

# COMMENT

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## Forever Green? An Examination of Pharmaceutical Patent Extensions

I.	Evergreening Explained .....	83
II.	<i>Novartis</i> and Therapeutic Efficacy .....	89
III.	Pharmaceutical Patents in the United States.....	93
IV.	A Modest Suggest for an Alteration.....	97

In April 2013, the Indian Supreme Court decided *Novartis AG v. Union of India*.<sup>1</sup> This case has sparked discussion surrounding the practice of “evergreening” in the pharmaceutical industry.<sup>2</sup> The pharmaceutical industry’s unique characteristics promote this practice: Demand for pharmaceuticals can potentially be inelastic—*i.e.*, a drug’s price will have only a minor or marginal effect on demand.<sup>3</sup> This dynamic can allow a pharmaceutical company to reap astronomical profits if they develop what is commonly referred to as a “blockbuster drug.”<sup>4</sup> But blockbuster drugs are not common, and the

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<sup>1</sup> *Novartis AG v. Union of India & Ors.*, (2013) SCR, Civil appeal No. 2728 (India).

<sup>2</sup> See, e.g., Dorothy Du, *Novartis Ag v. Union of India: “Evergreening,” Trips, and “Enhanced Efficacy” Under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).

<sup>3</sup> See SU LIU & DEBRAH CHOLLET, *Mathematical Policy Research, Inc., PRICE AND INCOME ELASTICITY OF THE DEMAND FOR HEALTH INSURANCE AND HEALTH CARE SERVICES: A CRITICAL REVIEW OF THE LITERATURE X–XI* (2006) (stating estimates of prescription drugs’ price elasticity range from -0.1 to -0.6 while also noting the price elasticity for specific drugs may vary).

<sup>4</sup> A blockbuster drug is “[a drug] that achieves acceptance by prescribing physicians as a therapeutic standard for, most commonly, a highly prevalent chronic (rather than acute) condition. Patients often take the medicines for long periods. And then there’s the financial component of the definition. A blockbuster drug is typically defined as achieving annual

costs associated with pharmaceutical development continue to rise.<sup>5</sup> Those costs are passed on to patients,<sup>6</sup> a fact causing an access problem for patients with limited resources.<sup>7</sup>

Broadly stated, “evergreening” is a range of strategies a patent holder can pursue to extend market exclusivity and elevate drug prices.<sup>8</sup> One strategy available to a patent holder, called patent layering, is to patent a substance’s secondary aspects. In contrast to primary patents, which protect an active ingredient directly, secondary patents protect a range of chemicals related to an active ingredient, methods of use, alternate formulations, or dosages.<sup>9</sup> One advantage of this strategy is that generic competition is deterred from market entry for the extended time period, keeping drug prices high while patients still purchase the drug’s name brand version.<sup>10</sup>

*Novartis* interpreted section 3(d) of the Indian Patent Act of 1970 (as amended in 2005) as having the explicit purpose of deterring evergreening.<sup>11</sup> The decision is fairly characterized as one reached with the goal of promoting access to pharmaceuticals.<sup>12</sup> This Article examines *Novartis* in the context of pharmaceutical evergreening, and

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worldwide sales exceeding \$1 billion. Those staggering revenues are generated by two components: the large number of patients who take the medicine and the premium price typically charged (compared to the older drug it replaced). Longterm use by patients, often consistent with guidelines issued by professional physician organizations, creates an annuity for the pharmaceutical company—at least until the patent protection runs out.” STAN FINKELSTEIN & PETER TEMIN, *REASONABLE RX* 6 (2008).

<sup>5</sup> Jason Millman, *Does it really cost 2.6 Billion dollars to develop a new drug?*, WASH. POST (Nov. 18, 2014), [https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/?utm\\_term=.b31b852d429f](https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/?utm_term=.b31b852d429f).

<sup>6</sup> Dennis Thompson, *What’s behind the sharp rise in prescription drug prices?*, CBS News (Aug. 26, 2016), <http://www.cbsnews.com/news/whats-behind-the-sharp-rise-in-prescription-drug-prices/>.

<sup>7</sup> Sreedhar Potarazu, *Rising cost of prescription drugs threatens health care gains*, CNN (Aug. 26, 2015), <http://www.cnn.com/2015/08/26/opinions/potarazu-drug-price-hikes/>.

<sup>8</sup> Rajarshi Banerjee, *The Success of, and Response to, India’s Law against Patent Layering*, 54 HARV. INT’L L.J. 204, 207 (2014).

<sup>9</sup> Maria Sittler, Bronwyn Hall & Christian Helmers, *An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile*, NAT’L BUREAU OF ECON. RESEARCH WORKING PAPER 20995, at 2.

<sup>10</sup> Gretchen Morgenson, *Working to Lower Drug Costs by Challenging Questionable Patents*, N.Y. TIMES (Nov. 27, 2015), [https://www.nytimes.com/2015/11/29/business/working-to-lower-drug-costs-by-challenging-questionable-patents.html?\\_r=0](https://www.nytimes.com/2015/11/29/business/working-to-lower-drug-costs-by-challenging-questionable-patents.html?_r=0).

<sup>11</sup> *Novartis AG v. Union of India & Ors.*, (2013) SCR, Civil appeal No. 2728, 11, 48 (India).

<sup>12</sup> See Du, *supra* note 2, at 255–57.

suggests that the U.S. intellectual property regime could be improved by adopting a provision similar to section 3(d). Part I discusses evergreening and the negative repercussions it has on both the U.S. patent system and society. Part II examines *Novartis* and the academic understanding of section 3(d)'s solution to evergreening. Part III briefly details the current state of pharmaceutical patent laws in the U.S. Finally, Part IV suggests what a similar provision in the U.S. system would look like.

## I EVERGREENING EXPLAINED

“Evergreening” is a series of legal strategies to extend market exclusivity on expiring patents.<sup>13</sup> Pharmaceutical companies can patent the active ingredient of a drug, an action providing protection for a term of twenty years.<sup>14</sup> When a profitable drug nears the end of its patent protection, the patent holder must determine how to maintain profits or else allow generic competition to enter the market, an event that can drastically lower profits.<sup>15</sup> One strategy is to patent a drug's secondary characteristics in anticipation of the initial patent term's end, creating a “patent portfolio.”<sup>16</sup> For example, an original patent holder might obtain a secondary patent on a slight variation of the original substance, its medical uses, particular formulations of the substance, dosage regimens, or production processes.<sup>17</sup> This strategy, called patent layering, benefits the patent holder because the secondary patents can effectively extend patent protection and deter generic market entry, keeping drug prices high.<sup>18</sup>

Following *Novartis*, there has been increased discussion of patent layering, with authors asserting both that this strategy is a burden on the patent system and that the strategy itself cannot exist as

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<sup>13</sup> Banerjee, *supra* note 8, at 207.

<sup>14</sup> FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, 41 (2002).

<sup>15</sup> See Morgenson, *supra* note 10.

<sup>16</sup> C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 620–21 (2011).

<sup>17</sup> Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents* PLoS ONE 7(12): e49470 (2012).

<sup>18</sup> Scott C. Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

described.<sup>19</sup> The debate on whether patent layering should be sustainable centers primarily on whether the secondary patents advance innovation.<sup>20</sup> If the secondary patents advance innovation, then the argument is that the strategy is beneficial.<sup>21</sup> In contrast, if the secondary patent does not reflect an innovation relative to the original substance, then the strategy of filing secondary patents is an abuse of the patent system.<sup>22</sup>

Some commenters have pointed out that patents that do not cover an advance over the prior substance are not valid, so no protection can be gained by filing such a patent.<sup>23</sup> Empirical studies suggest otherwise and indicate that the strategy of filing secondary patents has increased over time even though the patents sought consistently lack merit.<sup>24</sup> These studies suggest that the number of patents attached to a drug have increased over the last several decades.<sup>25</sup> For instance, between 1985 and 1987, FDA-approved pharmaceuticals had an average of 1.9 patents per drug.<sup>26</sup> In contrast, between 2000 and 2002, FDA-approved pharmaceuticals had an average of 3.9 patents.<sup>27</sup> Thus, the median number of patents per drug rose by one, from 1.5 to 2.5 in a fifteen-year period of time.<sup>28</sup> This results in an increase in nominal patent life, *i.e.*, the length of time the drug should be protected from infringement if it were not challenged.<sup>29</sup>

However, the presence of additional patents greatly increased the chance of a patent challenge being filed.<sup>30</sup> Further, the number of secondary patents is correlated with a higher likelihood of challenge and eventual invalidity.<sup>31</sup> Though the average nominal patent term has

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<sup>19</sup> Banerjee, *supra* note 8, at 208–10; Du, *supra* note 2, at 238–41.

<sup>20</sup> Banerjee, *supra* note 8, at 208–09.

<sup>21</sup> Du, *supra* note 2, at 239.

<sup>22</sup> Banerjee, *supra* note 8, at 208–09.

<sup>23</sup> See, *e.g.*, Du, *supra* note 2, at 239–41.

<sup>24</sup> Hemphill & Sampat, *supra* note 16; FTC, *supra* note 14, at iii–iv.

<sup>25</sup> Hemphill & Sampat, *supra* note 16.

<sup>26</sup> *Id.* at 620.

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

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

<sup>29</sup> *Id.* at 629 (explaining that for drugs that had both a patent to their active ingredient and a patent on a non-active ingredient [a secondary patent], the average nominal patent term added by the secondary patent is 1.9 years).

<sup>30</sup> Hemphill & Sampat, *supra* note 18, at 21 (stating of the patents challenged in the study, eighty percent were made against the patents covering the non-active ingredient).

<sup>31</sup> Hemphill & Sampat, *supra* note 16, at 633.

increased, the actual effective market life of a patent has remained stable.<sup>32</sup> This data suggests that generic firms challenge the weakest patents: those that occur after the original patent, extend nominal patent term, and cover a non-active ingredient of the original compound.

Even if a court eventually invalidates a secondary patent, a secondary patent can give a patent holder the benefits of a valid patent for an extended time, exposing several ways in which the strategy can negatively affect the patent system and society: First, evergreening creates an inefficiency in the legal system. Several aspects of the patent system effectively protect an invalid patent prior to and during the litigation process. For example, under the Hatch-Waxman Act, a secondary patent may trigger an automatic 30-month stay on generic approval and these 30-month stays can be layered by filing additional patents after a generic company files its paragraph IV certificate.<sup>33</sup> Additionally, under the “doctrine of equivalents,” the holder of a patent on a peripheral aspect of a drug may sue for infringement as if the infringement were made against the active ingredient in the drug.<sup>34</sup>

While courts typically invalidate secondary patents, the litigation can be expensive and potentially cost-prohibitive for a generic drug producer to pursue.<sup>35</sup> When determining whether or not to enter the market with a generic drug that is arguably already covered by a secondary patent, a generic drug producer’s choices are to pursue a “Paragraph IV certification,” risk releasing a generic version of the drug and being sued for patent infringement, or not enter the market.<sup>36</sup>

Litigating the validity of a patent can be intensive and time-consuming. For example, the expense of litigating a Paragraph IV challenge can be in the millions of dollars.<sup>37</sup> The length of time that litigation can take may also deter generic manufacturers from

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<sup>32</sup> Hemphill & Sampat, *supra* note 18, at 25.

<sup>33</sup> FTC, *supra* note 14, at 43–44.

<sup>34</sup> Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law’s Doctrine of Equivalents with the FDA’s Bioequivalence Requirement*, 66 SMU L. REV. 59, 104–06 (2013).

<sup>35</sup> Hemphill & Sampat, *supra* note 16, at 618.

<sup>36</sup> *Id.* (explaining that the Hatch-Waxman Act allows for a generic manufacturer to file an Abbreviated New Drug Application (ANDA) which contains a Paragraph IV certification that any number of the listed patents are invalid or will not be infringed by the generic’s entry into the market prior to the expiration of the drug’s patents).

<sup>37</sup> *Id.*

challenging pharmaceutical patents. By the time that the litigation is resolved, the secondary patent may have expired, essentially granting the effect of a valid patent to the non-generic drug producer.<sup>38</sup> Evergreening also allows for protection during the litigation process, a process which is structurally favorable to the patent holder.<sup>39</sup> Patent litigation in the pharmaceutical industry is notoriously risky and resource intensive, and it becomes more so where more patents and claims are involved.<sup>40</sup> The high risk of trying to litigate against those with systemic advantages eliminates potential challengers without the resources to wage multiyear patent battles.<sup>41</sup>

Second, evergreening may be contributing to inefficiencies in the patent application process. This problem stems in part from the fact that the USPTO is understaffed.<sup>42</sup> Consequently, there is currently a three-year backlog at the USPTO.<sup>43</sup> The combination of the USPTO being understaffed and the backlog can allow for patent approval that would otherwise not be granted after a perfunctory analysis, inflating the number of patents and allowing for abuse.<sup>44</sup> While evergreening is a problem that is inflated by the backlog at the USPTO, it may also be contributing to the problem, as developers file multiple frivolous patents in order to create a patent portfolio, thereby clogging an already overworked system.

Third, obstructing generic market entry keeps drug prices high and reduces access to important drugs.<sup>45</sup> Once a generic drug hits the market, consumers typically pay around twenty percent of the brand-name equivalent's cost.<sup>46</sup> The brand-name drug at issue in *Novartis*, for example, cost a consumer in India \$2,666 per month.<sup>47</sup> The

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<sup>38</sup> FTC, *supra* note 14, at 14–15.

<sup>39</sup> See, e.g., 35 U.S.C. § 282 (2012).

<sup>40</sup> Kapczynski, Park & Sampat, *supra* note 17, at 8.

<sup>41</sup> *Id.*

<sup>42</sup> Richard Posner, *Why there are too many patents in America*, THE ATLANTIC (July 12, 2012), <http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/>.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> See *Novartis AG v. Union of India & Ors.*, (Apr. 1, 2013) SCR, Civil appeal No. 2728 (India).

<sup>46</sup> Nadia, *The Clinical and Financial Value of Evergreened Drugs*, MEDTIPSTER (Aug. 31, 2011), <http://www.medtipster.com/blog/?p=720>.

<sup>47</sup> *Novartis AG v. Union of India & Ors.*, (Apr. 1, 2013) SCR, Civil appeal No. 2728 (India).

generic equivalent in India would cost the same consumer between \$177 and \$266 per month.<sup>48</sup>

Alternatively, some commenters argue that patent holders should be allowed to evergreen in an effort to recoup the high cost of developing a drug.<sup>49</sup> This argument rests on the premise that because the Hatch-Waxman Act has promoted generic market entry, pharmaceutical innovation has decreased, and development costs continue to rise.<sup>50</sup> It is true that a drug's patent term often partially expires while the drug is within the FDA testing phase.<sup>51</sup> And a large portion of development costs for a pharmaceutical are incurred in development and in testing and approval for sale by the FDA, all of which occurs before the drug enters the market.<sup>52</sup> Another cost that a pharmaceutical developer must bear are services that pharmaceutical companies must provide in addition to the actual production of the drug: the first entrants in the market are tasked with educating physicians on the drug and safety and efficacy testing.<sup>53</sup> Therefore, evergreening strategies are an important element of a developer's attempt to recoup costs, which in turn could further innovation by providing the funds necessary for future development.<sup>54</sup>

Several responses indicate that this argument may not be entirely compelling. First, evergreening reduces certainty to consumers who lack the means to afford brand-name drugs.<sup>55</sup> Because secondary patents are often frivolous, they are susceptible to challenge.<sup>56</sup> Whether or not this challenge will occur necessarily determines the speed at which access can be given. Therefore, this system of

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<sup>48</sup> *Id.*

<sup>49</sup> See Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 *FORDHAM INTELL. PROP. MED. & ENT. L.J.* 245.

<sup>50</sup> *Id.* at 260.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 267–68 (explaining that Big Brand Pharma must pay the cost of development, educating physicians, safety and testing efficacy, and the rising costs of products liability litigation while generics manufacturers do not).

<sup>54</sup> *Id.* at 272.

<sup>55</sup> See Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 *COLUM. L. REV.* 1788, 1819 (2011).

<sup>56</sup> Kapczynski, Park & Sampat, *supra* note 17, at 7–8.

strategies decreases the predictability to the end user of when a drug will be available.<sup>57</sup>

Second, if the problem truly lies in the need for additional time to recoup development expenses, then this strategy is not the proper solution. The Hatch-Waxman Act allows for a five-year patent term extension in order to compensate for testing, allowing for a pharmaceutical patent's term to extend to fourteen years from FDA approval for marketing.<sup>58</sup> Granted, this is three years less than the average effective patent life of other science and technology advancements and does not allow enough time for the vast majority of drugs to make profits during the initial patent term.<sup>59</sup>

Third, evergreening contravenes a primary purpose for protecting patents. Spurring innovation is one of the goals of protecting patents.<sup>60</sup> As noted above, a majority of the time the secondary patents do not actually advance innovation because the core compound that the patent covers is virtually the same as the original patent.<sup>61</sup> Essentially, patent layering allows for some protection with an incremental advancement on the original product, at best.<sup>62</sup>

Secondary patents are often frivolous and are invalidated upon challenge because they focus on the drug's peripheral aspects. While the necessity and appropriateness of the initial patent term is respected, the fact remains that our system allows secondary patents that may not actually advance a drug's efficacy—an additional patent may extend protection beyond the level of innovation that the patentee has actually brought to the industry.<sup>63</sup> Affording this

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<sup>57</sup> See Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1819 (2011).

<sup>58</sup> *Id.*; 35 U.S.C. § 156 (2013).

<sup>59</sup> Morris, *supra* note 49, at 268–69.

<sup>60</sup> William Fisher, *Theories of Intellectual Property*, NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 1 (Stephen Munzer ed., 2001).

<sup>61</sup> See Kapczynski, Park & Sampat, *supra* note 17, at 7–8.

<sup>62</sup> *See id.*

<sup>63</sup> Marc-Andrew Gagon & Joel Lerchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, PLOS MED. 5(1): e1, (2008) <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001>.

protection without advancement in the industry does not incentivize innovation; it merely allows for an end-run in the legal system.<sup>64</sup>

Because access to pharmaceuticals can literally be a matter of life and death for some patients, it is imperative that the law regulating pharmaceuticals be vigilantly analyzed and updated to make certain that they make sense in light of both the effect pharmaceuticals can have in patients' lives and the landscape facing pharmaceutical developers.

## II

### NOVARTIS AND THERAPEUTIC EFFICACY

Before India joined the TRIPS agreement, India recognized the right to claim a patent on “an invention for a substance itself intended for use, or capable of being used, as medicine or drug.”<sup>65</sup> Protection of this right was created by ordinance, but the ordinance would lapse.<sup>66</sup> India eventually codified these protections into law after the United States and several European nations filed actions with the World Trade Organization and India faced trade sanctions for noncompliance with TRIPS sections 70(8) and (9).<sup>67</sup> Under this pressure, India passed, albeit with rushed alterations, the Patents Act of 1970; however, the alterations in India's law contained a component not found United States patent law—section 3(d) of the Patents Act of 1970.

The Indian Supreme court, focusing on the purpose of section 3(d) in light of the history of patent law in India, found that a secondary patent is invalid unless it demonstrates an increase in therapeutic efficacy.<sup>68</sup> In *Novartis*, a drug developer sought to gain patent protection for the beta-crystalline form of imatinib mesylate,<sup>69</sup> a drug commonly known as Gleevec, which is used to treat leukemia.<sup>70</sup>

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<sup>64</sup> Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law's Doctrine of Equivalents with the FDA's Bioequivalence Requirement*, 66 SMU L. REV. 59, 104–06 (2013).

<sup>65</sup> *Novartis AG v. Union of India & Ors.*, (2013) SCR, Civil appeal No. 2728, 33 (India).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 94–96.

<sup>69</sup> *Id.* at 2–3.

<sup>70</sup> *Id.*

The original patent for Gleevec was found to be active in India in 2003, when exclusive marketing rights were granted to Novartis.<sup>71</sup> But Indian drug producers had entered the market with several generic forms of the drug during the time between its original patent and the implementation of changes to Indian law to create compliance with the TRIPS agreement.<sup>72</sup> The patent for Gleevec was filed in 1993 and a secondary patent was filed in 1998 for the beta crystalline form.<sup>73</sup> A similar application for a secondary patent was filed in the United States and approved after the Board of Patent Appeals overturned its rejection.<sup>74</sup> Thus, if the court had ruled on whether the patents were in existence during the infringement period, the court would have found violations.

However, the difference between Gleevec as imantib mesylate and its beta-crystalline form is a perfect example of a secondary patent that offers protection while only questionably advancing innovation in the field. Novartis identified three methods for producing the beta-crystalline form from the substance identified in the original patent claim.<sup>75</sup> The differences that Novartis' application claimed existed between the two forms were more beneficial flow properties, better thermodynamic stability, and lower hygroscopicity, all factors that made the beta-crystalline form "new" because it stored better and was easier to process.<sup>76</sup> Additionally, Novartis claimed the drug to be at least thirty percent more bioavailable.<sup>77</sup> However, there was no direct claim at any point in the application that the beta-crystalline form was superior to Gleevec as protected in the initial patent.<sup>78</sup> The court held that, essentially, the patent was made for an altered form of the drug that in no way altered the primary effect or substance in an innovative way.<sup>79</sup>

The Indian Supreme Court thus denied the secondary patent on several grounds. The first ground was that the beta-crystalline form was not a new product resulting from an invention beyond the initial

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<sup>71</sup> *Id.* at 96.

<sup>72</sup> *Id.* at 23.

<sup>73</sup> *Id.* at 7.

<sup>74</sup> *Id.* at 65–66.

<sup>75</sup> *Id.* at 3–5.

<sup>76</sup> *Id.* at 7.

<sup>77</sup> *Id.* at 87.

<sup>78</sup> *Id.* at 7.

<sup>79</sup> *See id.*

patent.<sup>80</sup> Therefore, it failed to meet the test of “invention” as laid out in section 2(1)(j) and section 2(1)(ja) of the Patents Act of 1970.<sup>81</sup> The court went on to explore the meaning and application of section 3(d) in this context.<sup>82</sup>

The Indian Supreme Court’s determination of section 3(d)’s purpose relied on the literal meaning of the text and the legislative history.<sup>83</sup> The court determined from debates during the passage of the amendments in 2005 that section 3(d)’s purposes are to prevent evergreening and to encourage incremental inventions.<sup>84</sup> The court relied heavily on Indian patent law’s historic reluctance to protect pharmaceutical patents and statements from the sponsoring minister to the 2005 amendment.<sup>85</sup> The court found that the minister’s following statement showed that evergreening was among the mischief to be remedied by the amendment:

In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of known process in a new product—these are exceptions, these will not be granted any patent—and substances obtained by a mere admixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents<sup>86</sup>

Once evergreening was determined to be a primary concern of the amendment, the *Novartis* court went about defining section 3(d)’s terms, particularly its requirement of enhanced efficacy.<sup>87</sup> “Efficacy” in section 3(d) refers to therapeutic efficacy.<sup>88</sup> The court first determined the threshold that a patent must meet in order for section 3(d) to apply.<sup>89</sup> This threshold is that (1) the second substance is a new form of previously known substance and (2) the efficacy of the first substance is known.<sup>90</sup> Once this threshold is triggered, the patent applicant must meet the standard as set forth in section 3(d). The text

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<sup>80</sup> *Id.* at 82.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 38.

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 40.

<sup>87</sup> *Id.* at 82–90.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 82.

<sup>90</sup> *Id.*

of the test in section 3(d) is as follows: “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 . . . [is not an invention within the meaning of the Act].”<sup>91</sup> This text is followed promptly by an explanatory section that reads:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of know substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.<sup>92</sup>

The court was clear that “efficacy” was the aspect of the substance that must be improved to pass the hurdle of filing a secondary pharmaceutical patent.<sup>93</sup> However, the court had to determine exactly what “efficacy” meant.

The court first used the dictionary meaning of the word: “efficacy” means “the ability to produce a desired or intended result.”<sup>94</sup> Therefore, the efficacy of the second substance would naturally depend on the purpose of the product under consideration. That means that in the pharmaceutical context, where drugs are aimed at curing diseases, the best measure of efficacy would be therapeutic efficacy.<sup>95</sup> The court next questioned how to determine one substance’s advantage over those of another substance in terms of therapeutic efficacy.<sup>96</sup> The court also determined that in light of the historic preference against evergreening, a court should consider efficacy narrowly.<sup>97</sup>

Within this inquiry, the court noted that when dealing with pharmaceutical substances certain properties coincide with the substance’s particular form.<sup>98</sup> For example, an alteration of a salt’s properties cannot be considered “invention” unless it alters the drug’s therapeutic effect.<sup>99</sup> Therefore, in certain circumstances, altering the substance’s form would increase its efficacy if the second substance

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<sup>91</sup> *Id.* at 90.

<sup>92</sup> *Id.*

<sup>93</sup> *See id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 90–91.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 91.

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

were more effective in curing the target disease. The court then determined that the second patent application was invalid because the applicant had demonstrated no evidence that the beta-crystalline form of Gleevec increased therapeutic efficacy.<sup>100</sup>

### III PHARMACEUTICAL PATENTS IN THE UNITED STATES

This Article requires also a brief discussion of pharmaceutical patent standards in the United States. First, this section will look at several rationales for protecting the market right. Second, the section will look at the judicially recognized purpose of the Intellectual Property Clause and its relationship to patent protection. An examination of the clause's purpose will necessarily direct a look at the current statutory standard. By setting this framework, the paper will advance an argument for how the concepts found in *Novartis* can assist in meaningful change to the U. S. patent system.

There are four primary approaches to understanding why we protect intellectual property.<sup>101</sup> These approaches are: (1) the utilitarian rationale, (2) the idea that people ought to be rewarded for the fruits of their labor, (3) the theory that intellectual property rights satisfy a fundamental human need, and (4) the aspirational theory—intellectual property rights should be protected in a manner that cultivates a just and attractive society.<sup>102</sup>

The first and fourth of these approaches underscore the potential downside of patent layering. The utilitarian rationale attempts to create balance between social need and market reality.<sup>103</sup> Under this rationale, the incentive to create is the exclusive market right.<sup>104</sup> The exclusive market right gives the inventor an opportunity to recoup the cost of developing the intellectual property.<sup>105</sup> This protection must be weighed against social utility.<sup>106</sup> As explained before, this balance is greatly tested by evergreening. And by looking at this issue using the aspirational theory as a lens, it is apparent that a practice that reduces

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<sup>100</sup> *Id.*

<sup>101</sup> Fisher, *supra* note 60.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

access to medicines, as the empirical data above suggests, should be carefully examined to ensure that our patent system does not over-privilege one group at the expense of the rest of society. As explained below, the motivation for protecting patent rights in the United States does not adhere strictly to any of the approaches.

The Constitution grants Congress the power to create laws “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>107</sup> The Intellectual Property Clause has been the subject of differing interpretations by the courts.

Despite the seeming lack of guidance in the language itself, over time the judiciary has provided insight into the Clause’s purpose. There are two primary competing interests that could be served by the “limited times” language, and courts have interpreted the Clause to protect both.<sup>108</sup> The first grants the inventor the exclusive right to the intellectual property, which promotes advancement by providing a monetary incentive.<sup>109</sup> The second interest is the introduction of the invention into the public domain—an introduction that promotes the clause’s purpose through establishing a higher baseline for inventors to work from.<sup>110</sup> However, the text does not discern which of the competing interests should be favored and, more importantly, provides little guidance on the limited nature of that right.<sup>111</sup>

Indeed, this statement was initially interpreted to mean that the promotion of science and the useful arts was best served by protecting individual property rights:

The securing to inventors of an exclusive right to their inventions, was deemed of so much importance, as a means of promoting the progress of science and the useful arts, that the Constitution has expressly delegated to Congress the power to secure such rights to them for a limited period. The inventor has, during this period, a property in his inventions: a property which is often of very great value, and of which the law intended to give him the absolute enjoyment and possession.<sup>112</sup>

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<sup>107</sup> U.S. CONST. art. 1, § 8, cl. 8.

<sup>108</sup> See *Ex Parte Wood & Brundage*, 22 U.S. 603, 608 (1824); see *Pennock v. Dialogue*, 27 U.S. 1, 23–24 (1829).

<sup>109</sup> See *Ex Parte Wood*, 22 U.S. 603, 608 (1824).

<sup>110</sup> See *Pennock v. Dialogue*, 27 U.S. 1, 23–24 (1829).

<sup>111</sup> See U.S. CONST. art. 1, § 8, cl. 8.

<sup>112</sup> *Ex Parte Wood*, 22 U.S. 603, 608 (1824).

Theoretically, granting an exclusive property right would incentivize innovation.

Just five years after the Court recognized an inventor's exclusive right to his or her intellectual property, the Court explored the value of introducing patented objects into the public domain.<sup>113</sup> In emphasizing the "limited period" language of the clause, Justice Story recognized a balance between the goals of "stimulating the efforts of genius" and promoting "the progress of science and useful arts," which Justice Story concluded can be achieved "by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible."<sup>114</sup> In recognizing this balance, Justice Story illuminates another potential manner in which patent laws can promote science and the useful arts: by limiting patent term length, new ideas will thereby enter the public domain and provide subsequent inventors with a heightened baseline from which to innovate.<sup>115</sup> Despite the Court's recognition of the "limited time" language requiring some limit, courts have declined to set such a limit, instead deferring to lawmakers.<sup>116</sup>

The U.S. Patent Act creates three primary requirements for patentability: the invention must be *useful*;<sup>117</sup> the invention must be *novel*;<sup>118</sup> and the invention must be *non-obvious*.<sup>119</sup> Of these statutory requirements, the novelty and non-obviousness requirements present

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<sup>113</sup> See *Pennock v. Dialogue*, 27 U.S. 1, 23–24 (1829).

<sup>114</sup> *Id.* at 19.

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

<sup>116</sup> *Id.*; see Thomas B. Nachbar, *Intellectual Property and Constitutional Norms*, 104 COLUM. L. REV. 272, 297, 325–28 (2004) (discussing judicial limits on the Intellectual Property Clause).

<sup>117</sup> 35 U.S.C. § 101 (1952) (explaining that an invention is "useful" if it provides some identifiable benefit and is capable of use); see *Bedford v. Hunt*, 3 F. Cas. 37, 37 (1817) (showing this requirement is not as important in the discussion presented in this paper because the patents in question are all likely useful).

<sup>118</sup> 35 U.S.C. § 102 (2015). (showing the "novelty" requirement exists to protect the public's right to use inventions that are already in the public domain. This is particularly complicated in the area of patent applications involving chemical compounds.). See also Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 932–58 (2011).

<sup>119</sup> 35 U.S.C. § 103 (1052) (explaining non-obviousness is satisfied if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains").

unique issues that can affect initial approval and/or a subsequent challenge of a pharmaceutical patent.<sup>120</sup>

Once a patent has been approved, courts are statutorily required to assume its validity.<sup>121</sup> This presumption places the burden on the challenger to prove that a patent is, for instance, non-obvious.<sup>122</sup> Combined with the fact that the U.S. Patent and Trademark Office is under-resourced, frivolous patents may be allowed to slip through, and there may be little *ex ante* incentive for a generic drug producer to attempt to enter the market.<sup>123</sup>

The Hatch-Waxman Act, however, altered the pharmaceutical patent landscape in 1983 and again in 2003, with the goal of increasing generic competition while also preserving incentives to innovate.<sup>124</sup> The Hatch-Waxman Act gave generics an easier and quicker method of market entry by incentivizing generic drug production.<sup>125</sup> For example, a generic manufacturer is allowed to use a developer's safety and efficacy data in seeking approval, and 180-day market exclusivity is granted to the first generic manufacturer to file an abbreviated new drug application (ANDA).<sup>126</sup> This was not allowed before the ANDA process established by the Hatch-Waxman Act.

The Hatch-Waxman Act, however, also works against generic market entry. The Act creates new wrinkles in the original patent life of a pharmaceutical.<sup>127</sup> For example, it allows for an extension of the original patent term for five years, provided that the total term does not exceed fourteen years from FDA approval to market.<sup>128</sup> Furthermore, there has been a correlation between evergreening

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<sup>120</sup> Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 932–58 (2011) (for a description of novelty challenges); Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*, 16 STAN. TECH. L. REV. 79 (2013) (for a description of the non-obviousness requirement).

<sup>121</sup> 35 U.S.C. § 282 (2012).

<sup>122</sup> *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 1359 (2007).

<sup>123</sup> Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 992 (2013); *see also* Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSP v. Teleflex*, 63 FOOD & DRUG L.J. 275, 286–89 (2008).

<sup>124</sup> Wendy H. Schacht, RL32377, CRS REPORT FOR CONGRESS THE “HATCH-WAXMAN” ACT: SELECTED PATENT-RELATED ISSUES, Apr. 1, 2002.

<sup>125</sup> *See* 21 U.S.C. § 355(j) (2016).

<sup>126</sup> *Id.*

<sup>127</sup> *See* 35 U.S.C. § 156 (2015).

<sup>128</sup> *Id.*

strategies and the implementation of the Hatch-Waxman Act, a fact suggesting that the amendments to prior patent law have actually caused the emergence of evergreening strategies.<sup>129</sup>

#### IV

##### A MODEST SUGGESTION FOR AN ALTERATION

The most recent large-scale adjustments to U.S. pharmaceutical patent law attempted to strike a balance between access to pharmaceuticals—in the form of incentives to generic drug manufacturers—and the incentive to develop drugs.<sup>130</sup> This alteration did not directly address evergreening; pharmaceutical patent law may need further alteration to eliminate this practice. There are several alterations that could be made to the patent laws that could eliminate patent layering, and any amendments should consider the addition of a provision similar to India's section 3(d).

The first change that could be made is the elimination of additional 30-month stays after a generic company has made a paragraph IV certification and the patent holder answers with an infringement suit.<sup>131</sup> A second addition to the patent system could be a right of action to challenge the validity of the secondary patent in the same proceeding as the infringement suit.<sup>132</sup> These changes would reduce the potential for abuse of the Hatch-Waxman Act's provisions without potentially stifling innovation. And, when combined with a standard similar to section 3(d), these changes could eliminate the additional protection afforded to secondary patents that would eventually be found invalid anyway.

Adopting an enhanced efficacy standard that would prevent patent protection for frivolous patents yet still afford it to those patents that are truly innovative proves a difficult task. Such an endeavor raises questions both of what the required showing for a patent holder would be and at what stage in the process the showing would have to be made. The showing required by *Novartis* is that the secondary patent manifests an increase in therapeutic efficacy over the prior

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<sup>129</sup> Hemphill & Sampat, *supra* note 16, at 619–20.

<sup>130</sup> FTC, *supra* note 14, at i.

<sup>131</sup> FTC, *supra* note 14, at iii–v.

<sup>132</sup> *Id.*

incantation.<sup>133</sup> This narrow interpretation of enhanced efficacy prioritizes the clinical outcome of the drug without considering protection for changes to the drug that improve it in other ways.<sup>134</sup> Even though it is narrow, this requirement is appropriate if the showing it requires occurs at the correct point in the litigation process.

If a generic producer makes a paragraph IV certification and a patent holder attempts to string additional 30-month stays together, either through a later filed patent or a version 2.0 of the drug, that patent holder should be required to make a showing, in front of the same court deciding the infringement suit, that the later filed patent has enhanced therapeutic efficacy. If the patent holder cannot produce evidence that the secondary patent does meet that requirement, then the additional 30-month stay should be denied.

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<sup>133</sup> *Novartis AG v. Union of India & Ors.*, (2013) SCR, Civil appeal No. 2728, 98-100 (India).

<sup>134</sup> *Du*, *supra* note 2, at 252.