

## NOTE

# PATENTS AND THE PHARMACEUTICAL INDUSTRY: CURBING THE ABUSIVE PRACTICES EMPLOYED BY BLOCKBUSTER DRUG COMPANIES TO PROLONG MARKET EXCLUSIVITY

*Kelley Chandler\**

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INTRODUCTION

Rising pharmaceutical drug prices, which place a substantial burden on consumers and the health care system as a whole, present an intractable problem in the modern economy.<sup>1</sup> These rising prices echo a fundamental challenge in the pharmaceutical space: the necessity of balancing the competing goals of incentivizing companies “to continue developing new treatments by providing sufficient exclusivity time on the market”<sup>2</sup> with “the needs of the public to have access to affordable treatment by allowing market competition to lower the cost of drugs.”<sup>3</sup> Patent law is at the heart of this challenge, as are strategies employed by brand drug companies to exploit the patent regime that are squarely at odds with “congressional judgement concerning the appropriate duration of patent rights.”<sup>4</sup> This paper will expound these strategies and suggest possible avenues to address them. Section I will provide an overview of patent law and its relationship to the pharmaceutical market and drug development. Section II will explain the Hatch-Waxman Act and its reverberating effects on the pharmaceutical market. Section III will propose potential ways to address the issues that have arisen as a consequence of the Hatch-Waxman Act and the patent law regime. Section IV will address counterarguments in support of the adequacy and desirability of the current system.

I. PATENT LAW, DRUG DEVELOPMENT, AND THE PHARMACEUTICAL MARKET

Understanding how patent law interacts with the pharmaceutical market and the new drug development is critical to understanding both the current challenges in the market and the strategies that brand companies use to gain (and keep) an advantage. Therefore, Part I will examine the process of how drugs are patented and developed, and the landscape prior to the Hatch-Waxman Act of 1984.

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<sup>1</sup> See Peter Loftus, *A Billionaire Pledges to Fight High Drug Prices, and the Industry Is Rattled*, WALL ST. J. (Oct. 21, 2018, 2:14 PM), <https://www.wsj.com/articles/a-billionaire-decided-to-fight-high-drug-prices-and-the-industry-is-rattled-1540145686>.

<sup>2</sup> JOANNA T. BROUGHER, *INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES: BALANCING INNOVATION AND THE PUBLIC’S HEALTH* 113 (2014).

<sup>3</sup> *Id.*

<sup>4</sup> See JOHN R. THOMAS, CONG. RES. SERV., R40917, *PATENT “EVERGREENING”*: ISSUES IN INNOVATION AND COMPETITION 1, 7 (2009).

### A. *Patent Law and Drug Development*

Patents are issued by the United States Patent and Trademark Office (USPTO) and each patent represents a property right in an invention that allows the inventor to enjoy market exclusivity in exchange for public disclosure.<sup>5</sup> Generally, a patent owner can expect a 20-year patent term beginning on the date of filing an application for a pharmaceutical drug.<sup>6</sup> However, the length of the patent term can vary based on the type of application and when the application was filed.<sup>7</sup> For example, utility patents filed on or after June 8, 1995 will enjoy a 20 year term from the earliest U.S. application, whereas those filed before this date may have 20 years from filing or 17 years from issuance.<sup>8</sup> Further, plant patents and design patents have 14 years from the date of issuance.<sup>9</sup> In each case, the patent term gives an exclusive time frame on the market in which no other companies can make, use, or sell the branded drug product.<sup>10</sup> Once the patent term expires, generic competitors are free to enter the market and compete with the brand company, which substantially restricts the amount of profits the brand company realizes.<sup>11</sup> This is especially important in the context of the pharmaceutical industry because studies have estimated the costs of researching, developing, and introducing new drugs to be close to \$1 billion—an estimate that may be conservative according to the Pharmaceutical Research and Manufacturers Association.<sup>12</sup> As a consequence, market exclusivity through patent protection is essential for a brand company to recoup its investment and to be incentivized to innovate to bring new drugs to market in the first place.<sup>13</sup>

Patent terms continue to be a growing concern for large pharmaceutical companies due to the high costs and the unique nature and length of the drug development process.<sup>14</sup> The Federal Food, Drug, and Cosmetic Act (FDCA) delegates authority to the Food and Drug Administration (FDA) to assess new drug products for safety and efficacy before the

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<sup>5</sup> Renu Lal, *Patents and Exclusivity*, FDA/CDER SBIA CHRON. 1 (May 19, 2015), <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf>.

<sup>6</sup> *Id.*

<sup>7</sup> *See* BROUGHER, *supra* note 2, at 116.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> BROUGHER, *supra* note 2, at 115.

<sup>11</sup> *See id.* at 116.

<sup>12</sup> *See* Richard G. Frank, Editorial, *New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 325, 325 (2003).

<sup>13</sup> *See* Brendan Murphy, *Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMEDICAL L. 37, 41–44 (2016).

<sup>14</sup> *See* BROUGHER, *supra* note 2, at 116.

drugs can be introduced on the U.S. market.<sup>15</sup> The FDA determines whether a product should be approved by analyzing a New Drug Application (NDA), which can take up to two years to complete.<sup>16</sup> However, in order to reach the point of submission of an NDA, a drug company must undergo an arduous amount of work.<sup>17</sup> First, the company must engage in discovery, which involves identifying molecules and manipulating their structure to yield a potential drug treatment.<sup>18</sup> Second, the company must conduct preclinical trials to establish a base level of legitimacy so that the FDA can determine whether the drug should move to the clinical stage.<sup>19</sup> Preclinical trials can run anywhere from three to six years depending on the molecules subject to testing.<sup>20</sup> Next, the drug company must submit an Investigational New Drug (IND) application to the FDA with the results of its preclinical trials, details about its new drug, and details about its subsequent plans to conduct clinical trials, and the FDA will either approve or deny its request to proceed to the clinical stage.<sup>21</sup> Clinical trials usually take around seven years and include four stages to test the drug's dose and safety in humans, effectiveness and side effects on large groups, and overall risk-benefit in a larger population.<sup>22</sup> The FDA reviews all NDAs for "a lack of substantial evidence that the drug will have the effect it purports or is represented to have."<sup>23</sup> At the final stages of the process, up to fifteen years may have passed, and a company's patent term—which has been running since the time of filing—is severely eroded.<sup>24</sup>

## B. History

Prior to the introduction of the Hatch Waxman Act in 1984, the pharmaceutical marketplace was largely governed by federal patent laws

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<sup>15</sup> *Id.* at 114. The 1962 Kefauver-Harris amendments to the FDCA added the "efficacy" requirement for approval of new drugs as a response to a Thalidomide issue which caused birth defects in infants. See Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 *FOOD & DRUG L.J.* 187, 187 (1999); see also *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN. (Aug. 29, 2019), <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history> [hereinafter *Milestones*].

<sup>16</sup> BROUGHER, *supra* note 2, at 115.

<sup>17</sup> See *id.*

<sup>18</sup> *Id.* at 114.

<sup>19</sup> *Id.* "This preclinical phase includes basic research experimentation, involving both animal and human models, to obtain preliminary efficacy, toxicity and pharmacokinetic information." *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 114–15.

<sup>22</sup> *Id.* at 115.

<sup>23</sup> 21 U.S.C. § 355(d) (2018).

<sup>24</sup> BROUGHER, *supra* note 2, at 115.

and the FDCA.<sup>25</sup> The requirements under the FDCA included long and expensive clinical trials and large wait times for approval.<sup>26</sup> This was especially burdensome for generic manufacturers, who had to duplicate the clinical processes that brand companies underwent in order to receive approval from the FDA, without the same ability charge a premium for a drug's novelty.<sup>27</sup> These challenges led to an environment where approximately 150 drugs on the market were "off-patent" with no low-cost generic equivalent to replace them.<sup>28</sup> Drugs in this group included some that the public are highly familiar with today, such as Valium and Motrin.<sup>29</sup>

The Court of Appeals for the Federal Circuit's decision in *Roche Products v. Bolar Pharmaceutical Co.* only exacerbated the issues plaguing generic market entry.<sup>30</sup> Prior to *Roche*, generic companies would conduct experiments with brand-name drugs before the brand's patent term expired in order to gather data for application to the FDA.<sup>31</sup> However, the Court in *Roche* refused to expand the "experimental use" defense and held that a generic company would infringe on a brand's patent where there were "unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business."<sup>32</sup> As Bolar argued, this holding had the effect of extending brand company monopolies under the FDCA "for an indefinite and substantial period of time while the FDA consider[ed] whether to grant a pre-marketing clearance" to generic companies.<sup>33</sup> If a generic company failed to gain clearance, it was required to wait until the brand drug's patent expiry to start the test trials required for approval.<sup>34</sup>

## II. HATCH-WAXMAN AND ITS IMPLICATIONS ON THE DRUG PATENT PROBLEM

Congress enacted Hatch-Waxman to address all of the pre-1984 issues that plagued the pharmaceutical market due to lack of generic entry and shrinking exclusivity periods for brand-name drug manufacturers.

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<sup>25</sup> Murphy, *supra* note 13, at 43.

<sup>26</sup> Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 298 (2015).

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

<sup>28</sup> H.R. REP. NO. 98-857, pt. 1, at 17 (1984).

<sup>29</sup> *Id.* Further, drugs such as Indocin and Dyazide (the tenth highest selling drug in the country at the time and the most widely used diuretic used to treat high blood pressure) were coming to the end of their patent term and ripe for a generic entrant. *Id.*

<sup>30</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>31</sup> See Kesselheim & Darrow, *supra* note 26, at 299.

<sup>32</sup> 733 F.2d at 863 (Fed. Cir. 1984).

<sup>33</sup> *Id.* at 864.

<sup>34</sup> See Kesselheim & Darrow, *supra* note 26, at 300.

Section II will give an overview of the Hatch-Waxman Act and its purpose. Additionally, it will examine some of the unintended consequences of the Hatch-Waxman Act in the pharmaceutical space in order to create a framework for understanding the challenges facing the pharmaceutical market today.

### A. *Background and Purpose of the Hatch-Waxman Act*

The Court of Appeals for the District of Columbia Circuit described the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act,<sup>35</sup> as a “product of compromise,” noting that it “emerged from Congress’ efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”<sup>36</sup> Put simply, the Act sought to:

[E]xpedit[e] the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without repeating the research done to prove them safe and effective. At the same time, the brand-name companies can apply for up to five years additional patent protection for the new medicines they developed to make up for time lost while their products were going through FDA’s approval process.<sup>37</sup>

As the costs of branded drugs and new drug development rise, bringing generic drugs to market in a timely fashion has been, and continues to be, an issue that pervades the pharmaceutical industry and the health care system as a public policy matter.<sup>38</sup> The FDA defines a generic drug as “a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use,”<sup>39</sup> before noting that the goal for drug similarity is to “demonstrate bio-equivalence, which means that a generic medicine works in the same

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<sup>35</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>36</sup> *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.D.C. 1990) (citing *Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988)).

<sup>37</sup> *Milestones*, *supra* note 15.

<sup>38</sup> See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* i (2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf). [hereinafter *FTC STUDY*].

<sup>39</sup> U.S. FOOD & DRUG ADMIN., *GENERIC DRUGS: QUESTIONS AND ANSWERS*, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/UCM100100.htm> (last updated June 1, 2018).

way and provides the same clinical benefit as its brand-name version.”<sup>40</sup> Because pharmaceutical expenditures increased rapidly, concern grew among consumers, healthcare providers, employers, and the government.<sup>41</sup>

Hatch-Waxman has been largely successful in remedying this situation by eliminating some of the hurdles that generics have to overcome and streamlining their path to market.<sup>42</sup>

Many would say that the Act is responsible for the modern generic drug industry by providing a safe harbor for generic companies and empowering them to file Abbreviated New Drug Applications (ANDA).<sup>43</sup> The safe harbor gives companies immunity from infringement “on account of making, using, offering to sell, or selling within the United States”<sup>44</sup> a product covered by a patent as long as it is done for the purpose of submitting “information under a Federal law which regulates the . . . sale of drugs.”<sup>45</sup> Thus, to combat the issue of the de facto patent term that brand companies enjoyed while generics waited to start a pre-market approval process with the FDA, the safe harbor empowers generics to start the approval process during the patent term in anticipation of entry immediately upon patent expiration.<sup>46</sup>

The ANDA allowed a generic manufacturer to simply establish sameness and bioequivalence, meaning that the active ingredients, dosage, strength, and route of administration match the brand drug<sup>47</sup> and the rate and extent of the absorption of the active ingredient are not significantly different.<sup>48</sup> Rather than repeating the entire NDA process, which includes long pre-clinical and clinical trials, ample time, and steep costs, the generic drug may simply file the ANDA with the appropriate FDA requirements<sup>49</sup> including Chemistry, Manufacturing and Controls (CMC)

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

<sup>41</sup> See FTC STUDY, *supra* note 38.

<sup>42</sup> Lisa B. Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, PRACTICAL LAW (2019), [https://www.westlaw.com/9-523-2397?transitionType=default&contextData=\(sc.Default\)&VR=3.0&RS=cbt1.0](https://www.westlaw.com/9-523-2397?transitionType=default&contextData=(sc.Default)&VR=3.0&RS=cbt1.0).

<sup>43</sup> See *id.*

<sup>44</sup> *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008).

<sup>45</sup> 35 U.S.C. § 271(e)(1) (2018).

<sup>46</sup> See *id.* Thus, the safe harbor incorporated in the Hatch-Waxman Act reversed the decision in *Roche*. See *Roche Products v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984).

<sup>47</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>48</sup> Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 594–95 (2003).

<sup>49</sup> See Murphy, *supra* note 13, at 46. But note that “[u]nder limited circumstances a generic product may have a different active ingredient, route of administration, dosage form, or strength. If any aspect of the generic product differs from the pioneer, the manufacturer must submit a suitability petition. A suitability petition cannot be approved, however, if the

information.<sup>50</sup> This effectively allows the generic company making the ANDA filing to “piggy-back[ ] on the brand’s NDA” which “[speeds up] the introduction of low-cost . . . drugs to market.”<sup>51</sup>

Although the bioequivalence pathway expedites the path to market for the generic drug companies, these contenders still had to consider the patents covering the brand-name drug in order to get FDA approval because the FDA does not approve generic drugs which infringe on a brand drug’s patent.<sup>52</sup> To provide information about the number and duration of patents on any given brand-name drug, the Hatch-Waxman Act and the FDA require brand manufacturers to submit the patent number and codes of their patents to be published in the Approved Drug Products with Therapeutic Equivalence Evaluations publication<sup>53</sup>, or the “Orange Book,” for reference by generic competitors.<sup>54</sup> Not only does this provide easy access for generic companies, but it also allows innovator companies to “protect and enforce” their patents.<sup>55</sup> Thus, the generic company seeking approval through an ANDA must certify to the FDA “to the best of [its] knowledge” that the brand drug to which its application pertains either: 1) does not have a filed patent; 2) has an expired patent; 3) will be expired when the generic intends to enter the market; or 4) that the patent covering the brand drug is invalid or that infringement will not follow from “manufacture, use, or sale” of the new generic drug.<sup>56</sup>

The most controversy has arisen around the so-called “Paragraph IV certification” due to disagreements between generic and brand manufacturers surrounding validity or noninfringement of the patent in question.<sup>57</sup> Once the generic company establishes its “opinion” that a patent on the innovator drug is invalid or will not be infringed, the legislation requires the generic company give the patent owner detailed notice of the

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difference would require studies to establish the safety or effectiveness of the generic product.” Weiswasser & Danzis, *supra* note 48, at 594.

<sup>50</sup> Weiswasser & Danzis, *supra* note 48, at 595. CMC information includes “(1) ‘a full list of articles used as components’ of the drug, (2) ‘a full statement of the composition’ of the drug, (3) a ‘full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of’ the drug, (4) samples of the drug and components as required by FDA, and (5) sample labeling.” *Id.* (citing 21 U.S.C. § 355(b)(1)(B)-(F) (2018)) (other citations omitted).

<sup>51</sup> Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–05 (2012) (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)).

<sup>52</sup> *Id.* at 405.

<sup>53</sup> See Weiswasser & Danzis, *supra* note 48, at 595.

<sup>54</sup> See *id.* The brand manufacturer must provide all patent information, including the patent on the main drug compound and any “method of use” patents to be listed in the Orange Book. See *id.*

<sup>55</sup> See *id.* at 599.

<sup>56</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>57</sup> Weiswasser & Danzis, *supra* note 48, at 600.



opinion and of the intent to move forward with approval and commercialization of the generic.<sup>58</sup> The giving of notice triggers constructive infringement and gives the brand the ability to file a lawsuit for patent infringement within forty-five days to trigger a thirty-month stay on approval of the generic.<sup>59</sup> However, “the patent or NDA holder does not forfeit its rights to sue for patent infringement under the Patent Act if it does not bring suit within this forty-five-day window. Rather, under the Hatch-Waxman Act, the patent or NDA holder loses only its rights to obtain the stay on FDA approval.”<sup>60</sup> The stay gives time for litigation to determine whether a patent is valid or not before a generic enters the market.<sup>61</sup> Further, as an incentive for generic companies to bear the costs of litigation and challenge the brand’s patent under Paragraph IV, Hatch-Waxman grants a 180-day market exclusivity to the first generic company to file an ANDA with this certification.<sup>62</sup> The addition of the ANDA pathway and the Paragraph IV certification have had the effect of “[d]eputizing generic manufacturers to break through the thicket of secondary patents surrounding the original patented molecule.”<sup>63</sup> These pathways sought to serve the important public policy goal of invalidating weak patents on peripheral aspects of a drug that would extend its patent life, without significant merit, in order to bring low cost drugs to market quickly.<sup>64</sup>

Brand companies also reap benefits through competition-free periods and the Patent Term Restoration section of the Hatch-Waxman Act.<sup>65</sup> First, the Act assures the brand manufacturers the ability to enjoy five years of market exclusivity to advertise and sell their new drugs, as well as recoup the massive expenditures from the development process.<sup>66</sup> Congress achieved this goal by mandating that no ANDAs would be subject to FDA review until the end of the five year window afforded to the innovator drug company.<sup>67</sup> Brands gained at least five years of exclusivity regardless of their drug’s patent timeline.<sup>68</sup> To be considered a truly “new chemical entity” under this provision of the act, a drug must “contain[ ] no active moiety that has been approved by FDA” in any other NDA submitted under section 505(b) of the Federal Food, Drug and Cos-

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<sup>58</sup> See 21 U.S.C. § 355(j)(2)(B) (2018).

<sup>59</sup> See Weiswasser & Danzis, *supra* note 48, at 600–01.

<sup>60</sup> *Id.* at 601.

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

<sup>62</sup> See *id.* at 603.

<sup>63</sup> See Kesselheim & Darrow, *supra* note 26, at 304.

<sup>64</sup> See *id.*

<sup>65</sup> See *id.* at 305–06.

<sup>66</sup> See *id.* at 305.

<sup>67</sup> See *id.*

<sup>68</sup> See BROUGHER, *supra* note 2, at 139.

metic Act.<sup>69</sup> Secondly, the Act provides that drug manufacturers may submit applications “for a drug, which includes an active ingredient . . . that has been approved in another application . . . if such application contain[ed] reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant.”<sup>70</sup> If these applications are approved, the FDA is precluded from approving any ANDA on that drug “before the expiration of three years from the date of the approval of the application.”<sup>71</sup> In other words, a brand company which makes changes to its marketed product by developing a new dosage, indication, or other form of the drug will be afforded three years of additional market exclusivity for that particular new indication in which no generic entrants may gain approval.<sup>72</sup> Lastly, Hatch-Waxman provides brand companies with longer patent terms to make up for lost time in the FDA process and clinical trials for any “patent which claim[s] a product, a method of using a product, or a method of manufacturing a product,”<sup>73</sup> so long as the patent hasn’t already been extended, and the term of the patent hasn’t expired before the application.<sup>74</sup> Brand companies are reimbursed in patent term for each day that the USPTO exceeds deadlines for prosecuting the patent, and for each day beyond three years from the day of filing that their patent sits awaiting approval.<sup>75</sup>

### B. *Unintended Implications of Hatch-Waxman on Drug Patents*

The Hatch-Waxman Act is largely considered a success in having championed generic entry in the pharmaceutical market, and some have claimed that the “robust generic drug industry owes its very existence to the Act.”<sup>76</sup> In 2012, eighty-four percent of all prescriptions dispensed

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<sup>69</sup> See 21 C.F.R. § 314.108(a) (1994). An active moiety is the underlying characteristic of the drug which ultimately drives its action in the human body. See 21 C.F.R. § 314.108(b) (1994).

<sup>70</sup> 21 U.S.C. § 355(c)(3)(E)(iii) (2018).

<sup>71</sup> See *id.*

<sup>72</sup> See BROUGHER, *supra* note 2, at 139. Note that a generic will still have access to approval for the previous version of the brand’s drug. *Id.* However, as Brougner makes sure to point out, generics often continue to be boxed out of the market during this time: “[t]his strategy is particularly useful when a drug changes its route of administration from being available only by prescription to being available over-the-counter. If the brand-name drug becomes available over-the-counter while generic drugs are only available by prescription, consumers are more likely to buy the over-the-counter brand-name drug rather than obtaining a prescription from their physicians. By being the first drug available over-the-counter, the 3-year exclusivity helps companies maintain a dominant position with consumers even following generic entry onto the market.” *Id.* at 122.

<sup>73</sup> 35 U.S.C. § 156(a) (2012).

<sup>74</sup> 35 U.S.C. § 156(a)(1)-(2) (2012). For specifics on the patent term extension, see 35 U.S.C. § 156(c) (2012).

<sup>75</sup> See BROUGHER, *supra* note 2, at 138.

<sup>76</sup> See Mossinghoff, *supra* note 15, at 194.

were generics,<sup>77</sup> compared to nineteen percent in 1984 (when Hatch-Waxman was first enacted), and forty-seven percent in 2002.<sup>78</sup> However, despite its general success, the Hatch-Waxman Act fostered its own unique set of unintended obstacles to generic entry<sup>79</sup> through incentivizing brand companies to create strategies to increase the patent life of their drugs.<sup>80</sup> Two of these strategies include “evergreening”<sup>81</sup> and “product hopping.”<sup>82</sup>

### 1. Evergreening

The practice of evergreening is described as “obtaining multiple patents that cover different aspects of the same product,” which has the effect of extending the patent term of the drug in question.<sup>83</sup> Evergreening may take the form of acquiring additional patents on the active ingredients, methods of manufacturing, formulations, or chemical intermediates of a drug, to name a few.<sup>84</sup> When a company first files a patent application on the active ingredient, its patent will be set to expire 20 years from the filing date.<sup>85</sup> However, if the company files an application for a secondary patent five years later based upon a secondary feature of the drug, such as an improved method of manufacturing, the approval of the secondary patent will prevent a generic company from using that method until the secondary patent expires.<sup>86</sup> The practical effect of this strategy is that a generic company seeking to enter the market will not be able to use the method of manufacture until the end of the *second* patent term, five years after the original patent term has expired.<sup>87</sup> Although a generic company is free to produce and sell the active ingredient once the patent on that ingredient expires, development of a generic drug is often difficult and costly without the ability to employ certain manufacturing methods.<sup>88</sup> In this way, brand companies build a “patent portfolio” around single drugs as a creative way to avoid surren-

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<sup>77</sup> Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES (Mar. 18, 2013), <https://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html>.

<sup>78</sup> FTC STUDY, *supra* note 38.

<sup>79</sup> See BROUGHER, *supra* note 2, at 157.

<sup>80</sup> See *id.* at 145.

<sup>81</sup> See THOMAS, *supra* note 4, at 7.

<sup>82</sup> See Arti K. Rai & Barak D. Richman, *A Preferable Path For Thwarting Pharmaceutical Product Hopping*, HEALTH AFF. BLOG (May 22, 2018), <https://www.healthaffairs.org/dof/10.1377/hblog20180522.408497/full/>.

<sup>83</sup> THOMAS, *supra* note 4, at 1.

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

<sup>85</sup> *Id.* at 4.

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

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

<sup>88</sup> BROUGHER, *supra* note 2, at 146.

dering market exclusivity due to primary patent expiration.<sup>89</sup> Studies show that evergreening has increased significantly since Hatch-Waxman passed.<sup>90</sup>

Features of a drug which are covered by a secondary patent are considered “peripheral”<sup>91</sup> and include things such as tablet coating or products produced from drug ingestion, dosages, or delivery routes.<sup>92</sup> For example, the patent application for the active ingredient of the drug Paxil, which is used to treat depression, was filed on December 17, 1974.<sup>93</sup> Of the several peripheral patent applications that were filed, the most recent patent was filed in 1998.<sup>94</sup> If a generic had not succeeded in Paragraph IV litigation in 2003, this would have given Paxil an additional sixteen years of patent term exclusivity beyond the initial 20 years.<sup>95</sup> Even given the generic challenger’s success, Paxil’s developers still enjoyed years of exclusivity beyond the original patent term due to their peripheral patents.<sup>96</sup> Similarly, peripheral patents on internal coatings for the heartburn drug, Prilosec, afforded the manufacturer extra market exclusivity.<sup>97</sup> Through strategically staggering patent applications on active drug ingredients and incremental drug improvements, a brand company can very “effectively extend the aggregate period of patent protection that applies to that product”<sup>98</sup> even where the patent is later invalidated.<sup>99</sup>

Another consequence of the Hatch-Waxman Act on evergreening practice was that brand companies were being granted multiple 30-month stays on generic approval by the FDA.<sup>100</sup> Before the generic’s approval, brands could acquire secondary patents and list them in the Orange Book, triggering an obligation for the generic to certify a challenge to the new patent and notify the brand of their intent to continue to market.<sup>101</sup> Because this notification provided the brand company with the right to initiate a lawsuit, companies could plan their patent applications strategi-

<sup>89</sup> THOMAS, *supra* note 4, at 4.

<sup>90</sup> See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 64 (2011).

<sup>91</sup> Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 313 (2015).

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

<sup>93</sup> *Id.* at 315; see also U.S. Patent No. 4,000,196 (filed Dec. 17, 1974).

<sup>94</sup> Ho, *supra* note 91, at 315; see also U.S. Patent No. 6,113,944 (filed June 30, 1998).

<sup>95</sup> Ho, *supra* note 91, at 315.

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

<sup>97</sup> *Id.*; see also U.S. Patent No. 4,786,505 (filed Apr. 20, 1987), U.S. Patent No. 4,853,230 (filed Apr. 20, 1987).

<sup>98</sup> THOMAS, *supra* note 4, at 7.

<sup>99</sup> Julian W. Marrs, Comment, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT’L L. 81, 85 (2016).

<sup>100</sup> THOMAS, *supra* note 4, at 6.

<sup>101</sup> *Id.*

cally in order to be able to file multiple lawsuits so as to trigger a new 30-month stay months after the existing 30-month stay began to run, giving the brand extra exclusivity through precluding generic approval at the FDA.<sup>102</sup> Congress addressed this issue in 2003 through an amendment to the Hatch-Waxman Act, known as the Medicare Modernization Act, which prohibits multiple 30-month stays.<sup>103</sup> Despite this change, evergreening remains a significant issue in the pharmaceutical space because secondary patents “remain enforceable proprietary rights against generic firms”<sup>104</sup> which “increase the infringement minefield that generics must navigate when bringing a product to market.”<sup>105</sup> The costs to society are rising drug prices and reduced access to necessary treatments.<sup>106</sup>

## 2. Product Hopping

A related strategy within the evergreening category is the practice of product hopping, which denotes the brand-company practice of making an incremental change to a blockbuster drug which will soon be facing patent expiry, “secur[ing] patents on that new formulation, and then discontinu[ing]” the first drug.<sup>107</sup> This takes place before any generics are on the market, and is usually combined with an aggressive marketing scheme in order to promote the new drug to consumers and physicians.<sup>108</sup> Once the new drug has permeated the market, people are less likely to switch again, even if a generic alternative becomes available.<sup>109</sup> Further, as Arti Rai and Barak Richman noted in their May 2018 article, because the new drug is not “therapeutically equivalent” to the old formation,

State-level drug substitution laws that allow pharmacists to substitute generic drugs prevent substitution of the generic version of Drug 1 for Drug 2 prescriptions. In short, patients . . . pay monopoly prices for a branded Drug 2 because there is no generic alternative, and the market for Drug 1 evaporates just as a generic becomes available.<sup>110</sup>

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

<sup>103</sup> Inderjit Singh Bansal et al., *Evergreening – A Controversial Issue in Pharma Milieu*, 14 J. INTELL. PROP. RTS. 299, 302 (2009).

<sup>104</sup> THOMAS, *supra* note 4, at 7.

<sup>105</sup> *Id.* at 8 (quoting Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275 (2008)).

<sup>106</sup> Marrs, *supra* note 99, at 86.

<sup>107</sup> Rai & Richman, *supra* note 82.

<sup>108</sup> Ho, *supra* note 91, at 317.

<sup>109</sup> *Id.*

<sup>110</sup> Rai & Richman, *supra* note 82.

Prilosec is a potent example of product hopping because the manufacturer successfully introduced an ostensibly new and improved version of Prilosec, widely known as “Nexium,” and influenced the market to “hop” before the patent expired on Prilosec.<sup>111</sup> Although Prilosec was not completely withdrawn from the market, the manufacturer switched it from the prescription market to the over-the-counter market, and pharmacists were not able to substitute generic Prilosec for prescription Nexium due to the fact that they were technically different.<sup>112</sup> While it is true that patients sometimes have the option to purchase the cheaper drug or the over-the-counter version when it remains on the market, the fact that pharmaceuticals represent a “unique market with noticeable information asymmetry” makes this much less likely.<sup>113</sup> Additionally, because doctors are not actually purchasing the drugs, cost considerations are often overlooked when they are writing prescriptions, and they may have other incentives that factor into their decisions.<sup>114</sup>

### 3. The New Business Model

Given the stakes, it is no surprise that brand pharmaceutical companies are increasingly turning to evergreening strategies to gobble up more market exclusivity for their blockbuster drugs.<sup>115</sup> In the year 2000 alone, Prilosec’s manufacturer, AstraZeneca, reported that the drug brought in \$6.3 billion,<sup>116</sup> which is a substantial percentage of their overall revenue of \$15.8 billion during that year.<sup>117</sup> Due to the sheer amount of revenue that brand-pharmaceutical companies stand to gain or lose, it is reasonable to conclude that there is a new business model that pervades the pharmaceutical market.<sup>118</sup> This model consists largely of evergreening and product hopping practices “turning out scores of minor variations, some of which become market blockbusters”<sup>119</sup> which then “generate steady profits throughout the ups and downs of blockbusters coming off patents.”<sup>120</sup> Notwithstanding that one of the goals of Hatch-Waxman was to spur brand companies to truly innovate and pioneer NCEs, only a minis-

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<sup>111</sup> Ho, *supra* note 91, at 319.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* at 320.

<sup>114</sup> *Id.* at 320–21. This is due to the fact that they are usually given studies conducted by the brand company and are the targets of multi-million dollar advertising campaigns. *Id.*

<sup>115</sup> Hemphill & Sampat, *supra* note 90, at 640.

<sup>116</sup> AstraZeneca, *Annual Report & Form 20-F 2000* 1, 8 (2001), <https://ddd.uab.cat/pub/infanu/40172/iaASTZENa2000ieng.pdf>.

<sup>117</sup> *Id.* at 1.

<sup>118</sup> See Donald Light & Joel Lexchin, *Pharmaceutical R&D: What do we get for all that money?*, 345 *BMJ* 22 (2012), <https://www.bmj.com/bmj/section-pdf/187604?path=/Bmj/345/7869/Analysis.full.pdf>.

<sup>119</sup> *Id.* at 23.

<sup>120</sup> *Id.*

cule percentage of brand company expenditures go towards researching new molecules.<sup>121</sup> However, it would seem that the Hatch-Waxman Act lead to a pharmaceutical market which now “depend[s] less on the breakthrough research that executives emphasize than on rational actors exploiting ever broader and longer patents and other government protections against normal free market competition.”<sup>122</sup> Contrary to Congressional intent, evergreening and product hopping issues have only been exacerbated in the post-Hatch-Waxman atmosphere.<sup>123</sup> It seems more and more that “when patent law realities are combined with . . . rational business decisions, all considerations point towards a focus on incremental drugs.”<sup>124</sup> Hence, the new business model.<sup>125</sup>

### III. PROPOSALS FOR COMBATTING THE DRUG PATENT PROBLEM

As discussed, patent law faces a unique problem in the pharmaceutical space. As such, unique solutions are needed to combat it. Section III will propose possible solutions to eliminate and/or mitigate the problem of evergreening practice and the new business model. It will also address potential counterarguments. Part A discusses cash prizes as an alternative for patents on incremental therapeutic advances, Part B discusses patent legislation that recognizes the particular nature of the pharmaceutical space, and Part C discusses reform at the USPTO.

#### A. *Cash Prizes in Lieu of Patents*

One possible solution to the problem of evergreening practice would be to employ a system that directly rewards pharmaceutical companies for benefits gained through incremental therapeutic variations to existing drugs.<sup>126</sup> Proponents of a system like this suggest that rewards be paid out of a “Pharmaceutical Innovation Fund” which would be largely financed through reduced government expenditures on patented drugs with monopoly pricing which persist due to evergreening.<sup>127</sup> This system would assign point values to innovations falling within certain categories, such as incremental advances in health or efficacy and cost-reducing innovations.<sup>128</sup> Based on estimates from 2004, government

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<sup>121</sup> *Id.* (noting that the “United States National Science Foundation and government reports indicate that companies have been spending only 1.3% of revenues on basic research to discover new molecules”).

<sup>122</sup> *Id.* at 24.

<sup>123</sup> See Hemphill & Sampat, *supra* note 90, at 640, for its conclusion.

<sup>124</sup> Ho, *supra* note 91, at 311.

<sup>125</sup> See Light & Lexchin, *supra* note 118.

<sup>126</sup> See Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation 1* (June 10, 2004) (unpublished draft).

<sup>127</sup> *Id.* at 1, 9.

<sup>128</sup> *Id.* at 9.

spending on pharmaceuticals was around \$80 billion dollars.<sup>129</sup> Decreasing yearly government expenditures on pharmaceutical drugs by making incremental advances with relatively trivial therapeutic value ineligible to receive patent protection would both allow generics to enter the market quickly and create an opportunity to reallocate savings into an innovation fund.<sup>130</sup> One of the most significant benefits of this proposal would be to “make the incentives to innovate proportional in a meaningful way to social value, since category awards give the drug registrant an award commensurate with the net benefit created by the drug.”<sup>131</sup> This is especially so because the current regime allows the brand to reap market exclusivity through patent protection that is grossly out of proportion to the contribution that the company has made to the public.<sup>132</sup> Awarding incremental innovation directly by employing cash prizes would advance the twin aims of the Hatch-Waxman Act by facilitating generic competition earlier and encouraging brand “quickly to innovate again.”<sup>133</sup> Direct prizes from a fund in exchange for incremental therapeutic advances would effectively incentivize brands to make changes in the most cost effective way possible, without creating an “evergreen” patent monopoly via which they could thwart the healthcare market.<sup>134</sup>

### B. *New Patent Legislation*<sup>135</sup>

Either new patent legislation or reform to existing legislation addressing the unique issues that plague the pharmaceutical space may be necessary. The premium prices that a patent owner can extract through the right to exclude others from making or selling a product is considered a necessary “social harm,” which is incurred in order to incentivize inventors to conduct and reveal useful innovations for the benefit of society.<sup>136</sup> This harm is then mitigated through the limited patent term.<sup>137</sup> However, the concept of “evergreening,” by definition, cuts against the

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<sup>129</sup> *Id.* at 13.

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 11.

<sup>132</sup> Marrs, *supra* note 99, at 88.

<sup>133</sup> Light & Lexchin, *supra* note 118, at 24.

<sup>134</sup> *Id.*

<sup>135</sup> On June 11, 2019, House Representatives Hakeem Jeffries and Doug Collins introduced the Terminating the Extension of Rights Misappropriated (TERM) Act, which amends 35 U.S.C. § 253 and purports to address the issue of evergreening through a strategy similar to the one employed by the India legislature, discussed below. *See* Press Release, Hakeem Jeffries, Representative, House of Representatives, Rep. Jeffries Introduces Bipartisan Legislation to Lower Skyrocketing Cost of Prescription Drugs (June 12, 2019), <https://jeffries.house.gov/media-center/press-releases/rep-jeffries-collins-introduce-bipartisan-legislation-to-lower>. If this becomes law, it could prove to be a promising step towards addressing the evergreening issue.

<sup>136</sup> Ho, *supra* note 91, at 304.

<sup>137</sup> *Id.* at 305.



limited patent term. Giving the same patent and period of protection to “important clinical breakthroughs” and changes that are simply “incremental” and “of little therapeutic importance”<sup>138</sup> frustrates the public policy goal of spurring innovation for general social value.<sup>139</sup> Further, it creates a path of least resistance and increases the likelihood that brand companies will focus exclusively on developing insignificant variations to existing drugs, especially where they are “able to rely on earlier clinical data to obtain regulatory approval for sale and thus substantially limit the usual time and cost to develop a truly new drug.”<sup>140</sup> Congress could adopt specific legislation with an eye towards addressing the problem of evergreening. For example, India’s legislature amended section 3(d) of the Patent Act to provide that discoveries that are merely “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” will not qualify as inventions.<sup>141</sup> While passing amendments similar to India’s to create a “statutory presumption against patentability of derivatives”<sup>142</sup> may address evergreening, an amendment that tailors specific standards for novelty and non-obviousness to be applied strictly to pharmaceutical patents may be necessary as well.<sup>143</sup>

### C. *Reform at the U.S. Patent and Trademark Office*

In their 2017 Policy Proposal, Michael D. Frakes and Melissa F. Wasserman recognize that because the USPTO “processes more than 500,000 patent applications a year,” it is unsurprising that there is an overwhelming backlog and invalid patents are being granted.<sup>144</sup> Frakes and Wasserman cite research suggesting certain aspects of Patent Office functioning inevitably cause the office to grant invalid patents.<sup>145</sup> First, because the Patent Office charges application fees which do not amount to the costs incurred in reviewing applications, the fee revenues do not meet operational demands and create incentives for the office to make up for costs elsewhere.<sup>146</sup> Many of the office’s other sources of revenue are conditioned on a patent being granted, so the writers “posit that when the Patent Office is unable to cover its operational costs through fees gener-

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<sup>138</sup> *Id.* at 312.

<sup>139</sup> *Id.* at 304.

<sup>140</sup> *Id.* at 312.

<sup>141</sup> THOMAS, *supra* note 4, at 11. *See also* The Patents (Amendment) Act, 2005, No. 15, § 3(d), Acts of Parliament, 2005 (India).

<sup>142</sup> THOMAS, *supra* note 4, at 11.

<sup>143</sup> *See* 35 U.S.C. §§102–103 (2012).

<sup>144</sup> MICHAEL D. FRAKES & MELISSA F. WASSERMAN, THE HAMILTON PROJECT, DECREASING THE PATENT OFFICE’S INCENTIVES TO GRANT INVALID PATENTS 1, 5 (2017).

<sup>145</sup> *Id.* at 5.

<sup>146</sup> *Id.* at 8.

ated at its current patent grant rate, it might grant additional patents, even if this means issuing more invalid patents, in an effort to generate additional fee income.”<sup>147</sup> Moreover, larger entities pay larger fees for patents, which means the granting of additional patents for the sake of generating revenues may be skewed towards patents for large companies.<sup>148</sup> Second, the office is inundated with repeat applications because there is no limitation on repeat filings after an initial rejection.<sup>149</sup> Therefore, one way for the Patent Office to alleviate the crushing burden of a growing backlog is to grant more patents.<sup>150</sup> Finally, constraints on time when examining applications lead to invalid patent grants because examiners are “in a weaker position to identify proper bases of rejections.”<sup>151</sup> This is a critical observation because a legal presumption of patent validity places the burden on the Patent Office to prove otherwise.<sup>152</sup>

The authors consistently note that these findings are “alarming because [they] suggest[ ] that factors other than the underlying quality of applications are affecting the . . . decision to allow patents.”<sup>153</sup> A 2002 study by the FTC highlighted the numerous amount of weak patents on the market through a finding that generic companies were successful in invalidating patents in 73 percent of Paragraph IV lawsuits.<sup>154</sup> While these observations are alarming for patent law in general, they are more detrimental in the pharmaceutical industry where there are potentially life-altering public health consequences.<sup>155</sup> Excessive patenting in the pharmaceutical space excludes generic competitors from the market at the expense of consumers accessing affordable treatments<sup>156</sup>—a problem which is only exacerbated by the coincidence of brand manufacturers submitting peripheral drug patent applications and Patent Office incentives which favor granting revenue generating patents to larger entities. This unfortunate combination results in a feedback loop, because while the problem of evergreening is exacerbated by flaws in the system at the

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<sup>147</sup> *Id.*

<sup>148</sup> *Id.* Based on the empirical studies conducted, the authors found that “[a]s theory predicts, the Patent Office does indeed grant patents at notably higher rates to large entities and applicants from high renewal rate technologies when it finds itself in a position of insufficient fee revenue.” *Id.* at 10.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* Note that due to the fact that less than 50% of the cost of patent evaluation is covered through application fees, “the Agency lacks the funds necessary to address the backlog of repeat filings through additional hiring efforts.” *Id.* at 10–11.

<sup>151</sup> *Id.* at 12.

<sup>152</sup> *Id.* at 11.

<sup>153</sup> *Id.*

<sup>154</sup> FTC STUDY, *supra* note 38, at vi.

<sup>155</sup> See Marrs, *supra* note 99.

<sup>156</sup> *Id.*

USPTO, flaws at the USPTO become more pronounced in part because of the influx of peripheral patent applications.<sup>157</sup>

Ultimately, the Frakes and Wasserman policy proposal concludes that reform should aim to make the Patent Office less reliant upon post-grant fees, limit repeat applications, and increase review time for patent examiners.<sup>158</sup> Making these reforms would help reign in rampant ever-green practice. If the office spent more time on pharmaceutical patents up front, the amount of invalid patents would decrease, and Paragraph IV lawsuits would decrease because they would no longer be necessary for a generic company to overcome a thicket of patents surrounding a brand drug in order to reach market. This approach is more desirable than using litigation as a vehicle to invalidate patents post-grant, especially given the issues that may arise in the context of Paragraph IV lawsuits.<sup>159</sup> Although others have suggested establishing more scrutiny by automatically “subject[ing] all Orange Book-listed patents to immediate re-examination by the PTO, where they would get a strong second look,”<sup>160</sup> the Frakes and Wasserman proposal would be more efficient because the Patent Office would simply spend more time reviewing the patents in the first instance. This would be a noteworthy step both for the patent space in general and towards meeting one of the twin objectives of the original Hatch-Waxman legislation.

#### IV. COUNTERARGUMENTS

The foregoing suggestions regarding the drug patent problem and evergreening practice raise several counterpoints worth addressing. Section IV will do so. Part A will discuss an argument about the adequacy and efficacy of current measures in place to deal with the patent problem. Part B will discuss an argument about the necessity of peripheral patents for fostering competition among pharmaceutical companies and an argument about reform as a disincentive to innovation.

##### A. *Adequacy of Current Measures Against Evergreening Strategy*

One argument against upsetting the status quo is that the current mechanisms available to challenge invalid patents are adequate and are doing their job. While Paragraph IV challenges made available by the Hatch-Waxman Act, and the new Inter Partes Review (IPR) proceedings

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<sup>157</sup> *Id.* at 86.

<sup>158</sup> FRAKES & WASSERMAN, *supra* note 144, at 13–15.

<sup>159</sup> For example, pay-for-delay settlements are a highly controversial scheme in the Paragraph IV context where generic manufacturers agree to surrender the market for an agreed upon period of time in exchange for a large settlement from a brand company. BROUGHER, *supra* note 2, at 149.

<sup>160</sup> C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, patent challenges, and effective market life in pharmaceuticals*, 31 J. HEALTH ECON. 327, 337 (2012).

made available through the America Invents Act of 2011<sup>161</sup> might currently be “society’s strongest defense against non-meritorious patents that would harm”<sup>162</sup> the market, this does not mean they are the best methods to defend against these patents. Paragraph IV challenges pioneered the generic market, and they have undoubtedly facilitated a “thorough-going second look at patents of doubtful merit.”<sup>163</sup> However, they nonetheless remain a wasteful and inefficient way to deal with patent invalidity because they are accompanied by “significant transaction costs.”<sup>164</sup> The “valuable commercial bounty” of six months of exclusivity awarded to the first generic company to challenge and invalidate a patent under this regime provides an indication of how significant transaction costs can be.<sup>165</sup> Moreover, there are “manifold opportunities to game the system,”<sup>166</sup> such as pay-for delay settlements and the misuse of the 30-month stay.<sup>167</sup>

IPR proceedings, which apparently created a quicker and cheaper route to invalidating a patent by way of administrative hearings in front of the Patent Trial and Appeal Board (PTAB), came with their own set of challenges.<sup>168</sup> Although the technology sector met IPR proceedings with enthusiasm because they vastly aided in dealing with “patent trolls,” the pharmaceutical industry again proved to be unique in its need for reform.<sup>169</sup> Because drug companies will often “face IPR challenges in addition to simultaneous suits in the federal courts,”<sup>170</sup> they are subject to a sort of “double jeopardy” which is inefficient and unnecessary.<sup>171</sup> Additionally, IPR proceedings have been a catalyst for questionable conduct among drug patent challengers and brand companies alike.<sup>172</sup> For example, hedge fund managers have exploited the IPR process as an inexpensive way of “publicizing patent challenges against pharmaceutical

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<sup>161</sup> See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 311 (2011).

<sup>162</sup> Hemphill & Sampat, *supra* note 160, at 337.

<sup>163</sup> Hemphill & Sampat, *supra* note 90, at 644.

<sup>164</sup> *Id.*

<sup>165</sup> Ho, *supra* note 91, at 322.

<sup>166</sup> Hemphill & Sampat, *supra* note 90, at 644.

<sup>167</sup> See BROUGHER, *supra* note 2, at 145.

<sup>168</sup> See Wayne Winegarden, *Fostering Innovation Requires Fixing the Patent System*, FORBES: ECONOSTATS (Nov. 1, 2017), <https://www.forbes.com/sites/econostats/2017/11/01/fostering-innovation-requires-fixing-the-patent-system/#2d1925182332>.

<sup>169</sup> *Id.*

<sup>170</sup> Meg Tirrell, *Here’s Why Apple, Big Pharma are Paying Close Attention to a Supreme Court Case Over a Fracking Patent*, CNBC (Nov. 27, 2017), <https://www.cnn.com/2017/11/27/supreme-court-case-could-deal-a-blow-to-mohawk-tribes-patent-plan.html>.

<sup>171</sup> Winegarden, *supra* note 168.

<sup>172</sup> See Tirrell, *supra* note 170.

companies while also betting against their shares.”<sup>173</sup> This practice involves filing a challenge against a company (regardless of merit) in order to short the company’s stock and financially benefit from the price decrease.<sup>174</sup> Brand manufacturers have responded to IPR proceedings and to the dubious behaviors of challengers by engaging in more of the same. The most outlandish case involves Allergan’s blockbuster drug Restasis.<sup>175</sup> Allergan transferred the Restasis patent rights to the Saint Regis Mohawk Tribe because Native American Tribes have sovereign immunity in the context of IPR proceedings.<sup>176</sup> The tribe then licensed the patent rights back to Allergan in exchange for a payment of 13.75 million dollars.<sup>177</sup> Even putting these blatant attempts to game the system aside, the reality is that both Paragraph IV suits and IPR challenges create “inefficienc[ies] in the legal system” by allowing secondary patent holders to be protected by an invalid patent before and during the litigation process.<sup>178</sup> Although these procedures were meant “to ensure that the public not be burdened by invalid patents,”<sup>179</sup> it would be less wasteful if the government addressed this issue by ensuring that truly invalid patents are not granted in the first place.

*B. Patent Protection on Peripheral Aspects of Drugs is Necessary for Real Advances, Recouping Costs, and Fostering Innovation*

Proponents of the current patent system argue that, because many advances in technology occur incrementally, peripheral patents incentivize innovation and provide value to the public.<sup>180</sup> While these arguments may be true for innovations which “cover advances that are of considerable medical significance,”<sup>181</sup> incentives to game the system still persist. The strategies proposed in this paper provide several options for addressing these challenges and are not meant to suggest that incremental changes should not be rewarded if they carry medical significance. Rather, the problem arises when “multiple patents that effectively cover the same marketed product . . . extend the aggregate period of patent

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<sup>173</sup> Joseph Walker & Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent, Short the Stock*, WALL ST. J. (Apr. 7, 2015, 7:24 PM), <https://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408>.

<sup>174</sup> See Wayne Winegarden, *Strike the Right Regulatory Balance to Promote Generic Medicines and Future Innovation*, FORBES: ECONOSTATS (Mar. 14, 2018), <https://www.forbes.com/sites/econostats/2018/03/14/strike-the-right-regulatory-balance-to-promote-generic-medicines-and-future-innovation/#1ee92621768e>.

<sup>175</sup> See Tirrell, *supra* note 170.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> Marrs, *supra* note 99, at 85.

<sup>179</sup> Ho, *supra* note 91, at 322.

<sup>180</sup> THOMAS, *supra* note 4, at 8.

<sup>181</sup> *Id.*

protection that applies to that product.”<sup>182</sup> Under any of the systems proposed, advances providing actual medical value to society would be amply rewarded, either through cash prizes or legitimate patents.

Further, many titans in the pharmaceutical industry cite the astronomical costs associated with research and development to urge the necessity of patent protection.<sup>183</sup> Here, the worry is that brand companies will discontinue their innovation if they are not able to recoup their costs through patent term exclusivity. However, evidence shows that brand companies are not truly innovating to begin with.<sup>184</sup> Compared to the “1.3% of revenues devoted to discovering new molecules,” independent analysis suggests that 25% of revenue is spent on promotions, which yields a “ratio of basic research to marketing of 1:19.”<sup>185</sup> It seems that because more resources are being allocated to patent and market existing drugs, removing weak peripheral patents may actually leave brand companies with no other option but true innovation to remain competitive. Moreover, “if ‘low quality’ patents are on innovations that do not require costly R&D (e.g., obvious changes to the drug) their elimination may not meaningfully affect R&D incentives.”<sup>186</sup> Lastly, evergreening practice detracts from true advancements and access to better treatment for consumers by making the availability of drugs unpredictable: “Because secondary patents are often frivolous, they are susceptible to challenge. Whether or not this challenge will occur necessarily determines the speed at which access can be given.”<sup>187</sup>

## CONCLUSION

As this Note has demonstrated, patent law in the pharmaceutical space presents unique challenges. Interactions between patent terms, the FDA, the drug development process, and the need for quality medical solutions create a complex dynamic which leads to uncertainty. This uncertainty makes it difficult to discern between solutions which might be effective, and solutions which will spawn new challenges where they so intently sought to eliminate old ones. Although Hatch-Waxman was a success in many ways, in other ways it has proven to frustrate the purposes behind its enactment. The suggestions presented here are a sound starting point for alleviating some of the burden plaguing the pharmaceutical market due to the misuse and misapplication of the patent laws. While there is no simple way forward, “it is imperative that the law regu-

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<sup>182</sup> *Id.* at 7.

<sup>183</sup> See Light & Lexchin, *supra* note 118, at 23.

<sup>184</sup> See *id.*

<sup>185</sup> *Id.* at 24.

<sup>186</sup> Hemphill & Sampat, *supra* note 160, at 337.

<sup>187</sup> Marrs, *supra* note 99, at 87.

lating pharmaceuticals be vigilantly analyzed.”<sup>188</sup> It can “literally be a matter of life and death.”<sup>189</sup>

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<sup>188</sup> *Id.* at 89.

<sup>189</sup> *Id.*

