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## Batten down the Hatch[es]! Restoring the Patent System's Role within the Pharmaceutical Industry

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# BATTEN DOWN THE HATCH[ES]! RESTORING THE PATENT SYSTEM'S ROLE WITHIN THE PHARMACEUTICAL INDUSTRY

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## INTRODUCTION

The early warning signs are often unclear. You may feel nauseous, clammy, short of breath after a particularly difficult workout. Then, as a severe chest pain migrates through your shoulders and to your jaw, its source becomes unmistakable; it is a heart attack. Cholesterol plaque obstructed coronary blood flow, which deprived your heart of much-needed oxygen. And despite daily exercise and a low-fat diet, predisposition to high cholesterol may be imminent if left untreated.<sup>1</sup>

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1. For more information regarding heart health, see *Heart Attack and Stroke Symptoms*, AM. HEART ASSOC., <https://www.heart.org/en/about-us/heart->

Cardiovascular disease kills more than 600,000 Americans each year.<sup>2</sup> That number accounts for one quarter of all deaths in the United States.<sup>3</sup> To combat heart disease, or any chronic disease, at-risk individuals take prescription medications daily.<sup>4</sup> And given the unsettling trend of pharmaceutical price increases, Americans often budget their expenses around prescription costs.<sup>5</sup>

Since 1998, Abbott has sold fenofibrate, a prescription drug used to treat high cholesterol levels, under the brand name Tricor.<sup>6</sup> Although Tricor's original patents expired years ago, Abbott dominated the fenofibrate drug market, accounting for three-quarters of all fenofibrate sales in 2009.<sup>7</sup> Despite several attempts, generic versions of fenofibrate, which studies suggested would save consumers 700 million dollars per year, remained unavailable throughout the early 2000s.<sup>8</sup> Through a series of minor reformulations and marketing tactics, Abbott maintained its market share without providing measurable benefits to patients who were prescribed Tricor for high cholesterol.<sup>9</sup>

As public salience of such tactics increases, Abbott's behavior appears to be the rule, not the exception.<sup>10</sup> The intersection of patent law and drug-safety regulation enables pharmaceutical companies to engage in anticompetitive behavior that deprives the public from

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attack-and-stroke-symptoms [<https://perma.cc/M2R4-W65B>] (last visited Apr. 25, 2020).

2. *Heart Disease Fact Sheet*, CTR. DISEASE CONTROL, [https://www.cdc.gov/heartdisease/docs/ConsumerEd\\_HeartDisease.pdf](https://www.cdc.gov/heartdisease/docs/ConsumerEd_HeartDisease.pdf) [<https://perma.cc/85HN-FT3U>].
3. *Id.*
4. *See generally Medications Used to Treat Heart Failure*, AM. HEART ASSOC., <https://www.heart.org/en/health-topics/heart-failure/treatment-options-for-heart-failure/medications-used-to-treat-heart-failure> [<https://perma.cc/CQ9N-D67L>] (last reviewed May 31, 2017).
5. *See, e.g.*, Carolyn Y. Johnson, *Why Treating Diabetes Keeps Getting More Expensive*, WASH. POST (Oct. 31, 2016, 10:25 PM), <https://www.washingtonpost.com/news/wonk/wp/2016/10/31/why-insulin-prices-have-kept-rising-for-95-years/> [<https://perma.cc/26YF-FB4J>].
6. Nicholas S. Downing et al., *How Abbott's Fenofibrate Franchise Avoided Generic Competition*, 172 ARCH INTERN MED. 724, 725 (2012).
7. *Id.* at 729.
8. *Id.* at 725.
9. *Id.*
10. *See, e.g.*, Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 22, 2016), <https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/#182159ba280c> [<https://perma.cc/Z486-SWJT>].

affordable prescription medication.<sup>11</sup> But before attempting to solve that problem, it is important to find and understand its source.

The Drug Price Competition and Patent Term Restoration Act,<sup>12</sup> colloquially known as the “Hatch-Waxman Act” (for its congressional sponsors), inserted America’s patent system into the core of the pharmaceutical industry. Enacted in 1984, the Hatch-Waxman Act sought to accomplish two main goals: (1) to lower drug costs by promoting generic market entry; and (2) to incentivize brand-name drug manufacturers to create innovative pharmaceutical products.<sup>13</sup> To the first end, the Hatch-Waxman Act lightened the regulatory burden for generic drugs seeking the Food and Drug Administration’s (FDA) approval while simultaneously encouraging generic manufacturers to challenge pioneer drug patents that would otherwise prevent generic competition.<sup>14</sup> Pioneer drug makers were given the benefit of a “Patent Term Readjustment” to lengthen the effective patent life of pioneer pharmaceutical compounds, extending their patent-provided legal monopoly.<sup>15</sup>

The Hatch-Waxman Act has remained basically unchanged since it was first enacted over three decades ago.<sup>16</sup> Notably, Congress and the FDA have not addressed many important issues created by the statutory scheme.<sup>17</sup> In turn, pioneer pharmaceutical manufacturers can manipulate that scheme to extend pioneer-drug-market exclusivity.<sup>18</sup> This strategic gaming of the Hatch-Waxman Act takes shape in various

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11. See Downing et al., *supra* note 6, at 725–26.
  12. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012), 35 U.S.C. §§ 156, 271, 282 (2012)).
  13. See Ashlee B. Mehl, *The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?*, 81 CHIKENT L. REV. 649, 650 (2006); Raymond J. Prince, *Pay-for-Delay: How Brand-Name and Generic Pharmaceutical Drug Companies Collude and Cost Consumer Billions*, 68 S.C. L. REV. 689 (2017).
  14. Mehl, *supra* note 13, at 653–54.
  15. *Id.* at 654.
  16. See Alyson L. Wooten, *FDA’s Hatch-Waxman Regulations Get a Long Overdue Update*, LEXOLOGY (Oct. 13, 2016), <https://www.lexology.com/library/detail.aspx?g=587095cc-6563-4d88-bcc4-0cf1ddcf1b56> (explaining that, prior to a new set of regulations enacted in 2016, the Hatch-Waxman Act regime had been “largely unchanged for over a decade”) [<https://perma.cc/TB99-P48H>].
  17. See *infra* Part IV (discussing Hatch-Waxman and its defects).
  18. See generally Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 NOTRE DAME J. LEG. 21 (2003).

forms—whether by “evergreening” pioneer drug patents, creating “authorized generics,” or promoting reverse settlements<sup>19</sup>—and often amounts to wasteful “rent-seeking” behavior.<sup>20</sup>

Unlike Hatch-Waxman’s relatively inert statutory scheme, the United States’ patent system is more dynamic now than ever. In 2011, the Leahy-Smith America Invents Act<sup>21</sup> (the “AIA”) introduced the most significant change in American patent law’s modern history. The AIA changed the United States from a “first-to-invent” system, to a “first-inventor-to-file” system.<sup>22</sup> Not only did the AIA abrogate some uncertainty in the United States’ patent system, it also helped bring the United States into alignment with a majority of foreign patent systems.<sup>23</sup> Moreover, the AIA introduced the *inter partes* review (“IPR”), a type of post-grant opposition proceeding where individuals can challenge granted patents in an administrative tribunal at the United States Patent and Trade Office (USPTO or the “Patent Office”).<sup>24</sup> IPR, as opposed to federal district court litigation, provides an expeditious means to determine the patentability of certain claims by mandating that the USPTO announces final disposition of the claims within eighteen months after instituting an IPR.<sup>25</sup> In effect, IPR works as a policing mechanism to ensure that the USPTO does not grant legal monopolies through “bad patents.”<sup>26</sup>

The importance of “good” patents is drastically understated.<sup>27</sup> Patent-law policy is germane to both utility and progress. Patents

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19. See *infra* Part IV(B).

20. Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 251–52 (1994).

21. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended at 35 U.S.C. §§ 1–390 (2012)).

22. Lee Petheridge et al., *America Invents, More or Less?*, 160 U. PENN. L. REV. 229, 230 (2012).

23. *Id.* at 235–36.

24. *Id.* at 234–35.

25. For an overview of IPR, see generally 35 U.S.C. § 311 (2012).

26. As discussed in Part II, examiners at the USPTO determine the patentability of claims within a patent application. While these examiners may have technical expertise, human error attributes to some patents being granted erroneously. Thus, IPR serves as a check on errors incurred during the patent examination process.

27. See, e.g., *International IP Commercialization Council U.S.A. Chapter's Symposium on Meeting the Challenges to America's Economic Future*, 67 CATH. U. L. REV. 605, 628 (2018) (Paul Michel, the former chief judge of the Court of Appeals for the Federal Circuit, “surmise[d]” that “many . . . good patents are being invalidated at the PTAB.”).

incentivize procompetitive behavior, focusing on both downstream, *ex post* conduct and upstream, *ex ante* conduct to maximize utility for all.<sup>28</sup> Patent law's general utilitarian framework, though embodied in a uniform patent code, is not a "one-size-fits-all" regime.<sup>29</sup> Rather, it embodies an incentives system that, while affecting each differently,<sup>30</sup> drives different industries all toward the same goals: advancing technology through invention, disseminating and disclosing new information, and securing innovative products for consumers.<sup>31</sup> That is why Hatch-Waxman's digression from nominally uniform patent law may also illuminate the Act's defects.<sup>32</sup>

This Note addresses how the Hatch-Waxman Act's unforeseen consequences conflict with contemporary patent-law policy. Part II details the relationship between the history of the patent system, fundamental patent law concepts, and contemporary rules governing patent law. Part III introduces pharmaceutical regulation in the United States and discusses the Hatch-Waxman Act's policy goals. Part III also explains the devices implemented by Hatch-Waxman to achieve its pronounced goals. Part IV describes Hatch-Waxman's effect on the pharmaceutical industry, including the anticompetitive behavior it induces. Finally, Part V first discusses how the Hatch-Waxman Act contradicts the policies discussed in Part II. It then concludes by suggesting that the AIA may have paved a way for realigning Hatch-Waxman with contemporary patent law policy.

## I. THE PATENT SYSTEM

### A. *The Fundamentals: Why We Patent*

Patent-law critics do not restrict their skepticism to pharmaceutical technology patents.<sup>33</sup> Nor do all legal skeptics believe that pharmaceutical patents are problematic.<sup>34</sup> The seemingly non-industry-specific disdain for the patent system is derived from society's

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28. See Daniel L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1586–87 (2003).

29. *Id.* at 1578, 1581.

30. *Id.* at 1580, 1675.

31. See *infra* Part II(A) and accompanying text.

32. See Burk & Lemley, *supra* note 28, at 1578–79.

33. See generally Dam, *supra* note 20.

34. Richard Posner, *Why There Are Too Many Patents in America*, THE ATLANTIC (July 12, 2012), <https://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/> [https://perma.cc/JQ4S-KJM9].

reservations regarding monopolistic behavior.<sup>35</sup> Section 2 of the Sherman Anti-Trust Act<sup>36</sup> expressly punishes individuals who “monopolize, or attempt to monopolize,” trade or interstate commerce.<sup>37</sup> This prohibition on monopolies is diametrically opposed to a patentee’s right to exclude, seemingly creating a patent–antitrust “paradox.”<sup>38</sup> Yet, patent law first principles—often misunderstood and more-frequently misapplied—provide guidance for reconciling the apparent doctrinal impasse: patents confer *legal* monopolies, not *economic* ones.<sup>39</sup>

Like other fundamental principles, patent-law doctrine has historic roots in the legal system. The Constitution’s Intellectual Property Clause gave Congress the power “[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>40</sup> Through this clause, the Framers recognized that an inventor’s “exclusive right” to his creations is fundamental.<sup>41</sup> So the First Congress quickly codified this right, enacting the Patent Act of 1790 as its third piece of legislation.<sup>42</sup>

In the following two centuries, Americans patented technology that led to the telegraph,<sup>43</sup> airplanes,<sup>44</sup> smartphones,<sup>45</sup> and virtual-reality devices.<sup>46</sup> And yet, despite rapid technological advances, the slow-

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35. See T. Randolph Beard et. al., *Quantifying the Cost of Substandard Patents: Some Preliminary Evidence*, 12 YALE J.L. & TECH. 240, 243–44 (2010).
36. Sherman Antitrust Act of 1890, ch. 647, 26 Stat. 209 (codified as amended at 15 U.S.C. §§ 1–7 (2012)).
37. 15 U.S.C. § 2 (2012).
38. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 762–63 (2002).
39. Neel U. Sukhatme, *Regulatory Monopoly and Differential Pricing in the Market for Patents*, 71 WASH. & LEE L. REV. 1855, 1857 (2014).
40. U.S. CONST. art. 1, § 1, cl. 8.
41. See, e.g., Rebecca A. Lindhorst, *Two-Stepping Through Alice’s Wasteland of Patent-Eligible Subject Matter: Why the Supreme Court Should Replace the Mayo/Alice Test*, 69 CASE. W. RES. L. REV. 731, 734–35 (2019); Gene Quinn, *Patents, Copyrights and the Constitution, Perfect Together*, IPWATCHDOG (Feb. 19, 2018) <http://www.ipwatchdog.com/2018/02/19/patents-copyrights-constitution/id=93941/> [<https://perma.cc/5KAF-DDSZ>].
42. CRAIG A. NARD, *THE LAW OF PATENTS* 20 (4th ed. 2016).
43. See *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 64 (1853).
44. E.g., U.S. Patent No. 821,393 (the Wright Brothers’ “flying machine”).
45. E.g., U.S. Patent No. 7,479,949 (Apple’s iPhone).
46. E.g., U.S. Patent No. 5,956,038.

handed legislature has done little to amend the law governing the proprietary nature of these discoveries. Indeed, there have been only three major amendments to the original patent act.<sup>47</sup> This paucity of patent-related legislation exemplifies the patent system's strength, not its perceived weakness.<sup>48</sup>

Judge Giles S. Rich, who helped draft the modern patent statute, articulated the justification for an enduring patent code during his famous 1964 Kettering Award speech.<sup>49</sup> "Before there were patents there were people,"<sup>50</sup> Judge Rich explains, and three economic and philosophical principles defining the person–patent relationship. First, "[H]ave-[N]ots" covet what "[H]aves" possess.<sup>51</sup> Second, without a patent system, the Have-Nots will copy the Haves if economically feasible.<sup>52</sup> Third, and perhaps most importantly, a monopoly of an in-demand good makes it possible for the monopoly owner to profit off that monopoly, which, absent demand, would be worthless.<sup>53</sup> Moreover, Judge Rich defied the notion that monopolies are inherently bad; rather, a "[m]onopoly is mere power. It is what is *done* with it that makes it good or bad."<sup>54</sup> Indeed, Judge Rich recognized that monopolies often have been put to good uses.<sup>55</sup> These axioms, which existed long before the Founders drafted the Intellectual Property Clause,<sup>56</sup> reveal the source of the enduring patent statute: human behavior. For it is human behavior—not technological advancement—that dictates whether monopolies will have positive or negative effects.

At its core, the patent system identifies the trouble presented by capitalizing information. Being inexhaustible and non-excludable,<sup>57</sup>

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47. See NARD, *supra* note 42, at 21–24 (explaining the history of the United States' patent system).
48. *Id.* at 6 (explaining that the patent code "can arguably be viewed as a common law enabling statute" which provides "ample room for courts to fill in" otherwise "elliptical" statutory provisions).
49. Giles S. Rich, *The Vague Concept of "Invention" as Replaced by § 103 of the 1952 Patent Act*, 14 FED. CIR. B.J. 147 (2004).
50. *Id.* at 149.
51. *Id.* at 151.
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.* at 148–51, 153 (explaining his maxims via Biblical passages, Ancient-Grecian philosophers, and the Victorian-era "Statute of Monopolies," the precursor to colonial patent law).
57. NARD, *supra* note 42, at 30 (adding that Thomas Jefferson once explained: "He who receives an idea from me, receives instruction himself without



economists classify information as a *public good*.<sup>58</sup> This creates issues of “free-riders,” or covetous Have-Nots, profiting from someone else’s creation. Put differently, absent a property right, an inventor would not be incentivized to derive a profit from his inventions. He would fear corporate competitors copying and industrializing the invention, against whom he would be unable to compete. Consequently, the inventor would not invent at all because the economic opportunity cost would exceed any profits he might gain by selling his invention.<sup>59</sup> Applying this logic *ad infinitum*, technological progress would stifle.<sup>60</sup>

To this end, the predominant patent rationale—the “*incentive to invent*”<sup>61</sup>—justifies a patent system that allows inventors to “internalize [their] externalities.”<sup>62</sup> That is, patents serve as vessels for inventors to profit (internalize) from their socially beneficial discoveries, now available to others (externalities). The opposite function, “externalizing internalities,” employs parallel reasoning: without a proverbial fence (patent) to protect his useful discoveries, the inventor cannot prevent copiers from pirating his ideas. He cannot recoup (externalize) his sweat equity (internalities) because the copier—who did not expend labor or resources to invent the invention—offers the stolen idea at a more consumer-friendly price.<sup>63</sup>

Concomitant with the incentive-to-invent theory, the *incentive to disclose* views patent prosecution as part of a social contract.<sup>64</sup> To obtain his limited monopoly, the inventor must disclose his discovery

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lessening mine; as he who lights his taper at mine, receives light without darkening me.”).

58. *Id.*

59. This dilemma is known as “Arrow’s Information Paradox.” Michael J. Burstein, *Exchanging Information without Intellectual Property*, 91 TEX. L. REV. 227, 228–29 (2012); see also Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (1962).

60. See Craig A. Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759, 771 (1999) (“The two distinctive features of public goods—inexhaustibility and nonexcludability—suggest that public goods will tend to be under produced, if produced at all, by the market.”).

61. NARD, *supra* note 42, at 34.

62. Harold Demsetz, *Towards a Theory of Property Rights*, 57 AM. ECON. REV. 347, 350.

63. NARD, *supra* note 42, at 34–35; see also Kenneth Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 247 (1994) (defining the free-rider problem as an “appropriability problem” that hinders innovation).

64. See NARD, *supra* note 42, at 35 (explaining that inventors must sufficiently disclose their inventions in return for patent rights).

to the public.<sup>65</sup> Assuming inventors seek patent protection for their inventions immediately upon creation—thereby disclosing the invention to the public—the public gains access to new information more readily in a patent system.<sup>66</sup> In turn, other inventors may develop further technological advancements from the newly revealed information.<sup>67</sup>

Finally, the incentive to innovate—the theory with the most explicit economic rationale<sup>68</sup>—justifies patents as providing a means for commercialization.<sup>69</sup> While the incentive to invent may encourage scientific advancement, innovation results when the invention reaches the consumer.<sup>70</sup> Colloquially described as “from [lab] bench to bedside,” innovation is the culmination of research and development, marketing, manufacturing, and distribution.<sup>71</sup> This theory dispels progress for progress’s sake; rather, it treats patents as a means for efficient coordination between various transacting parties.<sup>72</sup>

*B. The Modern Patent Statute: A Rich Vision for Incentive-Theory  
Jurisprudence*

As expressed in his Kettering Award speech, Judge Rich captured his patent-law philosophy in drafting the 1952 Patent Act.<sup>73</sup> Patent applicants must provide the USPTO with a written description of their inventions that enables a person skilled in the relevant technology to

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65. See *infra* notes 75–90 and accompanying text.
66. See NARD, *supra* note 42, at 35 (noting that trade-secrecy law contradicts the patent system’s disclosure function).
67. See generally Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010) (describing patents’ value in disseminating information).
68. See NARD, *supra* note 42, at 36.
69. See JOSEPH SCHUMPTER, CAPITALISM, SOCIALISM, AND DEMOCRACY 83 (1950) (delineating inventive activity from innovation, and positing that inventive activity is purely non-economic).
70. *Id.* at 84.
71. Constance E. Bagley & Christina D. Tvarno, *Pharmaceutical Public-Private Partnerships: Moving From the Bench to Bedside*, 4 HARV. BUS. L. REV. 373, 374 (2014). Burk and Lemley also recognize the “anticommons,” the theory that patenting creates innovation-inhibiting thickets. See Burk & Lemley, *supra* note 28, at 1611–12; see also Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).
72. Courts have long-understood the vital role that patents play in developing new technology, expressing hesitation to grant patents that are overly broad which would monopolize a set of ideas. See, e.g., *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1854).
73. Rich, *supra* note 49.

make and use the subject matter described in the application.<sup>74</sup> Following the written description, applicants must write “claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention.”<sup>75</sup> These claims must recite a novel, nonobvious, and useful invention.<sup>76</sup>

#### 1. The Patent Application and its Roles

A patent application comprises three core features: a specification, one or more figures, and claims.<sup>77</sup> The specification is a thesis-like description of the invention, generally providing context for the invention in view of the technology, which explains how to make or use the invention as further illustrated in the figures.<sup>78</sup> Claims denote the proprietary boundaries of the invention—the “fence” which signals the invention’s scope—as disclosed in the patent application.<sup>79</sup>

A specification that sufficiently describes the invention reinforces the incentive-to-disclose theory. Because the USPTO publishes patent applications eighteen months after filing,<sup>80</sup> a sufficiently descriptive disclosure allows other skilled inventors to develop new technologies from the subject application’s teachings.<sup>81</sup> Since applications rarely mature into grants within eighteen months,<sup>82</sup> or ever,<sup>83</sup> early publication leads to the public dissemination of new ideas.<sup>84</sup> Further, an application

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74. 35 U.S.C. § 112(a) (2012).

75. *Id.* § 112(b).

76. *Id.* §§ 101–03.

77. *Id.* § 111(a).

78. *See, e.g.*, U.S. Patent No. 7,479,949 (Apple’s iPhone).

79. *See* Nard, *supra* note 60, at 759 (“Patent law is about building fences. The demarcation of one’s proprietary interest is facilitated by requiring the inventor, when filing a patent application, to point out distinctly and with particularity what he regards as his invention.”).

80. 35 U.S.C. § 122(b) (2012).

81. *See* NARD, *supra* note 42, at 119 and accompanying text.

82. The USPTO takes an average of twenty-one months to grant a patent. *See How Long Does it Take to Get A Patent?*, ERIKSON LAW GROUP, <http://www.ericksonlawgroup.com/law/patents/patentfaq/how-long-does-it-take-to-get-a-patent/> [https://perma.cc/6S5L-S4TG] (last visited Apr. 25, 2020).

83. Some estimate that 2.3% of patent filings (roughly 100,000 applications) become abandoned. Michael Gzybowski, *IP in Depth: What Happens to Abandoned Patent Applications?*, CERAMIC INDUSTRY (Sept. 3, 2013), <https://www.ceramicindustry.com/articles/93441-ip-in-depth-what-happens-to-abandoned-patent-applications> [https://perma.cc/H65F-6ZCD].

84. *See* NARD, *supra* note 42, at 91 and accompanying text.

that does not issue and becomes “abandoned” still retains value. As applicants engage in a negotiation with the USPTO to obtain patent protection, failure to commercialize, applicant insolvency, and other reasons entirely unrelated to the application’s disclosure value may justify abandonment.<sup>85</sup> Abandoned applications still function as “prior-art” references, which can be cited against future applicants during patent prosecution, and their publication enshrines information so that it is not lost to the inventor’s fading memory.<sup>86</sup> Thus, disclosure, particularly “full, clear, concise” disclosure, preserves knowledge and consequently increases societal value.<sup>87</sup>

When the USPTO decides to issue a patent, the claims become the focus of the patent system’s disclosure function.<sup>88</sup> First, allowable claims “point out distinctly and with particularity” the subject-matter that circumscribes the patent’s scope.<sup>89</sup> By sequestering the formerly intangible fruits of the patentee’s intellectual labors, well-defined claims provide notice of what the inventor owns and what remains available to the public, thus preventing rent-seeking behavior and wasteful, duplicative research.<sup>90</sup> Second, claims must be sufficiently “enabled” by the specification so that one skilled in the art can make and use the claimed invention.<sup>91</sup> Patent law’s enablement requirement “keep[s] claim scope on a leash,” preventing overreaching inventors from obtaining the exclusive right to something without fulfilling their disclosure duty.<sup>92</sup>

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85. See Gzybowski, *supra* note 83 (explaining that waiting time and costs often result in abandonment).

86. See *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1854) (lamenting an over-broad claim: “when his patent expires, the public must apply to him to learn what it is”). See also Rich, *supra* note 49, at 147 (“The wrongly directed research that ends in a blind alley, if made known, may prevent another from making the same mistake.”).

87. 35 U.S.C. § 112(a) (2012).

88. See generally Nard, *supra* note 60, at 761 n.14, 795 (discussing the claims’ important notice function and suggesting that patent law should readdress the need for clear claim scope).

89. *Id.* at 759.

90. *Id.* at 759–60.

91. 35 U.S.C. § 112(a) (2012).

92. See Craig A. Nard, *Legal Fictions and the Role of Information in Patent Law*, 69 VAND. L. REV. 1517, 1532 (2016).

## 2. A Vague Concept of Invention: Strong Patents and the Notion of Good Monopolies

Novelty, nonobviousness, and utility are the *sine quibus non* of an invention's patentability, and thus, the bedrock of the patent system.<sup>93</sup> Inventions that fulfill these three<sup>94</sup> conditions are the ends which justify patent law's means. That does not suggest that an invention's patentability trumps the application requirements; quite the opposite: failing to satisfy either set of conditions bars the issuance of a patent.<sup>95</sup> Rather, a sufficiently disclosed discovery that is not novel, nonobvious, or useful provides no benefit to society.<sup>96</sup>

Whether an invention affords a "benefit" presupposes utility. Put differently, an invention's utility differs from its potential benefit because the former asks "does the invention operate as described?"<sup>97</sup> and the latter asks "what good does it accomplish?"<sup>98</sup> An inoperable invention necessarily lacks utility, and therefore it does not provide any inherent benefit. Further, "benefit" is a subjective guideline to which patent law remains mostly indifferent.<sup>99</sup> That said, a patent is not a "hunting license" under which inventors can delay others from developing nascent technologies.<sup>100</sup> Finally, unlike with novelty and nonobviousness, applicants enjoy the presumption of utility, which requires the USPTO to provide affirmative evidence of non-utility by a preponderance of the evidence.<sup>101</sup>

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93. Rich, *supra* note 49, at 156–57.

94. More patentability conditions exist, such as the subject-matter requirement, but these are the only three germane to this Note. *See generally* Lindhorst, *supra* note 41 (discussing the subject-matter requirement).

95. 35 U.S.C. § 151 (2012).

96. Rich, *supra* note 49, at 147, 158.

97. *See* USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.07(b) (9th ed., rev. 2018) (discussing utility requirement) [hereinafter MPEP]; *see also In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000) (creating the utility standard).

98. This latter question was considered under *Brenner v. Mason*, 383 U.S. 519, 534–35 (1966), but such a question is rarely analyzed by courts anymore. *See* MPEP, *supra* note 97, § 2107, for examination guidelines.

99. *Brenner*, 383 U.S. at 532–33.

100. *Id.* at 536.

101. *Cf.* MPEP, *supra* note 97, § 2107. Nascent technologies suffer utility rejections because their fields are not sufficiently established to determine whether they will work. *See Brenner*, 383 U.S. at 521–22 (describing technology ultimately lacking beneficial utility).

A truly “novel” invention is one that has never existed as claimed in the subject application.<sup>102</sup> Because humans have finite access to information, a “pure novelty” patent system cannot truly exist.<sup>103</sup> For example, an inventor seeking a patent would not suffer lack-of-novelty issues from a hobbyist’s prior, identical creation made unbeknownst to the rest of the world.<sup>104</sup> Instead, the Patent Office examiners determine novelty through prior-art references—typically previous patent applications, thesis papers, or other writings—which predate the invention’s creation or filing date.<sup>105</sup> Novelty is a historically low bar;<sup>106</sup> the prior art must disclose each element or limitation recited in an application’s claims to bar patenting for lack of novelty.<sup>107</sup> A four-legged chair would be novel in view of a three-legged chair, despite being otherwise identical.

That four-legged chair, however, may be considered *obvious* in view of the three-legged prior art. Section 103 of the patent code mandates that “[a] patent . . . may not be obtained . . . if . . . the claimed invention as a whole would have been obvious [in view of the prior art] . . . to a person having ordinary skill in the art to which the claimed invention pertains.”<sup>108</sup> Thus, if a person having ordinary skill in the art (“PHOSITA”) would consider the difference between a four-legged chair and a three-legged chair “obvious,” then the four-legged chair could not be patented.

Section 103 says very little about what makes novelty-defeating differences “obvious” to the invention as a whole.<sup>109</sup> Nor does § 103 define the hypothetical PHOSITA.<sup>110</sup> Instead, courts and tribunals must struggle through patent-law precedent to reach obviousness determinations, which was precisely the legislative intent behind the

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102. *Cf. Gayler v. Wilder*, 51 U.S. (10 How.) 477, 495–98 (1851) (holding that a previously known but forgotten invention did not invalidate a patent for the same “invention” independently created several years later).

103. *Id.* at 496–97.

104. *Id.* at 496–98.

105. *See infra* Parts II.B.2, II.C (AIA & novelty).

106. *Compare* MPEP, *supra* note 97, § 2131 (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”) (quoting *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)), *with* *Nard*, *supra* note 92, at 1525–26.

107. *See* MPEP, *supra* note 97, § 2131 (listing novelty examination guidelines).

108. 35 U.S.C. § 103 (2012).

109. *Rich*, *supra* note 49, at 160.

110. *Id.* at 157–58.

statute.<sup>111</sup> When determining obviousness, prior-art references provide the lens through which the PHOSITA looks. But first the court<sup>112</sup> must determine the correct prior art, how it differs from the claimed invention, and what level of skill is “ordinary” in the relevant technical field.<sup>113</sup> In determining “ordinary skill,” courts consider the inventor’s education level, the technology’s sophistication, and other similarly predicated contextual questions.<sup>114</sup> The PHOSITA is a legal fiction, tooled by the legislator, which gives courts the necessary flexibility to reach obviousness conclusions.<sup>115</sup>

There are countless other questions which § 103 raises but leaves for the courts to answer.<sup>116</sup> And courts undoubtedly fail to properly delineate what “obvious” truly means.<sup>117</sup> But obviousness’s vexatious nature, coupled with human error, do not undermine the patent system’s goal: to bring forth effort and reward those who succeed.<sup>118</sup> Independently required, patentability’s utility, novelty, and non-obviousness conditions determine *what* we should patent; their collective justifications determine *why*.<sup>119</sup>

To this end, Judge Rich provides the following illustrative historical accounts. In 1594, Galileo received a “privilege” for an irrigation system. Around the same time, the British monarch granted a monopoly to sell playing cards to one of her loyal supporters. Galileo’s “patent,” which he was entitled to monopolize, gave the public something *novel*—non-existent but for Galileo’s discovery. The Monarch’s subject achieved the opposite: his patent *took* from the

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111. *Id.* at 155–57.

112. Patent Office examiners and administrative law judges, though not technically Article III judges, also make these decisions. For administrative ease, fact-finding determinations made by “courts” duly applies to the Patent Office. *See generally* MPEP, *supra* note 97 (patent-examination guidelines).

113. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

114. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256–57 (Fed. Cir. 2007).

115. *See Nard*, *supra* note 92, at 1525–27 (describing the PHOSITA as “omniscient” for having access to all prior-known art).

116. *K.S.R. Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) is the standard currently used to determine obviousness. *See also* MPEP, *supra* note 97, §§ 2141–2145 (providing various examination guidelines to support or overcome obviousness rejections).

117. *See, e.g.*, Daralyn Durie & Mark Lemley, *A Realist Approach to the Obviousness of Inventions*, 50 WM. & MARY L. REV. 989, 994–99 (2008) (describing judicial treatment of obviousness under § 103).

118. Rich, *supra* note 49, at 147.

119. *Id.* at 148, 156–57.

public.<sup>120</sup> A “good” monopoly, therefore, must externalize something new for the monopolist to internalize its profits.

Before Galileo’s time, the pre-biblical Greeks granted to whomever cooked a “peculiar” and “excellent dish” monopolies that forbade others from making the dish for a year. The Greeks provided the year-long monopolies with the explicit intention of incentivizing greater culinary arts. If the dishes did not satisfy the statutory “excellency,” the monopoly retained no value. And so long as the monopolies did not take anything from the public, Judge Rich did not seem troubled by their existence.<sup>121</sup> To be sure, if the monopoly prevented others from refining the “peculiar” cooking method to create a palatable and worthy dish, the bad monopoly would intolerably stymie innovation.

Finally, Judge Rich details the conception of nonobviousness that evolved from the United States’ own jurisprudence. In *Hotchkiss v. Greenwood*,<sup>122</sup> the Supreme Court found that forming a doorknob by affixing a clay handle to a metal shank—a seemingly novel creation, despite both existing independently for centuries—lacked sufficient ingenuity to be a patentable improvement.<sup>123</sup> Germane to its reasoning, the Court stated that using clay instead of metal was “the work of the skillful mechanic, not that of the inventor.”<sup>124</sup> Thus, patents were not to be granted upon modifications made by a businessman in the “matter of course.”<sup>125</sup> To this end, obviousness protects against monopolizing modifications that would occur organically once the relevant prior art exists.<sup>126</sup> Put differently, requiring nonobviousness accomplishes more than preventing a monopoly on something the public already has, it incentivizes “those inventions which would not be disclosed . . . but for the inducement of the patent.”<sup>127</sup>

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120. *Id.* at 152–53.

121. *Id.* at 151–54.

122. 52 U.S. (11 How.) 248 (1851).

123. In this context, “improvement” referred to the clay handle’s resistance to cracking or deformation commonly observed in metal handles at the time. *Id.* at 266–67.

124. *Id.* at 267.

125. Rich, *supra* note 49, at 154.

126. NARD, *supra* note 42, at 329.

127. *Id.* (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966)).



*C. Patent System Failures and the Role of the America Invents Act*

Recent legislation, namely the AIA,<sup>128</sup> has brought the 1952 Patent Act into the twenty-first century by recognizing the need for a more unitary patent system in a global economy. In passing the AIA, Congress implemented legislation that not only aligned the United States' patent system with World Trade Organization member countries,<sup>129</sup> but also addressed dissonance between normative patent law under the 1952 Act and its underlying policy. Namely, the AIA transitioned the United States from a "first-to-invent" to a "first-inventor-to-file" patent system.<sup>130</sup> The AIA also created a post-grant oppositional IPR proceeding, where a third party can challenge patent claims as invalid for lacking novelty or nonobviousness.<sup>131</sup>

Under the 1952 Act, an inventor was entitled to a patent unless the invention was "known or used by others . . . before the invention thereof."<sup>132</sup> While the first filer of a patent application was presumed to be the inventor, that presumption was rebuttable upon a showing that the second applicant: (1) first conceived the invention; and (2) worked diligently in reducing the invention to practice.<sup>133</sup> This leads to a bizarre outcome if "early public disclosure [is] 'the linchpin of the patent system.'"<sup>134</sup> In some cases, disclosure plays second fiddle to conception of invention and diligent, though inefficient, work.<sup>135</sup>

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128. Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (codified at scattered sections of 15, 28, 35, 42, and 51 U.S.C. (2012)).
129. See Cristian Timmermann & Henk van den Belt, *Intellectual Property and Global Health: From Corporate Social Responsibility to the Access to Knowledge Movement*, 34 LIVERPOOL L. REV. 47 (2013).
130. See, e.g., Daniel J. Sherwinter & Patrick M. Boucher, *The America Invents Act*, 41 COLO. LAW. 47, 47 (2012).
131. 35 U.S.C. §§ 311–18 (2012).
132. *Id.* § 102(a) (2006) (amended 2011).
133. See *id.* § 102(g) (2006) (amended 2011), accord *Griffith v. Konamaru*, 816 F.2d 624 (Fed. Cir. 1987) (examining the latter applicant's justifications for delays and finding that applicant did not exercise "reasonable diligence"); see also Margo A. Bagley, *The Need for Speed (and Grace): Issues in a First-Inventor-to-File World*, 23 BERKELEY TECH. L.J. 1035, 1039 (2008) ("The second applicant . . . must show that not only was she the first to conceive the invention, but also that she diligently worked to reduce the invention to practice during the relevant time period.").
134. *Griffith*, 816 F.2d at 626 (quoting *Horwath v. Lee*, 564 F.2d 948, 950 (C.C.P.A. 1977)).
135. Some argue that, because priority disputes were so rare, there was no need to alter the system. See Bagley, *supra* note 133, at 1040 ("Many aspects of the [first-to-invent] patent procurement process involve uncertainty that a move to [first-inventor-to-file] will not eliminate."); see also Alexander

In contrast, the AIA's "first-inventor-to-file" system reinvigorates early public disclosure by ignoring such priority disputes.<sup>136</sup> The first-inventor-to-file distinction notes that the filer must have actually invented what he seeks to patent.<sup>137</sup> This distinction is important because the AIA adopted a pre-application "grace period" that enables disclosure of the invention without barring patenting.<sup>138</sup> When an inventor discloses his discovery via a sale or other public use, the AIA permits a one-year grace period before filing a patent application so that inventors may validate their invention's economic viability.<sup>139</sup> Accordingly, the AIA encourages prompt disclosure, limits waste of judicial or administrative resources used for interference proceedings, and avoids harmful, premature patent applications used to establish priority.<sup>140</sup>

IPR accomplishes a similar benefit by addressing the long-felt need<sup>141</sup> for expeditious review of "bad" patents.<sup>142</sup> The USPTO has the authority to institute an IPR when the petitioner demonstrates a "reasonable likelihood" that one or more challenged claims are invalid.<sup>143</sup> Petitioners can only challenge claims for lacking novelty or

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Poltorak, *First-to-File vs. First to Invent*, INTELL. PROP. TODAY, Apr. 2008, at 40 (discussing the differences between the first-to-invent and first-inventor-to-file systems), available at [http://www.generalpatent.com/ip\\_articles/Poltorak-IPToday-Apr2008.pdf](http://www.generalpatent.com/ip_articles/Poltorak-IPToday-Apr2008.pdf) [<https://perma.cc/X6JL-KS6S>].

136. *Cf.* 35 U.S.C. § 102(a)–(b) (2012) (describing prior art and bars to patenting); *cf. id.* § 135 (providing for derivation proceedings to determine whether "an individual named in an earlier application as the inventor or a joint inventor derived such invention from an individual named in the petitioner's application as the inventor or a joint inventor and, without authorization, the earlier application claiming such invention was filed.").
137. *See id.* § 102(b).
138. *See id.* § 102(a)–(b).
139. *Id.*; *see also* *Helsinn Healthcare v. Teva Pharm. USA Inc.*, 139 S. Ct. 628 (2019). In *Helsinn*, the Court was asked to determine whether the AIA changed the long-standing meaning of "on-sale" by including a catch-all provision at the end of the newly amended statute. The Court held that the catch-all provision does not modify the meaning of "on-sale" for purposes of the patent code. *Id.* at 633–34.
140. *But see* Poltorak, *supra* note 135, at 40–41 (discussing the concerns faced by individual inventors under the first-to-file systems).
141. *See* Nard, *supra* note 60, at 764 (proposing the implementation of *inter partes* proceedings twelve years before Congress enacted the AIA). Nard explains that the *inter partes* proceeding will help embolden "proprietary and competitive certainty ex ante." *Id.*
142. H.R. Rep. No. 112-98, at 39–40 (2011).
143. 35 U.S.C. § 314(a) (2012).

nonobviousness,<sup>144</sup> and the USPTO must render a final written decision on all claims challenged within eighteen months after instituting IPR.<sup>145</sup> By creating IPR procedures, the AIA ostensibly codified the need for timely patentability decisions for patents that would otherwise keep inventions from the public.<sup>146</sup> Unlike district court litigation—which often takes years,<sup>147</sup> but allows judges to hold patents invalid for any reason defined by the Patent Act and permits a finding of noninfringement<sup>148</sup>—IPR provides narrow grounds for invalidating patents that should never have been granted.<sup>149</sup>

## II. DRUG REGULATION & PATENT LAW: THE HATCH- WAXMAN ACT AND GENERIC COMPETITION

Despite being labeled as an “incentives system,” the Patent Act remains agnostic towards the actual monetary value of patented inventions.<sup>150</sup> A new, useful, and nonobvious invention is not guaranteed market success. Rather, it is the market that indicates which direction inventors should focus their efforts.<sup>151</sup> Consequently, some industries favor trade secrecy and early-market entry in lieu of patenting when the market signals a preference for rapid innovation.<sup>152</sup>

The pharmaceutical industry, however, favors patenting above all else.<sup>153</sup> Since the mid-1980s, studies have consistently illustrated that most pharmaceutical technologies would not exist but for the patent

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144. *Id.* § 311(b).

145. *Id.* § 316(a)(11); *see also* SAS Inst. v. Iancu, 138 S. Ct. 1348 (2018) (denying partial institution of IPR and also holding that the USPTO must institute IPR and render a written opinion on all claims challenged within the petition).

146. *See supra* Part II.B.

147. Joseph Berghammer & Charles Shifley, *The Basics of US Patent Litigation*, BANNER & WITCOFF (Oct. 1, 2002), [https://bannerwitcoff.com/media/\\_docs/library/articles/basiclit.pdf](https://bannerwitcoff.com/media/_docs/library/articles/basiclit.pdf) [<https://perma.cc/W5EQ-QUR2>].

148. 35 U.S.C. § 282(b) (2012).

149. H.R. Rep. No. 112-98, at 39–40 (2011).

150. NARD, *supra* note 42, at 2–3 (describing the patent system as a utilitarian, incentives-based regime).

151. *Id.* at 2.

152. *Id.* at 3–4, 4 n.15. Industries such as the chemical processing and high-technology Silicon Valley companies often favor trade secrecy above patents. *See id.* at 3.

153. *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986).

system.<sup>154</sup> This observation is a consequence of the Hatch-Waxman Act.<sup>155</sup>

*A. Pre-Hatch-Waxman Pharmaceutical Regulation*

Following the thalidomide birth-defect scare of the 1950s,<sup>156</sup> Congress amended the Food, Drug, and Cosmetic Act (FDCA)<sup>157</sup> to require that the FDA test drugs for safety and efficacy.<sup>158</sup> Under the 1962 amendments to the FDCA, pharmaceutical companies were required to conduct multi-phase clinical trials before the FDA could approve a new drug for marketing.<sup>159</sup> Pharmaceutical companies detailed the safety and efficacy studies in a New Drug Application (“NDA”), which the FDA would review before giving final approval.<sup>160</sup>

The 1962 FDCA Amendments unintentionally eroded the patent terms of pioneer drugs<sup>161</sup>—drugs protected by a New Chemical Entity (“NCE”).<sup>162</sup> Pioneer firms would patent an NCE to obtain priority as

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154. See Bhaven N. Sampat, *A Survey of Empirical Evidence on Patents and Innovation* 5 (Nat'l Bureau Econ. Research, Working Paper No. 25383, 2018) (noting that over 60% of pharmaceutical innovations are attributed solely to the existence of the patent system).

155. See *id.*

156. Michael Winerip, *The Death and Afterlife of Thalidomide*, N.Y. TIMES (Sept. 23, 2013), <https://www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html> [<https://perma.cc/HA3M-TLPV>].

157. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–95 (2012)).

158. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. §§ 301–81 (2012)).

159. Lisa C. Will, *Accelerated FDA Approval of Investigational New Drugs: Hope for Seriously Ill Patients*, 94 DICK. L. REV. 1037, 1039–41 (1990).

160. *Id.* at 1040.

161. Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003).

162. Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 23–24, 24 n.12 (2003); see also Ryan Timmins, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 216–17 (2015) (explaining the differences between small-molecule compounds, governed by Hatch-Waxman, and more recent legislation dedicated to “biologics,” therapeutic compounds such as insulin that cannot be made using ordinary methods). This Note addresses only small-molecule drugs. Furthermore, patents may cover aspects of a pharmaceutical product that are not the NCE. See *infra* Part IV(A)(ii).

first inventor,<sup>163</sup> but the new safety and efficacy requirements postponed pioneer drug sales by several years, cutting into the patent's seventeen-year exclusivity term.<sup>164</sup>

Conversely, generic drugs benefitted by the FDA's Abbreviated New Drug Application ("ANDA"), upon which generics could rely on a pioneer drug's safety and efficacy data for an expedited approval pathway.<sup>165</sup> Generic drugs would receive automatic approval if their ANDAs demonstrated "bioequivalency" with an approved pioneer.<sup>166</sup> ANDAs, however, applied only to pre-1962 pioneer drugs;<sup>167</sup> post-1962 generics were considered "new drugs," and generic manufacturers were required to submit supplemental data, similar to an NDA, before receiving FDA approval.<sup>168</sup> As a result, over 150 drugs with expired patents did not have any generic competition in 1984.<sup>169</sup>

#### *B. The Hatch-Waxman Act*

Congress passed the Hatch-Waxman Act in 1984 premised as a compromise between generics and pioneers. Specifically, the Act reflects "a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions."<sup>170</sup> To strike this balance,

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163. Notwithstanding the "first to invent" system under pre-AIA law, patent policy still favored early disclosure and dissemination of ideas. *See* *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1038 (Fed. Cir. 2001). For example, suppression or concealment of an invention could prevent an inventor from obtaining or enforcing a patent covering the concealed invention. *Id.* at 1035. Circumstantial evidence could lead to a reasonable inference of suppression or concealment if there was "an unreasonable delay in filing a patent application." *Id.* at 1038. In the pharmaceutical context, the delay period began once test results were "reasonably indicative of the desired [pharmacological] response." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996) (quoting *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980)). Importantly, any pharmacological response—irrespective of the drug's intended use or undiscovered properties—could trigger the delay period. *Id.*

164. *Powell-Bullock*, *supra* note 162, at 23–24.

165. *Weiswasser & Danis*, *supra* note 161, at 589.

166. *Id.*

167. *Id.*

168. *Id.* at 589–90.

169. H.R. Rep. No. 98-857, pt. 1 (1984); *see also* 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).

170. *Novo Nordisk A/S v. Caraco Pharma. Labs., Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010).

Congress relied on the patent system's incentives regime in an unprecedented commingling of two otherwise independent bodies of law.

Under the Hatch-Waxman Act, pioneers still must submit an NDA comprising the results of clinical trials for both safety and efficacy.<sup>171</sup> Pioneers must also include the information of any patent that may “*reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”<sup>172</sup> Once the FDA approves the NDA, the relevant patent information is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the “Orange Book.”<sup>173</sup> Patents listed there are subject to Patent Term Extensions.<sup>174</sup>

The Patent Term Extension was seen as a way to promote innovation,<sup>175</sup> and it directly addressed pioneer firms' complaints about the lengthy regulatory process that resulted from the 1962 Amendments to the FDCA.<sup>176</sup> Under both pre-AIA and current U.S. patent law, patents have a term of approximately seventeen years.<sup>177</sup> Prior to the 1962 Amendments, however, pioneer drugs enjoyed full patent terms—meaning that pioneers could profit from their drug without fearing generic competition for the patent's entire duration.<sup>178</sup> Under the current FDA requirements, clinical testing can stall drug approval for several years, and pioneer drugs cannot commercialize their patent until the FDA grants the NDA.<sup>179</sup> In the meantime, pioneers must still obtain patent protection because certain actions, including public use or offers

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171. Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 168–74 (2005) (describing the intricacies of the Orange Book and other Hatch-Waxman provisions).

172. 21 U.S.C. § 355(b)(1) (2000) (emphasis added).

173. Derzko, *supra* note 171, at 169.

174. 35 U.S.C. § 156 (2012).

175. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 62 (2009).

176. *Id.* at 44–46.

177. See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y, LAW, & ETHICS 717, 723 n.20 (2005).

178. See Carrier, *supra* note 175, at 44 (describing seventeen-year patent term for pre-AIA pharmaceutical patents).

179. See *id.* (describing how FDA approval of an application typically takes two years, and how clinical investigations for approval of new dosages and new uses of pre-existing drugs have a three-year period of exclusivity because of how long they take).

for sale, may constitute a patent-defeating event.<sup>180</sup> Thus, Patent Term Extensions allow pioneer drugs to reclaim effective patent terms by accounting for the amount of the patent's term spent in pre-market clinical testing and awaiting FDA approval.<sup>181</sup>

The Hatch-Waxman Act also overhauled the generic approval process and the use of ANDAs. Because anyone who “makes, uses, or sells” a patented invention infringes the patent, the Hatch-Waxman Act created an exception to generic companies preparing an ANDA.<sup>182</sup> Additionally, upon establishing bioequivalence<sup>183</sup> to an Orange Book-listed pioneer drug, the generic company must make at least one of the following four certifications: (1) there are no Orange Book patents for the pioneer counterpart; (2) the Orange Book patents are expired; (3) the Orange Book patents will be expired by the time the FDA approves the generic; or (4) the Orange Book patents are invalid or will not be infringed.<sup>184</sup>

The fourth listed certification, a “Paragraph IV” certification, constitutes an artificial infringement action and requires a pioneer drug manufacturer to commence an infringement action against the ANDA filer within forty-five days of receiving the required notice letter.<sup>185</sup> Otherwise, the FDA may approve the generic if the regulatory requirements are met.<sup>186</sup>

If the pioneer company commences an infringement action against the ANDA filer, the FDA must stay approval of the ANDA for thirty

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180. *See supra* note 139.

181. *See generally* 35 U.S.C. § 156 (2012) (setting out rules for patent-term extensions). *See also* Carrier, *supra* note 175, at 47.

182. 35 U.S.C. § 271(a) (2012) (“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.”); *see also* Roche v. Bolar, 733 F.2d 858 (Fed. Cir. 1984) (explaining that experimental-use exception does not apply to another's testing of a patented compound for FDA approval).

183. *See* 21 C.F.R. § 314.3 (2005) (defining “bioequivalency” generally as the “absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents . . . becomes available at the site of drug action”); *see also* Timothy O’Shea, *Debunking a Common Pharmacy Myth: The 80-125% Bioequivalence Rule*, PHARMACY TIMES (Aug. 6, 2016, 2:51 PM), <https://pharmacytimes.com/contributor/timothy-o-shea/2016/06/debunking-a-common-pharmacy-myth-the-80-125-bioequivalence-rule> [<https://perma.cc/5KPU-TYQ5>] (describing how the FDA conducts and analyzes bioequivalency studies).

184. 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

185. *Id.* §§ 355(j)(2)(iii), 271(e)(2).

186. *Id.* § 355(j)(5)(B)(iii).

months.<sup>187</sup> But if the ANDA filer prevails on a Paragraph IV certification, that generic enjoys 180 days of market exclusivity, during which the FDA cannot approve any other ANDAs.<sup>188</sup> This regulatory-exclusivity period forms a duopoly between the generic and pioneer, during which the generic attempts to maximize profits by offering its drug at a price marginally lower than the pioneer's.<sup>189</sup> As a result, generic sales made during the exclusivity period often account for a majority of the generic company's profits for the respective drug.<sup>190</sup>

Consumers, on the other hand, do not benefit from a successful Paragraph IV certification until after the generic's market exclusivity ends. Once that initial 180-day period expires, other generics can quickly enter the market without facing ANDA-related stays.<sup>191</sup> The increased competition thus results in lower prescription-drug prices for consumers.<sup>192</sup>

### III. THE EFFECTS OF HATCH-WAXMAN ON GENERIC AVAILABILITY AND ACCESS TO AFFORDABLE DRUGS

The Hatch-Waxman Act has succeeded in increasing generic availability. Only 18.6% of prescription drug sales were attributable to generics in 1984.<sup>193</sup> By 2010, studies indicated that generics accounted for 78% of all prescriptions.<sup>194</sup> Despite a persistent increase in generic availability, critics still lament the pharmaceutical industry's ability to

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187. *Id.*

188. *Id.* § 355(j)(5)(B)(iv)(I–II).

189. MARTIN VOET, *THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 123 (5th ed. 2016) (noting that the “single incentive” of market exclusivity, arising from a successful Paragraph IV certification, encourages generic firms to operate under the “law of averages”; that is, Paragraph IV certification success presumptively correlates to the number of challenges).

190. *Id.*

191. This assumes that the new generic “copies” the original ANDA filer and that the pioneer will not commence a frivolous law suit.

192. See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity*, 77 *ANTITRUST L.J.* 947, 954 (2011).

193. Xiangnong Wang, *Understanding Current Trends and Outcomes in Generic Drug Patent Litigation: An Empirical Investigation* 11 (June 27, 2012) (unpublished B.A. thesis, Stanford University), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2094545](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2094545) [<https://perma.cc/9AUN-778N>].

194. *Id.*



maintain market exclusivity well beyond the patent's original term.<sup>195</sup> And anticompetitive behaviors that inhibit generic entry—such as “evergreening,” authorized generics, and reverse settlements—rely on the Hatch-Waxman Act's contortion of the patent system to the public's detriment.

#### *A. Types of Anticompetitive Behavior*

Before proceeding, it is important to define anticompetitive behavior as something more than market exclusivity. For example, the 180-day generic-exclusivity period is not anticompetitive because consumers still benefit, even if only marginally, from newly-accessible generics. Instead, anticompetitive behavior in pharmaceutical marketing exhibits similar qualities to bad patents in that it takes away something useful from the public. Pioneer pharmaceutical companies exhibit anticompetitive behavior through several tactics, collectively referred to as “Pharmaceutical Life Cycle Management.”<sup>196</sup>

##### 1. Authorized Generics

“Authorized Generics” are pioneer drugs marketed under the guise of a generic name, often via a pioneer's licensing the drug to a third party.<sup>197</sup> Because the pioneer already received FDA approval for the licensed drug, Authorized Generics can compete with an ANDA generic during its 180-day exclusivity period.<sup>198</sup> Authorized Generics lower the ANDA generic's price and revenue—which pioneers contend is procompetitive—while undermining the purpose of the 180-day market exclusivity period.<sup>199</sup> Indeed, the Federal Trade Commission (FTC) acknowledged that generic companies *expect* pioneer firms to introduce Authorized Generics in response to a Paragraph IV certification.<sup>200</sup> The threat of Authorized Generics has even prevented generic companies

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195. See, e.g., Simon Wentworth, *Can Pharma Defend the Way it Defends Patents?*, LINKEDIN: PULSE (Mar. 3, 2019), <https://www.linkedin.com/pulse/can-pharma-defend-way-defends-patents-simon-wentworth/> [<https://perma.cc/HS7D-HMDF>]; see also *supra* notes 175–177 and accompanying text.

196. See VOET, *supra* note 189, at 1–6 (introducing life-cycle management and the role of the patent system).

197. FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 1 n.1 (2011).

198. *Id.* at 1.

199. *Id.*

200. *Id.* at 38.

from filing Paragraph IV certification—believing that litigation costs would exceed prospective profits.<sup>201</sup>

The use of Authorized Generics to discourage ANDA filings is the least explicit anticompetitive tactic exploited by pioneer firms. Empirical studies indicate that Authorized Generics have not affected ANDA filing rates in a meaningful way.<sup>202</sup> And the FTC suggests that Authorized Generics, absent other anticompetitive tactics, may benefit consumers by providing more competition during 180-day generic exclusivity periods.<sup>203</sup>

## 2. Evergreening

Through a practice referred to as “evergreening,” or “product hopping,”<sup>204</sup> pioneer firms leverage the patent system to extend their market exclusivity by patenting a drug’s different features as that new drug undergoes clinical trials.<sup>205</sup>

For example, in the NDA, a pioneer company may attempt to patent the drug’s active chemical compound.<sup>206</sup> If the FDA has never approved an NDA directed to that compound, the active chemical is dubbed an NCE.<sup>207</sup> Patents covering an expected NCE afford the best protection because they confer broad and strong exclusivity.<sup>208</sup> A common strategy is to first patent the *general* compound, broadly protecting the drug product irrespective of its use, formulation, or even

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201. *Id.* The FTC admits, however, that Authorized Generics may not deter some generic firms from filing Paragraph IV certifications. *Id.*

202. Hemphill & Lemley, *supra* note 192, at 982.

203. *See* FED. TRADE COMM’N, *supra* note 197, at 38.

204. *See* Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS’N J. E385 (2013) (describing pharmaceutical patent “evergreening” and its policy concerns); Gregory H. Jones et al., *Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD J. 1398, 1399 (2015) (explaining how state laws allow for “evergreening” or “product-hopping”). Abbot is explicitly mentioned as utilizing product-hopping, costing Americans approximately 700 million dollars per year for fenofibrate. *Id.*

205. VOET, *supra* note 189, at 160–62.

206. *Id.* at 160.

207. Hemphill & Lemley, *supra* note 192, at 982 n.144.

208. *Id.* (“In the case of new chemical entities (*drugs that contain no active ingredient previously approved by the FDA*), generic challengers must wait to submit an ANDA with a Paragraph IV certification until four years after the brand-name approval.”) (emphasis added). VOET, *supra* note 189, at 71–72.

quantity.<sup>209</sup> Then, a pioneer will patent the *particular* compound—usually a specific salt or ester of the original compound—that will become the active ingredient in the approved NCE.<sup>210</sup>

Additionally, an FDA-approved NCE confers a “data-exclusivity” period where ANDA filers cannot rely on the pioneer’s safety or efficacy data for approval.<sup>211</sup> The exclusivity period lasts at least four years and applies to all data related to the NCE, including trial-determined formulations and doses.<sup>212</sup>

As the NCE progresses through clinical trials, pioneer firms patent therapeutically-effective doses and formulations.<sup>213</sup> Likewise, pioneers may patent an NCE’s enantiomers—identically structured but mirror-image forms of a compound—or combination products, which include yet another off-patent compound.<sup>214</sup> Pioneers may also seek patent protection for alterations in drug delivery and drug synthesis.<sup>215</sup> But perhaps the most-common trend in follow-on innovation is the practice of reformulating drugs for sustained one-a-day administration.<sup>216</sup>

Patent evergreening is problematic because the societal benefits of follow-on patents do not justify their costs to consumers.<sup>217</sup> Follow-on patents are “weaker” and are likely obvious innovations made as a matter of course.<sup>218</sup> Because the FDA does not inquire into the strength of Orange Book patents, follow-on patents shift costs—namely,

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209. VOET, *supra* note 189, at 72; *see also* SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1311 (Fed. Cir. 2004) (finding unclaimed quantity of pharmaceutical compound did not render claim indefinite). *But see* Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 911 (2014) (“To tolerate imprecision . . . would diminish the definiteness requirement’s public-notice function and foster the innovation-discouraging ‘zone of uncertainty’”).

210. VOET, *supra* note 189, at 72.

211. *Id.* at 117.

212. Hemphill & Lemley, *supra* note 192, at 982 n.144 (citing 21 U.S.C. § 355(j)(5)(F)(ii) (2012)).

213. VOET, *supra* note 189, at 117–20.

214. Annabelle C. Fowler, Pharmaceutical Line Extensions in the United States 8–11 (unpublished manuscript), *available at* <https://www.nber.org/aging/valmed/WhitePaper-Fowler10.2017.pdf> [<https://perma.cc/QWC8-RB99>].

215. VOET, *supra* note 189, at 160–61.

216. *Id.*; *see also* TONY ELLERY & NEAL HANSEN, PHARMACEUTICAL LIFECYCLE MANAGEMENT: MAKING THE MOST OF EACH AND EVERY BRAND 116–18 (2012).

217. *See* Fowler, *supra* note 214, at 12–14 (outlining previous research regarding the strength of follow-on patents).

218. *Id.*; *see* NARD, *supra* note 42, at 329.

litigation costs—to generic companies while pioneers continue to collect their economic rent.<sup>219</sup>

Even if a generic prevails on a Paragraph IV certification, and invalidates a patent that blocked generic competition, state drug-product-substitution (“DPS”) laws create another barrier to generic entry. State DPS laws allow, or sometimes *require*, pharmacists to substitute pioneer drugs with the equivalent generic versions.<sup>220</sup> All fifty states have DPS laws that require the generic substitute to have the same therapeutic rating as the pioneer drug.<sup>221</sup> By making minor changes to the pioneer drug—i.e., reformulating a tablet as a capsule—the generic versions are no longer therapeutically equivalent.<sup>222</sup> Generics would then need to file a new ANDA to compete with the reformulated pioneer drug.<sup>223</sup>

### 3. Reverse Settlements

A reverse settlement occurs when a pioneer pays a generic company to delay market entry prompted by a Paragraph IV certification.<sup>224</sup> Because patent litigation is expensive and uncertain, pioneer and generic firms enter into reverse-settlement agreements to decrease both parties’ risks.<sup>225</sup> The pioneer maintains market exclusivity and the generic receives guaranteed revenue—both at the expense of the

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219. Fowler, *supra* note 214, at 4 (“[Follow-ons] do not require duplication of the R&D that was needed to develop the products active ingredient. Precisely because line extensions have the same active ingredient as an original product, line extensions and original products are typically in the same therapeutic class and are imperfect substitutes.”). Such behavior is the epitome of “rent seeking.” See Nard, *supra* note 60, at 768 n.42; see also VOET, *supra* note 189, at 158–59 (discussing the FTC’s view on evergreening).

220. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1017 (2010).

221. *Id.* at 1017–18.

222. Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 (2016) (defining “product-hopping” as “reformulating the product in a way that makes a generic version of the original product not substitutable”).

223. *Id.*

224. Carrier, *supra* note 220, at 1014.

225. *Id.*

public.<sup>226</sup> The increasing saliency of reverse settlements prompted the FTC to evaluate the types and harms of reverse settlements.<sup>227</sup>

According to a recent study, typical consumers might pay 1,400% more for drugs that would otherwise face generic competition but for reverse settlements.<sup>228</sup> Studies also indicate that reverse settlements take many forms.<sup>229</sup> For instance, a pioneer firm can pay a generic to delay market entry until after the Orange Book patents expire.<sup>230</sup> These so-called “pay-for-delay” settlements delay generic competition for an average of seventeen months, costing consumers billions each year.<sup>231</sup>

In 2013, the Supreme Court acknowledged the problems created by reverse-settlement agreements. In *FTC v. Actavis*,<sup>232</sup> the Court determined that reverse-settlement agreements may violate antitrust laws. The Court also found that patent law’s exclusionary principle does not shield a pioneer from antitrust liability.<sup>233</sup> In reaching these conclusions, the Court reasoned that reverse settlements delaying generic competition contradict the Hatch-Waxman Act’s purpose.<sup>234</sup> Notably, the Court *did not* suggest that reverse settlements are categorically unreasonable. Rather, the Court instructed district courts to employ a standard antitrust test—the “rule of reason” test—to punish actions that unreasonably restrict trade.<sup>235</sup> Germane to this finding, the Court noted that a presumption that the reverse settlement is unlawful applies only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and

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226. *Id.* (explaining that pioneers and generic firms align their interests through reverse settlements).

227. Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTEL. PROP. 249, 251 (2019); *see also* Raymond J. Prince, *Pay-for-Delay: How Brand-Name and Generic Pharmaceutical Drug Companies Collude and Cost Consumers Billions*, 68 S.C. L. REV. 689, 694–700 (2017) (conducting antitrust analysis of pay-for-delay settlements).

228. *See* GENERIC PHARM. ASS’N, 2016 GENERIC DRUG SAVINGS & ACCESS IN THE UNITED STATES REPORT 11 (2016), *available at* <https://www.gphaonline.org/media/generic-drug-savings-2016/index.html> [<https://perma.cc/83X7-96WF>].

229. Feldman & Misra, *supra* note 227, at 262.

230. *Id.* at 262–65 (discussing various pay-for-delay strategies).

231. *Id.* at 256–57.

232. 570 U.S. 136 (2013).

233. *Id.* at 147–48.

234. *Id.* at 152–53.

235. *Id.* at 159–160.

markets.”<sup>236</sup> Because the potential anticompetitive effect depends on multiple variables—including the payment’s size, its scope compared to future litigation costs, and the pioneer’s justification for the payment—the Court rejected the FTC’s burden-shifting argument.<sup>237</sup>

Following *Actavis*, the FTC identified three categories of reverse-payment settlements: (1) no restrictions on entry; (2) restrictions on entry plus compensation that constitutes potential pay-for-delay; and (3) restrictions on entry without explicit compensation.<sup>238</sup> The FTC does not clearly delineate these categories, prompting scholars to define an unnamed “Category X” to encompass agreements that do not fit neatly within any of the named categories.<sup>239</sup> Category X settlements include agreements that restrict generic entry without providing compensation—agreements comprising a “delay” without an explicit “pay.”<sup>240</sup> For instance, certain agreements may permit generic competition if the generic company agrees to pay royalty fees to the pioneer.<sup>241</sup> If the pioneer introduces an Authorized Generic, the royalty fee decreases.<sup>242</sup> Taken together, such reverse settlements would increase generic price—with the royalty fee diminishing the generic’s revenue—while simultaneously discouraging Authorized Generics that otherwise decrease drug costs. As some suggest, Category X settlements demonstrate that pioneers and generic firms are becoming more adept at disguising reverse settlements to escape antitrust scrutiny.<sup>243</sup> Even more troubling, Category X settlements have grown since the *Actavis* decision.<sup>244</sup>

#### *B. Parallel Behavior and the Patent System*

Critics on all sides lament the Hatch-Waxman Act’s shortcomings. Many contend that Congress should address the pharmaceutical-price crisis by enacting pro-generic legislation.<sup>245</sup> Others believe that Hatch-

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236. *Id.* at 159.

237. *Id.*

238. Feldman & Misra, *supra* note 227, at 263.

239. *Id.* at 264–65.

240. *Id.*

241. *Id.* at 265–66.

242. *Id.*

243. *Id.* at 265.

244. *Id.* at 264–65.

245. See, e.g., Jonathan Lapook, *Forced Switch? Drug Cos. Develop Maneuvers to Hinder Generic Competition*, CBS NEWS (Aug. 28, 2014, 8:40 PM), <https://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/> [https://perma.cc/QP64-KVUT] (interviewing

Waxman overcompensated by giving generic firms *too much* power.<sup>246</sup> In either case, the flaw is the same: the Act incentivizes profiteering. Moreover, Hatch-Waxman undermines incentives that the patent system otherwise encourages, namely, the incentives to invent, disclose, and innovate.

Hatch-Waxman undermines the incentive to invent by weakening patents. Patent Term Extensions do not sufficiently obviate regulatory delays. At most, Patent Term Extensions limit a pioneer's effective patent term to fourteen years.<sup>247</sup> Arrow's Paradox alludes to this precise issue—pioneer firms cannot adequately externalize their internalities without a sufficient right to exclude.<sup>248</sup> Because pharmaceutical research and development costs billions of dollars, which are often wasted if the FDA does not approve an NDA, pioneers rely on blockbuster drugs to compensate for other failed drug studies.<sup>249</sup> Accordingly, diminished patent terms decrease the value of such research.<sup>250</sup>

Similarly, the Hatch-Waxman Act neuters the incentive to innovate because the FDA's clerical role in Orange Book patents creates an implied preliminary injunction via a thirty-month ANDA stay. Evergreening and reverse payments encourage settlements, which, in turn, discourage generic competition.<sup>251</sup> To this end, Hatch-Waxman

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patients following forced-switch induced price hike, blaming pioneer firms for harming generic competition) [<https://perma.cc/QP64-KVUT>]; Center for Biosimilars, *House Passes CREATES, 2 Other Bills Targeting High Drug Prices*, CTR. BIOSIMILARS (May 29, 2019), <https://www.centerforbiosimilars.com/news/house-passes-creates-2-other-bills-targeting-high-drug-prices> [<https://perma.cc/K9DY-2CZ2>] (describing the Association of Accessible Medicines' support for the 2019 Creating and Restoring Equal Access to Equivalent Samples Act, which would permit generic drug developers to sue pioneer firms if the pioneer firms do not provide enough samples of a drug product for testing purposes).

246. *See generally* Emily M. Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 245 (2012) (taking the position that the Hatch-Waxman Act unduly harms pioneer firms).

247. *Compare* 35 U.S.C. § 156(c)(3) (2012) (limiting Patent Term Extensions to a 14-year maximum patent life), *with id.* § 154(a)(2) (stating that the patent grant “shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed”).

248. *See supra* text accompanying notes 57–63.

249. Morris, *supra* note 246, at 259 (further noting that only 30% of pioneer drugs' revenues turn a profit).

250. *Id.* at 257–59.

251. *See supra* Part IV.A.

often aligns pioneers' and generic firms' interests.<sup>252</sup> Thus, Hatch-Waxman incentivizes *legal* innovation to avoid antitrust laws, but it discourages less-certain scientific innovation.

Finally, Hatch-Waxman undercuts the incentive to disclose by offering pioneers exclusivity over certain data that they provide to the FDA.<sup>253</sup> These FDA-administered data rights have been referred to as “pseudo-patents” for the monopoly power they confer to pioneer brands.<sup>254</sup> For instance, pioneers may—as their patents expire—attempt to make a prescription medication available “over the counter.” To make that switch, pioneers must provide data to the FDA that demonstrates the safety and efficacy of over-the-counter use. Because the over-the-counter market essentially eviscerates the prescription market, the “pseudo-patent” further delays generic competition.<sup>255</sup> This entire process is susceptible to gamesmanship because data exclusivity runs independent of patent rights. And so pioneers are not incentivized to provide this data until later.<sup>256</sup>

#### IV. CORRECTING THE PHARMACEUTICAL INDUSTRY BY REALIGNING THE HATCH-WAXMAN ACT WITH CONTEMPORARY PATENT-LAW DOCTRINE

Understanding that the Hatch-Waxman Act's statutory scheme leads to anticompetitive behavior and absurd results,<sup>257</sup> Congress should enact legislation that encourages socially beneficial behavior on the part of both pioneer and generic firms. Admittedly, *ex ante* policy justifications struggle to address all downstream behaviors. That is why Congress should hesitate before distancing the pharmaceutical industry from the Patent Code—as others have suggested<sup>258</sup>—and instead use

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252. See Feldman & Misra, *supra* note 227, at 254–56.

253. See, e.g., 21 U.S.C. § 355(j)(5)(F)(iii) (2012).

254. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359 (2007).

255. *Id.* at 360.

256. Voet, *supra* note 189, at 100–01.

257. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007).

258. See Ryan Davis, *Waxman Opposes Hatch Plan to Keep Generics Out of PTAB*, LAW360 (Oct. 30, 2018, 7:22 PM), <https://www.law360.com/articles/1095340/waxman-opposes-hatch-plan-to-keep-generics-out-of-ptab> [<https://perma.cc/U9TF-23J4>]. In a dramatic exchange, the Hatch-Waxman Act's namesakes disagreed over generic firms' use of IPRs to invalidate patents. Former-representative Waxman opposed Hatch's plan to prevent generic firms from using IPR, stating “[i]t's not going to improve [the Act] according to Waxman, it may according to Hatch.” *Id.*



patent policy to guide subsequent Hatch-Waxman legislation. Patent law's unique nature promotes innovation by allowing decentralized behavior to make ex ante choices rather than constraining harmful decisions through ex post legislation.<sup>259</sup>

Congress can accomplish those goals in three ways. First, Congress should strengthen and redefine the IPR procedure. This solution addresses the main problem areas created by the disconnect between the Hatch-Waxman Act and patent law generally. An IPR quickly disposes of patents that stymie innovation. Because an IPR must issue a final written decision within eighteen months of its institution, generic firms can invalidate bad patents sooner.<sup>260</sup> This may prevent, or at least reduce, product hopping because pioneers could not obtain patents at a rate commensurate to IPR resolution.<sup>261</sup> Additionally, limiting product hopping will also decrease reverse settlements, as pioneers place greater value on market-entry timing.<sup>262</sup> Thus, generic firms gain bargaining power that pioneers may not sufficiently compensate in a reverse settlement. On the opposite end, IPRs also benefit worthy patents. Orange Book patent listings upheld through IPR strengthen the pioneer's bargaining power.<sup>263</sup> Indeed, studies indicate that pioneers and generic firms receive equal treatment at IPR.<sup>264</sup> Consequently, IPR provides an overall benefit by rewarding pioneers who create worthy, nonobvious drugs, while simultaneously expediting generic competition and reducing dilatory settlements.

Second, Congress should prohibit regulatory exclusivity on NCEs and provide pioneers with fully-restored patent terms upon the FDA's

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259. NARD, *supra* note 42, at 1–6.

260. *See supra* note 145 and accompanying text.

261. *See* Gzybowski, *supra* note 83.

262. Carrier, *supra* note 220, at 1035 (noting that “[a]bsent settlement, there is a chance that generic firms could successfully challenge the brand firm’s patent . . . allow[ing] immediate generic entry . . . pharmacists could offer [generics] . . . before the brand firm is able to switch”).

263. *See* 35 U.S.C. § 315(e)(2) (2012) (“The petitioner in an inter partes review of a claim in a patent . . . that results in a final written decision . . . may not assert either in a civil action . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.”). Similar to issue preclusion, “a real party in interest or privy with the petitioner” is also estopped from relitigating a patent’s validity on the same grounds raised in the IPR. *Id.*; *see also* Nard, *supra* note 60, at 795 (discussing the effects of oppositional proceedings on proprietary and competitive certainty *ex ante*).

264. Tulip Mahaseth, *Maintaining the Balance: An Empirical Study on Inter Partes Review Outcomes of Orange Book Patents and its Effect on Hatch-Waxman Litigation 1*, 22–23 (Nov. 29, 2018) (unpublished manuscript) (on file with author).

approval of an NDA. By removing regulatory exclusivity, generics could enter the market immediately upon pioneer entry if the pioneer's new compound relies on a bad patent.<sup>265</sup> Providing full patent-term restoration will also encourage pioneers to focus on inventive activity, as opposed to the current regime's patent-quantity-over-quality values.<sup>266</sup> Similarly, Hatch-Waxman incentivizes pioneers to be less inventive.<sup>267</sup>

Finally, Congress should update Hatch-Waxman to reconcile it with the changes implemented by the AIA. Such changes could include: (1) giving effect to IPR for Paragraph IV certifications;<sup>268</sup> (2) requiring that the FDA actively monitor Orange Book patents; or (3) clarifying which actions constitute patent-defeating conduct during NDA preparation.<sup>269</sup> Because the FDA and USPTO act independently, clearly defined boundaries could obviate idiosyncratic behavior that leads to absurd results.

### CONCLUSION

Given the trend of anticompetitive behavior within the pharmaceutical industry, it is important to understand the sources that encourage societal harm. Pharmaceutical companies routinely use the patent system to deprive the public of useful and affordable medicines. Such behavior would not be possible without the Hatch-Waxman Act, which mistakenly focuses on the patent system's means rather than its ends. Accordingly, Congress should resort to foundational patent-law principles—the incentives to invent, disclose, and innovate—if it hopes to salvage the pharmaceutical industry. Indeed, realigning the Hatch-Waxman Act and the patent system would promote innovation without further harming consumers. After all, we should be wary of “clear[ing] away a fence just because we cannot see its point.”<sup>270</sup>

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265. Assuming that generic firms can invalidate the patent before FDA-approval.

266. *See supra* Part III.

267. *See supra* Part II.B.

268. The current regime requires a final action in district court. 21 C.F.R. §§ 314.107(b), .108(b)(3) (2019). Generics must submit proof of judgement to the FDA to obtain regulatory approval. *Id.* § 314.107(e).

269. *Helsinn* provides an example of “elliptical” statutory phrasing that harms pioneers. *Helsinn Healthcare v. Teva Pharm. USA, Inc.*, 138 S.Ct. 2678 (2019).

270. *Artis v. D.C.*, 138 S. Ct. 594, 608 (2018) (Gorsuch, J., dissenting) (“Even if a fence doesn’t seem to have a reason, sometimes all that means is we need to look more carefully for the reason it was built in the first place.”).

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