Incentivizing Lower Drug Prices Through Patent Extension*

Awarding inventors with a legal monopoly through patents and regulatory exclusivities has proven to be a highly effective tool for making therapeutics more available to society, driving pharmaceutical companies to invest billions of dollars in high-risk, time-consuming research and development. However, this increased availability has come at a dire cost: unaffordability. While governmental regulations and enforcement have had some—albeit limited—success in curbing exorbitant increases in drug prices, cracking down on pharmaceutical profits could potentially chill innovation in the long run and ultimately decrease the availability of lifesaving therapeutics for everyone in society.

To balance the need for affordability and continued innovation, this Comment proposes an incentive system to lower drug prices using the most effective, tried-and-true "carrot" that pharmaceutical companies have been willing to go to great lengths to obtain: an extension of the legal monopoly awarded by the patent system. By calculating the patent extension period as an inverse function of price, the proposed system makes it more profitable for pharmaceutical companies to lower the prices of their products, thus making lifesaving therapeutics more available and accessible. After all, pharmaceutical breakthroughs are only meaningful if patients can access them.

INTRODUCTION

The United States has experienced explosive growth in the development of lifesaving medications over the past few decades. The Food and Drug Administration ("FDA") has approved an average of forty-three novel drugs per year between 2013 and 2022.[1] In 2023, the number of approvals grew to fifty-five.[2] In total, the FDA has approved more than 20,000 prescription drugs.[3] These drugs treat a wide range of common and rare ailments, including diabetes, obesity, HIV, neurological disorders, and various cancers.[4] Remarkably, in December 2023, the FDA approved the first cell-based gene therapies, Casgevy and Lyfgenia, to treat sickle cell disease by modifying patients' blood stem cells with the novel CRISPR/Cas9 genome-editing technology.[5]

1. *New Drug Therapy Approvals 2022: Advancing Health Through Innovation*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2022 [https://perma.cc/25MP-HKRE (staff-uploaded archive)] (last updated Jan 10, 2023) [hereinafter *New FDA Drugs 2022*].

2. Patricia Cavazzoni, *FDA Approves Many New Drugs in 2023 That Will Benefit Patients and Consumers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-voices/fda-approves-many-new-drugs-2023-will-benefit-patients-and-consumers [https://perma.cc/LMM2-TPKT (staff-uploaded archive)] (last updated Jan. 9, 2024) [hereinafter *New FDA Drugs 2023*].

3. U.S. FOOD & DRUG ADMIN. OFF. COMM'R, FDA AT A GLANCE: REGULATED PRODUCTS AND FACILITIES 1 (2020), https://www.fda.gov/media/143704/download [https://perma.cc/2G33-XSEQ (staff-uploaded archive)].

4. *New FDA Drugs 2022*, *supra* note 1; *New FDA Drugs 2023*, *supra* note 2; Press Release, U.S. Food & Drug Admin, FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014 (June 4, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014 [https://perma.cc/99T8-3UWX (staff-uploaded archive)].

5. Press Release, U.S. Food & Drug Admin., FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease (Dec. 8, 2023), https://www.fda.gov/news-events/press-

This rapid development in the discovery of lifesaving medications is driven primarily by the promise of a legal monopoly granted to inventors of novel therapeutics through patents and regulatory exclusivity protections.[6] Through the patent system, the government grants twenty years of exclusive property rights to those who invent a new product, process, or way to solve a problem.[7] In addition to these patent rights, inventors can obtain periods of regulatory exclusivity—additional periods of monopoly that may or may not run concurrently with the patent term.[8] The profits that inventors can amass during the exclusivity period—which can amount to billions of dollars annually[9]—are significant incentives that drive pharmaceutical companies to invest large amounts of time, money, and human capital in the race to find cures for various diseases.[10]

While a monopoly on lucrative therapeutics is a powerful driver of innovation, it has the undesirable side effect of making therapeutics expensive for—and arguably inaccessible to—many Americans. Americans spent a staggering $633.5 billion on prescription medication in 2022.[11] Between July 2021 and July 2022, the Department of Health and Human Services ("HHS") identified 1,216 drugs with price hikes significantly greater than the inflation rate, which was 8.5% for that time period.[12] For those drugs, the average price jump was 31.6%.[13] To take just one example, Zolgensma, a drug approved in

announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease [https://perma.cc/9XUF-H8U8 (staff-uploaded archive)].

6. KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING 5–6 (2024), https://sgp.fas.org/crs/misc/R46679.pdf [https://perma.cc/66EU-CNFS].

7. *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity [https://perma.cc/AV9N-J6WT (staff-uploaded archive)] (last updated Feb. 4, 2020) [hereinafter FDA, *FAQ*]; *Patents*, WORLD INTELL. PROP. ORG., https://www.wipo.int/patents/en/ [https://perma.cc/7DC2-CGQD].

8. FDA, *FAQ*, *supra* note 7.

9. *See* Press Release, AHIP, New Research: Big Pharma Companies Earn Big Revenues Through Patent Gaming (Dec. 13, 2021), https://www.ahip.org/news/press-releases/new-research-big-pharma-companies-earn-big-revenues-through-patent-gaming [https://perma.cc/3UTS-RFPH].

10. CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2 (2021) [hereinafter R&D IN THE PHARMA INDUSTRY], https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf [https://perma.cc/XM35-KUSH].

11. Eric M. Tichy, James M. Hoffman, Mina Tadrous, Matthew H. Rim, Katie J. Suda, Sandra Cuellar, John S. Clark, Mary Kate Newell & Glen T. Schumock, *National Trends in Prescription Drug Expenditures and Projections for 2023*, 80 AM. J. HEALTH SYS. PHARMACY 899, 899 (2023).

12. ARIELLE BOSWORTH, STEVEN SHEINGOLD, KENNETH FINEGOLD, NANCY DE LEW & BENJAMIN D. SOMMERS, OFF. OF HEALTH POL'Y, ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEPT. HEALTH & HUM. SERV., PRICE INCREASES FOR PRESCRIPTION DRUGS, 2016–2022, at 1 (2022), https://aspe.hhs.gov/sites/default/files/documents/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf [https://perma.cc/97AR-MCPB].

13. *Id.*

2019 to treat spinal muscular atrophy, has a price tag of $2,125,000 and is not always covered by insurance.[14]

The eye-popping price tags of novel therapeutics can be partially explained by the risk and high costs associated with their development. It takes an average of ten to fifteen years for a medicine to make its way from development to FDA approval.[15] Of all the therapeutics that enter clinical trials, only twelve percent (thirty-seven drugs total in 2022) ultimately obtain FDA approval.[16] When the cost of medicines that ultimately fail are taken into account, the average cost to develop a new medicine is estimated to be $2.6 billion.[17] Moreover, the threat of competition from generic and biosimilar drugs[18] always looms in the background. Unlike their brand-name counterparts, generic and biosimilar drugs do not need to go through the arduous preclinical and clinical testing process and are therefore much less costly to develop; generic drugs only cost between $1 million and $2 million and take around two years to develop, while biosimilar drugs cost $100 to $300 million and take approximately five to nine years.[19] Because first inventors of medicines have to compete with these generic

14. Hannah McQueen, *The 10 Most Expensive Drugs in the US*, GOODRX, https://www.goodrx.com/drugs/savings/most-expensive-drugs-in-us [https://perma.cc/W5ZX-K662 (staff-uploaded archive)] (last updated June 2, 2022). Other examples are Zokinky, Danyelza, and Kimmtrak—drugs that are approved to treat Hutchinson-Gilford progeria, neuroblastoma, and uveal melanoma and have to be taken regularly—which have annual price tags per consumer of $1,073,760, $1,011,882, and $975,520, respectively. *Id.*

15. Jocelyn Ulrich, *Research and Development Continues Long After a Medicine Is Initially Approved*, PHRMA (Feb. 1, 2022), https://phrma.org/en/Blog/research-and-development-continues-long-after-a-medicine-is-initially-approved [https://perma.cc/B7XK-S5FQ (staff-uploaded archive)].

16. R&D IN THE PHARMA INDUSTRY, *supra* note 10, at 2.

17. Ulrich, *supra* note 15; *New FDA Drugs 2022*, *supra* note 1.

18. Generics are drugs created to be equivalent to brand-name (small-molecule) drugs in terms of efficacy, quality, and safety. Seema Ledan, *Discussing Brand Versus Generic Medications*, U.S. PHARMACIST (June 18, 2020), https://www.uspharmacist.com/article/discussing-brand-versus-generic-medications [https://perma.cc/7Z5B-24XP (staff-uploaded archive)]. Biosimilars are drugs that are very similar in structure and function to a biologic drug, which is a drug that is generated in living systems. *Understanding Biologic and Biosimilar Drugs*, AM. CANCER SOC'Y (July 27, 2018), https://www.fightcancer.org/policy-resources/understanding-biologic-and-biosimilar-drugs [https://perma.cc/769L-UACX].

19. *The Development of Biosimilars*, PFIZER (2018), https://www.pfizerbiosimilars.com/biosimilars-development [https://perma.cc/M3KH-CXYV (staff-uploaded archive)] [hereinafter PFIZER, *Biosimilars*]; *see also* Miriam Fontanillo, Boris Körs & Alex Monnard, *Three Imperatives for R&D in Biosimilars*, MCKINSEY & CO. (Aug. 19, 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars [https://perma.cc/N42Q-BAEH] ("[A] typical biosimilar costs $100 million to $300 million to develop."); Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS: BUS. 469, 470–71 (2013) ("The investment needed to develop and market a biosimilar is considerably higher than the $1 million to $4 million that is required in the generic market."); Colleen Becker, *Decreasing Drug Costs Through Generics and Biosimilars*, NAT'L CONF. STATE LEGIS., https://www.ncsl.org/health/decreasing-drug-costs-through-generics-and-biosimilars [https://perma.cc/W3WN-Q7T6 (staff-uploaded archive)] (last updated Jan. 21, 2022) ("Biosimilars already in use typically launched with initial list prices 15%

and biosimilar manufacturers once their patents (and periods of exclusivities) expire or are invalidated, they must recoup the costs of research and development ("R&D") and rake in sufficient profits—through astronomical prices—during the monopoly period.

Because the skyrocketing cost of drugs is an issue afflicting almost all Americans, the federal and state governments have attempted to combat the issue through various means. The Biden-Harris administration enacted the Inflation Reduction Act ("IRA"),[20] which authorizes Medicare to negotiate prescription drug prices directly with manufacturers, caps insulin costs at $35 for Medicare beneficiaries, requires recommended adult vaccinations to be given for free, and forces pharmaceutical companies that raise prices faster than inflation to pay rebates.[21] In December 2023, the Administration also announced a proposal to seize the patents of drugs that are deemed too expensive through the exercise of "march-in rights."[22] Governmental enforcement agents—such as the Department of Justice ("DOJ"), the Federal Trade Commission ("FTC"), and states' departments of justice—have also attempted to crack down on excessive drug pricing through antitrust enforcement and litigation.[23]

Governmental efforts to rein in drug prices have had varying degrees of success. While the IRA appears to have successfully lowered the cost of

to 35% lower than list prices of the reference products. Research shows biosimilar drugs saved nearly $8 billion in 2020 alone. As new products enter the market and increase competition, savings in 2022 is projected to reach over $30 billion.").

20. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (codified as amended in scattered sections of 23, 26, 30, 42 and 43 U.S.C.).

21. *Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, WHITE HOUSE (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/ [https://perma.cc/W7UT-XL83] [hereinafter WHITE HOUSE, *Medicare Negotiation*].

22. *Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition*, WHITE HOUSE (Dec. 7, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/ [https://perma.cc/T7QW-MGFQ] [hereinafter WHITE HOUSE, *Promoting Competition*]; *see infra* Section II.A.

23. Press Release, Fed. Trade Comm'n, FTC, DOJ and HHS Work to Lower Health Care and Drug Costs, Promote Competition to Benefit Patients, Health Care Workers (Dec. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-doj-hhs-work-lower-health-care-drug-costs-promote-competition-benefit-patients-health-care [https://perma.cc/Z4JU-UT2Z (staff-uploaded archive)].

insulin,[24] Merck and other companies are challenging its constitutionality.[25] Besides, even when governmental interventions successfully lower drug prices, such interventions can have the unintended consequence of chilling innovation by hurting pharmaceutical companies' bottom lines. Even a mild to moderate chilling effect—by deterring at least *some* players from entering the market—could mean that fewer lifesaving drugs will be produced.[26] After all, while companies can be forced to lower prices through legislation, they cannot be forced to innovate.[27]

To balance the need for drug innovation and accessibility, this Comment proposes utilizing the incentivizing power of the patent system as a policy lever to lower drug prices. A pharmaceutical company that lowers the prices of its drugs below what it could charge as a monopolist would be awarded with a patent term extension. The period of extension would depend on how far below monopoly prices the company charges and could be calculated through an equation that ensures profitability for the pharmaceutical company by making the extension term an inverse function of the drug price.

This Comment proceeds in five parts. Part I discusses how drugs are developed and brought into the market. This part also highlights the durational and cost differences associated with developing a therapeutic for the first inventor and follow-on manufacturers. Part II discusses how the government incentivizes innovation through patents and regulatory exclusivities. This part also explores the lengths that pharmaceutical companies go to in order to extend their monopolies, often at the risk of scrutiny from government enforcement agencies. Part III discusses how the government has attempted or is attempting to control drug prices. This part highlights legislation that has been recently

24. Sarah Al-Arshani & Ken Alltucker, *Insulin $35 Cap Price Now in Effect, Lowering Costs for Many Americans with Diabetes*, USA TODAY, https://www.usatoday.com/story/news/health/2024/01/03/insulin-price-cap-diabetes/72093250007/ [https://perma.cc/PE52-H7FR] (last updated Jan. 3, 2024, 11:32 AM).

25. Daniel E. Troy, Opinion, *An Unconstitutional Offer Drug Companies Can't Refuse*, WALL ST. J. (June 8, 2023, 1:00 PM), https://www.wsj.com/articles/an-unconstitutional-offer-drug-companies-cant-refuse-merck-ira-innovation-5dba27e0 [https://perma.cc/XY4R-VTSR (staff-uploaded, dark archive)].

26. *See* Nicole Longo, *One Year Later: IRA's Unintended Consequences Are Becoming Reality*, PHRMA BLOG (Aug. 16, 2023), https://phrma.org/blog/one-year-later-iras-unintended-consequences-are-becoming-reality [https://perma.cc/7EZR-9YQE]; *The IRA Will Chill Rare Disease Innovation, Experts Warn. Can Lawmakers Reignite That Spark?*, STAT (Nov. 11, 2020), https://www.statnews.com/sponsor/2024/11/20/the-ira-will-chill-rare-disease-innovation-experts-warn-can-lawmakers-reignite-that-spark/ [https://perma.cc/2YRY-2KLJ].

27. *See* R&D IN THE PHARMA INDUSTRY, *supra* note 10, at 12 (explaining that when "expected profitability of new drugs declined—because of a change in federal policy . . . or for any other reason," the lower expected returns would translate to fewer new drugs); Matt Ridley, *Innovation Can't Be Forced, but It Can Be Quashed*, WALL ST. J. (May 15, 2020, 11:03 AM), https://www.wsj.com/articles/innovation-cant-be-forced-but-it-can-be-quashed-11589555004 [https://perma.cc/PQ75-5WFZ (staff-uploaded, dark archive)] (explaining that "[i]nnovation . . . requires sensible regulation that is permissive" and "cannot easily be forced").

enacted or proposed, and some enforcement actions that have been taken by the federal and state governments. Part IV discusses the search for a novel solution to incentivize pharmaceutical companies to lower prices without sacrificing innovation. This part explores various incentive systems that have been utilized and proposed to spur innovation and lower prices, highlighting their strengths and weaknesses. Finally, Part V describes a patent extension system that could be a powerful tool to spur pharmaceutical companies to lower drug prices and continue innovating. This part also explores whether such a system could work in real life by doing a case study on Humira. This part ends with a discussion of the potential limitations and drawbacks of the proposed system, as well as the advantages of using a patent extension rather than a regulatory extension system.

I. DEVELOPING AND BRINGING THERAPEUTICS TO MARKET

This part compares the time-consuming, risky, and expensive process of developing and marketing new therapeutics[28] with the relatively easy, fast, and inexpensive process of bringing "copycat" products to market.[29] While encouraging the entry of generics and biosimilars is important for keeping costs down, having a system that also incentivizes companies to undertake initial research and development efforts is equally critical. Without such a system, no company would be willing to take the initial risk, which would result in an overall reduction in the number of lifesaving therapeutics available to society.

A. *Research and Clinical Trials*

A pharmaceutical company typically starts the R&D process by identifying and screening enormous numbers of candidate medications. Preclinical laboratory research is then performed to identify and select promising candidates for clinical trials.[30] When a company is ready to commence clinical trials, it submits a proposed clinical study design to the FDA's Institutional Review Board ("IRB").[31] After obtaining written approval from the IRB, the company files an Investigational New Drug ("IND") application with the FDA.[32] The IND application must contain information about what the drug does, what condition or population the drug purports to treat, preliminary data from animal studies using the drug, and the proposed clinical study design.[33] The FDA then has thirty days to review and object to

28. *See* Ulrich, *supra* note 15; R&D IN THE PHARMA INDUSTRY, *supra* note 10, at 2–3.
29. PFIZER, *Biosimilars*, *supra* note 19.
30. *See id.*
31. 21 C.F.R. § 312.21 (2025).
32. *Id.* § 312.20.
33. *Id.* §§ 312.22 to .23.

the IND application, and if there are no objections, the company may commence clinical trials.[34]

Clinical trials occur in three stages.[35] Phase I trials are conducted on a small cohort of healthy human subjects, with an emphasis on evaluating the optimal and highest tolerable dose of the drug, safety, potential adverse side effects, and drug metabolism and excretion.[36] In Phases II and III, the drug is tested on larger cohorts of subjects who have the condition the drug seeks to treat.[37]

While developers of brand-name drugs need to show evidence of their safety and efficacy through lengthy, expensive R&D and clinical studies, developers of generic and biosimilar drugs need not repeat these studies.[38] A generic drug company only needs to produce sufficient data to show that its product is substitutable with a corresponding brand-name drug that has been demonstrated to be safe and effective.[39] As a result, generic drug manufacturers incur significantly lower R&D costs and can provide products at a more affordable price.[40]

B. *FDA Approval and Licensing*

1. New Drugs and Biologics

Approval of new small-molecule drugs[41] is governed by the New Drug Application ("NDA") process.[42] After completing clinical trials, companies submit an NDA to the FDA Center for Drug Evaluation and Research.[43] The NDA includes: (1) the results from the clinical trials; (2) a description of the drug, including a listing of drug components; (3) the drug's indications (the condition and population the drug targets); (4) information about manufacturing methods and facilities; and (5) proposed labeling.[44]

34. *Id.* §§ 312.40, 312.42.

35. *Id.* § 312.21.

36. *Id.*

37. *Id.*

38. *The Generic Drug Approval Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/cder-conversations/generic-drug-approval-process [https://perma.cc/554J-KTJU (staff-uploaded archive)] (last updated Mar. 17, 2022) [hereinafter FDA, *Generic Approval*].

39. *Id.*

40. *Id.*

41. A small-molecule drug is one that can enter cells easily because it has a low molecular weight; it can affect other molecules once inside the cells and may cause cancer cells to die. *Small-Molecule Drug*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/small-molecule-drug [https://perma.cc/U6ZT-LCTV]. "Many targeted therapies are small-molecule-drugs." *Id.*

42. *See* KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 10 (2020) [hereinafter CRS, DRUG PRICES], https://sgp.fas.org/crs/misc/R46221.pdf [https://perma.cc/MTM8-XUCE].

43. 21 U.S.C. § 355(b).

44. *Id.*; 21 C.F.R. § 314.50 (2025).

To obtain FDA approval, the company must submit "substantial evidence" that the drug is safe and effective and that its benefits outweigh potential side effects.[45] After review, the FDA sends the company one of four notices. The first is an approval letter giving the company the green light to proceed. The second is a tentative approval letter if there exist patents and/or exclusivities that preclude immediate approval. The third is a conditional approval letter, such as one stating that more post-market Phase IV clinical studies are required. The fourth is a "complete response letter," explaining how the NDA is deficient and should be remedied.[46]

The process to obtain a license to manufacture biological products (a "biologics license") is a little different, but comparable. Biological products, those derived from biological materials or generated through biotechnology in living systems, are generally more complex and variable than small-molecule drugs, making the process of characterization, manufacturing, and approval more challenging and complicated.[47] To obtain a license, the manufacturer of a biological product must submit a Biologics License Application ("BLA") to the FDA, which needs to include data from clinical and nonclinical studies, manufacturing information, proposed labels and packaging, and a proposed Medication Guide.[48] If the biologic is deemed to be "safe, pure, and potent," and the manufacturing and distribution processes meet applicable standards, the FDA issues the license.[49] If there are deficiencies, the FDA sends a "complete response letter" with reasons for the denial.[50] Under the Prescription Drug User Fee Act ("PDUFA"), the FDA aims to "[r]eview and act on 90 percent of standard NME [(New Molecular Entity)] NDA and original BLA submissions within 10 months of the 60-day filing date."[51]

45. "Substantial evidence" is defined by section 505(d) of the Federal Food, Drug, and Cosmetic Act as "adequate and well-controlled" investigations that could lead scientific experts to conclude that the drug has the purported effect. Federal Food, Drug, & Cosmetic Act of 1938, Pub. L. No. 75-517, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 355(d)) (amended by Drug Amendments of 1962 (Kefauver-Harris Amendment), Pub. L. No. 87-781, 52 Stat. 1049, 1052).

46. 21 C.F.R. §§ 314.105, 314.10 (2025).

47. U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS 1 [hereinafter FDA, BIOLOGICAL PRODUCTS], https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf [https://perma.cc/M6VM-JSWV (staff-uploaded archive)]. Examples of biological materials include viruses, toxins, blood components, and proteins. *See Biological Agents*, U.S. DEP'T LAB., OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/biological-agents [https://perma.cc/W3S8-HDMR (staff-uploaded archive)]. Examples of living systems include microorganisms, plants, or animal cells. FDA, BIOLOGICAL PRODUCTS, *supra*, at 1.

48. 21 C.F.R. § 601.2(a) (2025).

49. 42 U.S.C. § 262(a)(2)(C).

50. 21 C.F.R. § 314.110(a)(1) (2025).

51. U.S. FOOD & DRUG ADMIN., PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027, at 4 (2023) [hereinafter FDA, PDUFA], https://www.fda.gov/media/151712/download [https://perma.cc/P5QS-RK43 (staff-uploaded archive)]; *see also* Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified as amended in scattered sections of 21 U.S.C.).

2. Generics and Biosimilars

A generic drug is a copy of an innovator or brand-name prescription small-molecule drug.[52] To be approved by the FDA, a generic drug must have the same active ingredient, the same mechanism of action, and equivalent benefits as its brand-name drug counterpart.[53] Additionally, it must meet the same FDA standards for safety, quality, purity, strength, and efficacy.[54]

Prior to 1984, every new drug application—brand name and generic—had to be supported by clinical trial data that demonstrated safety and efficacy.[55] The Hatch-Waxman Act,[56] enacted in 1984, facilitated the market entry of generic drugs by providing a pathway for Abbreviated New Drug Applications ("ANDA"), which enabled generic manufacturers to rely on a Reference Listed Drug ("RLD"), a drug with the same active ingredient, to show the safety and efficacy of the generic version.[57] Instead of conducting arduous clinical trials, generic manufacturers only need to perform studies that show that its generic drug is pharmaceutically equivalent and bioequivalent to the RLD.[58] ANDA applicants must submit such showings, along with proposed labeling and any relevant patent certifications, to the FDA to obtain approval for their generic drugs.[59]

Biosimilars are biological products that are "highly similar to and ha[ve] no clinically meaningful differences from an existing FDA-approved reference product"—the biological product that has been FDA-approved and against which the biosimilar product is being compared.[60] They are approved through

52. FDA, *Generic Approval*, *supra* note 38.

53. *Generic vs. Brand-Name Drugs: Is There a Difference?*, UNIV. HOSP.: THE SCI. OF HEALTH (July 21, 2022), https://www.uhhospitals.org/blog/articles/2022/07/generic-vs-brand-name-drugs-is-there-a-difference [https://perma.cc/97AL-R8ZU]. Just as making, using, or selling a patented active ingredient is considered patent infringement, filing an application for generic drug approval can be considered patent infringement. *See* 35 U.S.C. § 271(a); *Small Business Assistance, 180-Day Generic Drug Exclusivity*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-180-day-generic-drug-exclusivity [https://perma.cc/7NME-EHGA (staff-uploaded archive)] (last updated Oct. 26, 2023) [hereinafter FDA, *Generic Exclusivity*]. However, a generic applicant can file for FDA approval to market a generic copy of a patented brand-name drug by filing a "paragraph IV certification," whereby the generic applicant provides a "paragraph IV certification" that the patent submitted for the brand-name drug is either invalid or not infringed by the generic applicant. *Id.*

54. FDA, *Generic Exclusivity*, *supra* note 53.

55. 21 U.S.C. § 355(b) (1982).

56. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (codified as amended in scattered sections of 15, 21, 28 and 35 U.S.C.).

57. 21 C.F.R. §§ 314.92, 314.94 (2025).

58. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. §§ 314.94, 320.21 (2025).

59. 21 U.S.C. § 355(j)(2)(A).

60. FDA, BIOLOGICAL PRODUCTS, *supra* note 47, at 1.

the Biologics Price Competition and Innovation Act ("BPCIA"),[61] an abbreviated approval process analogous to the process established in the Hatch-Waxman Act.[62] Biosimilars that produce the same clinical results in any given patient and can be freely substituted for the reference product without going through a health care provider are considered to be "interchangeable" products.[63]

Under the Generic Drug User Fee Amendments, the FDA aims to "[a]ssess and act on 90 percent of standard original ANDAs within 10 months of the date of ANDA submission."[64] Similarly, under the Biosimilar User Fee Act,[65] the FDA commits to "review and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60-day filing date."[66]

* * *

Being the first developer of a therapeutic is an expensive, risky, and time-consuming process. Although FDA review times for generic and biosimilar products are similar to the review times of their brand-name counterparts, due to FDA performance goals under the PDUFA,[67] generic and biosimilar products are significantly less time-consuming, risky, and expensive to develop because they bypass the R&D, preclinical, and clinical trial stages.[68] A company can spend billions of dollars and decades to develop a novel medication and

61. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (codified as amended at 42 U.S.C. § 201).

62. *Id.* § 7002, 124 Stat. 804–08; *see also Implementation of the Biologics Price Competition and Innovation Act of 2009*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009 [https://perma.cc/BK7J-2XWE (staff-uploaded archive)] (last updated Feb. 12, 2016).

63. *Implementation of the Biologics Price Competition and Innovation Act of 2009*, *supra* note 62.

64. U.S. FOOD & DRUG ADMIN., GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2023–2027, at 4 (2023) [hereinafter FDA, GDUFA], https://www.fda.gov/media/153631/download [https://perma.cc/MV8K-VK42 (staff-uploaded archive)].

65. Biosimilar User Fee Act of 2012, Pub. L. No. 112-144, 126 Stat. 1026 (codified as amended at 21 U.S.C. § 301).

66. U.S. FOOD & DRUG ADMIN., BIOSIMILAR BIOLOGICAL PRODUCT REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027, at 4 (2023) [hereinafter FDA, BSUFA], https://www.fda.gov/media/152279/download [https://perma.cc/TK6X-NMBJ (staff-uploaded archive)]; *see also* Biosimilar User Fee Act of 2012 § 301.

67. *See* FDA, PDUFA, *supra* note 51, at 4; *see also* FDA, GDUFA, *supra* note 64, at 4–6; FDA, BSUFA, *supra* note 66, at 4.

68. FDA, *Generic Approval*, *supra* note 38.

potentially never[69] recoup any of its investments.[70] Meanwhile, manufacturers of generics and biosimilars can just wait and see whether a therapeutic is successfully brought to market and then develop and market their products at a relatively low cost and risk.

Without the possibility of adequate returns on investment for the small percentage of therapeutics that make it to market, no rational, profit-maximizing company would bother innovating. Rather, a rational, profit-maximizing company would flood the generic or biosimilar market instead. The patent and regulatory exclusivity systems, which are discussed in Part II below, are very effective at incentivizing innovation in the pharmaceutical industry. However, awarding first developers with a legal monopoly has the undesirable effect of making medications exceedingly expensive, which is why a creative solution is needed to balance the competing needs for incentivizing innovation and reducing prices.

II. INCENTIVIZING INNOVATION

The primary methods to incentivize pharmaceutical innovation in the United States are the patent and regulatory exclusivity systems—two distinct systems of awarding periods of monopoly that are governed by different statutes, criteria, and agencies.[71] Patents are property rights that can be granted during the development of the drug.[72] On the other hand, regulatory exclusivities are periods wherein competitor drugs are precluded from receiving approval, and they can be granted after the primary drug is approved.[73] Notably, some therapeutics are protected by both patents and regulatory exclusivities, while others may be protected by only one or by neither.[74] Additionally, the patent and regulatory exclusivity periods may run concurrently, but they often

69. However, the profit afforded by a legal monopoly on the small percentage of medications that are successful is sufficient to make pharmaceutical companies profitable overall. *See* R&D IN THE PHARMA INDUSTRY, *supra* note 10, at 14, 20–21 (noting that only about twelve percent of drugs successfully enter clinical trials); Angus Liu, Eric Sagonowsky, Kevin Dunleavy, Fraiser Kansteiner & Zoey Becker, *The Top 10 Most Profitable Pharma Companies in 2021*, FIERCEPHARMA (June 14, 2022, 3:00 AM), https://www.fiercepharma.com/special-reports/top-10-most-profitable-pharma-companies-2021 [https://perma.cc/APH5-7PEW (staff-uploaded archive)] (noting that the three highest-earning pharmaceutical companies in 2021 each reported more than $20 billion in net income).

70. *See* Ulrich, *supra* note 15; R&D IN THE PHARMA INDUSTRY, *supra* note 10, at 2.

71. CRS, DRUG PRICES, *supra* note 42, at 2; FDA, *FAQ*, *supra* note 7; WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") 19 (2005), https://www.ipmall.info/sites/default/files/hosted_resources/crs/RL30756_050110.pdf [https://perma.cc/X9KC-PX3L].

72. FDA, *FAQ*, *supra* note 7.

73. *Id.*

74. *Id.*

do not.[75] Further, a product may be considered worthy to receive a patent but too risky to be approved for medicinal use (or conversely, a product may be patent-ineligible but worthy of approval for medicinal use); either way, a pharmaceutical company must account for both in its risk-profit analyses.[76] As discussed in this part, while patents and regulatory exclusivities are very powerful drivers of innovation—especially for pharmaceutical products—they also cause these products to be inaccessibly expensive for many Americans.[77]

A. *Patents*

A patent is a property right—in the form of a period of exclusivity—granted by the federal government to inventors who discover a "new and useful process, machine, manufacture, or composition of matter, or . . . improvement thereof."[78] The statute currently governing the patent system is the Patent Act of 1952 ("Patent Act"),[79] as amended by the 2011 Leahy-Smith America Invents Act.[80] To receive a patent, an inventor must file an application with the U.S. Patent and Trademark Office ("USPTO").[81] The USPTO patent examiner reviews the application for compliance with statutory requirements before issuing a patent.[82]

Once granted, a patent becomes the legal property of the patent holder, giving them the right to exclude others from unauthorized use of the invention.[83] When another person or entity infringes the patent by "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention, within the United States or import[ing] into the United States any patented invention during the term of the patent" without permission, the patent holder can sue the infringer in federal court to recover monetary damages, injunctive relief, or both.[84]

The period of exclusivity granted through patents is necessary to encourage pharmaceutical companies to undertake the arduous and expensive process of developing therapeutics and bringing them to market. A patent's

75. *Id.*

76. SCHACHT & THOMAS, *supra* note 71, at 19.

77. Medications that are prohibitively expensive may become seemingly affordable for those who have insurance. However, a system where medications are only affordable with insurance puts patients at the mercy of insurance companies and can have various negative consequences that are beyond the scope of this Comment.

78. 35 U.S.C. § 101; *see also* FDA, *FAQ*, *supra* note 7.

79. Act of July 19, 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.).

80. 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.).

81. 35 U.S.C. §§ 111, 131.

82. *Id.*

83. CRS, DRUG PRICES, *supra* note 42, at 6.

84. 35 U.S.C. §§ 271, 281, 283–85.

term typically expires twenty years after the original application filing date,[85] but pharmaceutical patent holders must wait until the FDA approves their product before being able to exercise their full rights with respect to the claimed invention.[86] To compensate, the Patent Act provides for extensions of the patent term—of up to five years for pharmaceutical products—when there are excessive delays in the patent examination or FDA approval process.[87]

Pharmaceutical patents may cover drug formulations; methods to use, administer, or manufacture the product; other chemicals related to the active ingredient; or improvements to a product.[88] To be successfully granted a patent, an applicant must claim an invention that is: (1) directed at a patentable subject matter (which encompasses most inventions except for "ineligible subject matters" such as laws of nature, natural phenomena, or abstract ideas); (2) new; (3) nonobvious; and (4) useful.[89] In addition to the substantive requirements pertaining to the invention, patent applications must follow statutory disclosure requirements,[90] which exist to ensure that the public—and future generic competitors—receive the full benefits of the invention after the patent expires.[91]

Under the Hatch-Waxman Act and BPCIA, generic and biosimilar manufacturers can develop and prepare their products during the patent term through information available from the public domain, experimentation, or both.[92] However, the filing of a patent application for a generic drug and a biosimilar or interchangeable biological product constitutes patent infringement under both the Hatch-Waxman Act and BPCIA, respectively.[93] Because of this, a generic or biosimilar manufacturer cannot submit their

85. 35 U.S.C. § 154(a).

86. *See* 21 U.S.C. § 321(g); CRS, DRUG PRICES, *supra* note 42, at 8.

87. 35 U.S.C. §§ 154, 156.

88. CRS, DRUG PRICES, *supra* note 42, at 8 n.65.

89. 35 U.S.C. §§ 101–03.

90. Section 112 requires that the specification section of the patent application "contain a written description of the invention, and of the manner and process of making and using it" sufficient "to enable any person skilled in the art . . . to make and use" the invention. 35 U.S.C. § 112(a). Additionally, the specification "shall set forth the best mode contemplated by the inventor or joint inventor." *Id.*

91. *Id.*; *see also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974) (disclose requirement); Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc) (written description requirement); *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988) (enablement requirement); Eli Lilly & Co. v. Barr Lab'ys, Inc., 251 F.3d 955, 963 (Fed. Cir. 2001) (best mode requirement).

92. The Hatch-Waxman Act provides that a manufacturer may make, use, or sell an invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" without infringing an existing patent. Hatch-Waxman Act, Pub. L. No. 98-417, §§ 202, 217, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 200 (2005) (referring to this provision as a "safe harbor").

93. CRS, DRUG PRICES, *supra* note 42, at 10; *see also* 35 U.S.C. § 271(e)(2)(A)–(C).

pharmaceutical to the FDA for approval without triggering a dispute until after the patent term ends.[94]

The legal monopoly granted through patent rights is arguably the most powerful driver of innovation and is especially significant for driving pharmaceutical innovation, where the R&D costs and risks of failure are especially high.[95] However, because monopolists lack competitors and have the power to dictate and raise prices,[96] the patent system has the undesirable effect of making innovative, lifesaving medications available yet expensive and out of reach for many Americans.[97]

B. *Regulatory Exclusivities*

A pharmaceutical patent holder can receive additional exclusivity periods that may extend beyond the original exclusivity period afforded by the successful patent. Federal law establishes such periods of regulatory exclusivity to balance the competitive force of abbreviated generic and biosimilar FDA approval pathways with the need to incentivize innovation.[98]

The two primary categories of regulatory exclusivity for new small-molecule drugs are: (1) data exclusivity, which bars generic and biosimilar manufacturers from relying on the FDA's safety and effectiveness data for the reference product; and (2) marketing exclusivity, which bars FDA approval of another application for the same product and use, even if the applicant did not rely on the safety and effectiveness data of the reference product.[99] New drugs can receive three to five years of data exclusivity from the time of approval.[100] Those that contain a new active ingredient, for example, a new chemical entity,

94. *See* CRS, DRUG PRICES, *supra* note 42, at 10; *see also* 35 U.S.C. § 271(e)(2)(A), (C). However, a generic applicant can file an Abbreviated New Drug Application and make a paragraph IV certification (that the patent is invalid or not infringed by the generic drug) for a patent covering its Reference Listed Drug before the patent term ends. *See* CRS, DRUG PRICES, *supra* note 42, at 35; 21 U.S.C. § 355(j)(2)(vii)(IV).

95. However, some contend that patents may stifle innovation. *See, e.g.*, Ridley, *supra* note 27.

96. Monopolists can change the market price by changing production quantities because they are the sole sources of production in the market. "When a monopolist produces the quantity determined by the intersection of [marginal revenue] and [marginal curve], it can charge the price determined by the market demand curve at [that] quantity. Therefore, monopolists produce less but charge more than a firm in a competitive market." *Monopoly Production and Pricing Decisions and Profit Outcome*, *in* ECONOMICS (BOUNDLESS) loc. 11.3 (2023); Irena Asmundson, *Supply and Demand: Why Markets Tick*, FIN. & DEV. MAG., https://www.imf.org/en/Publications/fandd/issues/Series/Back-to-Basics/Supply-and-Demand [https://perma.cc/MLH9-RWUA].

97. David Blumenthal, *It's the Monopolies, Stupid!*, COMMONWEALTH FUND BLOG (May 24, 2018), https://www.commonwealthfund.org/blog/2018/its-monopolies-stupid [https://perma.cc/B4EG-YASC (staff-uploaded archive)].

98. CRS, DRUG PRICES, *supra* note 42, at 15–32.

99. *Id.*

100. *Id.* at 13.

can obtain five years of data exclusivity from the time of approval.[101] On the other hand, new drugs that contain approved chemical entities that are sufficiently changed from the approved drug but still require additional clinical studies can receive three years of data exclusivity from the time of approval, during which time the FDA cannot approve (yet can still accept) new applications referencing the drug.[102]

New biologics receive two different periods of exclusivity, although the FDA has not formally clarified whether these are data or marketing exclusivity periods.[103] The FDA cannot accept applications referencing the biological product for the first four years and cannot approve applications for the first twelve years from the date on which the biological product was first licensed.[104]

In addition to the regulatory exclusivities for new and follow-on small-molecule drugs and biologics (that is, generics and biosimilars), there are regulatory exclusivities designed to incentivize entry into underserved markets.[105] These include: (1) orphan drug exclusivity, which provides seven years of marketing exclusivity for "orphan drugs" (that is, drugs that treat rare conditions); (2) competitive generic therapy, which provides 180 days of exclusivity in situations where there is inadequate generic competition for a specific drug; and (3) pediatric exclusivity, which adds six months to any existing exclusivities to incentivize manufacturers to test the safety and efficacy of their products for children.[106] The success that these regulatory exclusivities have had in spurring companies to produce orphan drugs and safety and efficacy data for pediatric products underscores the value of monopoly grants to pharmaceutical companies.

C. *Artificial Extension of Exclusivity*

To recoup the high R&D investments[107] associated with developing new therapeutics, pharmaceutical companies employ various tactics to artificially

101. *Id.*

102. *Id.*

103. *See id.*

104. *Id.* at 13–14.

105. *Id.* at 4, 15.

106. *Id.* at 15–16.

107. Pharmaceutical companies have a lot of freedom in deciding how highly to price their drugs and may price based on the drug's uniqueness, effectiveness, competition, and research and development ("R&D") costs. Julie Hawley, *How Pharmaceutical Companies Price Their Drugs*, INVESTOPEDIA, https://www.investopedia.com/articles/investing/020316/how-pharmaceutical-companies-price-their-drugs.asp [https://perma.cc/V6GX-NP7Y (staff-uploaded archive)] (last updated May 19, 2024). According to an economic evaluation study, the mean cost to develop a new drug between 2000 and 2018 was around $173 million. Aylin Sertkaya, Trinidad Beleche, Amber Jessup & Benjamin D. Sommers, *Costs of Drug Development and Research and Development Intensity in the U.S., 2000–2018*, 7 JAMA NETWORK OPEN, June 28, 2024, at 1. However, this number increases to around

extend their monopolies. Patent "evergreening" (also known as patent "layering" or "life-cycle management") refers to how pharmaceutical companies "prolong their effective periods of patent protection [by adding] new patents to their quivers as old ones expire."[108] In practice, this could be accomplished by patenting different aspects or improvements of a previously patented product.[109]

Patent evergreening can be done to such extremes as to create an "impregnable fortress" that makes it very challenging for competitors to create a "copycat" without infringing on one of the brand-name company's patents.[110] For example, to protect the world's best-selling drug, Humira (adalimumab), AbbVie applied for more than 247 patents—132 of which were granted.[111] This "patent thicket" includes many late-stage patents on manufacturing methods, formulations, and potential formulations, significantly prolonging AbbVie's monopoly over adalimumab.[112] Although the biologic drug's core patent expired in 2016, AbbVie's last patent on the drug extends through 2037 and competitors could not enter the market until 2023, when Humira's exclusivity in the United States expired.[113] AbbVie's patent thicket has been challenged as anticompetitive under section 1 of the Sherman Antitrust Act of 1890 ("Sherman Act")[114] but was ultimately held to be legal.[115]

Some pharmaceutical manufacturers employ patent evergreening in conjunction with "product hopping," the practice whereby brands use their market dominance to compel healthcare providers and consumers to switch (or "hop") to a newer version of a drug that is protected by later-expiring patents.[116]

$879 million if costs of drug development failures and capital costs are included. *Id.* The ratio of total sales to R&D spending was more than five to one as of 2019. *Id.*

108. CRS, DRUG PRICES, *supra* note 42, at 16 (quoting Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359 (2007)).

109. *See id.*

110. Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG: BUSINESSWEEK (Sept. 7, 2017, 6:00 AM), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug [https://perma.cc/XK97-75UC]; *"Patent Thickets" Are Anti-Competitive and Lead to Higher Drug Costs*, PCMA (May 17, 2021), https://www.pcmanet.org/rx-research-corner/patent-thickets-are-anti-competitive-and-lead-to-higher-drug-costs/05/17/2021/ [https://perma.cc/V38F-CFKT].

111. Ryan Knox & Gregory Curfman, *The Humira Patent Thicket, the Noerr-Pennington Doctrine and Antitrust's Patent Problem*, 40 NATURE BIOTECHNOLOGY 1761, 1761 (2022).

112. *Id.*

113. *Id.*; Fraiser Kansteiner, Eric Sagonowsky, Zoey Becker, Kevin Dunleavy & Angus Liu, *The Top 10 Drugs Losing US Exclusivity in 2023*, FIERCEPHARMA (Mar. 13, 2023, 3:00 AM), https://www.fiercepharma.com/special-reports/top-10-drugs-losing-us-exclusivity-2023 [https://perma.cc/C2AN-2ZFC (staff-uploaded archive)].

114. An Act to Protect Trade and Commerce Against Unlawful Restraints and Monopolies (Sherman Antitrust Act), ch. 647, § 1, 26 Stat. 209, 209 (1890) (codified as amended at 15 U.S.C. § 1).

115. Mayor of Balt. v. AbbVie Inc., 42 F.4th 709, 711, 716 (7th Cir. 2022); *see also* Knox & Curfman, *supra* note 111, at 1761; 15 U.S.C. § 1.

116. CRS, DRUG PRICES, *supra* note 42, at 20–24.

Like patent evergreening, product hopping is not statutorily forbidden, although antitrust laws may in some cases be used to challenge such practices.[117]

Some monopoly extension tactics have been deemed to violate antitrust laws. One such tactic is the "pay-for-delay" or "reverse payment" settlement, wherein brand-name drug manufacturers (1) pay the first generic competitor that would enter the market to delay their market entry or (2) have a side agreement with the generic manufacturer during patent litigation settlement.[118] Because the first generic manufacturer gets a 180-day exclusivity period under the Hatch-Waxman Act, such delayed market entry by the first generic manufacturer blocks other generic competitors from entering the market and effectively extends the brand-name drug's monopoly.[119] These tactics illustrate the great lengths to which brand-name pharmaceutical companies are willing to go to obtain even a modest extension in their period of monopoly.

* * *

Patents and regulatory exclusivities have proven to be extremely powerful incentives to discover invaluable lifesaving therapeutics. The extreme tactics that pharmaceutical companies employ to obtain even a slight extension in the period of monopoly underscore just how valuable such exclusivities are. Unfortunately, patents and regulatory exclusivities have the negative side effect of making these lifesaving therapeutics inaccessibly expensive. Without a counterbalance to this undesirable side effect, patents and regulatory exclusivities will remain imperfect policy levers. The following parts explore whether this counterbalance can be successfully achieved through direct governmental regulation or whether an incentivizing policy lever may be more effective.

III. REGULATING PRICES

This part highlights how the federal and state governments have attempted to balance the monopoly granted by patents and regulatory systems with various price-control regulations. Unfortunately, the success of such regulatory mechanisms has been limited at best. Even when they are successful, such regulations will likely disincentivize innovation and harm consumers in the long run. As such, regulatory price-control mechanisms need to be

117. *Id.* at 49.

118. *See id.* at 54; FTC v. Actavis, Inc., 570 U.S. 136, 136 (2013) (holding that reverse payment settlement agreements between patent holders and generic drug manufacturers could violate antitrust laws); *Allergan, Watson and Endo*, FED. TRADE COMM'N, https://www.ftc.gov/legal-library/browse/cases-proceedings/141-0004-allergan-watson-endo [https://perma.cc/3WNR-UTT7] (last updated Feb. 27, 2019) [hereinafter FTC, *Allergan, Watson, Endo*].

119. FTC, *Allergan, Watson, Endo*, *supra* note 118.

combined with incentivization tools to effectively lower drug prices in the long term without chilling innovation.

A. *Federal Regulation*

Federal regulations serve to offset the undesirable price effects of a patented drug's period of exclusivity, attempting to strike a balance between incentivizing innovation and protecting consumers from unreasonable drug prices. However, existing regulations fail to strike the correct balance, either disincentivizing innovation or failing to protect consumers from skyrocketing drug prices altogether.

The Biden-Harris administration attempted to tackle continuous increases in drug prices. Through the IRA, Medicare could directly negotiate the prices of certain brand-name drugs.[120] The IRA also made recommended vaccinations free and capped the out-of-pocket cost of insulin at $35 per month, saving some beneficiaries who depend on the drug hundreds of dollars per month.[121] Additionally, it cracked down on pharmaceutical price gouging, requiring companies that raise prices of Medicare Part B drugs[122] at a rate faster than inflation to pay inflation rebates back to Medicare.[123] The Biden-Harris administration seemed intent on enforcing the IRA: on December 14, 2023, HHS announced a list of forty-eight Medicare Part B drugs that had raised prices at a higher rate than inflation and were potentially subject to inflation rebates for the first quarter of 2024.[124]

To further crack down on price gouging, the Biden-Harris administration released a proposed framework for agencies to exercise march-in rights for

120. Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1191, 136 Stat. 1818, 1833 (codified at 42 U.S.C. § 1320f); *see also* WHITE HOUSE, *Medicare Negotiation*, *supra* note 21.

121. Inflation Reduction Act of 2022 § 11406; *see also* WHITE HOUSE, *Medicare Negotiation*, *supra* note 21.

122. Examples of rebatable Medicare Part B drugs include Abecma, Leukine, Prolia, Yescarta, and Zoladex. CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUM. SERVS., FACT SHEET: REDUCED COINSURANCE FOR CERTAIN PART B REBATABLE DRUGS UNDER THE MEDICARE PRESCRIPTION DRUG INFLATION REBATE PROGRAM 2–3 (2024), https://www.cms.gov/files/document/reduced-coinsurance-certain-part-b-rebatable-drugs-october-1-december-31-2024.pdf [https://perma.cc/24VN-VHR8].

123. WHITE HOUSE, *Medicare Negotiation*, *supra* note 21.

124. *Fact Sheet: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates*, WHITE HOUSE (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates [https://perma.cc/5PM7-LACY]; *Saving Money with the Prescription Drug Law*, MEDICARE, https://www.medicare.gov/about-us/prescription-drug-law [https://perma.cc/98G4-5X6X]; CTRS. FOR MEDICARE & MEDICAID, *supra* note 122, at 2–3.

taxpayer-funded drugs that are deemed unaffordable.[125] This march-in authority, while never exercised, is provided by the Bayh-Dole Act.[126] It allows inventors to be the patent holders of taxpayer-funded inventions, who thus may exercise exclusive rights during the duration of the patent.[127] However, the Bayh-Dole Act also allows the government to "seize" patents and license the invention to another party if the patent holder has not made the invention sufficiently accessible to the public.[128] While price was not considered a factor to determine accessibility under the Trump-Pence administration, the Department of Commerce ("DOC") and HHS under the Biden-Harris administration proposed a framework where price can be a factor in determining whether a taxpayer-funded invention is sufficiently accessible to the public.[129]

Although the Biden-Harris administration's anti-gouging regulations and proposals could have achieved the desired short-term effect of making lifesaving therapeutics reasonably accessible to the public,[130] their long-term viability and effects are less clear. Merck has filed a lawsuit against the government, claiming that the "Drug Price Negotiation Program for Medicare" part of the IRA is an "unconstitutional taking of the company's property and a violation of the company's freedom of speech."[131] Merck characterized the "negotiation" as an "extortion," akin to "an assailant point[ing] a gun at your head," and claimed that the negotiation is merely a "political Kabuki theater" that "involves neither genuine negotiations nor real agreements."[132] According to Merck, HHS is compelling drug manufacturers to sign an "agreement" promising to provide

125. WHITE HOUSE, *Promoting Competition*, *supra* note 22. The proposed framework does not seem to define what is considered an "unreasonable" price, but lack of competition and abuse of patent laws to stall generic and biosimilar entry could be relevant factors in determining what is unreasonable. Joshua P. Cohen, *Biden Administration Says It Plans to Use March-In Rights for Drugs to Lower Prices*, FORBES (Dec. 7, 2023, 6:45 PM), https://www.forbes.com/sites/joshuacohen/2023/12/07/biden-administration-says-it-plans-to-use-march-in-rights-for-drugs-to-lower-prices/ [https://perma.cc/5BFE-UC6M (dark archive)].

126. Bayh-Dole Act of 1980, Pub. L. No. 96-517, § 203, 94 Stat. 3015, 3022 (codified as amended at 35 U.S.C. § 203).

127. *See id.*

128. WHITE HOUSE, *Promoting Competition*, *supra* note 22; JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 7 (2024), https://www.congress.gov/crs_external_products/IF/PDF/IF12582/IF12582.3.pdf [https://perma.cc/J2G8-FTP5 (staff-uploaded archive)]; Jocelyn Kaiser, *Biden Wants NIH to Have 'March-In' Power to Override Patent Rights for High-Priced Drugs*, SCIENCE (Dec. 7, 2023, 5:20 PM), https://www.science.org/content/article/biden-wants-nih-have-march-power-override-patent-rights-high-priced-drugs [https://perma.cc/H7A7-B6SZ (staff-uploaded archive)].

129. Kaiser, *supra* note 128.

130. *See, e.g.*, Al-Arshani & Alltucker, *supra* note 24 (capping insulin at $35 dollars).

131. Troy, *supra* note 25.

132. Editorial, *Merck Sues to Stop the IRA's 'Extortion*,*'* WALL ST. J. (June 7, 2023, 6:35 PM), https://www.wsj.com/articles/merck-lawsuit-inflation-reduction-act-medicare-drug-price-scheme-cf01f0e4 [https://perma.cc/GB6A-3RBG (staff-uploaded, dark archive)]; *see also* Troy, *supra* note 25; Complaint at 2–4, Merck & Co. v. Becerra, No. 1:23-cv-01615 (D.D.C. June 6, 2023).

drugs to the government at whatever price Medicare deemed as "fair."[133] Even if Medicare demands the manufacturer to sell at a 90% loss, the manufacturer must comply or risk incurring a crippling daily excise tax, which starts at 186% and goes up to 1,900% of the drug's daily revenues, which can add up to hundreds of millions of dollars per day in penalties.[134] Merck characterized the excise tax as a "sword hanging over drug makers to guarantee compliance."[135] To add "constitutional insult to injury," Merck further complained that the IRA requires the manufacturers to performatively express the view that they think the HHS-forced prices are fair, which they contend is a violation of their First Amendment rights.[136]

With the large amount of litigation mounted or likely to be mounted against them,[137] the Medicare Drug Negotiation program and the Biden-Harris administration's other proposals may be short-lived. Merck's lawsuit has been described as compelling and is expected to reach the Supreme Court.[138] At least six other companies have filed lawsuits against the program.[139]

Even if these programs survive constitutional scrutiny, there looms the larger concern that such programs will reduce the incentive to innovate and potentially "deter both the biotech industry from collaborating with federal agencies and universities from using government grants."[140] After all, while the government may be able to commandeer prices, it certainly cannot "point[] a gun" at inventors' and investors' heads to force them to innovate.[141]

133. Troy, *supra* note 25.

134. *Id.*

135. *Merck Sues to Stop the IRA's 'Extortion,' supra* note 132.

136. *Id.*

137. *See* Lisa Munger, *PhRMA Joins Merck, BMS in Latest Lawsuit Challenging IRA's Drug Price Negotiations*, BIOSPACE (June 21, 2023), https://www.biospace.com/article/phrma-joins-merck-bms-in-latest-lawsuit-challenging-ira-s-drug-price-negotiations/ [https://perma.cc/6FJD-KVW3]; Celine Castronuovo, *State Drug Pricing Boards Tee Up New Front in Pharma Legal Fight*, BLOOMBERG L. (Oct. 17, 2023, 5:05 AM), https://news.bloomberglaw.com/health-law-and-business/state-drug-pricing-boards-tee-up-new-front-in-pharma-legal-fight [https://perma.cc/7LLC-SC4S (staff-uploaded archive)]; Kelly Lienhard, *New Drug Patent Proposal Sparks Worry over Gov't Overstep*, LAW360 (Dec. 8, 2023, 8:55 PM), https://www.law360.com/articles/1775316/new-drug-patent-proposal-sparks-worry-over-gov-t-overstep [https://perma.cc/PAV6-X55K (staff-uploaded, dark archive)].

138. *See* Troy, *supra* note 25 (noting that "[t]ime and time again, the Supreme Court has declared forced speech beyond the power of the government").

139. *See* Kevin Dunleavy, *Novo Nordisk Challenges CMS Drug Price Negotiations, then Signs on to the Program*, FIERCEPHARMA (Oct. 2, 2023, 11:15 AM), https://www.fiercepharma.com/pharma/novo-nordisk-challenges-cms-drug-price-negotiations-then-signs-program [https://perma.cc/HZ6B-XQAS (staff-uploaded archive)].

140. Lienhard, *supra* note 137.

141. *See Merck Sues to Stop the IRA's 'Extortion,' supra* note 132; Complaint, *supra* note 132, at 2–4, 23.

B. *State Regulation*

States have passed various types of regulations to rein in drug prices with varying levels of success. These include anti-gouging and price transparency laws, as well as regulations on and lawsuits against Pharmacy Benefit Managers ("PBMs")[142] and pharmaceutical companies.[143] To the extent that these enforcement strategies target unscrupulous tactics that do not spur innovation, they probably benefit consumers in the long run and are a necessary complement to an incentive-based system for lowering drug prices.

State price-gouging laws prohibit manufacturers from selling prescription drugs at unconscionable or excessive prices.[144] Such laws can focus on the base price of the drug or the magnitude of price increases over a period of time.[145] However, price-gouging laws have faced significant legal obstacles at the appellate level.[146] Maryland's price-gouging laws have been challenged—and struck down by the Fourth Circuit—on patent preemption, vagueness, and dormant Commerce Clause grounds.[147] Although the Supreme Court is yet to weigh in on the constitutionality of price-gouging laws, the high-profile adverse decisions against Maryland's price-gouging laws have had a chilling effect on other states.[148]

State drug transparency laws require manufacturers and downstream entities, such as PBMs, wholesalers, and health insurance companies, to provide drug pricing information that allows policymakers to understand drug pricing

142. Pharmacy Benefit Managers ("PBMs") are third-party intermediaries that act as negotiating middlemen between players in the drug supply chain. Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers*, CTR. FOR AM. PROGRESS (Mar. 13, 2024), https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/ [https://perma.cc/UF5F-V93E (staff-uploaded archive)].

143. *See NASHP's Proposal for Protecting Consumers from Prescription Drug Price Gouging*, NAT'L ACAD. STATE HEALTH POL'Y (July 6, 2020), https://nashp.org/nashps-proposal-for-protecting-consumers-from-prescription-drug-price-gouging [https://perma.cc/3654-W4GF] [hereinafter *NASHP Price Gouging*]; *State Pharmacy Benefit Manager Legislation*, NAT'L ACAD. STATE HEALTH POL'Y, https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/ [https://perma.cc/C9T6-H9DM] (last updated Oct. 21, 2024) [hereinafter *State PBM Legislation*]; Malathi Nayak, *Eli Lilly, Insulin Makers Sued by California over Prices*, BLOOMBERG L. (Jan. 12, 2023, 8:50 PM), https://news.bloomberglaw.com/health-law-and-business/eli-lilly-other-insulin-makers-sued-by-california-over-prices [https://perma.cc/CV66-B7V4 (staff-uploaded, dark archive)].

144. *NASHP Price Gouging*, *supra* note 143.

145. *Id.*

146. *Id.*

147. *Id.*; Brian Witte, *Federal Appeals Court Strikes Down Maryland's Drug Price-Gouging Law*, ASSOCIATED PRESS, https://apnews.com/general-news-349dc53f4bc240bcb899ee6c59060f05 [https://perma.cc/6BQZ-DYQK (staff-uploaded archive)] (last updated Apr. 13, 2018, 4:03 PM); Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018).

148. *See NASHP Price Gouging*, *supra* note 143.

and payment systems and design policies accordingly.[149] Vermont and thirteen other states have enacted drug transparency legislation.[150] Drug transparency laws can lay an important foundation in the effort to lower prices and seem to have reduced the number of excessive price *increases*.[151] However, the launch prices of drugs—and overall state spending on prescription drugs—have continued to rise.[152]

States have also passed laws to prohibit PBMs from engaging in unscrupulous tactics[153] and brought lawsuits against pharmaceutical companies and PBMs in response to increased drug prices.[154] These suits are based on theories of unfair business methods and practices, often memorialized in Unfair and Deceptive Acts and Practices laws.[155] It is not yet clear whether these suits will succeed. However, if companies can profit from unfair tactics, they may be less likely to engage in research and development to create new products. Therefore, an incentive system to lower prices working in tandem with enforcement against unfair business practices by PBMs and pharmaceutical companies is necessary to protect consumers and innovation in the long run.

C. *Antitrust Law*

Antitrust laws aim to control prices by protecting and promoting competition through the prohibition of "anticompetitive conduct and mergers that deprive American consumers, taxpayers, and workers of the benefits of competition."[156] Enforcement of federal antitrust laws occurs through actions brought by the DOJ Antitrust Division, the FTC, or lawsuits by a private party,

149. Johanna Butler, *Drug Price Transparency Laws Position States to Impact Drug Prices*, NAT'L ACAD. STATE HEALTH POL'Y BLOG (Jan. 10, 2022), https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/ [https://perma.cc/2S4J-2A2T].

150. Vermont was the first state to pass such a drug transparency law in 2016. *Id.* North Carolina has not passed an such drug transparency law. *See id.*

151. *Id.*

152. *Id.*

153. *State PBM Legislation*, *supra* note 143 (summarizing the laws that states have passed to prevent PBMs from engaging in tactics such as spread pricing, clawbacks/retroactive denials, and discrimination against nonaffiliated pharmacies).

154. *See, e.g.*, Nayak, *supra* note 143 (describing California's lawsuit against PBMs and insulin manufacturers).

155. *Id.*; Celine Castronuovo, *Hawaii Targets PBMs with Suit Alleging Unfair Pricing System*, BLOOMBERG L., https://news.bloomberglaw.com/health-law-and-business/hawaii-targets-top-pbms-with-suit-alleging-unfair-pricing-system [https://perma.cc/P4YF-QBG5 (staff-uploaded, dark archive)] (last updated Oct. 6, 2023, 1:48 PM); CAROLYN CARTER, NAT'L CONSUMER L. CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE EVALUATION OF UNFAIR AND DECEPTIVE PRACTICES LAWS 1–3 (2018), https://www.nclc.org/wp-content/uploads/2022/09/UDAP_rpt.pdf [https://perma.cc/M8ZS-2ETK].

156. *The Antitrust Laws*, U.S. DEP'T OF JUST., ANTITRUST DIV., https://www.justice.gov/atr/antitrust-laws-and-you [https://perma.cc/77CU-VWKN] (last updated Dec. 20, 2023).

which can be brought by the state attorney general on behalf of the private party.[157]

Section 1 of the Sherman Act prohibits agreements that unreasonably restrain trade.[158] While some agreements are deemed to be so blatantly anticompetitive that they are considered per se illegal,[159] many agreements are analyzed under a "sliding scale" of reasonableness.[160] In these cases, the court considers the totality of circumstances and potential procompetitive justifications under a burden-shifting framework before determining whether an agreement violates section 1 of the Sherman Act.[161]

Section 2 of the Sherman Act prohibits the willful acquisition and maintenance of monopoly power in "trade or commerce among the several States, or with foreign nations."[162] However, the Supreme Court has ruled that monopoly power is not per se illegal when it is acquired through "superior product, business acumen, or historic accident."[163] It is only illegal when "accompanied by an element of anticompetitive *conduct*."[164]

Mounting a successful antitrust suit against pharmaceutical companies has become increasingly challenging due to increasingly complex market structures and dynamics.[165] Such suits have only been successful in egregious cases such as the "Pharma Bro" case,[166] where Martin Shkreli orchestrated an egregious anticompetitive scheme that allowed him to increase the price of Daraprim—a treatment for toxoplasmosis, a parasitic infection that is potentially fatal—from $17.50 per tablet to $750 per tablet.[167] Additionally, reverse payment and pay-for-delay settlements have been successfully challenged.[168] Because

157. JOEL I. KLEIN, U.S. DEP'T OF JUST., ANTITRUST DIV., ANTITRUST ENFORCEMENT AND THE CONSUMER 3 (2001), https://www.govinfo.gov/content/pkg/GOVPUB-J-PURL-LPS16084/pdf/GOVPUB-J-PURL-LPS16084.pdf [https://perma.cc/2CNZ-727Y].

158. An Act to Protect Trade and Commerce Against Unlawful Restraints and Monopolies (Sherman Antitrust Act), ch. 647, § 1, 26 Stat. 209, 209 (1890) (codified as amended at 15 U.S.C. § 1).

159. Agreements to fix prices, divide markets, or limit outputs are generally considered per se illegal. CRS, DRUG PRICES, *supra* note 42, at 12–13.

160. Agreements that are not considered so obviously (per se) illegal are analyzed under the Rule-of-Reason or Quick-Look Analysis. *Id.* at 13–14.

161. *Id.*

162. Sherman Antitrust Act § 2.

163. Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) (quoting United States v. Grinnell Corp., 384 U.S. 563, 571 (1966)).

164. *Id.*

165. Makenzie Holland, *Litigants Face Tough Road with Antitrust Lawsuits*, TECHTARGET (Oct. 18, 2021), https://www.techtarget.com/searchcio/feature/Litigants-face-tough-road-with-antitrust-lawsuits [https://perma.cc/G697-NET6].

166. FTC v. Shkreli, 581 F. Supp. 3d 579, 643 (S.D.N.Y. 2022).

167. *Id.* at 590; Press Release, Fed. Trade Comm'n, FTC Asks Federal Court to Hold 'Pharma Bro' Martin Shkreli in Contempt (Jan. 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-asks-federal-court-hold-pharma-bro-martin-shkreli-contempt [https://perma.cc/KAA2-LUFQ].

168. *See supra* Section II.C.

anticompetitive conduct allows companies to profit through illegal conduct as opposed to competition on the merits, it can stifle innovation.[169] As such, strong antitrust enforcement is necessary, and ideally should complement a price-lowering incentive system, to protect consumers and innovation in the long run.

* * *

Governmental regulatory schemes at the federal and state levels attempt to strike a delicate balance between encouraging innovation and protecting consumers. While patents and regulatory exclusivities help companies recoup their investments and spur further innovation, they hurt consumers by increasing prices. While some regulations target unscrupulous tactics that could harm consumers and innovation, others could arguably disincentivize innovation. To maximize consumer welfare in the long run, we need a system that makes lifesaving therapeutics accessible and available. A robust regulatory enforcement system that cracks down on unscrupulous practices such as price gouging and reverse payment settlements is necessary to that end. However, such a system needs to be coupled with an incentive scheme that makes it profitable for pharmaceutical companies to lower prices.

IV. SEARCHING FOR A METHOD TO INCENTIVIZE LOWER DRUG PRICES

Scholars and legislators have proposed and tried various methods to incentivize pharmaceutical companies to undertake desired courses of action. These incentive strategies all have one thing in common: increasing the pharmaceutical companies' bottom lines. While incentive schemes have been proposed to drive innovation and research in neglected areas,[170] they have not been explored in the context of incentivizing pharmaceutical companies to address a different type of neglected area: affordability. This may be because simultaneously increasing profits and affordability seems paradoxical. Yet it does not have to be. In this part, this Comment explores various incentivization strategies that have been used and analyzes which strategy could potentially be employed to incentivize pharmaceutical companies to lower drug prices.

169. *See* Giulio Federico, Fiona Scott Morton & Carl Shapiro, *Antitrust and Innovation: Welcoming and Protecting Disruption*, 20 INNOVATION POL'Y & ECON. 125, 125 (2020) ("A dominant firm may engage in exclusionary conduct[,] . . . suppress[ing] innovation by foreclosing disruptive rivals and by reducing the pressure to innovat[e] on the incumbent.").

170. Dennis W. Choi, Robert Armitage, Linda S. Brady, Timothy Coetzee, William Fisher, Steven Hyman, Atul Pande, Steven Paul, William Potter, Benjamin Roin & Todd Sherer, *Medicines for the Mind: Policy-Based "Pull" Incentives for Creating Breakthrough CNS Drugs*, 84 NEURON 554, 557 (2014). Such neglected areas, for example, include nervous system disorders. *Id.* at 554.

A. *Financial Incentives*

Legislators and scholars have used or proposed using financial incentives to spur different types of innovation. Such incentives have taken the form of credits, grants, a fast-track FDA regulatory pathway, and extended exclusivity for "orphan" drugs.[171] For example, in 2023, the USPTO initiated an expedited examination process for cancer treatment methods, which allows certain cancer-related applications to be "advanced out of turn . . . for examination" and reviewed earlier and effectively increases the patent duration.[172] Scholars have also suggested using these expedited examination processes to prioritize technologies that are particularly beneficial to marginalized communities.[173] Other scholars have proposed using a "quasi-prize system"[174] by providing additional "carrots" to government-sponsored prescription drug insurance programs and using these carrots as a policy lever to incentivize the development of therapeutics for neglected diseases.[175] Additionally, some scholars have proposed utilizing the insurance system to encourage healthcare payers to develop knowledge on the administration and effects of therapeutics.[176] While these financial incentives may be effective at driving various types of innovation, they do not make medications more affordable for everyday citizens.

B. *Alternative Prize or Reward Systems*

Alternative prize or reward systems are another type of incentive system that has been proposed to combat the exorbitant prices stemming from intellectual property rights. Instead of awarding a patent monopoly, these prize and reward systems propose that the government provide monetary compensation—without the right to exclude others—in exchange for inventors

171. *Id.*

172. Cancer Moonshot Expedited Examination Pilot Program, 87 Fed. Reg. 75608, 75609 (Dec. 9, 2022).

173. *See, e.g.*, Peter Lee, *Toward a Distributive Agenda for U.S. Patent Law*, 55 HOUS. L. REV. 321, 345 (2017); Sarah Tran, *Policy Tailors and the Patent Office*, 46 U.C. DAVIS L. REV. 487, 498 (2012) (suggesting that "the USPTO could prioritize technologies on the basis of a given industry's potential to contribute to job creation"); Sarah Tran, *Expediting Innovation*, 36 HARV. ENV'T L. REV. 123, 138–42 (2012) (asserting that "particular categories of inventions . . . deserv[e] . . . expedited review due to their social worth").

174. *See, e.g.*, Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 185 (2016).

175. *Id.* at 202. As is, although governmental systems such as Medicaid "provide access to existing therapies, [they] comparatively penalize[] innovation into therapies for diseases primarily affecting poor Americans." *Id.* at 198.

176. Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCIENCES 3, 3–5 (2017) (asserting that because healthcare payers have "treasure troves of data" on the administration and effects of therapeutics and, unlike pharmaceutical companies, "stand to profit from the bad news," they can provide insights into the effects of medical treatments without having to conduct clinical trials).

placing their discoveries in the public domain.[177] The prize level can be set at the "minimum prize necessary" or the "optimal prize."[178] At the minimum prize level, some innovators would refuse to enter, while at the optimal level, the cost to taxpayers who fund the prize may be higher than would be desirable, resulting in deadweight loss.[179] Another potential problem is that although "government-funded research dollars [may] rival those from private research supported by the patent system,"[180] government dollars probably cannot compete with the potential profits a company stands to gain for discovering and marketing a blockbuster drug. Thus, this system will probably reduce pharmaceutical profits and ultimately reduce the incentive to innovate.

C. *Patent Monopoly*

To balance the need to drive innovation and keep costs affordable for pharmaceutical products, the government should use the tool that has proven to be a highly effective carrot for pharmaceutical companies—the award of a patent monopoly—as a policy lever to encourage them to lower prices. Based on the great lengths that pharmaceutical manufacturers are willing to go to merely to obtain a slight extension in the period of exclusivity,[181] they would probably be willing to work with the government to find a reasonable price for their products in exchange for an extended period of exclusivity. This would be especially true if the deal resulted in greater profits for the company.

Patent term extensions are statutorily provided to offset delays in market approval requirements by the FDA, and patent prosecution delays at the USPTO[182] have also been proposed as policy levers to incentivize innovation.[183] The premise of such proposals is that the one-size-fits-all patent system inadequately protects innovation for inventions that take longer and are more expensive to develop and market, although they may provide the most value to

177. Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 119 (2003); Keith Hylton, *A Patent and a Prize* 6 (Boston Univ. Sch. of L. Working Paper, Paper No. 23-7, 2023).

178. Hylton, *supra* note 177, at 6.

179. *Id.*

180. Abramowicz, *supra* note 177, at 120.

181. *See supra* Section II.C (discussing the various tactics pharmaceutical companies have employed to extend their exclusivity periods).

182. Patent Term Extension is provided in the Hatch-Waxman Act as a compromise for the increased ease of generic drug entry and allows an extension of up to five years to counteract delays in FDA approval; Patent Term Adjustment is used to counteract USPTO-related delays. Sarah R. Wasserman Rajec, *Patent Term Tailoring*, 99 IND. L.J. 475, 498 (2024) [hereinafter Rajec, *Patent Term Tailoring*]; 35 U.S.C. §§ 154(b), 156.

183. This is because inventions that take longer to bring to market tend to incur greater out-of-pocket R&D costs and opportunity costs and are at a heightened risk of failure and free riding. Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 672 (2014).

society.[184] Many scholars perceive patents to be especially "critical for protecting" investments in drug development and "most effective at spurring innovation in the pharmaceutical industry," where the R&D costs and risk of failure are especially high and the barriers to entry for competitive imitators are especially low.[185] Moreover, because the average time-to-market for products in the pharmaceutical industry is significantly greater than the time-to-market in other industries,[186] pharmaceutical products effectively have a shorter period of exclusivity than other types of products, despite the difficulty and societal need for developing them.

While innovation in the pharmaceutical industry is especially challenging and has an especially significant social welfare value—both because it produces lifesaving medications and adds a significant amount to the nation's wealth—the effective patent benefit successful pharmaceutical innovators enjoy is relatively small, after taking time-to-market, ease of imitation, risk of failure, and developmental costs into account.[187] For this reason, although some scholars have argued that extending patent terms in the pharmaceutical industry is universally undesirable,[188] exceptions could arguably be justified for well-deserving pharmaceutical innovators—those who have taken the painstaking effort to develop lifesaving therapeutics and bringing them to market. Especially well-deserving would be those innovators that are willing to make their invention more accessible to the public by charging less than they could in a complete monopoly. Thus, awarding patent extensions for developers of lifesaving therapeutics in exchange for lower prices is a viable policy tool to make therapeutics more affordable.

V. INCENTIVIZING LOWER PRICES THROUGH PATENT EXTENSIONS

While regulations and enforcement may provide the short-term benefits of reduced prices, they could potentially dampen innovation and hurt consumers in the long run.[189] As such, these measures need to be balanced with innovation-enhancing measures. Although financial incentives and alternative prize or reward systems are somewhat effective, monopolistic exclusivity remains the greatest incentive to innovation. After all, access to a greater consumer base may not yield significant profits in a competitive market. Thus,

184. *Id.* at 677–78.

185. *Id.* at 680 & n.25, 699.

186. *See id.* at 719 tbl.1.

187. *See* Rajec, *Patent Term Tailoring*, *supra* note 182, at 485–86.

188. *See, e.g.*, Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELL. PROP. L.J. 79, 79 (2024).

189. Philippe Aghion, Antonin Bergeaud & John Van Reenen, T*he Impact of Regulation on Innovation*, 113 AM. ECON. REV. 2894, 2894 (2023) ("Regulation reduces aggregate innovation by 5.7 percent.").

a system that ties the period of exclusivity directly to drug prices may be the optimal way to spur innovation and rein in prices.

A. *Description of the Proposed Patent Extension System*

This Comment proposes a system that would incentivize pharmaceutical companies to innovate and reduce prices at the same time—by increasing their profit margins in exchange for lower prices. The benchmark for lower prices would be lower than what a firm could charge in a purely monopolistic market,[190] but still somewhat supracompetitive[191]—higher than what it could charge in a perfectly competitive market.[192] By increasing the duration of the monopoly, even if the firm could only charge such supracompetitive prices during this period, the firm could recoup the same (or greater) profits than if it were to charge monopolistic prices without patent extension.[193]

To that end, this Comment proposes a formula to calculate a patent extension period that would guarantee profitability to the pharmaceutical firm.

The parameters of the formula are as follows:

P = period of exclusivity without patent extension

E = period of extension

MP = monopolistic price

SP = middle-ground supracompetitive price

CP = competitive price

For the system to be incentivizing (profitable) to the firm, we want:

$$SP \times (P+E) \geq MP \times P$$

190. "In a monopolistic market, firms are price makers because they control the prices of goods and services. In this type of market, prices are generally high for goods and services because firms have total control of the market." Steven Nickolas, *Monopolistic Market vs. Perfect Competition: What's the Difference?*, INVESTOPEDIA, https://www.investopedia.com/ask/answers/040915/what-difference-between-monopolistic-market-and-perfect-competition.asp [https://perma.cc/BQN2-XG83] (last updated Oct. 28, 2024).

191. Supracompetitive prices are higher than what would be charged in a perfectly competitive market but lower than what a monopolistic firm could charge.

192. "In a market that experiences perfect competition, prices are dictated by supply and demand. Firms in a perfectly competitive market are all price takers because no one firm has enough market control." Nickolas, *supra* note 190.

193. Consumers would arguably still be better off although they may pay higher prices in the long term. *See infra* Section V.D.

Solving for the period of extension (E) would then give us the following formula for calculating patent extensions:

$$E \geq \frac{(MP - SP) \times P}{SP}$$

The formula starts with the premise that for the system to be automatically profitable and incentivizing to the firm, the revenue that the firm gets at supracompetitive prices with the patent extension (SP × (P + E)) should always be equal to or greater than the revenue that the firm would get at the monopolistic price without the patent extension (MP × P).[194] If the equation is then solved for the period of extension (E), we get a formula to calculate a sufficiently long extension period based on the supracompetitive price that the manufacturer had set, or that the government requests. Under this model, lower supracompetitive prices would be rewarded with greater patent term extension. As such, everyone benefits.[195] Firms get to keep their profit margins high, while consumers can pay more "reasonable" prices for their much-needed medication. The amount of "deadweight loss"[196] associated with monopolies would also be smaller (or at least spread out over a longer period).

While extended exclusivity would incentivize lower prices for all types of pharmaceutical inventions, it may be particularly useful for expensive, cutting-edge therapeutics that people must take regularly over prolonged periods. Humira, a biologic that held a two-decade monopoly from 2002 through 2022,[197] is one such drug which provides a useful case study to analyze whether the proposed patent extension system would provide sufficient incentives for AbbVie, the manufacturer of Humira,[198] to lower prices.

B. *Case Study: Humira*

Humira (adalimumab) is a monoclonal antibody therapeutic that is widely used to treat autoimmune and chronic inflammatory diseases such as arthritis,

194. Although prices will not be static in reality, as this Comment is a proof-of-concept, the equation uses static prices for simplicity. However, in future research, the equation should be developed to incorporate price fluctuations during the patent term.

195. While consumers may have to pay higher prices during the patent extension period after paying lower prices during the monopoly period, they are still better off with this tradeoff. For a more detailed exploration on this issue, see *infra* Section V.D.

196. "A deadweight loss is a cost to society created by market inefficiency, which occurs when supply and demand are out of equilibrium." Alicia Tuovila, *What Is Deadweight Loss, How It's Created, and Economic Impact*, INVESTOPEDIA, https://www.investopedia.com/terms/d/deadweightloss.asp [https://perma.cc/9CP8-ZC5E] (last updated June 15, 2024).

197. Jonathan Gardner, *Two Decades and $200 Billion: AbbVie's Humira Monopoly Nears Its End*, BIOPHARMA DIVE, https://www.biopharmadive.com/news/humira-abbvie-biosimilar-competition-monopoly/620516/ [https://perma.cc/GL4B-QHZ6] (last updated Jan. 27, 2023).

198. *Id.*

psoriasis, and Crohn's disease.[199] It effectively reduces inflammation by inhibiting TNF-α, a cytokine that plays a key role in the inflammatory pathway and immune response.[200] Because it is very effective, has mild side effects, and can be self-administered via injection, Humira rose to be the "top-selling drug in the world" and "the most financially successful drug in history."[201] Humira has generated more than $200 billion in sales for AbbVie since its launch in 2002[202] and has produced an average annual revenue of $19.5 billion between 2017 and 2022.[203]

Unfortunately, Humira is also very expensive, with a Whole Acquisition Cost ("WAC") of around $6,922 for two 40-mg injections.[204] The entrant of biosimilars appears to have put some downward pressure on Humira prices.[205] However, Humira will probably remain expensive for the foreseeable future due to the complex effect PBMs exert on drug prices, coupled with the deals that AbbVie has entered into with several biosimilar competitors and the barrier to entry imposed by the formidable intellectual property wall AbbVie has built around Humira.[206]

The proposed patent extension model may be an effective solution to the problem because it would allow AbbVie to profit from lowering Humira prices. To test how much profit AbbVie can potentially gain under this model, the

199. Ollie Curtis, *The Most Lucrative Drug in Pharmaceutical Industry History*, HEALTHONOMIX (Aug. 26, 2023), https://healthonomix.substack.com/p/the-most-lucrative-drug-in-pharmaceutical [https://perma.cc/V23E-8ZCT (staff-uploaded archive)].

200. *Id.*

201. *Id.*

202. *Id.*

203. Revenues from 2017 to 2022 were $18.4 billion, $19.9 billion, $19.2 billion, $19.8 billion, $20.7 billion, and $18.6 billion. *Id.*; *see also* Jonathan Gardner, *Two Decades and $200 Billion: AbbVie's Humira Monopoly Nears Its End*, BIOPHARMA DIVE, https://www.biopharmadive.com/news/humira-abbvie-biosimilar-competition-monopoly/620516/ [https://perma.cc/QE88-9K6A] (last updated Jan. 27, 2023); Stanton Mehr, *18 Months of US Adalimumab Biosimilar Competition Yields $11 Billion in Savings*, BIOSIMILAR REV. & REP. (Aug. 12, 2024), https://biosimilarsrr.com/2024/08/12/18-months-of-us-adalimumab-biosimilar-competition-yields-11-billion-in-savings [https://perma.cc/U636-4VA9].

204. Curtis, *supra* note 199. Humira costs $6,922 (for 40-mg syringes) after it is no longer exclusive, but it seems to have not decreased in price after competitors entered; it was almost $2,784 for each 40-mg syringe in 2020. *Id.*; *see also* Skylar Jeremias, *Despite Steep Discounts, Humira Biosimilars Are Priced More than Original Originator Price*, AJMC (July 21, 2023), https://www.ajmc.com/view/despite-steep-discounts-humira-biosimilars-are-priced-more-than-original-originator-price [https://perma.cc/7JSD-TTFH].

205. *See* Curtis, *supra* note 199; Jeremias, *supra* note 204.

206. *See* Curtis, *supra* note 199. AbbVie has filed 250 patent applications around Humira since its launch in 2022, covering compositions of matter, indications, methods of treatment, formulations, manufacturing methods, and other aspects related to Humira. *Id.* Although the initial patent expired in 2016 and some of the follow-on patents expired between 2022 and 2024, some patents will not expire until 2034. *See id.* This makes it more challenging for competitors to manufacture Humira without infringing on one of AbbVie's patents. *See id.*; *see also* Knox & Curfman, *supra* note 111, at 1761.

monopoly price ("MP") of Humira can be set at $6,922,[207] while the competitive price ("CP") can be set at $4,486.33—the average price of Humira and the eleven biosimilars currently on the market.[208] The supracompetitive price ("SP") should be a number between the monopoly and competitive prices. For our hypothetical calculation, we can set the supracompetitive price at $5,320.33, which is also the average price of Humira between 2017 and 2022.[209] The period of exclusivity ("P") can be set at twenty years.[210] Under the model introduced by this Comment, and with these numbers, the extension period ("E") shall be:

$$E = \frac{(MP - SP) \times P}{SP} = \frac{(6922 - 5320.33) \times 20}{5320.33} = 6 \text{ years.}$$

Now, let us calculate whether it would be more profitable for AbbVie to sell Humira at $5,320.33 exclusively for six more years or to continue in its current situation. The average annual revenue generated by Humira between 2017 and 2022 (at an average price of $5,320.33 for two 40-mg syringes) is $19.5 billion.[211] If AbbVie obtains a six-year extension in exclusivity and sells Humira at $5,320.33 over the next six years, it will gain $19.5 billion in annual revenue over the next six years.[212] This is significantly greater than the $13.7 billion in revenue that the company forecasted for 2023 with the entry of biosimilars.[213] Even with the generous assumption that AbbVie can keep earning $13.7 billion

207. Humira's Whole Acquisition Cost price for two 40-mg syringes in 2023. Curtis, *supra* note 199; *see also* Phalguni Deswal, *Coherus Plans Humira Biosimilar Sale at 85% Discou*nt, PHARM. TECH. (July 14, 2023), https://www.pharmaceutical-technology.com/news/coherus-plans-humira-biosimilar-sale-85-discount/ [https://perma.cc/L5R8-FSE4].

208. When there are no biosimilars, the competitive price could be calculated based on a hypothetical number based on pricing models for biosimilars.

209. Humira prices for two 40-mg syringes were approximately $4,000, $4,500, $5,000, $5,500, $6,000, and $6,922 for 2017, 2018, 2019, 2020, 2021, and 2023, respectively. *See* COMM. ON OVERSIGHT & REFORM, U.S. HOUSE OF REPRESENTATIVES, DRUG PRICING INVESTIGATION, ABBVIE—HUMIRA AND IMBRUVICA 2 (2021) [hereinafter DRUG PRICING INVESTIGATION], https://docs.house.gov/meetings/GO/GO00/20210518/112631/HHRG-117-GO00-20210518-SD007.pdf [https://perma.cc/RH42-PXA8]; Deswal, *supra* note 207.

210. AbbVie launched Humira in 2002 and had a monopoly over the therapeutic through the end of 2022. *See* Curtis, *supra* note 199.

211. *See id.*

212. While the company must lower prices during the entire exclusivity period to obtain the extension, this calculation counts the potential profit under the proposed model during the extension period to compare that hypothetical number with actual profits that have been reported. The lower (supracompetitive or competitive) prices apply throughout the entire exclusivity period. As discussed later, consumers would still be better off although they would be paying more during the extension period than they otherwise would without the extension. *See infra* Section V.D.

213. *See* Leroy Leo & Patrick Wingrove, *AbbVie Trims Forecast for Humira Sales Drop on Favorable Coverage*, REUTERS, https://www.reuters.com/business/healthcare-pharmaceuticals/abbvie-raises-annual-profit-forecast-humira-stays-strong-new-drugs-impress-2023-07-27 [https://perma.cc/5S36-F8PN (staff-uploaded archive)] (last updated July 27, 2023, 1:55 PM).

in revenue over the next six years,[214] AbbVie would be much better off—$34.5 billion better off over the next six years—if it charges supracompetitive prices for an additional period of exclusivity under our model than it is in its current situation, even with the business and patent tactics AbbVie has savvily employed.

Even if the price of Humira is set at the competitive price of $4,486.33 (the average price among all the market players in 2023), AbbVie would still be better off than it would be in its current situation. If Humira is priced at $4,486.33, the period of extension under the model introduced by this Comment would be:

$$E = \frac{(MP - SP) \times P}{SP} = \frac{(6922 - 4{,}486.3) \times 20}{4{,}486.3} = 10.9 \text{ years.}$$

Selling Humira exclusively at $4,486.33 would generate an annual revenue of approximately $16.4 billion for the next ten years.[215] In total, AbbVie would generate an additional $51.5 billion through this course than it would under its current course of action, where it is only bringing in an average of $11.7 billion per year after biosimilars entered the market.[216] Therefore, at least for blockbuster therapeutics like Humira, the patent-extension model introduced by this Comment would likely be a strong incentive for pharmaceutical companies to lower the prices of their products.

C. *Patent Extension or Increased Regulatory Exclusivity*

Increased exclusivity can be achieved by either extending the patent term or the regular exclusivity period. The impact of these two classes of measures on prices and innovation is comparable. Rather, the distinction lies primarily in the ability of the patentee to exclude competitors from the field.

Awarding regulatory exclusivity without extending the patent term may allow competitors to enter the field sooner. Competitors would be able to make,

214. *See id.* In reality, the revenue will probably decrease in subsequent years as more competitors enter the market.

215. Since the average annual revenue between 2017 and 2022 was $19.5 billion when the average price for two 40-mg syringes for the same time period was $5,320.3, if the price is lowered to $4,486.3, the annual revenue would be approximately $16.4 billion. *See* DRUG PRICING INVESTIGATION, *supra* note 209.

216. Humira prices fell to $14.4 billion in 2023 and $9 billion in 2024. *AbbVie Struggles to Mitigate Humira Catastrophe with 5.9% Overall Drop in 2023*, GBI SOURCE (Feb. 2, 2024), https://source.gbihealth.com.cn/news/detail?id=2050496&utm_source=official [https://perma.cc/4A38-DYQA]; Matej Mikulic, AbbVie Key Product Revenues 2023–2024, Statista (Feb. 24, 2025), https://www.statista.com/statistics/417063/revenue-of-abbvie-from-key-products [https://perma.cc/E3LQ-FFXU].

use, and patent inventions during the extra exclusivity period (after the patent expires but before the total exclusivity period ends) without worrying about infringement—they just would not be able to market the invention. However, enabling competitors to patent improvements would limit the ability of the original inventor to make improvements on the invention.

On the other hand, patent term extensions can arguably impede progress in a specific field because competitors would be precluded from doing research in that field (or have to get around the patents). However, because the initial patentee is arguably in the best position to make improvements on that invention, giving inventors more "space" to operate through patent extensions may in fact increase follow-up innovations or improvements. Moreover, because patent extension arguably gives the first inventor greater power to preclude others from entering their research space, it is probably more valuable—and incentivizing—than an extension of regulatory exclusivity. Thus, patent extensions may be a more effective tool than regulatory exclusivities for incentivizing lower prices and maximizing long-term innovation.

D. *Potential Limitations and Concerns*

Although a patent extension system can be a strong tool to incentivize lower prices, it has some limitations. The model this Comment proposes will work the most effectively for "blockbuster" therapeutics—those that generate significant revenues due to high demand. Because blockbuster therapeutics generate high revenues, any incremental increase in the period of exclusivity is extremely valuable. Moreover, the high demand for these products motivates competing firms to generate and market generics and biosimilars as soon as the period of exclusivity of the original therapeutic ends. On the other hand, the model may not effectively incentivize lower prices for low-demand therapeutics, such as orphan drugs or drugs for neglected tropical diseases, because incremental increases in the period of exclusivity would be less valuable for these therapeutics. In fact, these manufacturers may have indefinite monopolies simply because competitors are not interested in entering the market. For this class of therapeutics, patent extensions would likely be better used as a policy lever to incentivize innovation, as has been discussed by other scholars.[217]

There is also a concern that many therapeutics would still be unaffordable to a substantial number of consumers at supracompetitive middle-ground prices. However, the unfortunate reality is that no matter what price is set, many therapeutics will be unavailable to *some* consumers. This is true even if the therapeutic is at a perfectly competitive price point. Thus, although the patent extension system this Comment proposes would not eliminate

217. *See supra* notes 171–76 and accompanying text.

unaffordability, it would shrink the percentage of the population that cannot afford such therapeutics. If the number of people that cannot afford the therapeutic is lower, it would be more feasible to assist them through various governmental programs.

One potential drawback of the proposed patent extension system is that consumers would be paying higher prices than the competitive price during the extension period. Critics may argue that because of this, consumers would be no better off than they are under the current system. However, a consumer is better off paying more affordable prices for longer periods of time than exorbitant prices for shorter periods. After all, cost-spreading is the essence of various measures used to make life necessities more affordable. For example, the insurance system is predicated upon spreading the cost of care over a larger population. Likewise, mortgages and financing plans make homes and cars affordable by spreading the purchase costs of a home and car over a longer period. Such mortgages and financing plans arguably make home and car buyers better off by making homebuying possible for a significantly larger segment of the population, even though they increase the total amount that the buyers must pay. They also make home and car sellers better off by expanding their customer bases and enabling them to charge higher prices.

Similarly, by making lifesaving therapeutics affordable to more consumers, the proposed system of using patent extension as a policy lever to lower prices will make consumers better off, even if they must pay more for the therapeutics during the extension period. This would be especially true for lifesaving therapeutics that have to be taken regularly for extended periods, where unaffordable prices during the original exclusivity period are essentially death sentences for many consumers. Keeping consumers alive for longer periods would in turn increase total profits for the company, offering an additional layer of financial incentive. Thus, just like mortgages and car financing plans are beneficial for home buyers and sellers alike, the proposed patent extension system is beneficial for both consumers and pharmaceutical companies. This type of cost-spreading is arguably even more appropriate for lifesaving medications than it is for homes and cars, which are considered somewhat of a life necessity, as such medications are arguably even more critical for consumers than homes and cars may be.

Other potential difficulties and complications lie in setting the parameters of the patent extension equation. One potential difficulty is determining what the monopoly, supracompetitive, and competitive prices would be in the absence of actual competitors. However, these parameters could be determined through various mathematical supply-demand models based on marginal and average costs, marginal revenue, and profit.[218] Another potential complication

218. *See supra* Section V.A.

is determining at what point the price parameters should be calculated and which patent to extend, as pharmaceutical companies tend to create a patent thicket around a prized therapeutic.[219] Because the core (initial) patent is the most comprehensive and because consumers are better off if prices are reduced earlier in the patent term, extending the core patent may be the optimal approach.

Another possible concern is that pharmaceutical companies may not want to take the deal and instead choose to just charge the monopolistic price for the duration of the patent. However, if prices are set according to the formula discussed above, it would be more profitable for the firm to lower prices and obtain a patent extension term. And if the lengthened lifespans of customers for whom the therapeutics became affordable as a result of the pharmaceutical manufacturers taking the deal is factored into the calculus, the increased profit the manufacturer can gain by taking the deal is even greater than the profit estimated by the proposed equation. Moreover, because exclusivity is so prized by pharmaceutical companies—demonstrated by their willingness to pay generic manufacturers to stay out of the market just to extend their period of exclusivity by a few months[220]—the prospect of a few years of additional exclusivity has the potential to be a strong policy lever for lowering drug prices.

One final concern worth noting is that granting patent extensions would cause global variations in patent length and potentially cause the United States to run afoul of the Trade-Related Aspects of Intellectual Property ("TRIPS") Agreement. However, the TRIPS agreement only requires a minimum level of intellectual property protection; while curtailment of the patent term is prohibited, increases beyond the minimum levels are allowed.[221] Furthermore, patent terms are presently far from being uniform, due to differential examination periods, Patent Term Adjustments, and Patent Term Extensions.[222] Therefore, using patent extensions as a policy lever for reducing drug prices will probably not cause the United States to run afoul of the TRIPS agreement.

219. *See supra* Section II.C; Phillip Areeda & Donald F. Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697, 702–03 (1975).

220. *See supra* Section II.C.

221. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994) ("Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement . . . ."); *id.* art. 33 ("The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."); *see also* Sarah R. Wasserman Rajec, *The Harmonization Myth in International Intellectual Property Law*, 62 ARIZ. L. REV. 735, 777 (2020) (discussing variable patent terms).

222. *See supra* text accompanying note 179.

CONCLUSION

Society needs therapeutics to be both available and accessible. The legal monopoly conferred by the system of patents and regulatory exclusivities has proven to be a very powerful and necessary tool to motivate pharmaceutical companies to invest in and undertake the arduous and risky research and development process necessary to make therapeutics for a wide range of ailments available to consumers. However, such monopolies have the undesirable side effect of making therapeutics unaffordable to many. While certain federal and state regulations have produced some short-term success in curbing exorbitant price increases—and are undoubtedly necessary to prevent unscrupulous business tactics that chill innovation—many regulations may disincentivize innovation in the long run.

To strike the optimal balance between availability and accessibility, we need a system that incentivizes pharmaceutical companies to innovate and charge lower prices. Because the award of a legal monopoly has proven to be the most effective motivator for profit-maximizing businesses, a system that awards legal monopoly for making an invention *available* to the public and layers an additional period of monopoly for making the invention *accessible* to the public strikes that delicate balance. When the additional period of monopoly is calculated as an inverse function of the price of the drug, reductions in prices are automatically rewarded with a longer monopoly period.

Pharmaceutical companies will undoubtedly try to "game" the system through various business deals. Some may even try to charge the monopoly price during the additional period of monopoly. As such, the proposed patent extension system needs to be coupled with strong federal and state regulations and enforcement to ensure greater accessibility and availability of cutting-edge medicine for society.

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