NOTE

PHARMACEUTICAL PATENT PROTECTION BEYOND THE TWENTY-YEAR STATUTORY TERM

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INTRODUCTION

Although many life-saving pharmaceuticals on the market have already seen their patents expire,[1] there are countless

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[1] *See* Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff,"* U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff [https://perma.cc/NT9J-

life-saving pharmaceuticals that still have patent protection, and many more are currently or will be seeking patent protection. Some of these pharmaceutical inventions still have patent protection despite the initial patents having been filed as far back as 1985.[2] The top-ten bestselling brand-name pharmaceuticals have an average projected duration of 40.5-years of patent protection, double the twenty-year statutory term of a patent, through an average of seventy-four patents.[3] This practice of obtaining extended patent protection is known as evergreening.[4] But this is not the only practice that pharmaceutical companies employ to extend patent protection. Other practices include product hopping and pay-for-delay settlement agreements with generic pharmaceutical manufacturers, both of which prevent the dispensing of generic pharmaceuticals.[5]

Part I of this Note will provide background information regarding the requirements to obtain a patent, what rights are conferred by a patent, and the process by which generic pharmaceuticals obtain FDA approval. Part II of this Note will discuss the main practices that brand-name pharmaceutical

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BHRA] ("Beginning in 2010, the pharmaceutical industry faced one of the biggest waves of drug patent expirations in history . . . .").

2 *See* I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 3 (2018), http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf [https://perma.cc/26DQ-BN3W] ("Herceptin, a cancer drug sold by Roche / Genentech, had patents first filed in 1985 and has current patent applications pending that could extend patent exclusivity until 2033, a 48-year potential monopoly span.").

3 Most data in this Note are from I-MAK's most recent prescription drug studies, which were based on data collected in 2021 and released in 2022. *See generally* I-MAK, OVERPATENTED, OVERPRICED: CURBING PATENT ABUSE (2022), https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf [https://perma.cc/VW4K-EELW] (detailing I-MAK's latest report); *America's Top Selling Drugs*, I-MAK, https://www.i-mak.org/2021-top-selling/ [https://perma.cc/B5ZE-GJZJ] (last visited Mar. 14, 2023) (summarizing I-MAK's latest data); *The Drug Patent Book*, I-MAK, https://drugpatentbook.i-mak.org [https://perma.cc/ZHB2-BXJF] (last visited Mar. 14, 2023) (I-MAK's database of patent data). I-MAK is a team of attorneys, scientists, and health experts with a mission to address structural inequalities in the medical system through research, education, and policy. *See Our Most Urgent Mandate*, I-MAK, https://www.i-mak.org/mandate/ [https://perma.cc/7CLN-DXEK] (last visited Mar. 14, 2023). For more information about I-MAK, visit https://www.i-mak.org.

4 *See* CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 16 (2020) [hereinafter CONG. RSCH. SERV., R46221].

5 *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171–72 (2016) (describing product hopping); FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 25–39 (2002) [hereinafter FTC GENERIC DRUG STUDY] (describing pay-for-delay).

companies employ in order to obtain extended patent protection. It will also highlight the top-ten bestselling brand-name pharmaceutical inventions, all of which have extended patent protection. Part III of this Note will discuss the effects that these practices have on the integrity of the patent system and a patient's ability to access life-saving pharmaceuticals. Finally, Part IV of this Note will discuss potential solutions to curb these practices so as to ensure that the patent system is neither stifling innovation nor injuring the public health.

I
BACKGROUND INFORMATION

A. Requirements to Obtain a Patent

The Progress Clause provides that Congress shall have power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[6] It is from this clause that Congress created our current patent system, which is housed in Title 35 of the United States Code. To obtain a patent, an inventor must meet the requirements for patentability. In sum, the inventor's invention must fall within patentable subject matter, have utility, be novel, be non-obvious, and be properly disclosed.[7]

Relevant to this Note are the novelty and non-obvious requirements. For an invention to be novel, it must not have been previously "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date."[8] For an invention to be non-obvious, "the differences between the claimed invention and the prior art . . . [cannot] have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."[9] Collectively, the novelty and non-obvious requirements create a form of heightened novelty. Although an invention may be novel in the literal sense, it may not be patentable if the inven-

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6 U.S. CONST. art. I, § 8, cl. 8.

7 *See* 35 U.S.C. § 101 (detailing patentable subject matter and utility); *id.* § 102 (detailing novelty); *id.* § 103 (detailing non-obviousness); *id.* § 112 (detailing written description).

8 *Id.* § 102(a)(1).

9 *Id.* § 103.

tion is a mere improvement that did not require ingenuity and skill, or a flash of creative genius to invent.[10]

B. Patent Rights and their Duration

The granting of a patent is sometimes referred to as a legal quid pro quo.[11] As evidenced by the Progress Clause, the patent system's ultimate goal is to bring new ideas and technologies into the public domain.[12] In theory, absent patent protection, inventors will not have a sufficient incentive to invest in inventing new inventions.[13] The granting of a patent gives an inventor the opportunity to recoup their investment cost and, at times, yield a profit.[14] It does this by extending to the inventor the "right to exclude others from making, using, offering for sale, or selling the invention," for a limited time.[15] To obtain this right, an inventor must fully disclose their invention so as to give the public complete possession of it.[16] During the patent term, the public is encouraged to improve upon the invention or to design around it.[17] When the patent term expires, the invention falls into the public domain; the inventor no longer has the exclusive right to the invention, and the public may practice the invention as they please.[18]

The patent system attempts to strike a balance between (a) incentivizing inventors to invest in new inventions, and (b) the right of the public to exploit new technologies and to

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10 *See, e.g.*, Hotchkiss v. Greenwood, 52 U.S. 248, 267 (1850) (invalidating a patent for a new doorknob because the substitution of clay or porcelain for previously used materials was not the result of ingenuity and skill); Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 85–86, 91 (1941) (invalidating a patent for an improvement in automobile cigarette lighters because the improvement was not the result of a flash of creative genius).

11 *See, e.g.*, Sean B. Seymore, *Symposium: The Disclosure Function of the Patent System*, 69 VAND. L. REV. 1455, 1455 (2016) (arguing that the patent system achieves its goal of encouraging dissemination of technical knowledge through a quid pro quo).

12 Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

13 *See, e.g.*, 1 PETER S. MENELL, MARK A. LEMLEY, ROBERT P. MERGES & SHYAMKRISHNA BALGANESH, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2021, at 18-25 (2021) (describing theories of patent law that explain the lack of incentive for inventors to invest in new inventions absent some form of protection). This theory rests upon two things: (1) that inventors are driven by market incentives, and (2) that information is difficult to control once released to the public. *See id.*

14 *See id.*

15 35 U.S.C. § 154(a)(1).

16 *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345–47 (Fed. Cir. 2010) (en banc).

17 *See* Seymore, *supra* note 11.

18 *See id.* at 1455–56.

improve upon them.[19] This is where the duration of the patent comes into play. If patents are granted for longer than necessary to incentivize inventors to invest in new inventions, the progression of technological advances may start to slow.[20] Accordingly, the term of a patent must be limited to a term that incentivizes inventors without slowing the progression of technological advances.

The interpretation of "limited [t]ime[ ]" within the Progress Clause varies significantly between different types of intellectual property and has changed many times since the adoption of the Constitution.[21] Throughout the history of the patent system, the term of a patent has varied from fourteen years to twenty-one years. The Patent Act of 1790 imposed a fourteen-year term from the date of issuance.[22] Inventors, however, complained that a fourteen-year term was insufficient to realize a return on their investment.[23] In response, Congress granted extensions on an individual basis.[24] The Patent Act of 1836 formalized the granting of an extension and allowed the Patent Commissioner to grant a seven-year extension (for a total of twenty-one years of protection) if the patent holder could demonstrate a lack of "reasonable remuneration for the time, ingenuity, and expense" in inventing the invention.[25] The extension process proved to be burdensome for the Commissioner, so, in 1861, Congress adopted a seventeen-year term without any extension.[26] This remained the standard until the Uruguay Round Agreements Act of 1994 changed the term to twenty years from the date of filing.[27]

C. FDA Approval of Generic Pharmaceuticals

Approval of generic pharmaceuticals by the Food and Drug Administration (FDA) is guided by the Hatch-Waxman Act and

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19 *See* Noah Adam, *Why Do Patents Expire?*, PAT. REBEL (Aug. 15, 2019), https://patentrebel.com/why-do-patents-expire-answered/ [https://perma.cc/8DTK-P6JU].

20 *See id.*

21 U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times . . . ."). For example, the current term of a copyright is the life of the author plus seventy years. 17 U.S.C. § 302(a). This longer term, however, is balanced by extending a narrower exclusive right to the author. *See id.* § 106.

22 Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 110.

23 *See* Simon Lester & Huan Zhu, *Rethinking the Length of Patent Terms*, 34 AM. U. INT'L L. REV. 787, 792 (2019).

24 *See id.* at 792–93.

25 Patent Act of 1836, ch. 357, § 18, 5 Stat. 117, 125.

26 *See* Lester & Zhu, *supra* note 23, at 793.

27 35 U.S.C. § 154(a)(2).

the Biologics Price Competition and Innovation Act. The Hatch-Waxman Act, which was passed by Congress in 1984, relates to small-molecule pharmaceuticals.[28] The Biologics Price Competition and Innovation Act, which was passed by Congress in 2010, relates to biologic pharmaceuticals.[29] Although the Acts relate to different types of pharmaceuticals, they both have the same goal—to create an easier pathway for generic pharmaceutical manufacturers to obtain FDA approval for generic versions of brand-name pharmaceuticals.[30]

Under these pathways, generic manufacturers do not have to independently prove that their generic pharmaceutical is safe and effective.[31] Instead, generic manufacturers only have to show that their generic pharmaceutical is bioequivalent (in the case of small-molecule pharmaceuticals) or biosimilar (in the case of biologic pharmaceuticals) to the brand-name pharmaceutical.[32] In doing so, generic manufacturers can rely on the data submitted to the FDA by brand-name companies to show that their generic pharmaceutical is safe and effective.[33]

For small-molecule pharmaceuticals, the approval process begins by filing an Abbreviated New Drug Application (ANDA). Under this process, a generic manufacturer can seek FDA approval for a generic version of a brand-name pharmaceutical even if the brand-name pharmaceutical still has patent protection.[34] When filing an ANDA, the generic manufacturer makes a Paragraph IV certification stating that (1) the generic version does not infringe any patent listed for the brand-name pharmaceutical, or (2) the patents listed for the brand-name pharmaceutical are invalid.[35] The generic manufacturer then notifies the brand-name company that they have filed a Paragraph IV certification with its ANDA.[36] The brand-name company can either (1) bring suit for patent infringement and receive an automatic thirty-month stay on the FDA's approval of the ANDA, or (2) do nothing and allow the generic manufacturer to receive FDA approval.[37] If the brand-name company sues and

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28 *See* JOANNA T. BROUGHER, INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES 137–45 (2014) (describing the Hatch-Waxman Act and the ANDA process).

29 *See id.* at 164–67 (describing the Biologics Price Competition and Innovation Act).

30 *See id.* at 164.

31 *See id.* at 143.

32 *See id.* at 143, 164–65.

33 *See id.* at 143.

34 *See id.* at 143–45.

35 *See id.* at 144.

36 *See id.*

37 *See id.* at 144–45.

the generic manufacturer prevails, the generic manufacturer receives a special period of generic pharmaceutical exclusivity following the approval of its ANDA.[38]

There are two main differences between the approval of small-molecule pharmaceuticals under the Hatch-Waxman Act and the approval of biologic pharmaceuticals under the Biologics Price Competition and Innovation Act. First, when a generic small-molecule pharmaceutical is approved, it is considered interchangeable.[39] This allows pharmacies to substitute the brand-name pharmaceutical with the generic version when dispensing the prescription even if a physician writes the prescription for the brand-name pharmaceutical (e.g., if a physician writes a prescription for "Lexapro," a pharmacy can substitute it for "escitalopram").[40] Generic biologic pharmaceuticals, however, are not considered interchangeable unless the generic manufacturer demonstrates through studies that the generic pharmaceutical is interchangeable.[41] As a result, if a generic manufacturer does not conduct additional testing to show that the generic pharmaceutical is interchangeable, a pharmacy cannot substitute the generic version of the brand-name pharmaceutical.[42] Second, in regard to generic pharmaceutical exclusivity, a generic small-molecule pharmaceutical receives 180 days of exclusivity, and a generic biologic pharmaceutical receives between twelve and forty-two months of exclusivity.[43]

II
EXTENDED PROTECTION

A. Obtaining Extended Protection

As noted above, there are many practices that brand-name companies employ in order to obtain extended patent protection for their inventions. Arguably the most common practice

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38 *See id.* at 145.

39 *See* Daphne E. Smith Marsh, *Bioequivalence and Interchangeability of Generic Drugs*, MERCK MANUAL (Sept. 2022), https://www.merckmanuals.com/home/drugs/brand-name-and-generic-drugs/bioequivalence-and-interchangeability-of-generic-drugs [https://perma.cc/AY4Y-2XGK].

40 *See id.* If, however, the physician writes "Dispense as Written" or "Brand Name Only" on the prescription, then the pharmacy cannot substitute the generic version of the brand-name pharmaceutical. *See id.*

41 *See Biosimilar and Interchangeable Products*, FDA (Oct. 12, 2021), https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices [https://perma.cc/2ELD-KNNM]; BROUGHER, *supra* note 28, at 165.

42 *See Biosimilar and Interchangeable Products*, *supra* note 41.

43 *See* BROUGHER, *supra* note 28, at 145, 166–67.

is evergreening. Other common practices include product hopping and pay-for-delay settlements. This section will explore each of these practices in further detail.

1. *Evergreening*

Evergreening is the practice where inventors artificially extend an invention's duration of patent protection by obtaining secondary patents that cover different aspects of the invention.[44] This practice occurs in many technology industries, but it is heavily prevalent in the pharmaceutical industry.[45] A pharmaceutical typically has patents covering the molecular structure of the drug as well as methods of using, manufacturing, or administering the drug.[46] The bulk of the patents contributing to evergreening are improvement patents that cover improvements to methods of using, manufacturing, or administering the drug.[47]

To briefly illustrate how evergreening works, here is an example of a pharmaceutical company patenting a new pharmaceutical. Company A files a patent application in 2023 for the molecular structure of Drug X. Barring any prosecution delays, Patent #1 would expire in 2043. Next, Company A files a patent application in 2025 for a method of manufacturing Drug X and files a patent application in 2027 for a method of administering Drug X. Barring any prosecution delays, Patent #2 would expire in 2045 and Patent #3 would expire in 2047. Then, Company A discovers an improved method of manufacturing Drug X (e.g., a different coating that allows the capsule to absorb slower in the intestine) and later discovers an improved method of administering Drug X (e.g., a different dosage). After filing patent applications in 2033 and 2035 for these respective improvements, and barring any prosecution delays, Patent #4 would expire in 2053 and Patent #5 would expire in 2055. With these additional patents, Company A has obtained thirty-two years of patent protection for Drug X (i.e., from the filing of the first patent in 2023 to the expiration of the fifth patent in 2055).

The above example highlights two broad groups of patents that contribute to evergreening. The first group is the initial round of secondary patents that relate to the methods of manu-

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44 *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 596 (2018).

45 *See id.* at 596–98.

46 *See* CONG. RSCH. SERV., R46221, *supra* note 4, at 8–9.

47 *See id.* at 16–17.

facturing and administering Drug X. This Note does not take issue with this group of patents, as it is customary in patent law to patent different aspects of an invention.[48] The second group of patents are the following rounds of secondary patents that are for improvements to the methods of manufacturing and administering Drug X. It is these improvement patents that pharmaceutical companies pursue in order to artificially extend the duration of a pharmaceutical's patent protection.[49] In the above example, the improvement patents added ten years of patent protection. This is on top of the additional five years of patent protection already obtained by the initial secondary patents and the twenty years of patent protection already obtained by the initial molecular structure patent.

2. *Product Hopping*

A common question arises when discussing the practice of evergreening—"Why do generic manufacturers not bring to the market a generic version of the old product that is no longer patented?" The unfortunate answer is that another practice called product hopping hinders a generic manufacturer's ability to bring such a generic version to the market.[50] Product hopping is the practice whereby brand-name companies will "switch" doctors, pharmacists, and patients to the new version of their pharmaceutical.[51] The switch occurs when brand-name companies (1) use their dominant market position to campaign for the new product to be prescribed, or (2) remove the old product from the market.[52]

The primary issue with product hopping is the fact that generic versions of brand-name pharmaceuticals can only be substituted if a physician prescribes the old brand-name version. Substitution of a brand-name version with a generic version does not extend to the new product, as the generic version

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48 *See* CONG. RSCH. SERV., R46221, *supra* note 4, at 9; *see also* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW, Ch. 2.III (3d ed. 2015) (ebook) (describing different categories of pharmaceutical patent claims, including substances, formulations, methods of using, and methods of making).

49 *See* CONG. RSCH. SERV., R46221, *supra* note 4, at 16–17; *see also* Feldman, *supra* note 44, at 597 ("78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs.").

50 *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 527–33 (2016) (describing how product hopping prevents generic pharmaceuticals from entering the market).

51 CONG. RSCH. SERV., R46221, *supra* note 4, at 20–21.

52 *See id.* These switches are commonly referred to as a "soft switch" when it involves marketing the new product and a "hard switch" when it involves removing the old product. *See id.*

of the old product is not considered interchangeable with the new product.[53] When the brand-name company leverages its dominant market position to campaign for the new version of the pharmaceutical, attention is taken away from the old brand-name version.[54] This campaigning comes in many forms, including convincing physicians to prescribe the new version as well as extending rebates and incentives to insurance companies and pharmacies.[55] As a result, there are less prescriptions for the old brand-name version and even less prescriptions dispensed with the generic version; thus, the profitability of bringing a generic version to the market is affected.

The issue with marketing is even more problematic with biologic pharmaceuticals, as the FDA has only approved two interchangeable biologic pharmaceuticals.[56] Not only must a physician specifically prescribe the old version of the biologic, but a physician must also specifically prescribe the generic version of the biologic. This adds additional campaigning by brand-name companies to convince physicians to continue prescribing the brand-name version.[57] Given that physicians regularly write prescriptions for the brand-name version and rely on pharmacies to substitute with the generic version (e.g., writing "Tylenol" instead of "acetaminophen"),[58] such campaigning decreases the dispensing of non-interchangeable biologics.

The limitations on interchangeability are even more prevalent when a brand-name company performs a hard switch by removing the old product from the market. When such a switch occurs, the viability of a generic version is virtually zero.[59] This is because there is no longer a brand-name version on the market for which a generic version can be substituted.[60] Furthermore, even if a physician were to specifically

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53 *See* Feldman & Frondorf, *supra* note 50, at 527–28.

54 *See id.*

55 *See id.* These rebates and incentives are usually short term. *See id.* Due to high transaction costs when switching products, companies do not usually reverse-switch when the rebates and incentives expire. *See id.*

56 Tony Hagen, *An Interchangeable Biosimilars vs Authorized Biologics Battle May Be Looming*, Ctr. FOR BIOSIMILARS (Oct. 27, 2021), https://www.centerforbiosimilars.com/view/an-interchangeable-biosimilars-vs-authorized-biologics-battle-may-be-looming [https://perma.cc/Y82B-8UMY].

57 *See* Feldman & Frondorf, *supra* note 50, at 528.

58 *See* Ken Flegel, *The Adverse Effects of Brand-Name Drug Prescribing*, 184 CAN. MED. ASS'N J. 616, 616 (2012) (stating that physicians are prescribing drugs more than ever using the brand name).

59 *See* Feldman & Frondorf, *supra* note 50, at 529.

60 *See id.*

prescribe a generic version, most insurance companies consider the generic to be a brand-name drug, as it is the only drug on the market; thus, patients are deterred from accepting the generic pharmaceutical as it would cost them more money.[61] As a result, a hard switch destroys the market for generic versions and constructively prevents generic manufacturers from bringing a generic version to the market.

3. *Pay-for-Delay Settlements*

The next arrow in a brand-name company's quiver is the practice of paying generic manufacturers to delay their bringing of a generic version to the market. These "pay-for-delay settlements" serve a dual purpose for brand-name companies. The primary purpose is to reduce the risk that their patents will be invalidated in order to extend the duration of patent protection.[62] The secondary purpose is to delay the entry of generic competition.[63] Given that it takes two to tango, it is reasonable to question why a generic manufacturer would agree to delay bringing a generic version to the market. As much as one would like to think that generic manufacturers are white knights that are here to save patients from high brand-name pharmaceutical prices, the reality is that they too have profit-seeking motives.

The average cost of litigating a pharmaceutical patent infringement case under the Hatch-Waxman Act is approximately $3.5 million.[64] This number includes pre- and post-trial expenses as well as appeals when applicable.[65] Although a generic manufacturer receives a period of generic exclusivity if they prevail, which is designed to help defray the cost of litigation, the unpredictability of litigation still serves as a deterrence to expending the high cost of litigation.[66] Furthermore, the period of generic exclusivity does not prevent the brand-name company from bringing an authorized generic to

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61 *See id.*

62 *See* CONG. RSCH. SERV., R46221, *supra* note 4, 28–29.

63 *See id.*

64 Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BL (Sept. 10, 2019, 8:01 AM), https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds [https://perma.cc/LPK8-HPJ3] (reporting results of the 2019 Report of the Economic Survey conducted by the American Intellectual Property Law Association); *see also* Stephanie E. O'Byrne, *IPRs and ANDA Litigation*, FED. LAW., Jan.–Feb. 2015, at 54-55 (stating that the average litigation costs range from $2.7 million to $4.5 million).

65 Nayak, *supra* note 64.

66 *See* BROUGHER, *supra* note 28, at 150.

the market in order to compete with the newly approved generic.[67] As a result, accepting a guaranteed payout is a financial win for the generic manufacturer.[68] This is also a win for the brand-name company, as such a payout is typically less than the profits they would lose due to generic competition.[69]

B. Pharmaceuticals with Extended Protection

As noted above, there are many pharmaceuticals that have patent protection extending beyond the twenty-year statutory term. This section will briefly discuss the top-ten bestselling pharmaceuticals, which all have extended protection. It then will provide an in-depth review of two of the biggest offenders, Humira (the biggest offender measured by number of patents) and Enbrel (the biggest offender measured by duration of patent protection).

1. *The Top-Ten Bestselling Brand-Name Pharmaceuticals*

The numbers speak for themselves. The top-ten bestselling brand-name pharmaceuticals have an average projection of 40.5 years of patent protection.[70] This is double the statutory term of twenty years. The least offending pharmaceutical is Imbruvica with a current projection of 29.2 years.[71] The most offending pharmaceutical is Enbrel with a current projection of 49.7 years.[72] The bestselling pharmaceuticals are protected through an average of 74.1 patents.[73] This is staggering given that, historically, the average pharmaceutical was protected through 3.5 patents.[74] The least offending pharmaceuti-

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67 *See id.* at 148–49 (stating that although there may be a competition benefit with authorized generics, they reduce revenues of the first generic by up to 50% and may serve as a deterrence to generic entry).

68 *See* FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (2010).

69 *See id.*

70 *America's Top Selling Drugs*, *supra* note 3. I-MAK created the list of bestselling drugs by analyzing net sales revenue as reported in SEC filings or earing reports. *Id.*

71 *Id.*

72 *Id.*

73 *Id.*

74 *See* Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 300 (2010). This number, however, is slightly misleading, as it is directed towards small-molecule pharmaceuticals. *See id.* Six of the top-ten bestselling pharmaceuticals are biologic pharmaceuticals. *America's Top Selling Drugs*, *supra* note 3. When removing the biologic pharmaceuticals from the analysis, the average number of patents for the small-molecule pharmaceuticals decreases slightly to approximately seventy patents. *See id.*

cal is Trulicity with a total of fifteen patents.[75] The most offending pharmaceutical is Humira with a total of 165 patents.[76] The bestselling pharmaceuticals filed on average sixty-six percent of the patents after obtaining FDA approval.[77] The least offending pharmaceutical is Biktarvy with twelve percent of the patents filed after FDA approval.[78] The most offending pharmaceutical is Humira with ninety-two percent of the patents filed after FDA approval.[79] For more data on the top-ten bestselling brand-name pharmaceuticals, see Table 1 below.

TABLE 1: PATENTING OF THE TOP-TEN BESTSELLING BRAND NAME DRUGS[80]

Brand Name Drug	**Projected Duration of Patent Protection**	**Number of Patents Granted**	**Percent Filed After FDA Approval**
Biktarvy	49 years	44	12%
Eliquis	34.1 years	22	37%
Enbrel	49.7 years	74	90%
Eylea	44.3 years	91	66%
Humira	43.3 years	165	92%
Imbruvica	29.2 years	96	62%
Keytruda	37.3 years	78	62%
Revlimid	42.9 years	117	74%
Stelara	39.5 years	39	75%
Trulicity	35.8 years	15	86%
Average	**40.5 years**	**74.1**	**66%**

2. *Humira and Enbrel*

Humira is a biologic pharmaceutical manufactured by AbbVie.[81] It is an immunosuppressant used to treat rheumatoid arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease, and ulcerative colitis.[82] Its development started in 1993 and the first patents were filed in 1994.[83] The first

75 *America's Top Selling Drugs*, *supra* note 3.
76 *Id.*
77 *Id.*
78 *Id.*
79 *Id.*
80 *Id.*
81 *See* I-MAK, OVERPATENTED, OVERPRICED SPECIAL EDITION: HUMIRA 2–3 (rev. 2021) [hereinafter I-MAK HUMIRA].
82 HUMIRA, https://www.humira.com [https://perma.cc/NR2A-8D76] (last visited Mar. 17, 2023) (listing the conditions that Humira treats).
83 I-MAK HUMIRA, *supra* note 81, at 3.

rounds of additional patents were filed in 1997.[84] Humira received FDA approval in 2002.[85] At this time there was a total of twenty-four patent applications, which covered nearly all of the indications for which Humira is approved.[86] After FDA approval, there was a total of 287 patent applications, with the last application filed in 2021.[87] Nearly half of these applications were filed after 2014, when the initial patents were set to expire.[88] Collectively, these 311 patent applications have resulted in 165 granted patents.[89] Humira is currently projected to have 43.3 years of patent protection, starting from the first patents in 1994 to the expiration of the last granted patents in 2038.[90] Given that there are still pending patent applications, and that more patent applicants could be filed, it is likely that this projection will increase. For a visual of Humira's patenting, see Figure 1 below.

Enbrel is a biologic pharmaceutical manufactured by Amgen.[91] It is an immunosuppressant used to treat rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, and ankylosing spondylitis.[92] The primary patent for Enbrel was filed in 1990 and expired in 2012.[93] The first rounds of additional patents were filed in 1995.[94] Enbrel received FDA approval in 1998.[95] At this time there was a total of sixteen patent applications.[96] After FDA approval, there was a total of 138 patent applications.[97] Collectively, these 154 patent applications have resulted in seventy-four granted patents.[98] Enbrel is currently projected to have 49.7 years of patent protection, start-

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84 *See id.*

85 *Id.*

86 *See The Drug Patent Book*, *supra* note 3; *see also* I-MAK HUMIRA, *supra* note 81 (noting that, as of 2019, 89% of Humira's patent applications were filed after Humira was on the market).

87 *See The Drug Patent Book*, *supra* note 3.

88 *See id.*; I-MAK HUMIRA, *supra* note 81, at 4.

89 *See The Drug Patent Book*, *supra* note 3.

90 *See id.*; *America's Top Selling Drugs*, *supra* note 3.

91 *See* I-MAK, OVERPATENTED, OVERPRICED SPECIAL EDITION: ENBREL 2–3 (rev. 2020) [hereinafter I-MAK ENBREL].

92 ENBREL, https://www.enbrel.com [https://perma.cc/X49K-6NGY] (last visited Mar. 17, 2023) (listing the conditions Enbrel treats).

93 *See The Drug Patent Book*, *supra* note 3 (showing that U.S. Patent No. 5,395,760 was filed on May 10, 1990, and expired on Mar. 7, 2012).

94 *See* I-MAK ENBREL, *supra* note 91.

95 *Id.*

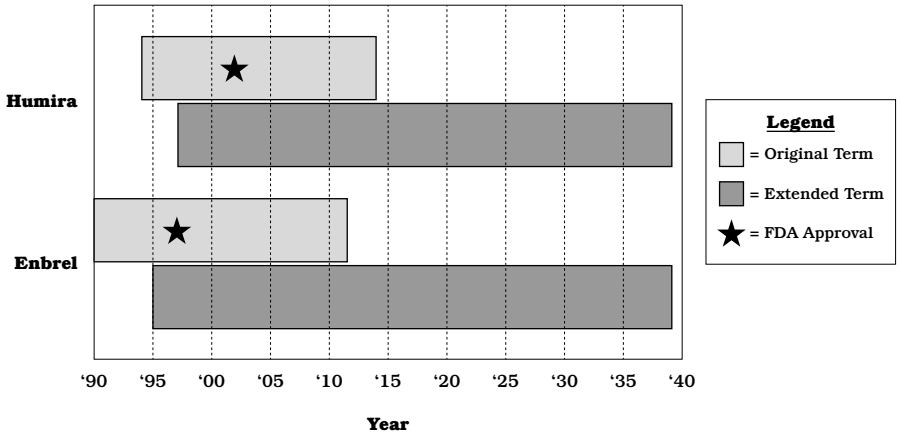
96 *See The Drug Patent Book*, *supra* note 3; *see also* I-MAK Enbrel, *supra* note 91 (noting that, as of 2018, 72% of Enbrel's patent applications were filed after Enbrel was on the market).

97 *See The Drug Patent Book*, *supra* note 3.

98 *See id.*

ing from the first patents in 1990 to the expiration of the last granted patents in 2039.[99] Given that there are still pending patent applications for Enbrel, and that more patent applications could be filed, it is likely that this projection will increase. For a visual of Enbrel's patenting, see Figure 1 below.

FIGURE 1: PATENTING OF HUMIRA AND ENBREL[100]



As shown, both Humira and Enbrel have been successfully evergreened. There have also been agreements related to product hopping, pay-for-delay settlements, and even antitrust lawsuits. Most notable for Humira are AbbVie's pay-for-delay settlements in 2017 with generic manufacturers.[101] These settlements were striking because the generic manufacturers agreed to delay bringing generics to the market in return for AbbVie allowing the generics to launch before the expiration of Humira's patents.[102] An antitrust lawsuit related to these settlements—where Humira purchasers argued that AbbVie asserted meritless patent infringement claims before entering into the settlements—was dismissed in 2020.[103] Most notable for Enbrel are Amgen's product hopping agreements in 2017 and 2019, which it entered into to preserve its market share of

99 *See id.*; *America's Top Selling Drugs*, *supra* note 3.

100 *See The Drug Patent Book*, *supra* note 3 (listing the most recent patent data); I-MAK HUMIRA, *supra* note 81 (noting Humira's 2002 FDA approval); I-MAK ENBREL, *supra* note 91 (noting Enbrel's 1998 FDA approval).

101 *See* Laura Karas, *When "Pay-for-Delay" Becomes "Delay-Without-Pay": Humira Antitrust Claims*, HARV. L. BILL HEALTH (Feb. 1, 2021), https://blog.petrieflom.law.harvard.edu/2021/02/01/pay-for-delay-humira-antitrust/ [https://perma.cc/9VK2-CXLK].

102 *See id.*

103 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 819 (N.D. Ill. 2020), *aff'd sub nom* Mayor of Baltimore v. AbbVie Inc., 42 F.4th 709 (7th Cir. 2022).

Enbrel in light of generic pharmaceutical entry.[104] In these agreements, Amgen leveraged its dominant market position by creating outcome-based payment deals with insurers to secure favorable insurance reimbursements in order to starve out generic competition.[105]

III
THE EFFECTS OF PHARMACEUTICALS WITH EXTENDED PROTECTION

A. Effect on the Patent System

The obtaining of improvement patents to extend the duration of patent protection brings into question the credibility of the patent system. As discussed above, the goal of the patent system is to promote innovation and to ultimately place new technologies into the hands of the public.[106] When brand-name companies obtain extended protection, the patent system's purpose of promoting innovation starts to take a backseat. Instead of promoting innovation, the patent system is serving to line the pockets of brand-name companies.[107] Likewise, the patent system starts to prevent the public from obtaining these new technologies, as the public does not receive the right to exploit the technologies until the patents expire.[108]

Furthermore, improvement patents arguably push the bounds of the patentability requirements, specifically the nonobvious requirement, as data has shown that these patents are frequently invalidated.[109] Although these improvements may be novel in the literal sense (e.g., Drug X did not exist in capsule form until Company A created it), these improvements are usually obvious (e.g., it was obvious to manufacture Drug X in capsule form, as a person of ordinary skill in the art would have thought to combine Drug X with the common capsule formulation). As discussed above, our patent system requires a form of heightened novelty where the invention is the result of ingenu-

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104 *See* Arlene Weintraub, *Amgen Snags Another Enbrel Outcomes-Based Payment Deal as It Seeks to Prop Up Aging Blockbuster*, FIERCE PHARMA (Dec. 4, 2019), https://www.fiercepharma.com/pharma/amgen-snags-another-enbrel-outcomes-payment-deal-as-it-seeks-to-prop-up-aging-blockbuster [https://perma.cc/78GY-ZQHD].

105 *See id.*

106 *See supra* Part I.B.

107 *See infra* Part III.B.

108 *See supra* Part I.B.

109 *See* FTC GENERIC DRUG STUDY, *supra* note 5, at 13 (finding that generic applicants prevailed in 73% of patent infringement cases and that 44% of those cases prevailed with the court invalidating the patent).

ity.[110] While there certainly are improvements that are the result of ingenuity, many of these improvements do not have any ingenuity because they are mere tweaks that do not involve any new science or development.[111]

B. Effect on Patients

Improvement patents arguably are the result of pharmaceutical companies trying to increase their profits at the expense of patients. These patents can be more valuable than the initial patents, as they serve to extend the monopoly of a well-established pharmaceutical.[112] Accordingly, brand-name companies have a profit-seeking incentive to "improve" existing drugs in order to extend their monopoly.[113] Unfortunately, this comes at the expense of investing in and inventing new drugs that may yield life-saving benefits to patients.[114] Although there are legitimate improvements being made to some pharmaceuticals (e.g., a new formulation that is more effective and has less side effects),[115] most of the improvements being made do not yield a significant benefit to patients.[116]

As discussed above, the bulk of improvement patents are obtained after receiving FDA approval, and there is a trend to start filing more patents as the initial patents are about to expire.[117] Paired with product hopping, this prevents generic manufacturers from successfully entering the market.[118] This results in higher prescription drug prices, hinders the ability of

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110 *See supra* Part I.A.

111 *See* Tahir Amin, *We Need to Take on Drug Companies' Abuse of the Patent System*, JACOBIN MAG. (Dec. 18, 2020), https://www.jacobinmag.com/2020/12/pharmeceutical-industry-patent-system-antitrust-law [https://perma.cc/EL6U-TXT5].

112 *See* CONG. RSCH. SERV., R46221, *supra* note 4, at 17–18; *see also* Christopher M. Holman, Timo Minssen & Eric M. Solovy, *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37 BIOTECH. L. REP. 131, 134 (2018) (stating that it is often the case that follow-on pharmaceutical patents can exceed the value of a primary pharmaceutical patent).

113 *See* Feldman, *supra* note 44, at 616 ("The high profit margins for blockbuster drugs provide a strong incentive for drug companies to invest in finding ways to extend protection.").

114 *See id.* at 617 ("Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products.").

115 *See, e.g.*, Holman, Minssen & Solovy, *supra* note 112, at 135 (explaining that the new formulation of the drug Lumigan decreased the drug's previous side effect of red eye).

116 *See, e.g.*, Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS'N J. 385, 385 (2013) (stating that the practice of evergreening does not look at whether there is a significant therapeutic advantage).

117 *See supra* Part II.B.

118 *See id.*

patients to afford their prescriptions, and ultimately affects the accessibility to quality healthcare.[119] Reports have shown that generic pharmaceuticals are, on average, 85% cheaper than brand-name pharmaceuticals.[120] It is estimated that the difference in price collectively saves patients about $300 billion a year in healthcare costs.[121]

Furthermore, the prices of brand-name pharmaceuticals are increasingly becoming more expensive. From 2016–2021, the top-ten bestselling brand-name pharmaceuticals increased in price, on average, by 44%, or 3.1 times the rate of inflation.[122] These price increases have occurred despite the pharmaceuticals being on the market, on average, for thirteen years.[123] Humira, which entered the market twenty-one years ago in 2002, has increased by 60%.[124] Enbrel, which entered the market twenty-five years ago in 1998, has increased by 54%.[125] For more information about the pricing and market duration of the top-ten bestselling brand-name pharmaceuticals, see Table 2 below.

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119 A recent survey revealed that approximately 30% of adults taking four or more prescriptions have difficulty affording their prescriptions. *See* Mollyann Brodie, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Oct. 20, 2022), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/84TZ-NNHA]. Likewise, approximately 20% of adults taking three or fewer prescriptions have difficulty affording their prescriptions. *See id.* Another recent study revealed that access to pharmaceuticals is responsible for 35% of the increase in life expectancy from 1990-2015. Gabby Migliara, *Study Finds Biopharmaceutical Innovation Is Responsible for 35% of the Increase in Life Expectancy from 1990 to 2015*, PHRMA (Oct. 21, 2020), https://catalyst.phrma.org/study-finds-biopharmaceutical-innovation-is-responsible-for-35-of-the-increase-in-life-expectancy-from-1990-to-2015 [https://perma.cc/2S8S-AUBM].

120 *See* CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 16, 22 (2022) (stating that in 2018 the average brand-name pharmaceutical cost $353, and the average generic pharmaceutical cost $17); Feldman & Frondorf, *supra* note 50, at 500–01 ("[G]enerics are priced at an 80% to 85% discount from their name-brand equivalents.").

121 U.S. Food & Drug Admin., Statement on Continued Progress Enhancing Patient Access to High-Quality, Low-Cost Drugs (Oct. 16, 2019) ("In 2018, competition from generic drugs saved the health care system about $293 billion.").

122 *America's Top Selling Drugs*, *supra* note 3.

123 *Id.*

124 *Id.*

125 *Id.*

TABLE 2: PRICING OF THE TOP-TEN BESTSELLING BRAND NAME DRUGS[126]

Brand Name Drug	**Price Increase 2016–2021**	**Market Duration**
Biktarvy	15%	5 years (since 2018)
Eliquis	50%	11 years (since 2012)
Enbrel	54%	25 years (since 1998)
Eylea	Unknown	12 years (since 2011)
Humira	60%	21 years (since 2002)
Imbruvica	57%	10 years (since 2013)
Keytruda	14%	9 years (since 2014)
Revlimid	56%	18 years (since 2005)
Stelara	44%	14 years (since 2009)
Trulicity	47%	9 years (since 2014)
Average	**44%**	**13 years (since 2010)**

C. Pharma's Defense

Brand-name companies defend the practice of obtaining extended patent protection with two main arguments. The first argument is that a portion of the patent term is lost during development of the pharmaceutical, prosecution of the pharmaceutical's initial patents, and obtaining FDA approval for the pharmaceutical.[127] The second argument is that the patents, and thus profits, from a brand-name pharmaceutical are designed to help recoup the cost of failed pharmaceuticals.[128] Both of these arguments, however, are misplaced.

The passing of the Hatch-Waxman Act was not a win solely for generic manufacturers, it was also a win for brand-name companies. The Act created a process where brand-name companies can have a patent term extended by up to five years for delays attributed to FDA approval.[129] Furthermore, with the passing of the Uruguay Round Agreements Act, an inventor may receive a patent term adjustment for delays at the PTO during the patent prosecution process.[130] Although these extensions/adjustments do not account for the patent term lost during development of the pharmaceutical, the obtaining of the

126 *Id.*
127 *See* CONG RSCH. SERV., R46221, *supra* note 4, at 18.
128 *See* Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFAIRS 302, 303 (2015).
129 *See* BROUGHER, *supra* note 28, at 138.
130 *See* 35 U.S.C. § 154(b) (describing patent term adjustments).

initial secondary patents already gives some protection beyond the twenty-year term, which more than enough compensates for the term lost during development.[131]

As for the second argument, the history of patent terms lends support to show that the patent for an invention serves only to recoup the costs attributed to that invention. As discussed above, the patent term was initially fourteen years and extensions were eventually allowed in order to increase the term to twenty-one years.[132] These extensions were not automatically granted—they were only granted upon a showing that the inventor had not recouped the cost of developing their invention.[133] Notably missing is the ability to receive an extension by showing that an inventor had not recouped the cost of failed inventions that preceded the successful invention. Furthermore, the continuous increasing of brand-name drug prices well after they have debuted on the market, as shown above, indicates that there is more to the calculus than merely trying to recover the cost of research and development attributed to the patented pharmaceutical and failed pharmaceuticals.

IV
POTENTIAL SOLUTIONS TO CURB EXTENDED PROTECTION

This Part discusses potential solutions to curb these practices. As discussed above, the competition from generic pharmaceuticals significantly decreases prescription drug prices and increases accessibility to quality healthcare.[134] Accordingly, the primary goal of these solutions is to increase generic pharmaceutical competition.

A. Evergreening and Product Hopping

Evergreening and product hopping work together in order to extend the brand-name pharmaceutical's duration of patent protection and to stifle the profitability of bringing a generic pharmaceutical to the market.[135] With that said, a solution that limits evergreening would also limit the effects of product hopping. When it comes to limiting evergreening, there are a few avenues that are available.

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131 *See supra* Part II.A.
132 *See supra* Part I.B.
133 *See id.*
134 *See supra* Part III.B.
135 *See supra* Part II.A.

The first avenue is to eliminate the practice completely. Once a pharmaceutical receives its initial primary and secondary patents, any patents serving to merely extend the duration of patent protection would be denied. This is the approach that some countries, such as India, have adopted.[136] Unless an inventor can show that the improvements to the pharmaceutical enhance therapeutic efficacy, an improvement patent cannot be obtained.[137] Although this practice would help eliminate the obtaining of extended protection, it is possible that it could cause more harm than good. Slight variations to the pharmaceutical may skirt around the boundaries of the existing patents and would allow generic manufacturers to enter the market before the brand-name company has received the full benefit of its patents.

The second avenue builds upon the first avenue and allows brand-name companies to obtain patents for minor improvements. If, however, a patent is granted, the patent would not receive a full term. Similar to the effect of a terminal disclaimer used in obviousness-type double patenting,[138] the improvement patent would expire when the initial patent expires. This would allow brand-name companies to patent small improvements without extending the duration of patent protection, thus allowing them to receive the full benefit of their patents. This is the approach that should be adopted in order to address evergreening.

A solution directed specifically at product hopping would likely require the changing of how the FDA and states regulate the substitution of generic versions for brand-name pharmaceuticals. As mentioned above, a pharmacy cannot substitute the generic version of the old product for the new product.[139] A potential solution would be to allow for such substitution so long as the new product is not more effective in treating the patient's condition. Another potential solution would be to require physicians, in most circumstances, to use

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136 *See* Shrimant Singh, *India's Tryst with "Evergreening"—An Ongoing Battle*, MONDAQ (Nov. 28, 2018), https://www.mondaq.com/india/patent/758788/india39s-tryst-with-evergreening-an-ongoing-battle [https://perma.cc/XDE5-94YU].

137 *See id.*

138 The use of the terminal disclaimer allows an inventor to obtain a second patent on an invention that is obvious in light of the first patented invention. *Terminal Disclaimer: Everything You Need to Know*, UPCOUNSEL, https://www.upcounsel.com/terminal-disclaimer [https://perma.cc/TC74-N92A] (last visited Mar. 18, 2023). When the first patent expires, the second patent also expires. *Id.*

139 *See supra* Part I.C.

the generic name when writing prescriptions, which would give pharmacies more autonomy to dispense generic pharmaceuticals. These solutions, however, are beyond the scope of this Note's purpose of discussing the patent system.

B. Pay-for-Delay

There are a few ways to approach the practice of pay-for-delay agreements. One way is to directly address the practice of pay-for-delay. Another way is to address other factors that influence generic manufacturers to accept pay-for-delay settlements. This section will discuss both approaches.

To directly address the practice of pay-for-delay, the straightforward solution is to void such agreements as against public policy. There have been instances of federal courts voiding certain agreements due to the agreements violating federal or state antitrust laws. For example, in 2003, the Sixth Circuit held that pay-for-delay agreements were per se illegal.[140] Other circuits, however, have muddied the waters and have upheld pay-for-delay agreements.[141] The implementation of this solution would bring harmony to the circuits and protect consumers from such anticompetitive agreements. Another potential solution, albeit inferior, would be to rigorously enforce state and federal antitrust laws. Given that generic manufacturers have prevailed in approximately 73% of ANDA challenges, and 44% of those wins resulted in invalidation of the challenged patents,[142] many pay-for-delay agreements serve to prevent the invalidating of bad patents. In addition to the agreements themselves being anticompetitive, it is also anticompetitive to attempt to keep a bad patent alive by entering into such agreements.

When it comes to factors that influence generic manufacturers to accept pay-for-delay settlements, the biggest factor is the brand-name company's use of authorized generics. As discussed above, the first generic manufacturer to prevail against a brand-name company receives a period of generic exclusivity.[143] During this period, however, a brand-name company

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140 *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003) (holding that the pay-for-delay agreement was a horizontal market allocation agreement that was per se illegal under the Sherman Act and corresponding state antitrust laws).

141 *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 205–06 (2d Cir. 2006) (affirming the district court's dismissal of the antitrust complaint and holding that pay-for-delay agreements do not violate antitrust laws).

142 *See* FTC GENERIC DRUG STUDY, *supra* note 5, at 13.

143 *See supra* Part I.C.

may launch an "authorized generic" to compete with the generic manufacturer.[144] Such competition can reduce revenues for the generic manufacturer by up to fifty percent.[145] Many of the pay-for-delay agreements include a provision that the brand-name company will not compete with an authorized generic.[146] It is, therefore, advantageous for the generic manufacturer to secure a guaranteed payout by delaying market entry and avoiding competition upon market entry. The best way to curb this influence is to exclude authorized generics from the generic exclusivity period. This would allow generic manufacturers to reap the full benefit of the generic exclusivity period, increasing the incentive for generic manufacturers to expend the cost to challenge the brand-name company's patents.

CONCLUSION

As this Note has demonstrated, the practices that brand-name companies employ to obtain extended patent protection are widespread. As a result, these practices threaten the credibility of the patent system and injure the public health. To decrease the obtaining of extended protection, solutions must be adopted to curb evergreening, product hopping, and pay-for-delay settlements. Although there are other practices that brand-name companies employ, tackling these three practices will likely increase generic pharmaceutical competition, which in turn will likely decrease drug prices and increase access to healthcare.

144 BROUGHER, *supra* note 28, at 148–49. An authorized generic is a brand-name pharmaceutical marketed as a generic pharmaceutical. *Id.* at 148.
145 *Id.* at 149.
146 *Id.*