat stability inside the body, longer shelf-life, and reduction of microbial growth—because they do not result in an enhanced healing effect on the body.<sup>86</sup> For example, if a medication that can be delivered to the body only via mucosal administration were made orally administrable, the increased absorption into the body caused by the modification would not be sufficient to make the product patentable under this interpretation of Section 3(d).<sup>87</sup> These improvements have the potential to increase the efficiency of drugs, lengthening their maximal potency and enabling patients to take smaller doses.<sup>88</sup>

Rather than limiting its interpretation of Section 3(d) to therapeutic efficacy, the Supreme Court of India should have adopted either of the two following interpretations.<sup>89</sup> First, the court could have reasonably found that the inventive-step and industrial-application requirements in Section 2(1)(j) encompass the enhanced-efficacy requirement.<sup>90</sup> Because "the inventive step and industrial application requirements themselves require some level of in-

<sup>82</sup> See Ahmed, *supra* note 80; Chandrasekaran, *supra* note 81.

<sup>83</sup> See Andrew Q. Leba, *Lowering the "Efficacy" Threshold for Section 3(d) of the Indian Patents (Amendment) Act 2005: A Case for a Broader Scope*, 28 EMORY INT'L L. REV. 649, 675–76 (2014); see also Chandrasekaran, *supra* note 81 (noting that there are concerns about the level of protection for intellectual property in the country).

<sup>84</sup> See 2005 Amendment § 3(d); Leba, *supra* note 83, at 678.

<sup>85</sup> Bioavailability is the "degree to which a drug or other substance is absorbed or reaches a target site in the body." Jodie Liu, *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act*, 56 HARV. INT'L L.J. 207, 220 (2015).

<sup>86</sup> See Leba, *supra* note 83, at 678–79; see also Liu, *supra* note 85, at 220.

<sup>87</sup> See Leba, *supra* note 83, at 679 ("[S]ince the oral version of the drug has the same 'healing effects' as the mucosal administration version, it does not have any 'therapeutic efficacy' and may not be protected by a patent.").

<sup>88</sup> *Id.* at 678–79.

<sup>89</sup> See *Novartis AG v. Union of India*, AIR 2013 SC, App. No. 2706-2716 of 2013, ¶ 187, <http://supremecourtindia.nic.in/outtoday/patent.pdf> [<https://perma.cc/53RA-2LDX>]; Du, *supra* note 5, at 242.

<sup>90</sup> See 2002 Amendment § 2(1)(j); Du, *supra* note 5, at 242.

creased efficacy above the prior art in order to obtain a patent,” functionally, Section 3(d) is not a second bar to clear, but rather is a reminder to patent examiners not to extend patents for drugs that are considered obvious.<sup>91</sup> Alternatively, the court could have found that enhanced-efficacy refers broadly to improvements in the functioning of drugs.<sup>92</sup> Either of these interpretations would have been more appropriate to apply because they are receptive to the fact that scientific innovation occurs incrementally.<sup>93</sup> Moreover, some innovations that have no healing effect on the body can nevertheless “produce significant improvements in drug delivery and allow more people to benefit from the drug’s effects.”<sup>94</sup> Thus, by limiting its interpretation of Section 3(d) to therapeutic efficacy, the Supreme Court of India may have hurt the potential beneficiaries of valuable ancillary drug improvements.<sup>95</sup>

### *B. The Supreme Court’s Faulty Understanding of Evergreening*

Evergreening is commonly misunderstood, and the threat it poses is perhaps exaggerated.<sup>96</sup> A drug company engages in evergreening when it extends 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.”<sup>97</sup> Evergreening, however, is sometimes described as obtaining a second patent for the same subject matter while a preexisting patent is in effect.<sup>98</sup> Obtaining such a patent would be impossible under Indian law because India requires that patents be granted only to products that feature an “inventive step” and are novel.<sup>99</sup> Other times, evergreening is described as enabling the creator of a reformulation of a drug to obtain an extension of the

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<sup>91</sup> See Du, *supra* note 5, at 243–44 (explaining that many developing countries grant patents for the same products as developed countries without considering in sufficient detail whether the advancement over the prior art is non-obvious).

<sup>92</sup> See *id.* at 242.

<sup>93</sup> Thamaray Govender & Danie Dohmen, Novartis A.G. v. Union of India—*The Gleevec Case and Evergreening*, LEXOLOGY (Oct. 8, 2013), <http://www.lexology.com/library/detail.aspx?g=97441a81-b27b-43aa-a8ee-bf2522339cf0> [https://perma.cc/B957-JARU] (“Whilst incremental innovation has been disregarded as trivial by critics, most innovation is incremental by nature as progression of technology, especially in the pharmaceutical sector, occurs in steps.”).

<sup>94</sup> See Liu, *supra* note 85, at 220.

<sup>95</sup> See *Novartis AG*, AIR 2013 SC ¶ 187; Leba, *supra* note 83, at 678–79.

<sup>96</sup> See Du, *supra* note 5, at 238; see also Leba, *supra* note 83, at 682–83 (“At least in the United States, fears of evergreening have not yet come to fruition.”).

<sup>97</sup> Liu, *supra* note 86, at 220 (quoting Joanna T. Brougher, *Evergreening Patents: The Indian Supreme Court Rejects Patenting of Incremental Improvements*, 19 J. COM. BIOTECH. 54, 55 (2013)).

<sup>98</sup> See Du, *supra* note 5, at 239.

<sup>99</sup> See *id.*

original drug patent.<sup>100</sup> This, too, evidences a misunderstanding of evergreening because patent expiration is a legal process that cannot be overridden or circumvented.<sup>101</sup>

The court in *Novartis AG* manifested a poor understanding of evergreening when it compared the beta crystalline form of imatinib mesylate to distant free-base imatinib, rather than imatinib mesylate.<sup>102</sup> Because it was not capable of being administered as a drug to humans in the first place, free-base imatinib lacked evergreening potential.<sup>103</sup> Counsel for Novartis testified that free-base imatinib, “[i]f given in solid dosage form, . . . would sit in the stomach like a brick and would pass out with no therapeutic effect.”<sup>104</sup> Despite the fact that free-base imatinib could not be administered as a drug, the court precluded Novartis from receiving a patent for a product that likely would have benefitted patients.<sup>105</sup> The court thus indicated that evergreening may include “the transformation of an entirely inert substance into one that actually produces an effect on the human body.”<sup>106</sup> This suggestion is unsettling because the court’s application of Section 3(d) barred the grant of a patent for a pharmaceutical product that the Indian Parliament, in targeting evergreening, likely had no intention to exclude.<sup>107</sup>

### C. Uncertainty Going Forward

The court’s failure to identify what constitutes sufficient evidence of enhanced efficacy creates great uncertainty for pharmaceutical companies seeking to obtain secondary patents in India in the future.<sup>108</sup> The court concluded that “whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data.”<sup>109</sup> Although the court ruled that Novartis did not provide sufficient research data, it did not identify what type or amount of data would be enough to prove enhanced efficacy.<sup>110</sup>

Even if a certain amount of data is sufficient to prove enhanced efficacy, it is unreasonable to require drug manufacturers to prove enhanced efficacy so early in the drug-development process.<sup>111</sup> In his amicus brief to the court

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<sup>100</sup> *See id.*

<sup>101</sup> *See id.* at 239–40.

<sup>102</sup> *Novartis AG*, AIR 2013 SC ¶ 175.; *see* Liu, *supra* note 85, at 224.

<sup>103</sup> *See* Liu, *supra* note 85, at 224.

<sup>104</sup> *Novartis AG*, AIR 2013 SC ¶ 175.

<sup>105</sup> *See id.* ¶ 195; Liu, *supra* note 85, at 224–25; Krishna & Whalen, *supra* note 79.

<sup>106</sup> Liu, *supra* note 85, at 225.

<sup>107</sup> *See id.*

<sup>108</sup> *Novartis AG*, AIR 2013 SC ¶ 189; Leba, *supra* note 83, at 678.

<sup>109</sup> *Novartis AG*, AIR 2013 SC ¶ 189.

<sup>110</sup> *See id.*; Leba, *supra* note 83, at 678.

<sup>111</sup> *See* Du, *supra* note 5, at 250–51.

in *Novartis AG*, Shamnad Basheer, a law professor at West Bengal University of Juridical Sciences, said, “it would be impractical for drug companies to seek patents only after they have conducted years of clinical trials that could provide definitive proof that updated drugs work better than their older versions.”<sup>112</sup> Pharmaceutical companies usually seek patents several years before they are able to sell a drug on the market.<sup>113</sup> Receiving a patent creates the incentive for drug manufacturers to perform the clinical trials through which they can obtain efficacy data because it guarantees that such data cannot be exploited by third parties.<sup>114</sup> Thus, requiring proof of efficacy at the time of patenting might block many efficacious drugs and thereby impede important drug development.<sup>115</sup>

### CONCLUSION

The scope of the impact of *Novartis AG v. Union of India* and similar cases is not yet clear, but it is already evident that the 2005 Amendment’s changes to Indian patent law are not favorable to multinational pharmaceutical companies. Section 3(d) poses the greatest threat to these companies by significantly restricting their ability to obtain secondary patents on important drugs. Because pharmaceutical products are exceedingly expensive to produce, drug manufacturers rely on the monopolistic rights offered by patents to recoup the exorbitant costs of researching and developing such products. Thus, when the likelihood of obtaining a patent for a drug is reduced, so too is the incentive to develop new drugs. Given the financial upside of participating in India’s fast-growing pharmaceutical market, the *Novartis AG* decision alone will likely not affect western drug companies’ willingness to participate in the Indian market. If the Indian courts continue to interpret Section 3(d)’s enhanced-efficacy requirement narrowly, however, this could obstruct important pharmaceutical innovations that—despite not having a healing effect on the body—promise to help citizens of developed and developing countries alike.

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<sup>112</sup> Leba, *supra* note 83, at 669, 680.

<sup>113</sup> Du, *supra* note 5, at 251.

<sup>114</sup> *See id.*

<sup>115</sup> *See id.*