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## YALE LAW & POLICY REVIEW

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### Patent Term Extensions and the Last Man Standing

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*In 1984, with the passing of the Hatch-Waxman Act, Congress orchestrated a compromise that permanently changed how drug markets operate. This piece of legislation created an expedited pathway for generics to enter the market, and, in exchange, brand drugs could extend their patents to account for time lost during their market approval process. Although this well-configured trade was supposed to help generics enter the scene quicker, the current drug market landscape makes one question whether this legislation has succeeded in its aims. The following study explores the lifecycle of top-selling brand drugs in comparison to the vision put forth by the Hatch-Waxman Act. Using the legislation as a framework, the article examines the data of 236 top-selling drugs, quantifying the average length of patent terms and their extensions, as well as any additional market monopoly time secured thereafter. This study finds that 91% of drugs that obtain patent term extensions continue their monopolies well past the expiration of those extensions, most often by relying on secondary patents. The Hatch-Waxman Act allows drug companies to request a single extension to their patent, limited to a particular length. Nevertheless, drug companies continue to extend their protections well past what is contemplated in the legislation, costing the system a conservatively estimated \$53.6 billion. The study ends with policy recommendations to impose limits on the time that can be added to the monopoly period of any drug that has already received a patent term extension. This includes a limit to the accrual of both secondary patents and exclusivities.*

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## I. INTRODUCTION

Next year marks the 40th anniversary of the historic legislation that ushered in the modern era of generic medicine. Officially titled the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>1</sup> the Hatch-Waxman Act (“Hatch-Waxman”) embodied a grand legislative compromise whose provisions reflect clear, deliberate expectations for how drug markets should play out. Hatch-Waxman extended core patents on a drug’s active ingredients, to the benefit of innovator pharmaceutical companies, in

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1. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

exchange for a process that would speed up generic entry upon expiration of the core protection. The present study looks to answer the question of whether this compromise is working as planned.

To answer the question, this study identified key life-cycle events for a large sample of high-cost drugs. Since passage of the Act, much of the academic literature has focused on ways in which various actors have exploited or manipulated the intricate details of the system. Researchers have aimed their academic firepower at various games that drug companies engage in (for example, 30-month stay; pay-for-delay; improper patents remaining on the books; manipulation of the use code system).<sup>2</sup> And it is complex legislation in whose weeds one can easily get lost. As commentators have focused on the intricate workings of the legislation, however, a key element of the grand design has been completely lost in the shuffle. That grand vision is written in the title of the legislation—The Drug Price Competition and Patent Term Restoration Act—and evident in its overall design. The extension of core patents is the basis of this legislation. Thus, on the eve of the legislation’s historic anniversary, this article sets out to examine how well Hatch-Waxman has succeeded in its goal of extending the duration of potential drug market monopolies for a limited time as specified in the legislation.

To identify Hatch-Waxman’s intent as to the duration of drug market monopolies, this study focuses on the patent term extension, which under Hatch-Waxman is granted for a drug’s core patent. In comparing that design with the protection that has evolved from the Act, the article demonstrates that brand companies are having their cake and eating it, too. On average, drugs are experiencing long monopoly times, regardless of whether they extended their core patents under the Hatch-Waxman Act.<sup>3</sup> In fact, a Hatch-Waxman patent term extension appears to be merely the first of many moves a drug company makes on its quest for more monopoly time.

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2. See Yuk Fung Hui, *FDA’s Proposed Rules on Patent Listing Requirements for New Drug and 30-Month Stays on ANDA Approval (Proposed Oct. 24, 2002)*, 12 ANNALS HEALTH L. 325 (2003); Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-For-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249 (2019); Jacob Wharton, *“Orange Book” Listing of Patents Under the Hatch-Waxman Act*, 47 ST. LOUIS UNIV. L.J. 1027 (2003); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 321 n.78 (2020).
  3. This Article finds that the average total market monopoly time for brand drugs with and without patent term extensions is 18.4 years and 19.7 years, respectively. See *infra* Section III.D.iv.

Analyzing the drift from the original design of the Hatch-Waxman Act requires understanding the modern patent landscape in the pharmaceutical space against its theoretical background. Although it may seem a basic point, patents are designed to last for a limited period of time. From the store of things that anyone in society might ordinarily make, use, or sell, we remove some for a limited period of time, dedicating them to the province of a few in the expectation that this will redound to the benefit of society as a whole. The goal is to encourage people to invent, and to share those inventions with society as a whole,<sup>4</sup> by teaching anyone skilled in the art the information necessary to take advantage of the invention when the patent term expires. When the patent term ends, competitors should be able to enter the market, driving prices down to a competitive level. In the best of all possible worlds, inventors return to the lab, applying their skill and ingenuity to the creation of great new things after garnering a reward from the prior successful invention.

That model of invention, reward, and return to the lab for invention has been altered in the pharmaceutical context. Pharmaceutical companies have become adept at extending monopoly protection on an initial chemical or biologic invention by adding on new types of patents and protections. For example, companies can make minor modifications to a drug's dosage, delivery system, formulation, or method of use. In one particularly striking example, a company took an existing drug that already had a digestive coating and wrapped the pill in an ineffective capsule.<sup>5</sup> Cutting the capsule in half, the old pill rolled out.<sup>6</sup>

Although the patent on the original chemical or biological molecule may have expired, a company can obtain new patents on the product, sometimes shifting the market to a new version that is marketed as enhanced or improved. The activity of new patents for old drugs occupies a remarkable amount of energy in modern pharmaceutical markets. In fact, 78% of the

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4. After all, an inventor could choose to keep an invention secret, relying on the protection of trade secret doctrines while taking the risk that someone else might reach the same point through independent invention or reverse engineering, either of which would be permitted under trade secret law.

5. See ROBIN FELDMAN & EVAN FRONDORF, *DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET* 74–76 (Cambridge Univ. Press 2017) (describing Asacol and Delzicol).

6. *Id.* at 75.

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drugs associated with new patents are not new drugs coming on the market; they are existing ones.<sup>7</sup>

Working with existing drugs has advantages. Over time, the medical field gains experience with a particular drug, learning about its side effects and most effective uses. In addition, even small, tinkering improvements may be of value—at least to some patients at some times. For example, some patients may prefer a smaller milligram version that allows them to titrate a drug, while others may prefer a larger milligram version that allows them to take fewer pills a day. Nevertheless, the cost of moving to the minor modification is likely to be quite small in comparison to the initial invention, as is the level of innovation necessary to make the shift.

Most important, many of these patents are weak, in the sense that they are likely to be overturned if challenged in court. The patent system has operated for some time according to what Professor Mark Lemley calls, “rational ignorance.”<sup>8</sup> The cost of carefully scrutinizing each claim exceeds the resources available to the U.S. Patent and Trademark Office.<sup>9</sup> Thus, the system is incapable of filtering out all improper patents and improper claims, but rather trusts that any claims that matter will be litigated and resolved in court.<sup>10</sup>

From one perspective, the resource constraint is unproblematic. Few patents ever garner a return for their owners, and most patents simply languish in the bowels of the patent office, moldering in their records.<sup>11</sup> Nevertheless, weak patents do provide friction in the system, and there is evidence that weak, secondary patents may be creating a drag on pharmaceutical competition. Secondary patents are more likely to be the subject of litigation, and when generic companies challenge either the validity of the patent or the application of that patent to the particular drug through the full litigation process, the generic wins most of the time.<sup>12</sup> That

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7. Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 617–18 (2018) [hereinafter *Evergreen*].

8. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495 (2001).

9. *Id.* at 1496–97.

10. *Id.* at 1496.

11. See *id.* at 1497–98, 1502–1506.

12. See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* viii (2002); C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCI. 1386, 1387 (2013) (showing that 89% of patents in

challenge process can take years and require considerable resources to pursue, deterring or adding to the cost calculation for potential entrants.

Primary patents play a unique role in the Hatch-Waxman Act patent term extension system. As noted, patent term extensions are only available on the primary, core patent related to the pharmaceutical. Thus, as part of the process of analyzing movements away from the design of the Hatch-Waxman Act, this article categorizes patents as primary or secondary.

On one side of the Act's balanced scale rests the goal of rapid generic entry when the branded drug's core patents expire. Thus, where reality falls short of the law's expectations, the study identifies the primary obstacles undermining the Hatch-Waxman framework. Specifically, the study found that drug companies use a mix of patents and exclusivities to elongate their monopoly periods after core patent expiration.

In this context, the study analyzed which patents served as the most common last-expiring protection, which this article will call the "last man standing." Using data obtained from a large sample of prescription drugs that account for major portions of federal healthcare spending in 2019,<sup>13</sup> this study tracks the key events in each such drug's life cycle and reveals that drug monopolies are ending much later than anticipated by the Hatch-Waxman legislation. Secondary patents, or those besides drug substance or drug product patents, were found to be the most common last-expiring protection, with some drugs acquiring well over thirty such patents.<sup>14</sup> The study also analyzed the cost that these barriers impose on society. Namely, for every year a drug extended its monopoly past its core patent expiration date, society incurs an average cost of \$42 million, conservatively. In light of these findings, this study proposes measures for Congress, agencies, and courts to take to restore Hatch-Waxman's vision of speedy generic entry upon expiration of a drug's core patents; these recommendations include cabining the number of patents or exclusivities upon which brand companies can rely to maintain monopolies, establishing more "safe harbors" for generic activity, and curtailing the improper granting of non-innovative secondary patents.

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settled litigation disputes are secondary patents, which courts usually—68% of the time—find invalid or not infringed).

13. For a description of the dataset and methodology, see *infra* Section III.B.
14. Some scholars refer to follow-on device patents as tertiary. For ease of reading, the article includes those in the category of secondary patents. See Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 142 (2018).

II. WHAT HATCH-WAXMAN ENVISIONED

Hatch-Waxman is a landmark federal law that governs generic drug approval. Since its passage in 1984, Hatch-Waxman has done a remarkable job of ushering generic drugs to market and encouraging price-lowering generic competition.<sup>15</sup> In recent years, however, both the stagnation of pharmaceutical innovation as well as rising prices for drugs that have been around for many years<sup>16</sup> are calling into question whether modern pharmaceutical markets are living up to Hatch-Waxman's vision.

This Part reviews Hatch-Waxman's several components to provide a sense of how the law anticipates drug markets operating over time. The law's two key features are its protocols for the rapid approval of generic drugs<sup>17</sup> and its provisions enabling brand drugs to seek patent term extensions.<sup>18</sup> Recognizing that the rapid approval of generics cuts significantly into drug companies' profits, Congress acceded to patent term extensions as a compromise with the industry. As explained below, Hatch-Waxman anticipates most breakthrough medical innovations receiving no more than fourteen years of market protection after FDA approval, followed quickly by price-lowering generic competition.<sup>19</sup> One should note that the maximum length of a patent at the time was only seventeen years.<sup>20</sup> The maximum length was increased to twenty years in 1995 in response to international agreements.<sup>21</sup>

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15. Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).
  16. See Tito Fojo, Sham Mailankody & Andrew Lo, *Unintended Consequences of Expensive Cancer Therapeutics—the Pursuit of Marginal Indications and a Me-Too Mentality That Stifles Innovation and Creativity: The John Conley Lecture*, 140 JAMA OTOLARYNGOLOGY—HEAD & NECK SURGERY 1225 (2014) (explaining how cancer drug innovation is slowing because of rising drug prices and an ability to sell drugs that have only marginal improvements in efficacy).
  17. See *infra* Section II.A.
  18. See *infra* Section II.B.
  19. See 35 U.S.C. § 156(c)(3) (providing that a patent term plus any extension cannot extend more than fourteen years after FDA approval, thus demonstrating that even drugs that qualify for an extension cannot obtain a market monopoly period of more than fourteen years).
  20. *2701 Patent Term*, USPTO, (Feb. 16, 2023), <https://www.uspto.gov/web/offices/pac/mpep/s2701.html> [<https://perma.cc/65XS-BMRU>].
  21. *Id.*

*A. Title I: Designed to Enable Rapid Generic Entry Following Initial Period of Market Exclusivity*

The first part of Hatch-Waxman establishes a straightforward pathway for generics to penetrate drug markets.<sup>22</sup> Prior to Hatch-Waxman, generics faced an uphill battle trying to enter the market. First, generic drug companies were unable to start the drug testing required by the FDA, let alone apply for FDA approval, until the expiration of the brand drugs' patents. Such testing was deemed patent infringement and thus brand companies enjoyed de facto monopoly extensions.<sup>23</sup> In addition to awaiting expiration of brand drugs' patents and bearing the costs of drug development itself, each hopeful generic entrant had to bear the hefty costs of running clinical trials to gain FDA approval.<sup>24</sup> The risk of taking this initial step loomed even larger, given that first-moving generics were not guaranteed an exclusivity period. Regarding the cost burden of challenging patents that were improperly granted or improperly applied to a particular brand drug, the first-mover generic would bear the entirety of that burden while all subsequent generics would benefit from the first-mover's efforts. Obstacles such as these allowed brand companies to make monopoly level profits well past the expiration of their patents.<sup>25</sup>

In addition to the structural barriers, brand companies were not eager to share with generics the clinical trial information already provided to the FDA, as the entrance of generics drives down drug prices and therefore profits. The brand company could spend money on clinical trials of the drug with the knowledge that success would bring a period of market exclusivity from the patent. Generic drugs harbored no such expectation. Nor would it make sense for society to subject patients to additional clinical trials for established products, or for patients to sign up for those trials. This was particularly the case for placebo trials, in which some patients receive the generic drug and some receive a sugar pill, as few patients would sign up for the opportunity *not* to be given a drug that already has proven effective. Therefore, little incentive existed for generic manufacturers to seek

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22. 21 U.S.C. § 355(j).

23. FELDMAN & FRONDORF, *supra* note 5, at 22.

24. *Id.*

25. *See id.* at 21 (discussing de facto patent extension and ongoing monopoly profits for brands prior to Hatch-Waxman in the context of a generic's inability to begin applying for FDA approval until after the brand's patent expiration).



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approval to enter entrenched drug markets that surely would not welcome them with open arms.<sup>26</sup>

As a solution, Hatch-Waxman allows generic companies to rely on brand drugs' safety and efficacy data when seeking FDA approval. Those brand companies sought approval for the new drug by submitting a new drug application ("NDA" or "brand application") and supplying extensive data to prove its safety and efficacy.<sup>27</sup> Under Hatch-Waxman, generics can submit an abbreviated new drug application ("ANDA" or "generic application"). Instead of conducting their own tests, generic applicants can piggyback on the brand companies' test data and are required to demonstrate only that their products are bioequivalent to the brand drugs to which their applications refer.<sup>28</sup>

These abbreviated applications can be submitted before the expiration of the brand drug patents, thereby cutting down on not only the immense costs but also the lost time that generics used to endure.<sup>29</sup> In other words, generics could go through the approval process, clear any patent rights issues out of the way, and be ready to hit the ground running as soon as the brand's patents expire.

On the other side of the equation, Hatch-Waxman provides original drug manufacturers a five-year data-exclusivity period for "New Chemical Entities." This means that a company with a never-before-approved active moiety (portion of a molecule) will enjoy a minimum of five years after FDA approval without having to face the threat of an abbreviated drug applicant using its data, as abbreviated new drug applications may not even be submitted during that window.<sup>30</sup>

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26. Richard E. Caves, Michael D. Whinston & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 18-21 (1991).

27. 21 U.S.C. § 355(b)(1).

28. 21 U.S.C. § 355(j)(2)(A)(iv).

29. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

30. 21 U.S.C. § 355(j)(5)(F)(ii). This time period decreases to four years if the abbreviated new drug application comes with a paragraph IV certification attesting that each patent on the relevant brand drug is invalid or will not be infringed by the generic. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Strictly speaking, Hatch-Waxman permits the FDA to approve generics at any time through the ordinary new drug application pathway, *see* 21 U.S.C. § 355(b)(1)(A), but that pathway would require the generic to conduct its own tests.

A company that applies for approval of a drug with a previously approved active moiety and includes reports of new clinical investigations will enjoy a slightly shorter, three-year data-exclusivity period after FDA approval. During that three-year period, no abbreviated new drug application using that company's data can be approved for any indication revealed by any new clinical investigation.<sup>31</sup> For drugs that fall under these two specific categories, potential generic competitors are free to rely on the original drug company's testing data after the exclusivity period ends to speed up the approval process.

In addition, Hatch-Waxman immunizes generic manufacturers from infringement lawsuits that would otherwise arise in the process of preparing an abbreviated new drug application.<sup>32</sup> Generics no longer need to wait for the brand's last patent to expire before beginning to research and develop the generic version.

Finally, the original drug company must report all the patents that it believes cover its products, and the FDA must make the list of rights publicly available.<sup>33</sup> No longer can brand drug makers surprise—or even threaten to surprise—generic manufacturers with costly patent infringement lawsuits. Rather, potential generic companies know up front what rights may be asserted against them and when those rights will expire, as well as being able to make a judgment about the strength or weakness of those rights. Hatch-Waxman also provides an added incentive for generic companies to challenge the patents underlying a brand drug: A 180-day period of generic marketing exclusivity is awarded to the first generic drug manufacturer that submits a paragraph IV certification challenging a brand drug patent and that thus opens itself to infringement litigation by the brand.<sup>34</sup>

All together, these provisions form the framework of facilitating speedy generic entry. By eliminating the redundancy in testing, reducing the threat of patent infringement, and resolving these issues before patent expiration, Hatch-Waxman made it significantly cheaper, faster, and overall more attractive to seek approval as a generic. The law's patent declaration requirement gives generics the confidence that brands will not hit them with an unexpected infringement suit. And Hatch-Waxman's safe haven from infringement suits allows generics to be ready to spring onto the scene as soon as a brand's patents expire, eliminating a de facto if not statutorily

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31. 21 U.S.C. § 355(j)(5)(F)(iii).

32. 35 U.S.C. § 271(e)(1).

33. 21 U.S.C. § 355(b)(1)(A)(viii), (j)(7)(A).

34. 21 U.S.C. § 355(j)(5)(B)(iv); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

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mandated period of additional monopoly time during generic development that brand drug companies could previously rely on.

### *B. Title II: How the Extension of Core Patents Was Tailored to Avoid Certain Types of Manipulation*

Title I of the Hatch-Waxman Act cuts deeply into brand pharmaceutical companies' hegemony and profits. Thus, it is unsurprising that the industry had major misgivings about the law, and that pharmaceutical companies sought a major concession from Congress as compensation for Hatch-Waxman's industry-altering effects. Namely, Congress included Title II, which provided a mechanism allowing innovator companies to extend the lives of their ground-breaking patents.<sup>35</sup> Title II was a conscious compromise: Congress made it significantly easier for generics to enter drug markets, and, in exchange, brand companies had the opportunity to prolong—for a limited, statutorily defined time—their patent-enabled market monopoly. Taken as a whole, the law reveals Congress's clear expectations of how drug markets would play out over time.

Before exploring Title II's specific provisions, one should note that the brand companies' position is rational. Patents offer innovators the opportunity to earn enormous value by excluding others from their inventions, but they last only for a limited time. In the case of pharmaceutical products, much of that time is eaten up by the FDA, which may take years to approve a drug before it can be sold. By allowing generics to piggyback on innovators' safety testing, Congress forced brands to absorb the cost of full-time and expensive testing processes, while providing generics an alternative route. Extending the life of a patent based on the length of the FDA's regulatory review process was, therefore, a natural and intuitive compromise for brand companies that sought to enjoy the "full lifespan" of their patents, despite the FDA's time-consuming approval process.

The procedure by which an innovator company seeks a patent term extension is fairly straightforward. Following FDA approval, the applicant has sixty days to submit an application to the U.S. Patent and Trademark Office ("Patent Office").<sup>36</sup> Upon receipt of the application, the Patent Office requests that the FDA state whether the product was subject to a regulatory

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35. 35 U.S.C. § 156.

36. 35 U.S.C. § 156(d)(1).

review period and, if so, the period's length.<sup>37</sup> The FDA publishes its determination of the regulatory review period in the Federal Register, after which the Patent Office uses several statutorily defined criteria, discussed below, to determine whether the patent is eligible for an extension and, if so, for how long.<sup>38</sup> The process is complete when the Patent Office grants a certificate, visible as part of the patent's record, officially extending the patent's expiration date.<sup>39</sup>

With that in mind, a close look at how Congress structured the rules for patent term extensions reveals, with remarkable specificity, the timeline that the statute contemplates for new drugs retaining and then losing their market dominance. First, Congress explicitly restricted eligibility for patent term extensions to patents on *active* ingredients; such patents are referred to herein as core or marker patents. Secondary patents covering, for example, inactive binding agents are excluded from the definition of drug products that may receive a patent term extension.<sup>40</sup> Moreover, only one patent may be extended per regulatory review period that a product was subject to, even if multiple patents cover its active ingredient.<sup>41</sup> A regulatory review period comprises two phases: the testing phase, which runs from when a drug company's investigational new drug application becomes effective (and the company may thereby begin clinical testing) until submission of the company's new drug application; and the approval phase,

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37. 35 U.S.C. § 156(d)(2)(A)(ii).

38. 35 U.S.C. § 156(c).

39. 35 U.S.C. § 156(e)(1).

40. Textually, the limitation to active ingredients operates as follows. The provision begins by stating, "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent." 35 U.S.C. § 156(a). It then specifies that "[f]or purposes of this section, . . . [t]he term 'product' means . . . [a] drug product," and, in turn, "[t]he term 'drug product' means the active ingredient of . . . a new drug, antibiotic drug, or human biological product" 35 U.S.C. § 156(f)(1)-(2).

41. 35 U.S.C. § 156(c)(4). Because the statute provides that only one patent may be extended "for the same regulatory review period," it is technically possible for a drug to receive multiple patent term extensions if the brand company submitted multiple new drug applications that each went through a separate period of regulatory review and that are approved on the same day. Such was the case for two drugs analyzed in this study, Differin and Lyrica. See Jeffrey S. Boone, *Patent Term Extensions for Human Drugs Under the US Hatch-Waxman Act*, 4 J. INTELL. PROP. LAW & PRAC. 658, 662-63 (2009) (explaining the rare circumstance in which the drug Lyrica received two patent term extensions).

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which runs from submission until approval of that new drug application.<sup>42</sup> In general, the length of an extension is equal to the duration of a drug's approval phase plus one half of the duration of its testing phase.<sup>43</sup>

An additional restriction precludes drug makers from seeking patent term extensions for new versions of old drugs. Not only must an extension go to an active ingredient, but it must also go to an active ingredient that has not been previously approved for marketing.<sup>44</sup>

Most important, the statute caps extensions at five years.<sup>45</sup> The statute further specifies that no extension may extend a patent's expiration date beyond fourteen years from the time of the drug's FDA approval.<sup>46</sup> In other words, in Congress's eyes, drugs that had more than fourteen years of patent-protected market time did not need additional protection.

Anticipating that drug makers would delay seeking their patents in order to maximize market exclusivity, Hatch-Waxman does not count FDA approval time before a patent's issuance towards an extension of that patent.<sup>47</sup> In other words, Congress, in extending drugs' monopolies, refused to give a patent credit for an FDA review period that occurred before the patent issued. No matter how long it took the FDA to approve a new drug, Congress said, the product's monopoly must come to a timely end.

Notably, the legislative history indicates congressional intent to prevent patent holders from obtaining multiple extensions of protection beyond the patent term extension on the original, core patent. As explained in the report of the House Judiciary Committee, the Committee rejected a proposed amendment supported by the Patent Office because "the net

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42. 35 U.S.C. § 156(g)(1)(B)(i)-(ii).

43. 35 U.S.C. § 156(c)(2); Jaime F. Cardenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1310 (2015) (describing each of the two components of the formula separately).

44. 35 U.S.C. § 156(a)(5)(A).

45. 35 U.S.C. § 156(g)(6)(A).

46. 35 U.S.C. § 156(c)(3). A patent can expire more than fourteen years after FDA approval absent any extension, but an extension cannot give a patent any additional time past fourteen years after FDA approval. There is also a "due diligence" requirement, but on only one occasion was an extension shortened because of a lack of due diligence, and in that case the applicant volunteered that they did not act with due diligence. As Cardenas-Navia points out, the requirement likely adds little to no benefit to the Act's incentive structure. *See* Cardenas-Navia, *supra* note 43, at 1358-62.

47. 35 U.S.C. § 156(c).

result of [this proposed] amendment was to permit multiple patent term extensions on what was essentially the same drug product.”<sup>48</sup> Ultimately, what the Patent Office supported was to enable patent holders to extend even their secondary patents through patent term extensions.

After considering these arguments, the Committee rejected the amendment, citing a “need to avoid multiple patent term extensions” and concluding that “only the first patent on a drug-type product should be extended” because it is the only patent that “experiences any substantial regulatory delay.”<sup>49</sup> The Committee elaborated on this last point, stating that “subsequent patents on approved drug products are frequently not the same magnitude of innovation as occurs with respect to the initial patent.”<sup>50</sup> In other words, the Committee recognized that secondary patents do not provide the same degree of innovative contribution to society as the original patent on the drug itself.

To be clear, the Committee rejected a proposal to grant patent term extensions for secondary patents. Nevertheless, the Committee’s logic pushes against the use of secondary patents at all for the purposes of extending a drug’s monopoly past the extension of the core patent, even if the secondary patents are not themselves extended. The simple takeaway is that core patents are the only patents deserving extension, should receive only one extension, and should be the longest and last-expiring protection on a drug—not other patents on essentially the same drug. As the data presented below will show, however, the exact opposite is playing out. For roughly 75% of the drugs in this study, core patents are not the last-man-standing protection.<sup>51</sup>

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48. H.R. REP. NO. 98-857, pt. 2, at 7 (1984). According to the report, the Patent Office had supported the proposed amendment and argued that, absent the amendment, the bill “would create two different types of patents for drugs; those which are extendable and those which are not extendable.” *See id.* at 8.

49. *Id.* at 8.

50. *Id.*

51. *See infra* Sections III.D.i, iii. This percentage should not be confused with the percentage of PTE-receiving drugs that received secondary monopoly time (127 out of 139, approximately 91%). In this study’s adjusted sample of 236 drugs with core patents, 176 received secondary monopoly time. Thus, the last man standing protection for those 176 drugs was not their core patent.

*C. Hatch-Waxman and Follow-on Regulatory Exclusivities*

In addition to extending patents, Hatch-Waxman provides brand drugs with other, non-patent related methods for protecting their monopoly time. As mentioned briefly in our discussion of Title I, there are two data exclusivities available to certain first movers that block the approval of abbreviated new drug applications for a set amount of time. One of these protections is termed the “New Chemical Entity” exclusivity. As stated, this provision prohibits submission of an abbreviated new drug application that piggybacks on the data from a brand drug that had applied with a never-before-approved active ingredient; the prohibition runs for five years<sup>52</sup> from when the FDA approves the brand drug’s application.<sup>53</sup> Although generic manufacturers could conduct their own safety and efficacy tests to avoid the four- or five-year wait, the costs would be immense.<sup>54</sup> Thus, qualifying brand-name drugs enjoy a peaceful four or five years of money-making before any realistic threat of competition. This period without competition is in addition to the amount of time it would take an abbreviated new drug application submitted after the exclusivity period to be processed and approved.

The other non-patent exclusivity baked into Title I of Hatch-Waxman grants brand drugs protection if they present new clinical data that support changes to how a previously approved drug is formulated or used.<sup>55</sup> Termed the New Clinical Investigation exclusivity, the provision operates by

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52. Or sometimes four, *see supra* note 30.

53. 21 U.S.C. § 355(j)(5)(F)(ii); *see also* 21 C.F.R. § 314.108(b)(2) (2023) (noting the five-year prohibition). A parallel New Chemical Entity exclusivity bars submission of a 505(b)(2) application, which is another kind of simplified new drug application, *see* 21 U.S.C. § 355(b)(2), for the same period. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

54. *See* Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588–90 (2003) (discussing absence of generics on the market before the Hatch-Waxman Act); *see also supra* text accompanying note 24 (referencing the high costs generic manufacturers had to pay to conduct clinical trials for FDA approval prior to Hatch-Waxman).

55. 21 U.S.C. § 355(j)(5)(F)(iii); *see also* 21 C.F.R. § 314.108(b)(4) (2023) (noting that an NDA containing new clinical investigations essential to the application will bar approval of a 505(b)(2) application or an abbreviated new drug application for three years). A parallel exclusivity for new clinical investigations bars submission of a 505(b)(2) application, *see* 35 U.S.C. § 156(c), for the same period. *See* 21 U.S.C. § 355(c)(3)(E)(iii).

prohibiting abbreviated new drug applications that use another company's safety and efficacy data from gaining FDA approval for any uses or formulations revealed by the new clinical investigation; the prohibition runs for three years from when the other company gets FDA approval.<sup>56</sup> These two limitations that Hatch-Waxman places on approval of abbreviated new drug applications can be viewed as additional concessions to brand companies. In exchange for giving up certain data rights, brand drugs receive guaranteed protection of that data for a period of years, in addition to receiving some time back after FDA delays. That, however, appears to be the extent of the vision of brand company entitlement. Hatch-Waxman's construction of unique protections for brand drugs, with explicit eligibility criteria and clear time limits for both the exclusivities and patent extensions, indicates a desire for the timely conclusion of market monopolies after the expiration of such unique protections.<sup>57</sup>

In statutes other than Hatch-Waxman, Congress authorized three additional exclusivities.<sup>58</sup> Roughly two years before enactment of Hatch-

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56. 21 U.S.C. § 355(j)(5)(F)(iii).

57. Although legislative reports on the bill that became Hatch-Waxman warned that these exclusivities could give brand companies undue monopoly power, the language of Hatch-Waxman's final, as-enacted version effectively ignored those warnings. The Report of the House Energy and Commerce Committee urged that nothing in the legislation should function to extend, directly or indirectly, any patent term beyond the extension period allowed by the Act's express patent-term extension provision. And the Report of the House Judiciary Committee expressed concern that the power to grant a drug monopoly—including the power to grant an exclusivity—should reside not with the FDA but rather with appropriate federal agencies such as the Patent Office. But the plain language of Hatch-Waxman as enacted ran roughshod over these cautions. That plain language permits the exclusivities to extend beyond a patent's expiration date and to be granted by the FDA. The consequent swelling of brand companies' monopoly power raises the question whether Congress should review and reassess the wording of Hatch-Waxman's exclusivity provisions. See Robin Feldman, *New Clinical Investigation: A Regulatory Exclusivity Run Amok* (2023) (unpublished manuscript) (on file with author) (discussing warnings in Hatch-Waxman's legislative reports and how the Act's plain language ignores those warnings).

58. The Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, tit. VII, subtit. A, §§ 7001-03, 124 Stat. 119, 804-21 (2010), also contains an additional set of exclusivities that apply to biologic drugs, distinct from the small-molecule, non-biologic drugs covered by Hatch-Waxman. For a discussion and list of these exclusivities, see Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 82-84,103 (2016).



#### PATENT TERM EXTENSIONS AND THE LAST MAN STANDING

Waxman, Congress introduced the Orphan Drug exclusivity.<sup>59</sup> Passed as part of the Orphan Drug Act of 1983,<sup>60</sup> and amended in 1984,<sup>61</sup> 1985,<sup>62</sup> and 1988,<sup>63</sup> this exclusivity is available to drugs that treat rare conditions.<sup>64</sup> If a drug is approved for Orphan Drug protection, the FDA is unable to approve abbreviated new drug applications—or, for that matter, new drug applications or 505(b)(2) applications—for the same drug and indication for seven years.<sup>65</sup> Intending the Orphan Drug exclusivity to benefit drugs for which the drug-maker had no reasonable expectation of recouping its development costs,<sup>66</sup> Congress in 1984 added a short-cut for measuring lack of ability to recoup costs by making the exclusivity available to any drugs

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59. 21 U.S.C. § 360cc(a).
  60. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).
  61. Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, 98 Stat. 2815 (1984).
  62. Orphan Drug Amendments of 1985, Pub. L. No. 99-91, 99 Stat. 387 (1985).
  63. Orphan Drug Amendments of 1988, Pub. L. No. 100-290, 102 Stat. 90 (1988); *see also* OFF. INSPECTOR GEN., DEP'T HEALTH & HUM. SERVS., THE ORPHAN DRUG ACT—IMPLEMENTATION AND IMPACT 1, 4 (2001) (stating that Congress amended the Orphan Drug Act in 1988).
  64. 21 U.S.C. §§ 360bb(a), 360cc(a).
  65. 21 U.S.C. § 360cc(a); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMS. & TECH. L. REV. 345, 359 n.58 (2007) (noting that Orphan Drug exclusivity does not prohibit FDA approval of “another drug for the same disease or condition, or . . . the same drug for another disease or condition”). The Orphan Drug exclusivity can run concurrently with the New Chemical Entity or New Clinical Investigation exclusivities. *See* Maya Durvasula C. Scott Hemphill, Lisa Larrimore Ouellette, Bhaven N. Sampat & Heidi L. Williams, *The NBER Orange Book Dataset: A User's Guide* 12 (Nat'l Bureau of Econ. Rsch. Working Paper No. 30628, 2022). At the time when the Orphan Drug Act was first enacted, the exclusivity applied only to unpatentable drugs, and it was not until 1985, after the passage of Hatch-Waxman, that the Orphan Drug Act was amended so that the exclusivity also applied to patentable drugs. Orphan Drug Amendments of 1985, Pub. L. No. 99-91, § 2(1), 99 Stat. 387 (1985) (“[Strike] out ‘and for which a United States Letter of Patent may not be issued’ in subsection (a)”).
  66. Orphan Drug Act, Pub. L. No. 97-414, §§ 1-2, 96 Stat. 2049, 2049-51 (1983) (codified at 21 U.S.C. § 360bb(a)(2)) (amending § 526(a)(2) of Federal Food, Drug, and Cosmetic Act).

that serve a population of fewer than 200,000 patients.<sup>67</sup> Companies have become adept at dividing a drug's population into smaller market segments,<sup>68</sup> and the Orphan Drug Act has become associated with highly profitable drugs.<sup>69</sup> For example, in 2015, seven of the ten highest-revenue drugs were associated with an Orphan Drug designation.<sup>70</sup>

The Generating Antibiotic Incentives Now, or GAIN, exclusivity became available in 2012 under the Food and Drug Administration Safety and Innovation Act.<sup>71</sup> This protection is applicable to drugs designated as qualified infectious disease products, meaning they treat certain life-threatening infections.<sup>72</sup> Obtaining this designation extends an existing exclusivity, namely the New Chemical Entity, New Clinical Investigations, or Orphan Drug exclusivity, by five years.<sup>73</sup>

The third non-Hatch-Waxman exclusivity was introduced as part of the FDA Modernization Act of 1997 and is commonly referred to as the "Pediatric Exclusivity."<sup>74</sup> To obtain this protection, a company must submit studies to the FDA demonstrating that its drug is beneficial to pediatric populations.<sup>75</sup> If the FDA grants this protection, the designated drug extends its last protection, whether it be a patent or an exclusivity, by six months.<sup>76</sup>

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67. Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, § 4, 98 Stat. 2815, 2817 (1984) (codified, *inter alia*, at 21 U.S.C. § 360bb(a)(2)).

68. For an example of how this plays out specifically with regard to antineoplastic drugs, *see, e.g.*, Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 1, 14–18 (2020).

69. *Id.*

70. *See* Sarah J. Tribble & Sydney Lupkin, *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, KAISER HEALTH NEWS (Jan. 17, 2017), <https://kffhealthnews.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/> [<https://perma.cc/V23P-PQ36>] (citing statistics from EvaluatePharma).

71. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 801–06, 126 Stat. 993, 1077–82 (2012) (codified at 21 U.S.C. § 355f(a)).

72. *Id.* at 1077.

73. *Id.*

74. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 1, 111 Stat. 2296, 2305–09 (codified at 21 U.S.C. § 355a(b)(1)).

75. *Id.* at 2305.

76. *Id.*

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These three protections constitute the exclusivities available to small-molecule drugs, besides the two embedded in Hatch-Waxman.

In sum, the time limitations expressly set in Hatch-Waxman envisioned well-defined patent term extensions of no more than five years, and for core patents only, and determined that drugs that have enjoyed market monopolies of more than fourteen years need no extension beyond fourteen years, regardless of any amount of FDA delay. These clear textual limitations on patent term extensions, and the secondary patents and exclusivities that are nonetheless used by brand companies to elongate their market monopolies, would appear to be working at cross-purposes.

### III. THE STUDY

#### *A. Overview*

Hatch-Waxman established as its goal rapid generic entry upon expiration of the brand drug's core patent. This study aims to evaluate how closely drug markets conform to Hatch-Waxman's vision. It does so by tracking—within two samples of prescription drugs that account for a large portion of federal healthcare spending—the key events in the life cycle of a drug. Explained in greater detail below, the selection of drugs analyzed in this study takes advantage of Hatch-Waxman's patent term extension provisions. Specifically, drugs that receive extensions thereby indicate the core patents on the drugs and, by extension, provide a benchmark against which to compare each drug's actual cycle of protection. Thus, the analysis derives a frame of reference by operating on Hatch-Waxman's own terms. The law, in other words, instructs us where to look and what we should find.

Whereas most academic, government, and industry studies of drug markets do not focus on the significance of Hatch-Waxman's patent term extension, the present analysis tracks the prevalence of patent term extensions, measures their average duration, and calculates the average time drugs are on the market prior to their core patents expiring. Further, where the study finds that generic competitors are not able to enter the market immediately following the core patent's expiration due to the obstacle of other patent or non-patent rights, the study seeks to identify those obstacles. Specifically, the study asks what other protections are being used, how often are these protections employed, and, on average, how much more monopoly time do these protections give a company? In other words, this study will explore what is obstructing Hatch-Waxman's vision of limited patent term extensions and speedy generic entry.

### B. Methodology

The following methodology provides far greater detail than much of the work on patents in the legal literature. The additional detail increases the transparency of the work<sup>77</sup> and provides a roadmap for future researchers in the area.

This study examines two samples of prescription drugs. Specifically, the study looks at Medicare Part D and Medicaid spending data from the year 2019.<sup>78</sup> The data is publicly accessible and comes from the Centers for Medicare and Medicaid (“CMS”) spending dashboard. Both datasets separate yearly spending by drug, which is helpful for this study’s analysis. In addition, all drugs used in this study had to be active in 2019, meaning that there was Medicare Part D and/or Medicaid spending on the drug in 2019.

To further narrow this group of active drugs, the study applied two more conditions. The first condition was that total Medicare Part D and Medicaid spending on a drug in 2019 had to be \$10 million or more, excluding rebate spending. This requirement ensures that the study is concerned only with drugs that constitute a large monetary cost to the federal government and hence to the public. The second condition is that a drug must have been on the market for at least ten years, with market time defined as the time between the approval date of a drug’s new drug application and the end of 2019. This condition is necessary because tracking the important stages of a drug’s life cycle requires sufficient time for a drug to advance to those stages. If the study included drugs that were not on the market for a substantial amount of time, the likelihood of inaccurate results would increase. Specifically, the study would run the risk of assuming that manufacturers of certain drugs chose not to apply for patent term extensions or to add additional protections after the core patent’s expiration, when they merely lacked sufficient incentive to do so. These two conditions on spending and market time ensure that the results of the study are both relevant and accurate.

After identifying all eligible drugs, the study defines certain, important moments in the life of a drug. The study divides a drug’s lifetime into two

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77. Robin Feldman, Mark Lemley, Jonathan Masur & Arti Rai, *Open Letter On Ethical Norms In Intellectual Property Scholarship*, 29 HARV. J. L. & TECH. 1 (2016).

78. *CMS Drug Spending*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/data-research/statistics-trends-and-reports/cms-drug-spending> [<https://perma.cc/UD6Z-SY9G>].

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portions termed the *primary monopoly period* and the *secondary monopoly period*. The primary monopoly period is the monopoly time between the NDA approval date and the core patent and any patent term extension expiration date. The secondary monopoly period is the extra monopoly time, after the primary monopoly period, that patent holders have obtained. The secondary monopoly period extends until the drug's last-expiring protection, whether a patent or an exclusivity; that last-expiring protection is referred to herein as "the last man standing." The study analyzed average information for these two periods across the dataset. In short, the primary and secondary monopoly periods are the two life-cycle stages that are relevant for the present study: the monopoly time granted via the core patent and the Hatch-Waxman Act, and the extra monopoly time after that, if any.

To examine the average length of these two time periods, this study needed to identify drugs whose core patents received patent term extensions, a step that required translation among different government data sources. The Medicare Part D and Medicaid data do not indicate which drugs are protected by patents that have patent term extensions. Thus, the study identified drugs with patents that received a patent term extension by cross-checking the dataset against a list of patent term extensions available on the Patent Office website.<sup>79</sup>

The Patent Office website sorts patent term extensions by product name, patent number, and original patent expiration date. At the time of the study's initial foray, the Patent Office website cautioned that the list was incomplete, and correspondence with Patent Office staff confirmed that the website likely had not been updated in the prior two years.<sup>80</sup> Thus, the study used a secondary method to update the list by hand. Specifically, drug names that did not appear on the website's list were searched in the Federal Register for the following reason: when a drug company applies for a patent term extension, the FDA is required to publish in the Federal Register a notice of its determination of the length of the drug's regulatory review period. Thus, for those drugs for which a determination appeared, the associated patent or patents were searched in the Patent Office's Patent Center website for a certificate of extension, which identifies the length of

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79. *Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. § 156*, USPTO (Sept. 5, 2023, 12:05 PM EST), <https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156> [<https://perma.cc/ZZ46-SKAQ>].

80. Email from Ali Salimi, Senior Legal Advisor, USPTO, to author (May 28, 2022, 11:48 EST) (on file with author).

the extension and the patent's original expiration date. For the study data to be as up-to-date as possible, drugs that received extensions from the Patent Office as of July 2022 were included in the study's dataset. Fortunately, the Patent Office updated its own list of patent term extensions in August 2022.<sup>81</sup> Thus, the study reconfirmed its results in that manner as well. Patents that were determined to be eligible for an extension but had not yet been granted an extension by the Patent Office at the time of the study were excluded. At the end of the day, these methods produced the set of all drugs with patent term extensions during the study period of 2005 to 2019, as well as the original and extended patent expiration dates for all such drugs.<sup>82</sup>

After identifying the drugs with and without core patent extensions, the study was able to determine the length of each drug's primary and secondary monopoly period—both for those drugs with a patent extension and those without. To do this, the study referenced an internal database, created with data from the Orange Book from 2005 to 2018, along with data from the National Bureau of Economic Research and the 2019 Orange Book itself.<sup>83</sup> These sources made it possible to identify the expiration date of the core patent for drugs without extensions.

It is important to note that where drugs did not obtain patent term extensions, they do not necessarily have easily identifiable core patents, defined as patents on the drug's active ingredient. To identify such patents or ones of similar strength, this study looked for Drug Substance ("DS") or

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81. *Applications for Patent Term Extension*, *supra* note 79.

82. *See supra* note 41. Although generally a drug with a patent term extension could receive only one such extension, there were two drugs that received two patent term extensions. In order to determine the primary monopoly time for these drugs, the lesser of the following two values is used: the sum of the two patent extension lengths or the difference between the earlier of the original patent expiration dates and the later of the extended patent term expiration dates.

83. *Evergreen Drug Patent Database: About*, UNIV. CAL., COLL. L. S.F., <https://sites.uchastings.edu/evergreensearch/about/> [https://perma.cc/E9CH-LXC9]; *Orange Book Patent and Exclusivity Data 1985-2016*, NAT'L BUREAU ECON. RSCH., <https://www.nber.org/research/data/orange-book-patent-and-exclusivity-data-1985-2016> [https://perma.cc/27AD-DYAE]. Data from the Orange Book was used to find the FDA application approval date for all eligible drugs, the core patent expiration date for drugs without patent term extensions, and the "last man standing" protection for all eligible drugs. Data from the National Bureau of Economic Research was used to bolster the Orange Book in terms of patent and exclusivity data.

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Drug Product (“DP”) patent codes. A “DS” code indicates a patent on a drug’s active ingredient and a “DP” code indicates a patent on a drug’s formulation. When identifying a core patent for a drug, a “DS” code was preferred.<sup>84</sup>

The internal database with data from the Orange Book, along with the supplemental data from the National Bureau of Economic Research, made it possible to identify not only the core patents for drugs without extensions but also, for all drugs, the FDA application approval date and all protections a drug obtained after the expiration of its core patent. To calculate the primary monopoly period of a drug, this study measured the amount of time between each drug’s FDA approval date and the expiration of its core patent or core patent extension, if applicable.

Calculating the secondary monopoly time for drugs required further effort. Unlike the primary monopoly period, which has start and end dates that correspond to consistent milestones, the secondary monopoly period has only a consistent start date, that being the expiration of the core patent. The end date of this period is merely defined as the last protection to expire after that date. Thus, to find this “last man standing” required sifting through all patent and exclusivity data for each eligible drug using the sources mentioned previously.

Before key limitations of this work can be addressed, it is important to explain the logistics that enabled the use of the data for this study.

First, by considering only drugs with new drug applications, the study hoped to deal with only small-molecule drugs. Unfortunately, prior to 2020, biologics also had new drug application numbers recorded in the Orange

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84. One might ask why, if these drugs cost Medicare and Medicaid enough to be included in our analysis (with spending in excess of \$10 million in 2019), did the companies producing them not pursue patent term extension? The answer in most cases is straightforward: the large majority of those drugs included in our study which did not receive any patent term extension (70 out of 97, or 76%) were statutorily ineligible because they received marketing approval with at least fourteen years of their patent term remaining. Thus, they had no need for a patent term extension, as the motivation behind an extension in the original Hatch-Waxman compromise (i.e., limited patent term owing to a lengthy regulatory review) did not apply. For the remaining twenty-seven drugs that did not receive any patent term extension, asserting definitively why their manufacturers did not pursue an extension is difficult. However, as a group, these drugs that appear eligible for but did not receive an extension seem to have been less profitable or popular than those drugs that received patent term extensions. Looking at spending per drug, they seem less likely to cost Medicare and Medicaid over \$100 million (19% versus 29% of drugs with PTE) and over \$400 million (4% versus 11%).

Book.<sup>85</sup> To ensure that only the new drug applications of small-molecule drugs made it into our sample, the study cross-checked the 2022 Purple Book. If any of the study's new drug applications appeared in the Purple Book, the associated drug was excluded from the sample.

Second, Medicare Part D and Medicaid spending data were chosen as the main dataset with all other datasets mapped onto it. But, because each dataset organizes its data differently, the question of how one defines "a drug" becomes relevant. This question unfolds in a context where Medicare Part D and Medicaid spending data use drug names only at the most granular level of analysis. Drug names, however, are not unique. The same drug name can apply to multiple formulations or types of the drug.<sup>86</sup> This problem was resolved by making new drug application numbers the granular level of analysis.<sup>87</sup> Although each new drug application could have multiple dosages or delivery systems of the drug,<sup>88</sup> this study assumed that everything within the same new drug application was a single drug. This approach is consistent with the way the FDA looks at an individual drug in terms of the need for additional testing and data and likely consistent with the way practitioners look at a drug. For instance, a physician prescribing

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85. *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Actions Advancing the Agency's Biosimilars Policy Framework*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-actions-advancing-agencys-biosimilars-policy> [<https://perma.cc/DTZ3-R4M6>].

86. From the data used for this study, examples include Depakote (which comes in both "Depakote Sprinkles" 125mg tablets and extended release 250mg and 500mg tablets) and Isentress and IsentressHD (which come in 400mg and 600mg tablets, respectively). See *Depakote Formulations*, DEPAKOTE (May 9, 2023), <https://www.depakote.com/depakote-formulations> [<https://perma.cc/5Q4F-CBBW>]; *About Isentress and IsentressHD*, ISENTRESS (May 9, 2023), <https://www.isentress.com/> [<https://perma.cc/GR2F-UYU8>].

87. Within our dataset, there were 129 drugs that were associated with only a single new drug application. For the remaining 107 new drug applications in our analysis, there were an average of three new drug applications per drug name. See *supra* note 41.

88. Isentress and IsentressHD are a good example, as both were included within New Drug Application 022145. Readers can compare with Depakote ER and Depakote Sprinkles, which had four different applicable new drug applications between them. See *supra* note 86.



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200mg of a drug would likely view one 200mg tablet and two 100mg tablets as functionally the same for therapeutic purposes.<sup>89</sup>

Using the Orange Book data, which is organized by new drug application number, but also includes drug names, this study was able to add the appropriate new drug application number to apply to each drug name. If multiple drug names were associated with the same application number, then that application number was used as the unit of analysis, and the drug spending for each of the drug names was summed. If, on the other hand, one drug name was found to be associated with multiple new drug application numbers,<sup>90</sup> each new drug application was treated as its own drug. In these situations, the one spending value associated with the drug name in the Medicare Part D and Medicaid data was split equally among all associated new drug application numbers. This was done (instead of assuming each drug was associated with the total spending value) so as not to artificially inflate the amount of government spending that occurred.

The Patent Office dataset posed a similar issue given that its data is organized by drug name, not new drug application number. Thus, the study used the same process and Orange Book data to map the Patent Office dataset onto the spending dataset, keeping new drug application numbers as the core unit of analysis. In addition, given that both the Patent Office and Orange Book datasets include core patent numbers, this study was able to use the mutual core patent numbers along with the drug names as an additional check to ensure accurate matching. These steps were completed before application of any limiting conditions or identification of any of the important events in a drug's life cycle.

### *C. Limitations*

This study, as with any study, has limitations. First, the study assumes that if a drug company files a new drug application and receives FDA approval, then the drug is a brand drug and not a generic; however, it is technically possible for a generic company to file a new drug application. For reasons discussed above,<sup>91</sup> that would be economically unwise and thus very unlikely. Similarly, the study uses new drug application approval as a

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89. For a discussion of this dynamic and potential health policy implications, see Robin Feldman, Natalie Feldman & Enrique Seoane-Vazquez, *A Patient Price Guide for Prescription Medication*, 175 ANN. INTERN. MED. 885 (2022).

90. See *supra* note 87.

91. See *supra* text accompanying notes 28–29.

proxy for the beginning of a brand drug's monopoly period, even though it is technically possible for the drug to remain off-market after approval.

Limitations also reside in the logistics of combining the study's datasets. As a reminder, if a drug name was associated with more than one new drug application number, the study treated each application number as its own data point and assumed each accounted for an equal fraction of the spending. The study made this assumption because in the study's limited dataset from Medicare Part D and Medicaid, spending is associated only with a drug name. Thus, when one drug name is associated with more than one new drug application number, there is no way to know which new drug application is responsible for which portion of the spending. Although assuming an even split may not be a perfect reflection of reality, it avoids artificially inflating government spending, and that avoidance is a more important objective for the purposes of this study.

Another limitation stems from the datasets. Specifically, the study used Patent Office and Federal Register data up to the year 2022 to identify patent term extensions. On the other hand, the study's data on secondary monopoly time (i.e., the use of exclusivities and secondary patents) only went up to the year 2019.<sup>92</sup> In other words, drugs that obtained extensions between 2020 and 2022 may appear to have no secondary monopoly time even if they later obtained such time. This discrepancy means that the study may be underestimating secondary monopoly time. This limitation, however, is consistent with the study's general approach of using conservative measures wherever possible.

Our calculation of the average length of a patent term extension requires further comment. This calculation includes only drugs that received patent term extensions and is not an average for all drugs. Thus, one cannot use the results described in this study to say that, out of all drugs, brand companies received a certain average amount of extra time from patent term extensions because this measure examined only a subset of all drugs.

One should also keep in mind that our sample represents drugs that cost the federal government the most money. It is quite likely that the prevalence

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92. It would have been preferable for this study to use only patent term extensions and secondary patent/exclusivity data through 2019, as that was the final year of the spending data used by this study. However, because the Patent Office does not release an annual document reflecting available patent term extensions but only intermittently updates the database (unlike the FDA's annual release of the Orange Book), using the most up-to-date data from the Patent Office was necessary to assure that the data was as robust and accurate as possible.

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of extensions is higher for these top-spending drugs than for most other drugs, given that drug companies are likely to expend the greatest effort to protect the drugs that bring the highest returns. In the same vein, the drugs that are eligible for an extension—drugs with novel active ingredients—may be more likely to be lucrative, independent of the extension. Either way, one should be aware that the prevalence of extensions among top-spending drugs may be higher than it is for less lucrative drugs. As a result, once again, the study overstates the length of time that Hatch-Waxman anticipated giving to pharmaceutical companies by studying the companies that likely have received the longest amount of time. Measured across all drugs, it is likely that Hatch-Waxman conferred a more-limited primary monopoly period, and the impact of follow-on manipulations is even greater than estimated. Again, this approach is consistent with an effort to answer the questions in a conservative manner.

### D. Findings

As noted above, even taking the more conservative view of Hatch-Waxman’s language, Congress expected the monopoly power flowing from the extra protection that patent term extensions added to patents would last no more than fourteen years after drug approval.<sup>93</sup> Without a patent term extension, the drafters of the legislation anticipated that drugs would have on average nine years of protection after coming to market,<sup>94</sup> but were willing to allow up to five years to be added back in an effort to encourage

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93. See *supra* note 46 and accompanying text (explaining that in the cases in which the patent had more than fourteen years left at the time of approval, Hatch-Waxman does not allow the patent term extension to extend the term of protection).

94. For example, Congressman Waxman during House floor debates noted that “representatives of the drug industry have testified that the average patent time left after approval is between 8 and 10 years.” 130 CONG. REC. 23,057 (1984). Interestingly, nine years is also the period of time during which small-molecule drugs are exempt from the 2022 Medicare negotiation provisions of the Inflation Reduction Act, combining the seven years during which a small-molecule drug’s price cannot be negotiated and the two years during which it cannot be subject to the negotiated price. See Benjamin Rome et al., *Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022*, 4 JAMA HEALTH F. 1, 2 (2023).

investment.<sup>95</sup> The study found that over time, however, companies have managed to game the patent system well beyond the anticipated fourteen years. Our study results also reveal that the end of monopoly time rarely comes at the expiration of a core patent (or its patent term extension), but rather after the many secondary patents and exclusivities that drugs accumulate regardless of whether they have received a patent term extension. One drug, for example, accrued an additional forty-eight patents.<sup>96</sup>

Taken together, the data paints a picture in stark contrast to what Hatch-Waxman envisioned. Instead of speedy generic entry, makers of brand drugs are extending their monopolies well beyond marker patent expiration dates, especially those brand drugs that took advantage of Hatch-Waxman's patent term extension. The drug companies that received extensions are even more desperate to elongate their monopolies and apply protections after their core patents expire; they scramble to obtain all of the monopoly time they possibly can, thwarting Hatch-Waxman's goal of rapid generic penetration into drug markets.

#### 1. Threshold Data

Using the methodology and constraints outlined above, the resulting sample size of active, eligible high-spending drugs was 236.<sup>97</sup> Specifically, 228 (97%) were used in both Medicare Part D and Medicaid programs (with the spending data summed from both), while the remaining 8 (3%) were used solely in Medicaid. Of these 236 drugs, 139 (roughly 47%) received patent term extensions, and 97 did not. Among those 139 drugs that received a patent term extension, the average length of the extension was 3.1 years, with a range of 0.9 years to 5.0 years, which is the legal maximum.<sup>98</sup>

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95. *See, e.g.*, 130 CONG. REC. 23,054 (1984) ("It is hoped that this [up-to-five-year] extension of exclusive rights will encourage increased research and development efforts by pharmaceutical companies.").

96. *See infra* text accompanying notes 109-110 and text following note 111.

97. No drugs were used solely in Medicare Part D.

98. Six drugs had more than one patent term extension. If the extensions were overlapping, then this study measured from the earliest start to the latest end. If they were not overlapping, then this study took the sum of the lengths.

#### PATENT TERM EXTENSIONS AND THE LAST MAN STANDING

Among all 236 drugs with identifiable core patents,<sup>99</sup> the average primary monopoly time was 13.5 years with a maximum of 23.7 years.<sup>100</sup> This average primary monopoly time approximately coincides with the fourteen years anticipated by Hatch-Waxman.

Examining the primary monopoly time in a more granular fashion, the 139 drugs with patent term extensions had an average primary monopoly time of 11.3 years with a maximum of 14.0 years.<sup>101</sup> For the 97 drugs without patent extensions, the average primary monopoly time was 17.1 years with a maximum of 27.4 years.<sup>102</sup> Thus, the primary monopoly time is longer for those drugs without a patent term extension.

Although this finding may seem odd, it makes sense under the scheme of the Hatch-Waxman Act. The only drugs that can receive a patent term extension are those whose core patents have had their time eaten away by FDA delay. The Act, however, limits the amount of time that can be recouped to five years, for a maximum of fourteen years past approval.<sup>103</sup> In contrast, those without patent term extensions have no such limitation, with the result that their total *primary* monopoly time may be longer.<sup>104</sup>

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99. In the study's sample of drugs, 236 drugs have core patents, comprising 139 drugs that have patent term extensions (and thus by definition have core patents) and 97 drugs that have no patent term extensions but do have identifiable core patents.

100. The range of primary monopoly time for all 236 drugs with identifiable core patents was 4.4 years to 23.7 years. Because for the purpose of this study primary monopoly time was based on the expiration of marker patents (applying to the active ingredient of a drug), it was possible for some of the drugs in the study to have a primary monopoly time greater than twenty years (as was the case for 31 of the drugs analyzed).

101. The range was 4.2 to 14.0 years.

102. The range was 6.5 to 27.4 years. Primary monopoly time could extend past the traditional twenty years afforded for a single patent for the reasons described *supra* in note 100. The difference between the maximum primary monopoly time described in the range for the data as a whole (23.7 years) and for the subset of drugs without a patent term extension (27.4 years) is a result of the fact that this study trimmed the data at a level of 5% to calculate each mean, which is standard statistical practice.

103. *See supra* text accompanying notes 45–46 (discussing 35 U.S.C. § 156).

104. *See supra* Section III.B.

## 2. Prevalence and Length of Secondary Monopoly Time

Although Congress may have expected the time of the core patent plus any patent term extension to mark the end of patent protection, such is not the case in modern pharmaceutical markets. Most drugs with patent extensions obtained some amount of secondary monopoly time—that is, protection beyond the life of the core patent plus any patent term extension. Specifically, roughly 91% of drugs with patent term extensions enjoyed secondary monopoly time. That is a remarkable percentage, and one that is highly discordant with the vision expressed in Hatch-Waxman.

The average length of this secondary protection time beyond the end of the patent term extension is 7.8 years with some drugs obtaining as much as 16.8 years of protection beyond the patent term extension.<sup>105</sup> The results are quite different, however, for those drugs without patent term extensions, only about 51% of which had secondary monopoly time, with the average length of 5.5 years and a maximum of 13.3 years.<sup>106</sup> For the group as a whole, combining both those drugs with and without patent term extensions, the results unsurprisingly fell close to the middle. Nearly 75% of eligible drugs with primary monopoly time had some amount of secondary monopoly time,<sup>107</sup> averaging 7.2 years with a maximum of 16.4 years.<sup>108</sup> In sum, it is more common for a drug with a patent term extension to have secondary monopoly time and for that secondary monopoly time to be, on average, longer (7.8 years) than it is for drugs that do not have patent term extensions (5.5 years).

## 3. Last Man Standing Is Usually a Secondary Patent

In addition to calculating length, the study also examined what type of protection marked the end of secondary monopoly time. As the discussion below demonstrates, in most cases among all groupings, the “last man

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105. The range was 0.7 to 16.8 years.

106. The range was 0.5 to 13.3 years.

107. As determined by the identification of marker patents, 176 out of the total 236 drugs with primary monopoly time had some amount of secondary monopoly time.

108. The range was 0.5 years to 16.4 years. Note the difference in range maximums between the total group (16.4 years) and the with- and without-patent-term-extension groups (16.8 years and 13.3 years, respectively). This is a result of the 5% trimming that this study performed to calculate means, as described *supra* in note 102.

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standing” protection was a patent. In other words, additional patents are stretching the end times the most, not any type of non-patent exclusivity.

Specifically, among the 176 drugs that have secondary monopoly time, 81% of the last man standing protections were patents, as opposed to exclusivities. For drugs with patent term extensions, 78% of the last man standing protections were patents. For drugs without patent term extensions, a full 88% of the last man standing protections were patents.

In short, the most common last man standing protection for drugs that have a secondary monopoly period is a secondary patent. This is true regardless of whether a drug has a patent term extension or not.

How specifically are drug companies creating this secondary monopoly time? For those drugs with patent term extensions, each drug is protected by an average of roughly six additional patents and one exclusivity.<sup>109</sup> For drugs without patent term extensions, this average drops to roughly three additional patents and zero exclusivities.<sup>110</sup> In the most extreme cases, the maximum total number of patents being used during secondary monopoly time is thirty-seven and forty-eight, for drugs with and without patent term extensions, respectively. This means that some drugs are obtaining over thirty additional patents whose terms continue *after* their core patents expire. Commentators have discussed concerns about secondary patents related to biologic drugs, particularly the drug Humira;<sup>111</sup> clearly, secondary patents are problematic in the world of small molecule drugs as well.

What is especially troubling, though, is that the abundant use of these secondary patents is explicitly counter to what Congress intended when crafting the Hatch-Waxman legislation. As the discussion in the report of the

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109. The exact averages were 6.4 patents (with a range of 0 to 37) and 1.3 exclusivities (with a range of 0 to 7).

110. The exact averages were 2.6 patents (with a range of 0 to 48) and 0.3 exclusivities (with a range of 0 to 4).

111. *Overpatented, Overpriced Special Edition Humira*, I-MAK (Sept. 2021), <https://www.i-mak.org/wp-content/uploads/2021/09/i-mak.humira.report.3.final-REVISED-2021-09-22.pdf> [<https://perma.cc/6RTS-F8WZ>]; W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 527-28 (2014); Christopher M. Holman, *AbbVie Hopes to Maintain Humira Exclusivity Through Secondary Patents and Regulatory Barriers to Entry*, 36 BIOTECHNOLOGY L. REP. 9 (2017). *But see* Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 712-14 (7th Cir. 2022) (holding that Humira’s 132 secondary patents did not constitute an antitrust violation); *cf.* Feldman, *Evergreen*, *supra* note 7, at 617 (finding that, for small-molecule drugs, 78% of drugs associated with new patents are in fact existing drugs rather than new drugs entering the market).

House Judiciary Committee indicates, the Committee stressed the “need to avoid multiple patent term extensions” and viewed secondary patents as providing less of an inventive contribution to society; the Committee thus rejected the notion of allowing term extensions of secondary patents.<sup>112</sup> On the whole, the implication of the Committee’s decisions and discussions suggest that core patents are the only patents deserving extension, they should receive only one extension, and they should be the longest and last-expiring protection on a drug—not other patents on essentially the same drug. But, as the data presented here show, the exact opposite is playing out. For roughly 75% of the drugs in this study, core patents are not the last man standing protection. And when a core patent is not the last man standing, 81% of the time that last man standing is a secondary patent. Thus, through secondary patents, the Patent Office has accomplished what it could not persuade Congress to enact.

#### 4. Total Time Similar for Drugs with Patent Term Extensions and Those Without

Zooming out, the average total monopoly time, meaning primary and secondary monopoly times added together for all drugs in the sample, is 18.9 years with a maximum of 27.5 years.<sup>113</sup> This number hovers around the same mark for drugs both with and without patent term extensions. The total amount of patent protection for drugs with patent term extensions is 18.4 years on average with a maximum of 26.2 years.<sup>114</sup> The total amount of time of protection for drugs without patent term extensions is 19.7 years on average with a maximum of 30.3 years.<sup>115</sup>

Thus, regardless of whether a drug receives a patent term extension, companies on average are receiving about five more years of post-approval protection than the fourteen-year limit set by Hatch-Waxman, with the maximum reaching to over seventeen years longer than that limit.

In addition, the Hatch-Waxman Act represented a compromise, evidencing the intent to provide additional patent protection through the patent term extension of the core molecule patent in exchange for allowing generic companies to rely on the brand’s safety and efficacy studies. The

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112. *See supra* notes 48–51 and accompanying text (citing the House Judiciary Committee’s report and discussing the logic of a rejected amendment).

113. The range was 11.9 to 27.5 years.

114. The range was 11.9 to 26.2 years.

115. The range was 12.2 to 30.3 years.



similar monopoly times between drugs with patent term extensions and those without patent term extensions further demonstrates that society has departed from Hatch-Waxman's legislative scheme. Through a variety of additional strategies and methods, those drugs without additional monopoly time from a patent term extension—presumably including those that could not qualify for one—are able to receive roughly the same additional monopoly as those with a patent term extension. In short, drugs are receiving more protection than anticipated and receiving it in ways beyond the historic legislative compromise.

#### 5. Costs to Society of Secondary Monopoly Time

Based on these numbers, this study also estimated the cost that society incurred due to these secondary monopoly periods. The calculation first required multiplication of each drug's spending in 2019 by its secondary monopoly time to generate the total spending that occurred for each of the 176 drugs during its secondary monopoly time. A certain percentage of this spending is the cost to society: The precise question is how much cheaper (expressed as a percentage) are generic drugs than brand drugs.

Referencing a recent FDA report on Generic Competition and Drug Prices,<sup>116</sup> this study chose to use 31%, 51%, and 95% to create a feasible range.<sup>117</sup> Thus, the cost to society for each drug was calculated assuming generic drug prices were 31%, 51%, and 95% lower than brand drug prices. This assumption yielded three values per drug. Summing these values across all drugs for each of the three groups then yielded the three values that represent the estimated total cost to society incurred because of the drugs' secondary monopoly time. Assuming generics are 31% cheaper, the total cost to society comes to \$53.6 billion.<sup>118</sup> This figure jumps to \$88.1

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116. RYAN CONRAD & RANDALL LUTTER, U.S. FOOD & DRUG ADMIN., *GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 2-3* (2019).

117. These three percentages were chosen for the following reasons mentioned in the FDA report. *See id.* If there was a single generic drug in the market, then the generic prices were 31% lower than the brand prices before generic competition. *Id.* at 2. If there were six or more generic drugs in the market, then the generic prices were lower by more than 95% compared to brand prices. *Id.* at 3. The median price of generics relative to brands is 49%. *Id.* Thus, the three chosen percentages in this study would yield a range for the estimated cost to society as well as a median value.

118. This total was composed of \$41.7 and \$11.9 billion from drugs with patent term extensions and those without, respectively.

billion<sup>119</sup> if one assumes generics are 51% cheaper, and to \$164.1 billion<sup>120</sup> if one assumes generics are 95% cheaper. Thus, stated most conservatively, the secondary monopoly time of the 176 top-selling drugs imposes a \$53.6 billion cost on consumers.<sup>121</sup>

This method of determining estimated cost to society over the study period has potential limitations. First, the value for spending on a given drug over the course of its secondary monopoly period is generated by multiplying the length of that secondary monopoly period by the 2019 spending on the drug, as that is the last year of spending from which this study draws. This approach might produce an overestimation of the cost of the drug both because of inflation and any increase in drug prices over time, and because even under conditions of stable unit prices, a drug might increase in sales over the length of its monopoly as more people learn about the drug and its popularity grows. These uncertainties counsel reliance on this study's conservative estimate of the cost to society, as the conservative

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119. This total was composed of \$68.6 and \$19.5 billion from drugs with patent term extensions and those without, respectively.

120. This total was composed of \$127.7 and \$36.4 billion from drugs with patent term extensions and those without, respectively.

121. The calculation of the estimated cost to society rests on several assumptions: that no generic version was or will be able to break the granted monopoly until the expiration of all protections; that the spending on and pricing of these drugs stayed the same during the secondary monopoly time; and that the number of patients stayed unchanged during the secondary monopoly time. Again, the estimated cost to society was based on the 2019 rebated spending from Medicare Part D and Medicaid. The Medicare Part D rebate percentage found in the CMS Trustees report was 26.5% for all drugs in 2019. *Trustees Report & Trust Funds*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/data-research/statistics-trends-and-reports/trustees-report-trust-funds> [https://perma.cc/HNK8-RCRD]. In order to only reflect the rebate percentage of brand drugs, we needed to adjust this rebate percentage. Based on the assumption that the brand drugs spending share was 77%, the Part D adjusted rebate percentage became 34.4%. For Medicaid rebate percentage, we relied on a report from MACPAC. Chris Park, *Trends in Medicaid Drug Spending and Pricing*, MEDICAID AND CHIP PAYMENT AND ACCESS COMM'N (Oct. 27, 2022), [https://www.macpac.gov/wp-content/uploads/2022/10/07\\_Trends-in-Medicaid-Drug-Spending-and-Rebates-Chris.pdf](https://www.macpac.gov/wp-content/uploads/2022/10/07_Trends-in-Medicaid-Drug-Spending-and-Rebates-Chris.pdf) [https://perma.cc/YJ5N-8LU2]. The report mentioned that Medicaid gross spending was \$68.2 billion and net spending was \$31.1 billion. Thus, the rebate percentage was 54.4%. Also, the report mentioned that the brand drugs spending share was 83%. From that, we could adjust the rebate to become 65.5%.

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estimate of the generic price decrease—i.e., the estimate based on the 31% figure discussed above—should counteract any incidental overestimation of long-term drug spending. Second, it is technically possible that generic companies might not enter the market immediately or at all had these secondary monopolies not precluded competition. However, the high prices of brand drugs, along with the fact that the first-to-market generic competitor who files a paragraph IV certification benefits from a 180-day generic marketing exclusivity period, incentivize rapid market entry in the United States. This incentivization is especially likely given that the drugs analyzed in this study were the highest spend drugs for Medicare Part D and Medicaid, a fact that would make them a more compelling target for generic competition. Thus, for the purposes of this study, it is reasonable to assume speedy generic marketing upon the conclusion of brand monopoly time.<sup>122</sup>

#### IV. RECOMMENDATIONS

Hatch-Waxman's vision of speedy generic entry upon expiration of the marker patent is not playing out. But the obstacle is likely not due to shortcomings in Hatch-Waxman itself. The problem, rather, lies in the proliferation of secondary patents that undermine Hatch-Waxman's focus on each drug's core medical innovation. Indeed, studies have shown that secondary patents and exclusivities of the sort that block generic competition have become far more prevalent in recent years compared to when Hatch-Waxman was young.<sup>123</sup>

If nothing else, one of Hatch-Waxman's provisions remains remarkably useful insofar as it allows the public to easily identify the obstacles to the realization of its vision. Hatch-Waxman's requirement that drug makers

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122. Even after the expiration of a statutorily authorized monopoly, it is often strategic activity by a brand drug company that keeps generics from immediately entering the market. *See, e.g.*, Robin Feldman, Evan Frondorf, Andrew Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 70–72 (2017) (revealing that many generic drugs find their FDA approval delayed because brand drug companies file frivolous citizen petitions expressly designed to extend monopoly periods). In particular, the delay of FDA approval caused by brand companies filing frivolous citizen petitions—a delay that functionally extends secondary monopoly time—was not included in the time-period analysis performed for this study.

123. Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies—Should Competition Law Intervene?*, 51 INT'L REV. INTEL. PROP. & COMPETITION L. 1062, 1067 (2020); Feldman, *Evergreen*, *supra* note 7, at 618–21.

publicly declare applicable patents and exclusivities enables one to pinpoint which of these protections are getting in generics' way. But for the secondary patents and exclusivities that extend well beyond the single, time-limited extension created by the Act, brand drugs would be facing market competition much sooner. The lower drug prices intended by Hatch-Waxman would be prevailing in the market much sooner as well.

Hatch-Waxman, on balance, has increased access and lowered prices for life-saving medicines across the board. However, as this and many other studies demonstrate, brand companies' ability to prolong their periods of market exclusivity prevents the Hatch-Waxman framework from living up to its full potential.<sup>124</sup> In light of the evergreening practices that sustain brand drug monopolies, this Part proposes and discusses a range of measures that can reduce blockages in the generic drug pipeline. None is a perfect fix, but each is a potential starting point for constructive reform. Possible remedies can be advanced by Congress, administrative agencies, and the courts, and range from gradual adjustments to drastic and sweeping overhauls. Although the remedies can take many different forms, limiting the patents and exclusivities that may cover a drug is a viable first step to realizing Hatch-Waxman's goal of facilitating speedy generic entry. Alternatively, or in addition, Congress, the Patent Office, and courts can take steps to reinvigorate patentability standards and thereby reduce brand companies' ability to weaponize the patent system and stave off competition.

#### A. *Limiting the Grip of Patents and Exclusivities on Drug Markets*

One relatively simple way to eliminate evergreening is to limit brand drugs to one category of patent or exclusivity. This limit might focus on the core patent on active ingredients, preempting the development of large secondary patent portfolios that have historically facilitated long-term monopolies on a drug, but for which generics would swiftly arrive on the market. This "one-and-done" approach establishes the timeline early in a drug's "life" and eliminates the possibility of adding to or compounding data-exclusivity periods defined by Congress. Such a prospect is attractive,

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124. See *supra* Parts II and IV; Feldman, *Evergreen*, *supra* note 7, at 618; Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 8 (2012); Anna Laakmann, *The Hatch-Waxman Act's Side Effects: Precautions for Biosimilars*, 47 LOY. L.A. L. REV. 917, 928–29 (2014).

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as it cuts to the core of evergreening by allowing generic drug makers to confidently enter the market without fear of litigation from unexpected intellectual property disputes. A one-and-done approach is also preferable to more tailored reforms because it reduces the possibility of cat-and-mouse games wherein increasingly complex regulation fosters only increasingly complex workarounds. There are various forms that a one-and-done policy reform could take: The FDA and the Patent Office might (a) allow applicants to select which exclusivity they wish to enforce, (b) permit applicants to obtain regulatory exclusivities but limit them to one drug or molecule, or (c) cap the number of enforceable patents and exclusivities at a number higher than one but well below the record high of forty-eight in this study's data set.

Mechanically, any of these systems would likely operate by requiring applicants to waive additional patent rights with respect to the drug in question as a condition of regulatory approval (or providing that a generic's paragraph IV certification need certify only to the one patent or exclusivity elected by the brand). Such a one-and-done approach would likely have to come from Congress; without legislative blessing, executive agencies almost certainly would prove unable to convince courts that they alone can make this change to a patent's operability.<sup>125</sup>

A plausible variation of this policy reform is to establish certain "safe harbors" for generic drugs. This idea amounts to congressionally defined activities that are immune from patent (and exclusivity) enforcement. Imagine, for example, a law that protects all persons from patent lawsuits that arise from their producing and marketing a generic drug, provided that certain conditions are met. Lawmakers might provide a safe harbor for generic companies entering the market to compete with a brand drug that has been approved for, say, at least twenty years; a brand drug for which no generic is already approved; a brand drug for which no therapeutic competitor exists; or a brand drug for which the patent on the active ingredient has already expired. In short, Congress can prevent brand drugs from using patents to block generics in certain circumstances simply by saying that they cannot. Though a "safe harbor" approach may, depending on how it is constructed, function similarly in practice to a "limiting patents" approach, focusing on an encouraged, protected activity instead of on a

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125. Historically, it is outside the purview of federal agencies to determine whether a valid patent is enforceable. Although the Patent Office can rescind the validity of a U.S. patent through *inter partes* review, patent enforceability is otherwise relegated to courts. See, e.g., S. REP. NO. 93-1298, at 196 (1974) (noting that the U.S. International Trade Commission is not empowered to "set aside a patent as being invalid or to render it unenforceable").

hard-to-pin-down, prohibited activity could allow legislators to tailor the law more easily to the desired outcomes. The threat of an expensive lawsuit, even a completely bogus one, is a powerful deterrent for potential generics. The more direct the approach, the more certainty all players will have when planning around a drug's life cycle.

Were Congress to take this approach, it would be following a well-trodden path insofar as Hatch-Waxman already established a significant patent safe harbor. Recall that the law, as originally passed, provides that no generic maker can be held liable for infringement that occurred in preparing an abbreviated new drug application.<sup>126</sup> Of course, Hatch-Waxman does not allow generics to compete during the anticipated initial period of market exclusivity, while the reforms advocated for here may allow a generic to enter a market that might otherwise be an exclusive one. However, the point is that there is nothing to stop Congress from setting up another safe harbor against monopolies that, in Congress's view, have gone on too long.

Carrying out any of these policies, whether it be the establishment of a safe harbor or a one-and-done approach to monopoly extending practices, could prove politically difficult given the legislative influence available to pharmaceutical companies. The undertaking of such a legislative reform might require its own contemporary version of Hatch-Waxman's grand compromise. Congress might, for instance, strike a deal among the various stakeholders in this debate, such that in exchange for a one-and-done cap on these monopoly lengthening, patent term extensions, exclusivities, and secondary patents, Congress also agrees that patent terms can be extended further than is now statutorily permitted. This extension might take us from the fourteen years envisioned by the original Hatch-Waxman legislation and extend it an additional four or five years to the eighteen or nineteen years of total monopoly time that the average drug currently experiences.<sup>127</sup> In exchange for those additional few years of guaranteed monopoly, brand drug companies would be required to let go of this endless patent gaming, allowing generics to enter the market in a clearly-delineated timeframe so

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126. *See* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990) (“[Section 202 of the Hatch-Waxman Act] added to the provision prohibiting patent infringement, 35 U.S.C. § 271, the paragraph at issue here, establishing that ‘[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.’ 35 U.S.C. § 271(e)(1). This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.”).

127. *See supra* text accompanying notes 113-115.

that consumers can finally reap the benefits of high innovation and low prices.

*B. Eliminating 'Bad' Patents*

One way to minimize the impact of evergreening on prescription drug prices is to reduce the number of improperly granted patents. According to the history, theory, and statutory language behind U.S. patent law, a patentable invention must be new, useful, and nonobvious to one skilled in the relevant art.<sup>128</sup> The patents that prolong drug monopolies, however, are seldom the core patents on the medical breakthrough but are, instead, secondary patents that frequently stretch the criteria for patentability. As described above, the long monopoly extensions that have arisen unanticipated by the Hatch-Waxman Act cost consumers, health plans, and taxpayers a conservatively estimated \$53.6 billion during the secondary monopoly time period that, but for these unwarranted secondary patents, would have remained in people's pockets. These costs happen even for drugs that did not receive a patent term extension.<sup>129</sup> Fortunately, there are many avenues for reducing the prevalence of bad patents without radically altering the landscape of patent law or pharmaceutical regulation.

The Patent Office, for its part, can and should hold patent applications more strictly to the requirements set out by America's patent laws. One could make a plausible argument that the Patent Office has not succeeded in filtering out all of the patent applications that should be rejected. Constraints on human and financial resources do, in fairness, force the Office to spend very little time considering any given patent application.<sup>130</sup> However, to the extent that the Patent Office guidelines for examining patent applications misleads examiners, the Office should reform its guidelines to better reflect the necessity of weeding out patents that are not innovative, non-obvious, or novel. And to the extent that the Office is simply under-resourced, Congress should consider supporting the agency more so that it has the capacity to effectively do its job.

As an aside, there is a compelling argument that relying on the Patent Office to sort good patents from bad ones is not cost-efficient. Some twenty years ago, Professor Mark Lemley famously argued that it is simply not worth the necessary resources to create an office that is able to effectively

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128. 35 U.S.C. §§ 101-103.

129. *See supra* text accompanying notes 118-121.

130. FELDMAN & FRONDORF, *supra* note 5, at 29-30.

evaluate patentability since bad patents of economic consequence may be effectively weeded out during the litigation process or agency review.<sup>131</sup> As the argument goes, the Patent Office sees millions of patent applications, the majority of which are not commercially viable or economically significant, so the system can tolerate lots of bad patents when most of them are for useless inventions. As long as post-grant proceedings, such as litigation, can be relied on to invalidate consequential bad patents, the market should protect itself.<sup>132</sup> Lemley nicely dubs this behavior as “rationally ignorant.”<sup>133</sup>

A more recent analysis, following roughly the same calculation but with more recent and reliable inputs, reveals that Lemley’s calculation points to the opposite conclusion: that the Patent Office’s granting of many bad patents is, indeed, inefficient.<sup>134</sup> Specifically, the analysis concludes that costs associated with giving examiners more time to check patents are greatly outweighed by the savings resulting from the elimination of post-grant litigation proceedings.<sup>135</sup> Thus, in addition to tidying up the stage for easier generic entrance, providing examiners with more time and resources appears to be the most economical choice as well. Congress should seriously consider these positive effects of granting the Patent Office the necessary support it needs to effectively review all patents.

The balance that policymakers should seek—indeed, the balance at the very heart of patent theory—is between incentivizing innovation and ensuring public access. And a balance it must be. This study and its recommendations assume throughout that there is little or no benefit provided to the public by many of these secondary patents, either in terms of innovation or public access. The policy dilemma boils down to weighing type one error (whereby a bad patent is granted) against type two error (whereby a valuable patent is rejected), with a certain amount of each being inevitable. Thus, although reducing access to patent and regulatory protection may discourage certain worthwhile experiments, the overwhelming evidence provided by this study and others shows that the current system, as it plays out on the ground, leaves innovators with far more gate-keeping power than lawmakers intended.

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131. See Lemley, *supra* note 8, at 1510-11.

132. *Id.*

133. *Id.* at 1497.

134. Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 980-81 (2019).

135. *Id.* at 1028-29.



V. CONCLUSION

The Hatch-Waxman compromise represented the greatest legislative innovation in drug development in a generation, and it approached the issue with a balanced understanding of the needs and motivations of many stakeholders. To support innovators, the Act allowed for brand companies to extend their patents and devised other methods by which market monopolies on new drugs could be protected from competition. To support follow-on drug makers, the legislation created a mechanism by which generic companies could more quickly and cheaply come to market and make more affordable versions of drugs available. The public was meant to benefit from both halves of this compromise, reaping the rewards of new medical treatments that would, in a swift and orderly fashion, decrease in price.

As this study has demonstrated, however, such a compromise has not truly come to pass. The very system by which Hatch-Waxman meant to motivate brand drug companies to make new drugs to be later sold as generic versions has been co-opted, alongside other legislative and regulatory tools, to keep generics off the market. Even some drugs that can no longer be considered new by any stretch of the imagination remain firmly protected from competition. Indeed, the legislative aspiration of an (at most) fourteen-year monopoly in most cases, which was itself meant to be a limited extension of what was at the time a nine-year monopoly on average, has been dwarfed by actual monopoly times that can rise to over twice what was intended. Thus, the vision of Hatch-Waxman has proven, at least at the current juncture, illusory. This need not be the case, however. Rather, the legislative and regulatory reforms advised in this study can bring drug markets more in line with what the Hatch-Waxman legislation sought, affording consumers the dual benefits of pharmaceutical innovation and greater access.