Do Not Collect $200: The Power of Patent Monopolies and the Ramifications on Pharmaceutical Startups and Innovation

Lauren Bertino*

"Most scholars would likely agree that considering how to optimize or at least not distort innovation is an important part of legal scholarship. However, to date, there has been little recognition, let alone robust discussion, of how patent and related laws promote problematic innovation of drugs . . . ."[1]

I. INTRODUCTION

America loves innovation—so much, in fact, that the Founding Fathers enshrined it into the Constitution of the United States.[2] For centuries, the United States built and maintained a complex patent system that promotes innovation while protecting the progeny of the country's brightest minds.[3] As it stands today, however, the patent system allows large pharmaceutical companies, often collectively referred to as "big pharma," to eclipse smaller competitors through practices inconsistent with the founding principles of patent law.[4] Although the

* J.D. Candidate, Suffolk University Law School, 2022; B.S. 2017, Northeastern University. I would like to thank my Note Advisor, Dean Leah Chan Grinvald, for her exceptional guidance in writing this Note. Thanks to Anna Thornton, Nicholas Calabraro, and my fellow Law Review members for their tireless work. Finally, I would like to thank my partner Holden and my dear friends for their never-ending support.

1. Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 507 (2014).

2. *See* U.S. CONST. art. I, § 8, cl. 8 (creating exclusive right to writings and discoveries by inventors); Gary Shapiro, *America Is Innovation*, FORBES (Oct. 24, 2012, 10:29 AM), https://www.forbes.com/sites/garyshapiro/2012/10/24/america-is-innovation/#64c708e95ddf [https://perma.cc/YE5Y-QK34] (highlighting importance of innovation in U.S. culture). The government grants a patent to encompass the limited right to exclude everyone but the inventor from making, using, or selling an invention. *See* Gene Quinn, *What Is a Patent? Understanding Patents and Patent Law 101*, IP WATCHDOG (June 29, 2013), https://www.ipwatchdog.com/2013/06/29/what-is-a-patent/id=42703/ [https://perma.cc/4G5H-7TCL] (defining patent and listing types of patents).

3. *See* Eugene Sisman, Note, *Protecting the Incentive to Disclose for Small Inventors in the Wake of Patent Reform*, 35 T. JEFFERSON L. REV. 77, 81-82 (2012) (identifying U.S. patent law's historic ability to entice and protect inventors). *See generally* Morgan Sherwood, *The Origins and Development of the American Patent System*, 71 AM. SCIENTIST 500 (1983) (detailing early history of U.S. patent law).

4. *See* Colleen V. Chien, *From Arms Race to Marketplace: The Complex Patent Ecosystem and Its Implications for the Patent System*, 62 HASTINGS L.J. 297, 299 (2010) (describing companies' goal of outdoing rivals by acquiring patents); *see also* James M. Rice, *The Defensive Patent Playbook*, 30 BERKELEY TECH. L.J. 725, 725-27 (2015) (noting how changes in patent landscape differ from original purpose of promoting innovation).

patent system intends to let society prosper as citizens invent, in practice, the strongest modern innovators—startups—suffer under the system.[5]

The pharmaceutical industry, otherwise known as pharma, in particular utilizes the patent system as intended for economic benefit.[6] Many scholars consider pharma to epitomize patent success.[7] Pharmaceutical companies may invest billions of dollars to bring a drug to market that generic rivals can easily copy for a reduced price once patent protections expire.[8] Pharmaceutical companies rely on the patent system to protect their investments in research and development, which then incentivizes companies to make their life-saving treatments available to the public.[9]

Although the patent system seems to benefit pharma as a whole, popular practices within the world of pharmaceuticals systemically disadvantage the small inventors seeking to enter the market and maintain a presence.[10] Patent monopolies, created by the exclusivity provisions in patents, generate a hostile environment for startups to navigate.[11] Meanwhile, defensive patenting procedures

5. *See* Don Tiller, *Devaluing Invention: The Push for Patent Reform*, 14 TEX. WESLEYAN L. REV. 119, 121 (2007) (identifying increasing belief patent system reduces incentive to invent); Colleen V. Chien, *Of Trolls, Davids, Goliaths, and Kings: Narratives and Evidence in the Litigation of High-Tech Patents*, 87 N.C. L. REV. 1571, 1571-72 (2009) (discussing litigation complications arising from patent system); Sisman, *supra* note 3, at 79-80 (explaining how recent legislation disadvantages small companies); *see also infra* Section II.C.2 (discussing innovative power of startups).

6. *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) (describing pharma's strong patent system use). Pharma's complex patent procedures and requirements allow companies to charge high prices for drugs without fear of generic competition. *Id.* As such, pharmaceutical companies spend millions every year lobbying to maintain this profitable system. *See id.* at 303-04 (discussing how pharmaceutical companies' lobbying efforts highlight importance of patent system).

7. *See, e.g.*, *id.* at 300 (calling pharma "poster child" of patent system); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507 (2009) (calling pharma "golden child" of patent system).

8. *See* Amanda Fachler, Note, *The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities*, 24 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1059, 1067 (2014) (describing rationale behind patenting drugs); *see also* Roin, *supra* note 7, at 508 (discussing pharma's need to recoup investments through patent protection).

9. *See* Roin, *supra* note 7, at 509 (describing importance of patent law in commercializing inventions for public use). For pharma specifically, companies must rely on patent exclusivity terms to recoup research and development costs before cheaper, generic counterparts can flood the market. *See id.* at 510-11 (explaining difference in costs and requirements between new and generic drugs).

10. *See* Amy L. Landers, *The Antipatent: A Proposal for Startup Immunity*, 93 NEB. L. REV. 950, 955-56 (2015) (discussing scholarly belief patent procedures block rivals' success). Many of these practices, to be discussed further in this Note, cripple smaller entities trying to compete. *See* Kristin Garr, *IP Protection for Startups: The Role of Legislation in Stopping Patent Trolls and Encouraging Innovation*, B.C. INTELL. PROP. & TECH. F., Aug. 30, 2018, at 1-2, http://bciptf.org/wp-content/uploads/2018/08/Kristin-Garr-S18.pdf [https://perma.cc/E6G8-G52D] (describing how small companies cannot pay licensing fees for excess patents); Chien, *supra* note 5, at 1577 (calling strategic patent litigation against smaller rivals "predatory"); *infra* Section II.C (discussing disparities in patent system between large and small companies).

11. *See* Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 677-78 (2014) (discussing lack of incentive for innovation due to patent monopolies); *infra* Section II.C.3 (explaining how pharma's patent practices generate monopolies of sort). Many companies will also extend

create a different kind of patent monopoly that similarly limits the workable space for innovation.[12] Unlike big pharma, smaller companies struggle to secure the funding necessary to capitalize on the benefits of the system.[13]

In actuality, patent system success in the pharmaceutical world relies on factors far more extraneous than the ability to innovate.[14] This Note exposes the pitfalls of the patent system as they apply to the pharmaceutical industry, and suggests potential remedies that allow smaller, innovative startups to thrive.[15] Specifically, this Note begins by discussing the historical relationship between patents and pharmaceuticals and distinguishes important features of innovators big and small within the system.[16] Next, this Note identifies the results of common patent practices, limitations on the presence of small innovators in pharma, and subsequent ramifications on innovation.[17] Finally, this Note highlights opportunities for the patent system to be equitably improved and the potential impact on small companies, startups, and independent innovators seeking to provide society with life-saving medicinal inventions.[18]

---

the life of their patents through a process called "evergreening," which allows the company to extend their monopoly for decades longer than the original patent term. *See* Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 486-87 (2020) (highlighting process of artificially extending monopolies through evergreening).

12. *See* Chien, *supra* note 4, at 321-22 (explaining defensive patenting protects companies from lawsuits and preserves space for their innovation); Rice, *supra* note 4, at 728 (calling expansive patent portfolios "an obstacle to future innovation"). Larger companies more commonly participate in defensive patenting, which increases many costs for startups. *See* Chien, *supra* note 5, at 1583 (noting larger companies tend to engage in defensive patenting); Rice, *supra* note 4, at 750 (describing three ways defensive procedures increase startup costs).

13. *See* Sisman, *supra* note 3, at 79, 92-93 (describing funding limitations for startups pursuing patent applications); Chien, *supra* note 5, at 1587 (identifying difficulty in enforcing patents with limited finances).

14. *See* Fachler, *supra* note 8, at 1071 (noting increased costs of development and decreased success diminishes startups' market survival). Most approved patents belong to large corporations financially capable of both patenting in excess and litigating extensively, allowing them to dominate the market at all points of the patent lifecycle. *See* Garr, *supra* note 10, at 1-3 (describing disadvantages for startups).

15. *See infra* Part III (proposing changes to patent system offering incentives and protections for startups); *see also* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5-7 (2003), https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf [https://perma.cc/3SXW-3F9U] (describing how common patent practices deter market entry and innovation); John Wu & Robert D. Atkinson, *How Technology-Based Start-Ups Support U.S. Economic Growth*, INFO. TECH. & INNOVATION FOUND. (Nov. 28, 2017), https://itif.org/publications/2017/11/28/how-technology-based-start-ups-support-us-economic-growth [https://perma.cc/9KMP-2U8G] (explaining technology startups' innovative and economic impact).

16. *See infra* Section II.B.

17. *See infra* Section II.C.

18. *See infra* Part III.

II. HISTORY

A. The Patent Procedure

1. A Historical Prelude

Patent law is an American tradition older than baseball.[19] Originally based on the English system, U.S. patent law received official constitutional recognition in 1787 with the intent to foster innovation and idea sharing through economic incentives for inventors.[20] Since that initial constitutional recognition, however, legislators have made many changes to the laws and procedures for patenting an invention.[21] From the first Patent Act of 1790 to the Leahy–Smith America Invents Act (AIA), patent law has evolved right alongside the inventions it serves to protect.[22]

In 1984, Congress passed one of the more modern and impactful laws, the Hatch–Waxman Act.[23] This Act attempted to balance the interests of innovators and generic competitors by extending greater protections to innovators while easing regulations on bringing generic drugs to market.[24] Twenty-six years later, Congress—as part of the Affordable Care Act—passed the Biologics Price Competition and Innovation Act (BPCIA), which shares similarities with the Hatch–Waxman Act.[25] The BPCIA imposed regulations for the biologics market by

19. *See* U.S. CONST. art. I, § 8, cl. 8 (securing patent rights in 1787); MITCHELL NATHANSON, A PEOPLE'S HISTORY OF BASEBALL 7 (2012) (noting first rules of baseball written around 1845). The origins of modern baseball are largely credited to a mid-1800s New York organization. *See* NATHANSON, *supra*.

20. *See* Sherwood, *supra* note 3, at 500 (discussing how Founding Fathers adopted English patent ideas). Colonial America began patenting inventions before the Constitution recognized the practice as a social and economic benefit. *See id.* (reviewing history of patents).

21. *See* JANICE M. MUELLER, PATENT LAW 38-39 (6th ed. 2020) (discussing legislative changes to patent system).

22. *See* Sherwood, *supra* note 3, at 500-01 (noting first law created patent board and fourteen-year exclusivity term); Leahy–Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.) (amending patent system to first-to-file model).

23. *See* Drug Price Competition and Patent Term Restoration (Hatch–Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.) (introducing new drug and generics regulations); Janet A. Gongola, Note, *Prescriptions for Change: The Hatch–Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787, 787-88 (2003) (describing impact of Hatch–Waxman Act).

24. *See* Hatch–Waxman Act § 101, 21 U.S.C. § 355(j); Gongola, *supra* note 23, at 787 (noting purposes of Hatch–Waxman Act). A generic drug is a medication formulated to have the same clinical benefit as a patented, brand-name drug. *See Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (June 1, 2018), https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers [https://perma.cc/JZF3-JMME] (defining generic drugs). The Hatch–Waxman Act created patent barriers for generic small-molecule drug applications to compensate patent owners for time spent testing the drug's safety and efficacy. *See* Erika Lietzan, *The History and Political Economy of the Hatch–Waxman Amendments*, 49 SETON HALL L. REV. 53, 55 (2018) (explaining benefits to patent owners). At the same time, the Hatch–Waxman Act authorized generic drug manufacturers to rely on the data of the original drug for approval instead of requiring those companies to perform their own clinical trials. *See* Gongola, *supra* note 23, at 787.

25. *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 35 U.S.C. § 271; 42 U.S.C. § 262) (introducing regulations for

creating similar boundaries around the production of biosimilars—the generic counterpart of complex biologic drugs.[26]

In 2011, through the AIA, Congress overhauled the system for identifying an invention's owner.[27] Previously, patent law recognized and protected the first inventor to create the technology; the AIA altered this framework by granting patent ownership instead to the first applicant.[28] Now, the law grants patent protections to the first inventor to file with the U.S. Patent and Trademark Office (USPTO), regardless of whether they were the first to have the idea.[29] Congress altered this structure to provide greater certainty to patenting entities, as the new system need only look at the date of filing to determine patent rights.[30]

2. Modern Patent Procedures and Innovation

Today's patent offers twenty years of exclusivity to the first inventor to file.[31] Although twenty years may sound like a generous time period, an invention's exclusivity term on the market is often far shorter due to the time-consuming processes of gaining USPTO approval and actually bringing the invention to market.[32] The twenty-year exclusivity period begins tolling from the date of filing, and USPTO approval takes about two-and-a-half years to finalize.[33]

---

biologics); Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 376 (2019) (noting BPCIA's similarity to Hatch–Waxman Act).

26. *See* Gervais, *supra* note 25, at 376 (describing intent of BPCIA to regulate biologics). A biologic drug is generally derived from complex living materials, such as antibodies and proteins. *Id.* at 375. Small molecules are easier to replicate, while biosimilars can only be substantially similar to their biologic counterparts due to the size and complexity of the drug, thus requiring a slightly different approach to regulation of biologics. *See id.* at 376.

27. *See* Leahy–Smith America Invents Act § 3 (deciding inventorship rights based on first-to-file system). Congress's partial intent in adopting the first-to-file model was to synchronize the U.S. patent system with international practices. See Sisman, *supra* note 3, at 78 (stating rationales for passing AIA).

28. *See* Leahy–Smith America Invents Act § 3; Garr, *supra* note 10, at 6 (noting change from first-to-invent to first-to-file model under AIA).

29. *See* Sisman, *supra* note 3, at 85 (stating only first inventor to file may receive patent protections). Under the AIA, if the second to invent is the first to file, the first to invent is subsequently denied patent rights. *See id.* at 86.

30. *See id.* (stating only effective filing date relevant to determining rights under AIA). The AIA thus creates a greater incentive for inventors to disclose their inventions. *Id.* at 85-86.

31. *See* 35 U.S.C. § 154(a)(2) (stating patent term ends twenty years from date of filing); MUELLER, *supra* note 21, at 21 (noting twenty years of exclusivity granted to patent owners since 1995). Although inventors receive a twenty-year term from filing, a patent is not enforceable until it is issued. *See* MUELLER, *supra* note 21, at 22 (explaining discrepancy between patent term and enforceability period).

32. *See* MUELLER, *supra* note 21, at 22 (stating twenty-year period inaccurate due to USPTO pendency); PHARMACEUTICAL PRODUCT DEVELOPMENT 4 fig.1.2 (Vandana B. Patravale et al. eds., 2016) (depicting patent applications typically filed years before commercialization of drug).

33. *See* MUELLER, *supra* note 21, at 22 (noting exclusivity runs from effective filing date but applications pend for approximately two-and-a-half years). Ironically, though years' worth of wait may seem like a long time to inventors, the patent examiners at the USPTO determining the outcome of these applications report frustrations with how little time they actually receive to review each submission. *See* Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 978-79 (2019) (discussing patent examiners' frustration with allotted time).

To receive patent protection for an invention, the inventor must first determine that their product is indeed patentable.[34] If so, the inventor must prepare and submit the initial application along with relevant fees.[35] After some back and forth with the patent examiner, an application that meets USPTO requirements will receive official approval.[36] Upon the patent's eventual expiration, protections for the invention end and competitors are able to join the market, eventually influencing the cost of the product.[37]

Requiring inventors to adhere to these patenting procedures helps to foster innovation in two ways.[38] First, the patent system creates a bargaining process between the inventor and the government on behalf of society.[39] This bargain creates an economic incentive for the inventor to recoup their costs from research and development by receiving governmental protections.[40] Second, the patent application puts the invention into the public domain, where other inventors can use previously patented technology as a stepping-stone to newer and potentially better developments.[41] The cumulative innovation process allows inventors to use patented technologies as both tools and inspiration for their own

34. *See Patent Process Overview*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents-getting-started/patent-process-overview [https://perma.cc/CZ5L-PP5R] (recommending patent search to determine if invention already in public domain). The USPTO website allows potential inventors to search previous public disclosures to confirm that their invention is unique and therefore patentable. *Id.*

35. *See id.* (describing fees and application submission process). Most patents require a basic fee, search fee, examination fee, and issue fee. *Id.* Patent applications can be submitted online through the USPTO's electronic filing system. *Id.*

36. *See id.* (discussing examiner review process prior to approval). Applications must meet the statutory requirements in 35 U.S.C. § 111(a) to be approved. *Id.*; 35 U.S.C. § 111(a) (requiring inventors submit specification, drawing, and declaration of invention for patent application). Inventors that do not receive approval may appeal their rejection to the Patent Trial and Appeal Board. *Patent Process Overview*, *supra* note 34.

37. *See* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch–Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 298 (2015) (stating patent expiration allows competitors to join market and prices to fall). In the pharmaceutical world, both the healthcare system and the patients within it benefit from the expiration of the patent because competition causes drug prices to drop. *See id.* at 300-01 (noting lower prices lead to increased patient compliance). Increased drug competition leads to better patient outcomes due to a greater range of treatments at notably lower costs. *See id.*

38. *See* Sisman, *supra* note 3, at 82 (calling incentive to invent most direct effect of patent law); Ofer Tur-Sinai, *Cumulative Innovation in Patent Law: Making Sense of Incentives,* 50 IDEA 723, 725 (2010) (stating new innovation often builds on previously patented inventions).

39. *See* Sisman, *supra* note 3, at 81 (discussing "quid pro quo" nature of patents between inventors and society).

40. *See id.* at 82 (stating inventors develop technology to profit off temporary monopolies). The economic incentive lies in the inventor's exclusive right, created by the patent, to profit off her invention. *Id.* In pharma, higher research and development costs also cause companies to rely on the patent system to support their investments. *See* Roin, *supra* note 7, at 513 (identifying reasons for pharma's elevated reliance on patent system).

41. *See* Tur-Sinai, *supra* note 38, at 731-32 (describing scenarios where inventors use prior art to advance their own inventions). The process of using a previous patented invention to develop one's own invention has been coined "cumulative innovation." *Id.* at 731.

innovation.[42] Thus, the patent system creates an incentive to invent for both original and follow-on inventors.[43]

B. Patents in the World of Pharma

1. Bringing a Drug to Market

To best utilize the patent system, pharmaceutical companies must face a long and expensive drug discovery process to invent a drug worth patenting.[44] A typical drug development timeline encompasses twelve to twenty years and multiple stages of development.[45] Potential therapies generally face a high risk of failure at virtually every step of the process and require large sums of money to advance to the market.[46]

Pharmaceutical companies must also seek approval from the Food and Drug Administration (FDA) when bringing a drug to market.[47] As yet another factor minimizing the patent exclusivity term, the FDA requires potential drugs to complete three-phase clinical trials to ensure consumer safety.[48] The clinical trials

42. *See id.* at 732, 735 (noting use of inventions for research tools or to advance original technology). As one example of follow-on innovation, the COVID-19 vaccines created by Pfizer-BioNTech and Moderna in 2020 take a novel approach to vaccines by utilizing older vaccination technology. *See* Walter Isaacson, *mRNA Technology Gave Us the First COVID-19 Vaccines. It Could Also Upend the Drug Industry*, TIME (Jan. 11, 2021, 5:10 AM), https://time.com/5927342/mrna-covid-vaccine/ [https://perma.cc/K8AK-3G7G] (discussing updated method of vaccination used in COVID-19 vaccines). Until recently, vaccination technology was based on 18th century, ethically questionable experiments. *See id.* (detailing history of vaccines and immunity building). For the COVID-19 vaccine, scientists combined the traditional method of vaccination—introducing one's system to weakened or dead components of the virus—with modern recombinant DNA techniques to instead deliver a harmless snippet of the virus's genetic code with which the immune system can safely build an immune response. *See id.* (explaining new vaccines' use of genetic instructions); *see also Understanding and Explaining mRNA COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 24, 2020), https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html [https://perma.cc/9AFQ-XDW3] (noting difference between new and old vaccine technology). This groundbreaking follow-on invention to vaccine creation offers many improvements, including shorter development and manufacturing times, better scalability, and broader disease application. *See Understanding and Explaining mRNA COVID-19 Vaccines*, *supra* (stating benefits of new vaccine technology).

43. *See supra* notes 40-41 and accompanying text (describing how all types of inventors find incentives in patent procedures).

44. *See* PHARMACEUTICAL PRODUCT DEVELOPMENT, *supra* note 32, at 2 (noting time-consuming and resource-intensive process of new drug development). Drug patents are typically filed far before the drug reaches the market—if the drug even accomplishes that goal. *See* Fachler, *supra* note 8, at 1066-67 (noting early filing of drug patents).

45. *See* PHARMACEUTICAL PRODUCT DEVELOPMENT, *supra* note 32, at 2. The drug discovery process begins with the identification of potential therapies and requires many preclinical and clinical studies to develop a marketable drug. *See id.* at 4 fig.1.2 (depicting phases of pharmaceutical development).

46. *See infra* notes 57-58 and accompanying text (describing costs and success rates of bringing drugs to market).

47. *See Development & Approval Process | Drugs*, U.S. FOOD & DRUG ADMIN. (Oct. 28, 2019), https://www.fda.gov/drugs/development-approval-process-drugs [https://perma.cc/8SHB-SYFR] (discussing pharmaceutical companies' requirement to test and receive approval from FDA).

48. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-

alone take years to complete and cost millions of dollars.[49] Since the inventor usually files a patent fairly early in the drug discovery process, the patent loses a large chunk of its original exclusivity term just by satisfying drug-development regulations before reaching the market.[50]

Meanwhile, pharmaceutical companies' biggest competition—the generic drug companies—face far fewer barriers to enter the market.[51] The generic counterparts to name-brand pharmaceuticals can follow a substantially similar manufacturing procedure to the original drug, but need not go through the same clinical trial process required of branded drugs.[52] Although generics have their own hurdles to cross, the relaxed FDA requirements allow generic drugs to enter the market at a significantly lower cost, as the manufacturers have lower recuperating costs than the original drug manufacturers.[53]

2. The Patent "Poster Child"

With the stakes so high and generic competition looming, pharmaceutical companies look to patent law to protect their investments in new drugs.[54] For this reason, scholars believe that the pharmaceutical industry is the perfect illustration of how the patent system should work.[55] Pharmaceuticals are extremely

---

ensuring-drugs-are-safe-and-effective [https://perma.cc/56XN-5DUA] (describing stages of FDA drug review). Pharmaceutical companies must first show the FDA that the potential drug is reasonably safe to test in humans before clinical trials begin. *See id.* Phase one trials are conducted with healthy volunteers, whereas phases two and three utilize patients afflicted with the targeted disease. *See id.* The potential treatment must be reevaluated at the end of every phase before it can move onto the next and eventually reach final approval. *See id.*

49. *See id.* (noting clinical trials take several years to complete); Fachler, *supra* note 8, at 1069 (stating pharmaceutical companies often spend millions on clinical trials to satisfy FDA regulations).

50. *See* Fachler, *supra* note 8, at 1066-67 (noting diminished patent exclusivity term for drugs). Due to the typical timing for filing, pharmaceutical patent terms tend to start tolling well before clinical trials have even begun, leading some drugs to reach the market with anywhere from a few years to no time at all remaining on its patent term. *See id.*

51. *See* Roin, *supra* note 7, at 511 (noting generic drug exemption from FDA clinical trial requirements).

52. *See id.* (highlighting efficiency of generic drugs). Because generic companies create a substantially similar drug to the patented one, the FDA allows those companies to rely on the data and clinical trial results of the patented drug instead of recreating those experiments. *See* Fachler, *supra* note 8, at 1067 (explaining generic companies' reliance on patented drugs' data).

53. *See* Roin, *supra* note 7, at 511-12 (noting lower price of generics reflects lower production costs). Generic drugs cost manufacturers millions less to produce than their branded counterparts and subsequently can be sold at lower prices because the FDA does not require the same rigid approval process. *See id.* Generics are not without regulations—companies must demonstrate to the FDA that their generic drug meets the same safety and effectiveness standards as the original patented drug. *See Generic Drug Facts*, U.S. FOOD & DRUG ADMIN. (June 1, 2018), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts [https://perma.cc/A7Q6-NDWE] (stating generics must meet same standards to receive approval).

54. *See* Ouellette, *supra* note 6, at 302-03 (calling patent law "essential" legal protection for pharma inventions); *see also* Fachler, *supra* note 8, at 1066 (stating patent security drives pharma innovation). Some studies suggest that pharma is one of few industries where patents are regarded as an effective and essential means to developing new inventions. *See* Ouellette, *supra* note 6, at 303.

55. *See supra* note 7 (demonstrating scholarly adulation of patents in pharma).

expensive and complicated to create—but less complex to copy—and thus depend entirely on a well-functioning patent system to maintain incentives.[56]

Creating a drug is no ordinary expense: A 2020 study found that the average cost to bring a drug to market was $985 million, though other studies suggest a sum upwards of $2.6 billion.[57] Despite these exorbitant price tags, only 12% of the tens of thousands of potential compounds reach clinical trials, and only 0.01% will actually make it to market.[58] Thus, the pharmaceutical world's booming success in spite of massive scientific and economic barriers can be attributed in large part to the industry's masterful use of the patent system.[59]

C. Where Pharma Falls Short

1. Small Companies and Innovators Are Left in the Dust

Although the features above are attributed to pharma as a whole, there are startling differences between the large and small companies within the industry.[60] Big pharma is defined as "large pharmaceutical companies considered especially as a politically influential group" and typically refers to the top fifteen pharmaceutical companies by market value.[61] The companies that make up big pharma enjoy $200 billion market values, notably large shareholder yields, and profit margins of 20% or more.[62] Many big pharma companies also spend almost 10% more on marketing than researching and developing new drugs.[63] Relying

56. *See supra* note 8 and accompanying text (noting expensive but easily copied development process requires stringent protections).

57. *See* Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018*, 323 JAMA 844, 849 (2020) (noting average cost to bring drug to market); *Research & Development*, PHARM. RSCH. & MFRS. OF AM., https://www.phrma.org/en/Advocacy/Research-Development [https://perma.cc/9CUB-42D3] (noting average cost of $2.6 billion to develop new medicine).

58. *See Research & Development*, *supra* note 57 (stating only 12% of new drug candidates receive FDA approval); PHARMACEUTICAL PRODUCT DEVELOPMENT, *supra* note 32, at 2 (stating 1 in 5,000–10,000 molecules reach market).

59. *See supra* note 54 (explaining pharma's use of patent system essential to drive industry success).

60. *See infra* notes 62, 67-68 (discussing differences between big and small pharmaceutical companies).

61. *See Big Pharma*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/Big%20Pharma [https://perma.cc/HUG2-B6XH] (defining big pharma); Sean Williams, *7 Facts You Probably Don't Know About Big Pharma*, MOTLEY FOOL (Oct. 18, 2018, 2:18 PM), https://www.fool.com/investing/value/2015/07/19/7-facts-you-probably-dont-know-about-big-pharma.aspx [https://perma.cc/F4ES-52B9] (listing companies considered "big pharma"). In 2018, the typical big pharma companies included: Johnson & Johnson, Novartis, Roche, Pfizer, Merck, Sanofi, Bayer, Novo-Nordisk, Bristol-Myers Squibb, AbbVie, GlaxoSmithKline, Eli Lilly, AstraZeneca, Teva, and Shire. *See* Williams, *supra*.

62. *See* Cami R. Schiel, *Leveraging Pharma to Lower Premiums: Medical Loss Ratio Regulation in the Pharmaceutical Industry*, 2018 BYU L. REV. 205, 236-37 (discussing statistics of big pharma). In 2013, big pharma held the top slot for average profit margins at 19%, while the second highest industry sat at only 12%. *See id.* Meanwhile, shareholder yields for big pharma companies like Pfizer eclipsed 6% in 2015, while the median for other top 500 companies hovered at 2%. *Id.* at 236.

63. *See id.* at 239 (naming big pharma companies with staggering advertising costs). Nine big pharma companies spent 23% of their revenue on marketing in 2013, when the average research and development costs hit about 16% of revenue. *See id.* In 2014, big pharma ad spending increased 18% from the prior year. *See* Williams, *supra* note 61 (noting substantial increase in pharmaceutical marketing expenditures).

on profits from "blockbuster drugs" to drive these numbers, big pharma companies are incentivized to focus their innovation efforts on protecting their existing drugs.[64] Big pharma's financial endeavors are accordingly focused on intense lobbying efforts to further protect their investments in blockbuster drugs.[65]

In contrast, startups do not enjoy the same market value or financial resources as big pharma.[66] Instead, startups must seek venture capital funding or ultimately merge with larger companies to secure funding for clinical trials and FDA approval.[67] While big pharma has revenue from blockbuster drugs to rely on, startups rely on investments to stay afloat.[68] Additionally, small startups have proportionally small spheres of influence and thus do not have the global reach to use marketing tactics with the same success as their big pharma counterparts.[69]

2. Startups: Low in Funds, High in Innovation

Despite big pharma's significant financial advantages, thirty of the forty-eight drugs receiving FDA approval in 2019 did not belong to big pharma companies.[70] With strong reliance on strict patent protections, startups have become far more innovative by pursuing less popular avenues.[71] Startups function as innovation

64. *See* Christopher Megaw, Note, *Reviving Essential Facilities to Prevent REMS Abuses*, 47 COLUM. J.L. & SOC. PROBS. 103, 105-06 (2013) (describing incentive to protect blockbuster drugs for revenue interests); Hacohen, *supra* note 11, at 523 (stating pharma has more incentive to improve existing drugs than create new drugs). A "blockbuster drug" is a drug whose annual global turnover exceeds $1 billion. *See* Alex A. Jurisch, Note, *A Prescription for Biopharmaceutical Patents: A Cure for* Inter Partes *Review Ailments*, 41 SEATTLE U. L. REV. 1211, 1219 n.62 (2018) (defining "blockbuster drugs").

65. *See* Eugene McCarthy, *The Pharma Barons: Corporate Law's Dangerous New Race to the Bottom in the Pharmaceutical Industry*, 8 MICH. BUS. & ENTREPRENEURIAL L. REV. 29, 59-60 (2018) (detailing pharma's massive lobbying efforts). For nearly twenty years, pharma has repeatedly held the top seat for industry lobbying expenditures. *See id.* at 59. In 2016, big pharma spent enough money on lobbying to employ two lobbyists for every member of Congress. *See* Ashley Duckworth, Note, *Fighting America's Best-Selling Product: An Analysis of and Solution to the Opioid Crisis*, 26 WASH. & LEE J.C.R. & SOC. JUST. 237, 275 (2019). By June 2020, pharma already topped the charts by spending over $156 million on lobbying efforts. *See* Patrick Smith & Sarah Tincher, *Big Spenders: The Players, the Money and the Firms in 2020 Lobbying*, LAW.COM: THE NAT'L L.J. (Sept. 30, 2020, 6:00 PM), https://www.law.com/nationallawjournal/2020/09/30/lobbying-2020-the-players-the-money-and-the-firms/?slreturn=20210109152527 [https://perma.cc/8J77-ZBMS] (noting pharma's upward-trending lobbying costs).

66. *See* Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787, 802-03 (2017) (noting financial disadvantage startups face when bringing drugs to market).

67. *See id.* at 805 (discussing startup reliance on venture capital or sale of discoveries to big pharma); Jurisch, *supra* note 64, at 1219-20 (stating startups seek mergers when unable to rely on venture capital).

68. *See* Jurisch, *supra* note 64, at 1219 (stating small companies cannot rely on blockbuster drugs for financial support).

69. *See* Richman et al., *supra* note 66, at 802 (noting established pharmaceutical companies maintain global advantage due to superior marketing capabilities).

70. *See* Asher Mullard, *2019 FDA Drug Approvals*, NATURE REVS. DRUG DISCOVERY, February 2020, at 79, 80-81 tbl.1, https://www.nature.com/articles/d41573-020-00001-7 [https://perma.cc/652X-QLL5] (listing drugs receiving approval in 2019). The remaining eighteen drugs receiving approval are attributed to the top fifteen big pharma companies. *See id.*; *see also* Williams, *supra* note 61 (naming top fifteen drug companies).

71. *See* Brenda M. Simon, *Patents, Information, and Innovation*, 85 BROOK. L. REV. 727, 748 (2020) (noting smaller companies convince investors by avoiding products with risk of infringing other patents); *see also*

powerhouses namely because these companies can more easily secure venture capital funding by targeting new, patentable inventions.[72] Small pharmaceutical companies are also likely to create orphan drugs, a category of drugs treating rare and dire medical conditions, as a way to enter the market.[73] Startups' proclivity to pursue orphan drugs stems from the incentives and protections the Orphan Drug Act provides, allowing for easier market entry.[74] Many of these incentives further support startups in their quest to attract and maintain investors.[75] Scholars also note that big pharma increasingly relies on licensing or purchasing others' inventions instead of innovating internally, and thus looks to startups to lead the industry's innovative efforts.[76]

3. Patent Swords and Shields

The purpose (and economic incentive) of a patent is to allow the owner to bar competitors from producing similar products for the term of the patent, creating a "monopoly" of sorts over the invention's profits.[77] In addition to the economic hurdles of creating the invention, startups must also attempt to innovate in the operable space around active patents and often face substantial legal and financial obstacles to enter the market if their invention falls too close to another.[78] Although the long FDA approval process notably limits the patent monopoly

---

Cheryl L. Kozdrey, *Robbing the Cradle: The Implications of Depleting Financial Incentives for Orphan Drug Manufacturers and Imposing Stricter Research Guidelines for Rare Pediatric Diseases*, 55 CAL. W. L. REV. 387, 419 (2019) (noting small companies use patent exclusivity to make guarantees to stockholders).

72. *See* Simon, *supra* note 71, at 748 (stating intellectual property rights foundational for securing commercial alliances). Startups can more easily attract investors and create financial alliances to bring an invention to market by securing strong patent protections on technology that does not risk infringement of other patents. *See id.*

73. *See* Kozdrey, *supra* note 71, at 394 (stating orphan drug legislation makes market participation feasible for startups). An orphan drug treats a disease that affects 200,000 or fewer patients in the United States. *Id.* at 392. Big pharma sees the disease population as too small to recoup investments, but smaller companies consider orphan drugs profitable. *See id.* at 393, 419.

74. *See id.* at 393-94 (stating Orphan Drug Act successfully incentivizes pharma startups); Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 21, 26, 35, and 42 U.S.C.) (stating purpose to incentivize development of orphan drugs). Some of the incentives afforded to orphan drug manufacturers include FDA grants, tax credits for clinical testing expenses, faster FDA approval rates, and seven years of market exclusivity. *See* Dov Greenbaum, *Incentivizing Pharmacogenomic Drug Development: How the FDA Can Overcome Early Missteps in Regulating Personalized Medicine*, 40 RUTGERS L.J. 97, 121-22 (2008) (summarizing drug development incentives in Orphan Drug Act).

75. *See* OFF. OF INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., THE ORPHAN DRUG ACT: IMPLEMENTATION AND IMPACT 8 (2001), https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf [https://perma.cc/BXG3-5Q6B] (calling incentives like marketing exclusivity critical to small companies raising capital).

76. *See* Richman et al., *supra* note 66, at 801 (discussing big pharma's increasing dependence on acquiring startups to fuel innovation). One study suggests that over 25% of the ten largest pharmaceutical companies' sales can be attributed to in-licensed products from startups. *Id.* at 805.

77. *See* FED. TRADE COMM'N, *supra* note 15, at 2 (noting patents confer right to exclude others). Patent monopolies are considered an integral part of a well-functioning economy, balancing competitive interests with societal gain. *See id.* at 2-3 (describing patent monopolies' relationship with competition and consumer gain).

78. *See* Landers, *supra* note 10, at 986 (noting startups face large licensing and litigations costs when entering market with many incumbents).

period, pharmaceutical companies have discovered methods to manipulate the patent process in their favor.[79]

For example, companies can request product label changes, which delay generic entry to the market.[80] Some companies will even file citizen petitions to delay FDA approval on a generic equivalent to their drug.[81] Other companies will look to patent processes such as "evergreening," where the patent life of a single drug is extended by filing multiple follow-on patents.[82] Evergreening can allow a highly profitable drug to drastically extend its exclusivity period through a breadth of related follow-on patents.[83] Loopholes such as these inevitably incentivize big pharma to re-patent inventions instead of discovering new ones.[84]

Although big pharma companies can aggressively pursue patent-system loopholes to prevent competition, many will adopt these measures with defensive intent.[85] Evergreening efforts are often fueled by a desire to extend protections for a heavily invested invention and deter concurrent competitive efforts.[86] Big pharma also dips into its deep pockets to create, buy out, or license peripheral

79. *See supra* note 50 and accompanying text (explaining FDA approval process limits patent term); Ana Jemec Friedman, Comment, *An Antidote to Efforts by Drug Manufacturers to Delay the Entry of Generic Competition via Sham Petitioning*, 92 N.C. L. REV. 277, 278-79 (2013) (discussing complaints about big pharma manipulating FDA processes to extend monopolies).

80. *See* Friedman, *supra* note 79, at 285 (noting label changes delay generic market entry). The FDA requires a statement of use that is translated into a "use code" for the drug, but there is little scrutiny of big pharma companies creating or altering the codes. *See* Hacohen, *supra* note 11, at 510. Because generics must utilize the same code system, big pharma can manipulate their use codes over time to be overbroad and thus delay a generic's market entry. *See id.* (calling use-code procedure "ripe for abuse").

81. *See* Friedman, *supra* note 79, at 287 (describing big pharma's abuse of citizen petition process). The FDA is required to allow any member of the public to petition for additional testing of a generic before its approval. *See id.* at 286. Because the FDA must respond to every citizen petition, and response time can take months, big pharma companies can submit a citizen petition shortly before the expiry of their product's patent term and force a delay in the generic counterpart's approval, essentially extending the patent term. *See id.* at 287.

82. *See* Hacohen, *supra* note 11, at 486 (explaining extension of pharmaceutical monopolies through follow-on patenting). A follow-on patent typically covers trivial improvements to an existing legal invention that, although minimally valuable to the drug's recipients, creates an entirely new patent term for essentially the same drug. *See id.* at 485-86. Some of these "improvements" to a drug include changes to the dosage, the drug's release mechanism, or even the tablet's coating. *See* Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 313, 317 (2015) (noting various minute changes to drugs allowing for new patents).

83. *See* Hacohen, *supra* note 11, at 486-87 (noting arbitrary extension of highly profitable drugs through evergreening).

84. *See id.* at 523 (discussing big pharma's incentive to improve existing drugs instead of creating new ones).

85. *See* Rice, *supra* note 4, at 728 (noting shift to developing large patent portfolios for defensive purposes). Many companies use their patent portfolios as a "shield" from litigation or to proactively carve out protected space for continued innovation. *See* Chien, *supra* note 4, at 321-22 (highlighting some defensive uses of patents). The Federal Circuit's expansive rulings on patent law during the late-twentieth century led many companies to choose filing new patents instead of paying licensing fees, sparking the use of many defensive patenting procedures seen today. *See* Rice, *supra* note 4, at 727-28 (describing Federal Circuit's broadening of patent scope and relaxation of patentability standards). Scholars attribute the rise in strategic patenting behavior to the Federal Circuit's changes to the law. *See* Tiller, *supra* note 5, at 137 (noting effect of lowering patentability standards).

86. *See* Hacohen, *supra* note 11, at 499 (discussing evergreening's dual benefit of deterring competition and extending legal protections).

patents to its drugs, creating a legal "patent thicket" to ensure company investments are heavily insulated from any attempts at litigation.[87] Many of the patents that make up a patent thicket are considered "questionable" because the claims are confusing, overly broad, or likely invalid.[88] Despite defensive intent, patent thickets result in increased costs for startups trying to invent around others' patents, acquire new patents, or avoid litigation.[89]

Some startups will avoid inventing in the thicket space altogether due to fears of infringement leading to costly litigation.[90] But when it comes to litigating the surplus of patents, big corporations have the resources to survive the courtroom while startups may face their demise due to funding constraints.[91] In 2017, this lethal combination of offensive and defensive patent procedures created an average of 125 patent applications per drug, leading to thirty-eight years of exclusivity—nearly double the period originally granted under the law.[92] Thus, big pharma companies both rely on and threaten the innovative power of startups, requiring small innovators to strike a delicate and difficult balance in order to survive.[93]

4. Today's Archetypal Monopolies

Pharma giant AbbVie's preeminent immunosuppressive drug, Humira, serves as a prime example of abusive patent practices in action.[94] Humira was the top-

87. *See id.* at 491-92 (explaining how patent thickets raise costs and risks for opponents trying to litigate); *see also* Chien, *supra* note 4, at 308-10 (discussing dynamics of growing and licensing patent portfolios). Chien describes the goal of patent thicketing as creating "the freedom to operate without having to worry about being sued." Chien, *supra* note 4, at 310.

88. *See* FED. TRADE COMM'N, *supra* note 15, at 5 (defining questionable patents); Hacohen, *supra* note 11, at 491-92 (noting pharmaceutical companies acquire multiple problematic patents to deter competition).

89. *See* Rice, *supra* note 4, at 750 (noting patent thickets increase costs for startups); *see also* Tiller, *supra* note 5, at 137 (explaining costs of inventing around prior patents and licensing reduce incentive to invent).

90. *See* FED. TRADE COMM'N, *supra* note 15, at 5-6 (discussing questionable patents' effect on innovation). If a startup were to attempt to license the invention in a questionable patent, it likewise must navigate complications and high fees due to the broad and confusing nature of the patent. *See id.* at 7.

91. *See* Jay M. Mattapally, Comment, *Goliath Beats David: Undoing the Leahy–Smith America Invents Act's Harmful Effects on Small Businesses*, 58 LOY. L. REV. 981, 1018 (2012) (noting large companies with expansive resources conduct frivolous litigation against smaller competition); Garr, *supra* note 10, at 2-3 (discussing large corporations' ability to afford abusive litigation). Startups face a separate issue in litigation from nonpracticing entities (NPEs) that create revenue from demands for licensing fees on patents the NPEs do not actually use. *See* Garr, *supra* note 10, at 2 (raising concern for frequent legal battles between startups and NPEs). NPEs will specifically target startups to use their precarious financial situation as leverage in seeking licensing fees. *See id.* at 5.

92. *See* I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 6 (2018), http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf [https://perma.cc/3HUB-SASV] (tabling key patent metrics for top twelve grossing drugs of 2017). Many of the top drugs considered in these calculations have already been on the market for fifteen years. *Id.*

93. *See supra* notes 76, 89-90 and accompanying text (highlighting big pharma companies' simultaneous pressure and reliance on startups).

94. *See* I-MAK, *supra* note 92, at 8 (putting Humira on list of "worst offenders" for patent system abuse). Humira is a monoclonal antibody drug delivered subcutaneously to treat various arthritis conditions, psoriasis,

selling drug on the market in 2017, generating $18 billion in global revenue.[95] The original patent for this monoclonal antibody expired in 2016.[96] Nevertheless, AbbVie has 247 follow-on patents filed for Humira as part of their strategy to fend off competition.[97] These follow-on patents extend Humira's patent protections until 2034, and would cost a staggering $3 million per patent for competitors to challenge.[98]

With exceptional protections on an already-prosperous drug, AbbVie has successfully defended the challenges to its patent thicket in court.[99] In the 2020 class action suit *In re Humira*, the court dismissed an action alleging that AbbVie violated antitrust laws by preventing competition from creating biosimilars.[100] The court ultimately found that AbbVie's patent thicket and market agreements did not violate antitrust law and notably stated that just one valid and enforceable patent in a thicket of questionable ones is enough to keep competitors off the market.[101]

Another notable example of patent system abuse comes from Amgen's blockbuster drug Enbrel.[102] Fourth on the list of global top-selling drugs in 2017, Enbrel earned $7.9 billion despite being on the market for two decades.[103] Amgen filed Enbrel's primary patent in 1990, with FDA approval following in

---

and Crohn's disease. *See* HUMIRA, https://www.humira.com/ [https://perma.cc/Y2C9-AQ7E] (describing drug and its uses).

95. *See* I-MAK, *supra* note 92, at 8 (calling Humira "world's number one selling drug").

96. *See* CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 26 (2020), https://fas.org/sgp/crs/misc/R46221.pdf [https://perma.cc/9XY7-JYWG] (noting Humira's patent expiry). Biosimilars to Humira can enter the market in 2023. *Id.*

97. *See id.* at 25 (stating number of follow-on patent applications AbbVie filed). So far, 132 of those patents have been issued in relation to Humira. *Id.*

98. *See id.* at 25-26 (noting patent protection extension and alleged cost to litigate).

99. *See* Richard G. Gervase, Jr. et al., *AbbVie's Enforcement of Its 'Patent Thicket' for Humira Under the BPCIA Does Not Provide Cognizable Basis for an Antitrust Violation*, MINTZ (June 18, 2020), https://www.mintz.com/insights-center/viewpoints/2231/2020-06-18-abbvies-enforcement-its-patent-thicket-humira-under [https://perma.cc/6WC2-SR4X] (discussing AbbVie's successful defense of Humira against suit); *In re* Humira (Adalimumab) Antitrust Litigation, 465 F. Supp. 3d 811, 853 (N.D. Ill. 2020) (ruling in favor of AbbVie).

100. *See In re Humira*, 465 F. Supp. 3d at 819 (discussing antitrust claims against AbbVie for Humira patent activity); Gervase, Jr. et al., *supra* note 99 (noting judge dismissed case on motion to dismiss).

101. *See In re Humira*, 465 F. Supp. 3d at 834 (finding AbbVie's activities immunized from antitrust scrutiny). The court specifically noted a lack of antitrust injury because "all it would have taken was one valid and infringed patent to preclude market entry" by plaintiffs, which AbbVie's intellectual property portfolio clearly included. *See id.* at 846 (justifying holding).

102. *See* I-MAK, OVERPATENTED, OVERPRICED SPECIAL EDITION: ENBREL 7 (2020), https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf [https://perma.cc/2C9B-A43G] (arguing Amgen's patent thicket perpetuates drug overpatenting problem). Enbrel is a protein-based biologic used to treat various inflammatory diseases like rheumatoid arthritis. *See* ENBREL, https://www.enbrel.com/ [https://perma.cc/TM6Y-3F8B] (listing uses for Enbrel); Jenny M. Alsup, Note, *You Can Dance if You Want to? Initial Interpretations of the BPCIA's Patent Dance with Sandoz and Amgen*, 8 HASTINGS SCI. & TECH. L.J. 137, 144 (2016) (describing Enbrel's drug makeup and use).

103. *See* I-MAK, *supra* note 102, at 5 (describing annual spending on Enbrel).

1998 and eventual patent expiry in 2010.[104] Amgen subsequently filed fifty-seven additional patent applications for Enbrel—72% of which came after FDA approval—extending its exclusivity until 2029.[105] By 2024, estimates suggest that the drug will reach a historic $139.8 billion in lifetime sales.[106]

The current COVID-19 pandemic has also shifted the public eye to the danger of impenetrable monopolies and the ethical quandary that follows patent-system abuse.[107] For example, Gilead's experimental COVID-19 treatment, Remdesivir, made waves in 2020 when Gilead attempted to reap orphan-status benefits for the drug.[108] Originally patented to treat Ebola and related diseases, Remdesivir is now used experimentally to treat severe COVID-19 cases.[109] Although Gilead still retains its patents for the drug and the ability to enforce them, the company abandoned its attempt to seek orphan-drug status for the new use of Remdesivir only after intense public criticism.[110] Nevertheless, Gilead earned a staggering $2.8 billion in sales from Remdesivir in 2020.[111] With both the law and financial prosperity currently on their side, companies like AbbVie, Amgen,

104. *See id.* at 3 (noting primary patent-filing and expiration dates); Alsup, *supra* note 102, at 144 (stating Enbrel received FDA approval in 1998).

105. *See* I-MAK, *supra* note 102, at 3 (noting patent statistics for Enbrel). Currently, nineteen of those patents are active and extending Enbrel's commercial exclusivity. *Id.*

106. *See* Arlene Weintraub, *Amgen's Enbrel Fends off Biosimilar Threat—and Heads Toward Blockbuster Superstardom*, FIERCE PHARMA (July 2, 2020, 10:35 AM), https://www.fiercepharma.com/pharma/amgen-catches-a-break-enbrel-biosimilar-threat-as-federal-court-upholds-patent-win [https://perma.cc/GK25-8HVR] (stating Enbrel poised to join ranks of best-selling drugs of all time). If Enbrel meets this estimate, it would rank third on the list of all-time best sellers behind Humira and Pfizer's Lipitor. *See id.*

107. *See, e.g.*, Elliot Harmon, *How Patent Abuse Could Hurt the Fight Against the Pandemic*, SLATE: TECHNOLOGY (Apr. 27, 2020, 1:29 PM), https://slate.com/technology/2020/04/patent-abuse-government-research-coronavirus.html [https://perma.cc/U3NY-BVJH] (discussing patent-abuse impacts on pandemic research); Ryan Davis, *How COVID-19 Could Shake Up Patent Strategies*, LAW360 (Apr. 6, 2020, 9:26 PM), https://www.law360.com/articles/1260795/how-covid-19-could-shake-up-patent-strategies [https://perma.cc/LXW8-6W98] (discussing terrible optics of patent enforcement stemming from public scrutiny during pandemic).

108. *See* Hailey Konnath, *After Backlash, Gilead Ditches 'Orphan' Status for Virus Drug*, LAW360 (Mar. 25, 2020, 10:58 PM), https://www.law360.com/articles/1257167 [https://perma.cc/3WZL-QTBV] (stating Gilead gave up orphan-drug designation after public backlash).

109. *See* Anders Heebøll-Nielsen & Michael Bech Sommer, *What Patent Protection Does Gilead's COVID-19 Treatment Remdesivir Have?*, AWAPOINT (Apr. 30, 2020), https://awapoint.com/what-patent-protection-does-gileads-covid-19-treatment-remdesivir-have/ [https://perma.cc/9H26-UPM2] (discussing inception and current use of Remdesivir). Gilead received approval for Remdesivir to treat Ebola in August 2017. *See* U.S. Patent No. 9,724,360 (filed Oct. 29, 2015).

110. *See* Heebøll-Nielsen & Sommer, *supra* note 109 (noting Gilead still has patent right to prevent competition); Konnath, *supra* note 108 (stating Gilead revoked orphan-drug status after harsh criticism from officials and public health groups).

111. *See* Press Release, Gilead Sciences, Gilead Sciences Announces Fourth Quarter and Full Year 2020 Financial Results (Feb. 4, 2021), https://www.gilead.com/news-and-press/press-room/press-releases/2021/2/gilead-sciences-announces-fourth-quarter-and-full-year-2020-financial-results [https://perma.cc/2FCW-KVG2] (charting $2.8 billion in Remdesivir product sales for 2020).

and Gilead can look forward to decades-long monopolies that hinder competition and innovation itself.[112]

III. ANALYSIS

In the current patent system, startups and independent innovators face adversity at every step.[113] Perhaps unsurprisingly, studies suggest that large companies bring the highest number of patent suits to court, while independent innovators make up the smallest margin of suits initiated.[114] Many small entities cannot afford to survive these suits, so some will delay or avoid innovating in heavily thicketed intellectual property spaces to evade legal challenges and retain investors.[115] Some legal scholars have also noted the uniformity of the patent system—treating every inventor and patent the same—stifles innovation and small inventors seeking market entry.[116]

The notably short period of time USPTO examiners receive to review patent applications inflames the patent system's shortcomings.[117] When questionable follow-on patents slip through those cracks, they receive the same deference and exclusivity as their novel, groundbreaking counterparts.[118] As large companies use their vast resources to blanket the operable intellectual property space, small companies and innovators are sidelined.[119] Nevertheless, simple changes to the

112. *See* Gervase, Jr. et al., *supra* note 99 (suggesting *In re Humira* decision validates patent-thicketing strategies); I-MAK, *supra* note 92, at 11 (stating excessive patenting on top-grossing drugs enables prolonged commercial monopolies). Notably, four of the twelve best-selling drugs have been on the market for twenty years and seek to extend patent life with an average of 125 patent applications per drug. *See* I-MAK, *supra* note 92, at 2-3.

113. *See supra* notes 66, 90-91 and accompanying text (discussing financial and legal challenges startups face when entering market).

114. *See* Chien, *supra* note 5, at 1572 (listing percentages of patent suits by entity in recent study). Chien notes that defensive patenting is a misnomer, as large companies initiated 42% of all lawsuits included in the study. *See id.* Meanwhile, independent investors brought only 4% of the lawsuits studied, and 18% were initiated by small companies against larger ones. *Id.*

115. *See* Garr, *supra* note 10, at 1-2 (stating startups lack financial stability to pay licensing or litigation fees); Simon, *supra* note 71, at 748 (noting hesitation of investors if invention may infringe another's patent); *see also* FED. TRADE COMM'N, *supra* note 15, at 5-6 (discussing competitors' avoidance of already-patented research areas).

116. *See* Landers, *supra* note 10, at 956 (stating current patent system locks all innovators into same scheme regardless of impact); Roin, *supra* note 11, at 677 (discussing negative impacts of one-size-fits-all patent system on innovation).

117. *See* Frakes & Wasserman, *supra* note 33, at 978 (stating patent examiners spend average of only eighteen hours reviewing each application). Inadequate time to research patent applications leads examiners to approve patents that they may otherwise reject after a comprehensive review. *See id.* Patent applications are legally presumed valid, so examiners with insufficient time to research and articulate grounds for rejection are likely to grant approval to invalid patents. *See id.* at 982.

118. *See* Roin, *supra* note 11, at 676 (stating patent system applies uniform set of rules to all inventions and industries). With the lengthy research and development periods that come with drug development, the standard patent term incentivizes short-turnaround projects like improvements to current drugs instead of research for novel treatments. *See id.* at 752-53 (discussing impact of patent term on pharma's research interests).

119. *See supra* Section II.C.3 (discussing common patent procedures available to large, well-funded pharmaceutical companies).

current patent system can bring small inventors and innovation back to the front line of the patent world.[120]

A. Changes in the USPTO

A common complaint among innovators is the uniformity of patent terms for every type of invention.[121] Granting the same exclusivity term to every approved patent lets simple follow-on inventions acquire the same protections as groundbreaking discoveries.[122] Pharmaceutical companies also build their questionable patent thickets by accumulating multiple patents for negligible improvements of existing drugs.[123] By implementing policies targeting follow-on patents for existing drugs, however, the USPTO ostensibly could limit the impact of these thickets on startups entering the market.[124]

As evergreening efforts allow pharmaceutical companies to receive patents for changes to drugs with minimal societal benefit, one forthright approach is to limit the patentability of nominal drug changes altogether.[125] Other approaches include implementing a more stringent nonobviousness requirement, or allowing third-party challenges to patents.[126] Either option could curtail the evergreening and thicketing efforts that lead to a drug's extended exclusivity.[127] Scholars note that the United States is unlikely to implement such changes due to concerns about substantial delays in the patent office.[128]

---

120. *See* Roin, *supra* note 11, at 686 (arguing tailoring of patent award length will stimulate subsequent innovation); Landers, *supra* note 10, at 956 (suggesting limited patent-free zone for startups to safely gain traction); Fachler, *supra* note 8, at 1062 (arguing reform to FDA process will streamline market entry and preserve innovation); Frakes & Wasserman, *supra* note 33, at 978 (indicating increased review time for patent examiners will decrease number of approved invalid patents). Frakes and Wasserman also conclude that increasing the time examiners have with each patent application will ultimately lead to decreased prosecution and litigation costs. *See* Frakes & Wasserman, *supra* note 33, at 1021 (estimating millions of dollars in savings from increased examination time reducing grants of invalid patents).

121. *See, e.g.*, Roin, *supra* note 11, at 676-77 (discussing social costs of broad patent system application); Landers, *supra* note 10, at 956 (criticizing effect of patent law's uniformity on startups).

122. *See* Ho, *supra* note 82, at 314 (stating all patents have same exclusivity term but secondary patents extend commercial exclusivity).

123. *See supra* note 88 and accompanying text (describing pharma's use of questionable patents for thicketing).

124. *See infra* notes 132, 136 and accompanying text (describing opportunities to limit patent-thicketing activities in pharma).

125. *See* Ho, *supra* note 82, at 298, 300 (suggesting societal cost of menial drug patents warrants revisiting patentability standards).

126. *See id.* at 346-47 (discussing opportunities to curb patent evergreening). Some countries like India, for example, have taken hardline approaches to innovation by barring patents for common evergreening targets that offer minimal improvement to the original invention. *See id.* at 326 (describing India's legal approach to incremental pharmaceutical innovation). Ho suggests that some alternative approaches may similarly work in the United States. *See id.* at 346-47.

127. *See id.* (stating other opportunities could address evergreening).

128. *See id.* at 347 (addressing difficulties in implementing policies in United States). Although different approaches to the follow-on patent issue have worked for other countries, pharma would likely resist these changes in the United States. *See id.* (indicating likely objections from pharmaceutical industry).

Perhaps a more versatile approach would be for the USPTO to instead consider a flexible patent term for drugs based on objective qualities denoting the patent's strength.[129] For example, basing a patent term off the invention's time-to-market could encourage additional research into drug targets that require extensive research and development time.[130] Extended patent protections for novel targets could also support pharma startups' efforts to secure venture capital funding.[131] Alternatively, awarding shorter patent lengths to applications that are essentially drug "updates" may limit patent thickets and thus encourage startups to innovate on both ends of the time-to-market spectrum.[132] This approach stands out in terms of feasibility because it offers both flexibility and incentive for all pharma entities based on the types of projects they pursue.[133]

Another factor impacting pharmaceutical companies' abilities to procure questionable patents is the limited time USPTO examiners have to scrutinize each patent application.[134] Studies show that the less time an examiner has to review an application, the more likely she is to grant an invalid patent.[135] By increasing the allotted time per application, an examiner can perform a more thorough search of prior art, and thus is more likely to reject questionable applications that comprise many pharmaceutical companies' thickets.[136] Subsequent effects may even include less patent litigation for startups, as well as greater

129. *See* Roin, *supra* note 11, at 684 (suggesting strategy for tailoring patent terms based on patent strength).

130. *See id.* at 752 (noting longer patent terms may motivate novel drug development). The time-to-market measurement encompasses the entire timeline from idea formation to the product's first sale. *Id.* at 684. Some drugs that would require development periods longer than the current patent term may become viable targets if pharmaceutical companies receive enough time to recoup investments through extended exclusivity periods. *See id.* at 752 (noting types of drugs rarely developed due to excessive development times needed).

131. *See supra* note 72 (noting startups attract more funding by targeting novel inventions); *see also* Landers, *supra* note 10, at 1009 (stating patent claims against startups deter venture capitalists from investing).

132. *See* Roin, *supra* note 11, at 753 (discussing lack of single optimal patent length for all drugs). Having the flexibility to tailor exclusivity periods offers the USPTO a powerful tool for balancing drug development efforts with equitable patent protection. *See id.* (considering ability to address patent costs and benefits through time-to-market flexibility).

133. *See id.* at 752-53 (suggesting flexibility in patent-term length may incentivize longer projects). Meanwhile, shortening the patent term length of follow-on drugs could limit the impact of patent thickets on small pharmaceutical companies. *See supra* notes 88-89 and accompanying text (noting composition and effect of patent thickets on startups).

134. *See* Frakes & Wasserman, *supra* note 33, at 982 (concluding examiners grant invalid patents when lacking proper time to evaluate applications). Patent examiners reportedly recognize that they are not given enough time to properly perform their job functions. *See id.* at 978-79 (quoting examiners' complaints about insufficient examination time).

135. *See id.* at 984 (summarizing conclusion of application granting research). Since applications are legally presumed valid, examiners are expected to approve all applications unless they can articulate a reason for rejection. *See id.* at 982. If an examiner has less time to review an application, "the less active she becomes in searching for prior art, the less likely she becomes to make time-intensive rejections, and the more likely she becomes to grant the patent" regardless of its validity. *Id.* at 984.

136. *See id.* at 985-86 (concluding increased examination time will limit grants of questionable patents); s*ee also supra* note 88 and accompanying text (describing questionable patents and their role in patent thickets).

innovative capacity, because small innovators would face less concern over legal challenges to their work.[137]

Finally, a more radical approach to protecting startup innovation could include creating immunity from patent prosecution and infringement suits altogether.[138] With startups facing dangerously high stakes from potential patent suits, a voluntary opt-out system may allow them to focus their time and finances on innovation.[139] Amy Landers proposes a system that exchanges a startup's patent-filing ability for total immunity from infringement claims.[140] In the pharmaceutical world, such a program would allow small innovators to attract and retain funding for their endeavors and operate without fear of litigation from big pharma's large portfolios.[141] The assumption that small inventors will continue to innovate without the financial incentives a patent has to offer, however, is critical to the success of this program.[142]

B. Changes in the FDA

Although the FDA sets up necessary safety barriers through clinical trials and other requirements, its lack of harmony with the patent system ultimately erodes the actual time that a drug receives market exclusivity.[143] Neither the FDA nor the patent approval process sufficiently account for the other, and this disconnect drives pharmaceutical companies to choose less valuable projects with quicker

137. *See* Frakes & Wasserman, *supra* note 33, at 994 (discussing how increased application scrutiny may lead to less litigation); FED. TRADE COMM'N, *supra* note 15, at 5-6 (stating biotech firms avoid innovating in areas that might infringe others' questionable patents). Decreasing the likelihood of litigation may serve the dual function of attracting investors and increasing the legal landscape in which a startup can innovate. *See* Simon, *supra* note 71, at 748 (discussing business partners' hesitation to invest in startups if infringement likely); FED. TRADE COMM'N, *supra* note 15, at 5 (noting competitors will not innovate in questionable legal spaces).

138. *See* Landers, *supra* note 10, at 957 (proposing voluntary opt-out patent system for startups).

139. *See id.* at 979 (discussing devastating impact of litigation on startups' funding). Landers specifically notes that "startups are the most likely entities to be slowed to a crawl or financially devastated by a patent suit." *Id.* at 965.

140. *See id.* at 957 (describing "antipatent" for startups). This system would allow startups to obtain full immunity from patent infringement suits for a twenty-year term, but they must forgo any potential patents for inventions crafted during that time. *See id.* The startup's inventions would instead pass directly into the public domain. *Id.*

141. *See id.* at 1009 (discussing importance of avoiding litigation for venture capitalists investing in biotech startups). Although studies suggest patents in startups are more technologically innovative, inadequate funds limit a startup's ability to enforce its patent rights. *See id.* at 968, 997 (discussing startups' inability to assert their more innovative patents). Relieving pharma startups from this burden could allow them to prosper without battling big pharma's strategic overshadowing through patent thickets. *See id.* at 977 (highlighting ways rivals strategically shutter patent competition); *see also supra* note 87 and accompanying text (explaining big pharma's use of patent thickets).

142. *See* Landers, *supra* note 10, at 957 (setting forth need for inventors in voluntary opt-out system to have alternative incentives to patents); *see also supra* note 9 and accompanying text (considering pharma's incentives in pursuing patents).

143. *See supra* notes 48-49 and accompanying text (commenting on FDA hurdles); Fachler, *supra* note 8, at 1094 (noting FDA approval process shortens patent term).

turnaround over drug targets with higher social value.[144] Instead of operating two systems in disharmony, one scholar suggests granting authority over exclusivity regulations to the FDA.[145] Exclusivity periods under the FDA's influence would begin upon a drug's entry to market, which would allow startups to focus on innovating socially valuable drugs instead of meeting narrow patent expectations in order to attract investors.[146] FDA market exclusivity would still incentivize startups to innovate, while also potentially relieving the pressure on startups to gain patent protections and avoid questionable litigation.[147]

Another innovation-enhancing specialty of the FDA is its ability to offer reward-based incentives.[148] Grants and prize money for companies that pursue novel drugs could help keep startups out of precarious financial situations in exchange for their innovative efforts.[149] Other prioritization efforts on behalf of the FDA, like tax credits or fast-track approvals for novel drug targets, could also work to propel innovative startups into the market with confidence and security.[150]

C. Legislative Change

While many opportunities for change lie in the hands of patent law's governing agencies, Congress holds a pivotal role in its ability to introduce significant

144. *See* Fachler, *supra* note 8, at 1097 (recognizing patent term and FDA dichotomy forces choice between viable drug targets). Fachler notes that both systems' failure to account for the other can render a patent term worthless in the pharmaceutical world. *See id.* at 1094. Faults within the patent system, like overbroad novelty and usefulness requirements, inhibit innovation and have little bearing on FDA approval. *See id.* at 1089 (explaining drawbacks of patent system related to FDA approval).

145. *See id.* at 1094 (suggesting FDA extend control over pharma market exclusivity). The FDA already exercises some control over data and market exclusivity for pharmaceutical companies. *See id.* at 1095 (analyzing FDA's current exclusivity regulations). Fachler argues that a shift to regulatory exclusivities would better serve socially valuable drug products. *Id.* at 1096.

146. *See id.* at 1097 (discussing FDA market exclusivity's influence on socially valuable drugs); *see also supra* note 72 and accompanying text (observing startups' need for strong patent protection to attract investors). Fachler specifically argues that FDA exclusivity regulations would also improve innovation by protecting drugs that did not meet strict patentability standards but are nonetheless socially valuable. *See* Fachler, *supra* note 8, at 1095 (arguing for protecting socially valuable, nonpatentable drugs).

147. *See* Fachler, *supra* note 8, at 1094 (stating FDA regulations can enhance pharmaceutical innovation); *supra* note 72 (noting startups attract more funding by targeting novel patentable inventions); *see also* Landers, *supra* note 10, at 1009 (recognizing patent-infringement claims deter venture capitalists from investing).

148. *See* Fachler, *supra* note 8, at 1092 (stating agencies like FDA could incentivize innovation with rewards); Greenbaum, *supra* note 74, at 133 (observing FDA can provide various incentives to develop and bring drugs to market).

149. *See* Fachler, *supra* note 8, at 1092 (suggesting rewards incentives for drug targets); *supra* note 13 (describing startups' need for funding to innovate); *supra* text accompanying note 91 (indicating startups cannot fund litigation efforts). Startups are more likely than big pharma companies to pursue opportunities for prize money and recognition. *See* Greenbaum, *supra* note 74, at 148.

150. *See* Fachler, *supra* note 8, at 1092 (stating potential incentives support front-end costs to allow market entry); *see also* Greenbaum, *supra* note 74, at 145-47 (contending various FDA credits and incentives would support developing specific drug family). The FDA has already seen success in this manner through the incentives provided by the Orphan Drug Act. *See supra* note 74 and accompanying text (describing Orphan Drug Act's successful incentives).

new policies and procedures to the patent system.[151] Legislation such as the Orphan Drug Act has already proven to successfully incentivize innovation.[152] Nevertheless, Congress has the power to continually facilitate positive change that can directly impact the viability of pharma startups within the industry.[153] Congress could follow the lead of the Orphan Drug Act and enact new legislation that provides similar incentives to develop other novel drug families or groundbreaking targets startups often pursue.[154] For example, Congress might create an act using the Orphan Drug Act's framework that incentivizes companies to use modern technology to pursue targets for diseases with only antiquated and inadequate treatments available.[155] Further, Congress has the ability to support the USPTO and FDA, and subsequently startups, with legislation that increases funding or limits an applicant's ability to pass questionable patent applications through the system.[156]

D. The Best Path Forward

Despite having many moving pieces, these remedies are not mutually exclusive; changes can occur in both the USPTO and FDA to simultaneously facilitate the improvement of patent processes.[157] The USPTO could ostensibly increase

151. *See* Roin, *supra* note 11, at 681 (suggesting change to USPTO uniformity policy); Fachler, *supra* note 8, at 1094 (suggesting FDA implement market exclusivity policy); *see also* Kozdrey, *supra* note 71, at 393-94 (stating Congress's passage of Orphan Drug Act achieved many policy goals).

152. *See supra* note 74 and accompanying text (discussing innovation success of Orphan Drug Act).

153. *See* US CONST. art. I, § 8, cl. 8 (authorizing Congress to promote science and useful arts); *see also* Kozdrey, *supra* note 71, at 396 (commenting Congress effectively addressed underserved diseases through Orphan Drug Act); *supra* note 72 (demonstrating startups use novel targets to secure capital investments).

154. *See* Greenbaum, *supra* note 74, at 126 (suggesting Congress create similar legislation to Orphan Drug Act for different drug family). Greenbaum proposes that an act mirroring the Orphan Drug Act, with some caveats, would incentivize greater development of pharmacogenomic drugs. *See id.* at 134-35 (proposing use of market exclusivity incentive from Orphan Drug Act). A pharmacogenomic drug is one that, in essence, utilizes genetic and physiological information to decrease adverse drug reactions and improve drug efficacy. *See id.* at 100. Although pharmacogenomic drugs can achieve orphan-drug status, they face additional disincentives due to the length and cost of necessary studies. *See id.* at 101, 128 (explaining disincentives for pharmacogenomics distinct from other orphan drugs).

155. *See* Orphan Drug Act § 1(b), Pub. L. No. 97-414, 96 Stat. 2049, 2049 (1983) (facilitating drug development for rare diseases); Greenbaum, *supra* note 74, at 126 (suggesting Congress use Orphan Drug Act to frame new legislation); *see also supra* note 42 (discussing use of modern technology to improve antiquated vaccine application through follow-on innovation).

156. *See* FED. TRADE COMM'N, *supra* note 15, at 7-8 (recommending legislation to create post-grant review of patents). The Federal Trade Commission has suggested that Congress's enactment of post-grant reviews would allow competitors to challenge questionable patents more adequately. *See id.* at 8. Another notable recommendation from the Federal Trade Commission includes increasing funding for the USPTO, ensuring it "receive[s] funds sufficient to enable it to ensure quality review." *Id.* at 12-13 (advocating for more USPTO funding). Legislation that reduces or inhibits patent thickets could subsequently clear the path for startups seeking market entry. *See supra* note 89 and accompanying text (describing negative impact of patent thickets on startups).

157. *See, e.g.*, Landers, *supra* note 10, at 957 (proposing voluntary opt-out patent system for startups); Greenbaum, *supra* note 74, at 133 (discussing FDA's ability to increase drug development incentives). For instance, a startup that opts out of patent protections would still need to seek FDA approval for its drug target, but this

the amount of time examiners receive to review patents, while the FDA could implement additional fast-track approvals or incentives for startup-sought, novel drug targets.[158] Altering the exclusivity period of a patent based on objective qualities of the drug application would likely offer a more significant amount of flexibility to the USPTO and FDA timelines while opening doors for small competitors.[159] The most likely hindrance to many of these remedies is funding.[160] Ultimately, Congress holds the keys, both to evolution of the law and the financial support to effect change.[161] If Congress acted as the driving force behind these changes, however, pharma startups would likely see a more robust and long-lasting improvement of the laws and regulations that currently hold them back.[162]

E. What Will Big Pharma Think?

Perhaps the jealousy monster is as green as the money lining big pharma's deep pockets—one major consideration for enacting meaningful change on behalf of startups is whether big pharma will oppose it through lobbying efforts.[163] Big pharma, notoriously the highest-paying industry for lobbying in the United States, has significant influence in both Congress and the FDA.[164] When certain proposed policies hinder their business efforts, big pharma is unlikely to acquiesce to approval of the legislation.[165] Some policies, however, could serve as

process would allow the startup to bring its invention swiftly into the public domain. *See* Landers, *supra* note 10, at 957 (describing antipatent invention's path to public use); *Development & Approval Process | Drugs*, *supra* note 47 (noting pharmaceutical companies' requirement to test and receive approval from FDA).

158. *See* Frakes & Wasserman, *supra* note 33, at 1028-29 (concluding USPTO should increase allotted examination time because benefits outweigh costs); Greenbaum, *supra* note 74, at 140-41 (discussing opportunities for FDA to implement credits or fast-track approvals).

159. *See supra* note 130 and accompanying text (describing flexibility of exclusivity term based on time-to-market). Although Roin describes a time-to-market approach, other objective datapoints such as research and development costs, follow-on status, or type of entity could similarly provide beneficial patent term flexibility. *See* Roin, *supra* note 11, at 699 (considering costs and cumulative innovation for impact on patent term length).

160. *See* FED. TRADE COMM'N, *supra* note 15, at 13 (calling for Congress to increase funding to USPTO); Fachler, *supra* note 8, at 1092 (arguing FDA could incentivize innovation with monetary rewards).

161. *See* U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress to promote science and useful arts through patent laws); *see also* FED. TRADE COMM'N, *supra* note 15, at 13 (asking Congress to better financially support USPTO).

162. *See* Kozdrey, *supra* note 71, at 396 (commenting on effectiveness of Congress's prior initiatives like Orphan Drug Act); *see also supra* text accompanying notes 73-74 (discussing positive impact of Orphan Drug Act on startups).

163. *See* Duckworth, *supra* note 65, at 274-75 (noting Congress's difficulty passing laws big pharma opposes); McCarthy, *supra* note 65, at 60 (quantifying drug companies' large lobbying expenditures).

164. *See* McCarthy, *supra* note 65, at 59 (discussing big pharma's massive lobbying efforts). Major drug companies have consistently placed allies in positions of power within the federal government. *See id.* at 61-62 (naming federal officials with ties to big pharma companies).

165. *See* Duckworth, *supra* note 65, at 274-75 (discussing immense difficulty passing opioid legislation due to big pharma's opposition). In contrast, where legislation furthers big pharma's interests, lobbying efforts directly impact the bill's passage. *See* McCarthy, *supra* note 65, at 60 (tracing successful lobbying effort for pharma-approved legislation).

mutual incentives for large and small companies alike.[166] A parallel consideration for pharma's top players is their own reliance on startups' innovation.[167] By supporting policies and legislation that promote startup success, both big pharma and society at large will benefit from startups' innovation.[168]

IV. CONCLUSION

The patent system has fundamental problems that negatively impact small innovators in the pharmaceutical world. Startups, and society, need the system to be more equitable. Big pharma's ability to legally monopolize the system with patent thickets and manipulative practices has gone largely unaddressed despite the detrimental impacts on small innovators' ability to bring novel medicines to the market. Only well-funded entities can participate in questionable patenting and litigation practices to exploit the system. Yet opportunity exists for legislation and policymaking that can curtail these practices and provide small innovators with a fair playing field.

Congress and relevant agencies should consider flexible patent terms, stricter follow-on patentability standards, and increased or diverse market incentives to make room in the field for the entities that are typically the most innovative but least funded. Ideally, a combination of agency incentives and legislative changes would best serve those same entities—the pharma startups and independent innovators—that deserve the opportunity to persist through an equitable patent system. By tailoring patent term lengths and providing commercial incentives to startups, Congress and its agencies substantially increase the avenues through which pharma startups can financially and logistically bring their inventions to market.

Importantly, this is not a mutually exclusive proposition: Big pharma companies also benefit from elevating startups because the efforts of smaller inventors increasingly fuel their own innovation. Ultimately, any effort to equalize the patent system would allow for all pharma entities to share in the industry's exceptional patent reputation and subsequently ensure that society enjoys the best of pharmaceutical innovation.

166. *See* Roin, *supra* note 11, at 752 (noting increased time-to-market protections would incentivize new drug targets); Greenbaum, *supra* note 74, at 126 (suggesting new drug-target incentives for pharmaceutical world). *But see* Konnath, *supra* note 108 (discussing failed big pharma attempt to utilize orphan-drug status for Remdesivir).

167. *See supra* note 76 and accompanying text (describing big pharma's increasing reliance on startup innovation).

168. *See* Richman et al., *supra* note 66, at 801 (noting big pharma shift to acquiring startups for innovation); Fachler, *supra* note 8, at 1095-96 (arguing FDA policy changes support socially valuable drugs). Big pharma recognizes that change is coming, as "[t]he locus of innovation is shifting from inside large firms to smaller startups." Richman et al., *supra* note 66, at 801.