NOTE

Antitrust Enforcement in the Pharmaceutical Industry: Analyzing Patents Under the Rule of Reason

Charles W. Schmidt[*]

ABSTRACT

American consumers and lawmakers across the political spectrum agree that prescription drug prices are far too high. This Note identifies an antitrust cause of action that could drastically reduce the prices of the most expensive prescription drugs. Under section 1 of the Sherman Antitrust Act ("Section 1"), all agreements that unreasonably restrain trade are illegal. Patents are agreements between inventors and the public, and under antitrust "rule of reason" analysis, some patents, i.e., patents covering lifesaving medicines for which there are no close substitutes, may unreasonably restrain trade and therefore violate Section 1. The rule of reason analysis in this Note weighs the long-term economic benefits of robust patent protection against the relatively short-term economic inefficiencies of patent protection.

While the benefits of patents almost always outweigh the harms, patents on lifesaving medicines for which there are no close substitutes are economically unique. Demand for these medicines remains immense, regardless of how high prices climb, because patients need them to live. Prices soar, sometimes to millions of dollars per dose, and the public ultimately shoulders the cost. This Note argues that under Section 1 rule of reason analysis, the patents that enable these extraordinarily high prices may unreasonably restrain trade.

---

* J.D. 2024, The George Washington University Law School; B.A. 2019, University of Colorado Boulder. I owe many thanks to: *The George Washington Law Review* editors—especially Devin Louis—for working to prepare this Note for publication; Professor William Kovacic for discussing early stages of this Note idea with me; Mark Obmascik for pointing me in the right direction with drug research; and my parents, Corky and Jane Schmidt, for their consistent love and support.

For now, the antitrust action proposed in this Note is likely unavailable under Supreme Court precedents that appear to immunize patents from antitrust scrutiny. This Note suggests amendments to federal law that would abrogate patents' implicit antitrust immunity and, where a Section 1 violation is proven, provide for compulsory patent licensing to generic drugmakers for a reasonable royalty. These amendments could save Americans billions annually on prescription drugs while preserving pharmaceutical companies' incentives to develop new medicines.

Table of Contents

Introduction

Prescription drug spending in the United States has captured considerable public attention in recent years[1]—and with good reason. In 2021, American patients and their insurers spent $603 billion on

1 *See* Elisabeth Rosenthal, *Public Opinion is Unified on Lowering Drug Prices. Why Are Leaders Settling for Less?*, KFF Health News (Nov. 18, 2021), https://khn.org/news/article/public-opinion-prescription-drug-prices-democratic-plan [https://perma.cc/W8UA-BYKZ]; Ashley Kirzinger, Audrey Kearney, Mellisha Stokes, Liz Hamel & Mollyann Brodie, *The Public Weighs In On Medicare Drug Negotiations*, Kff (Oct. 12, 2021), https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations [https://perma.cc/DV6H-WXQF].

prescription drugs,[2] and they spend more than twice as much on prescription drugs per capita than the average comparable country.[3] But many are unable to participate in the spending: in a June 2020 survey, 24% of Americans reported that they or a member of their household did not purchase drugs prescribed to them because they could not afford to.[4] Those who cannot afford their medications pay an even more staggering price: a 15–22% higher mortality rate.[5]

The prescription drug market is divided between brand-name drugs, which make up just 16% of prescribed drugs but account for 88% of drug revenue, and unbranded generic drugs ("generics"), which make up 84% of prescribed drugs and account for just 12% of drug revenue.[6] Brand-name drugs are more expensive than generics in part because brand-name drugs are often protected by one or more patents on, for example, the active ingredient or method of manufacturing the drug.[7] With sufficient patent protection, a prescription drug manufacturer can legally exclude competitors from the market for the drug covered by their patent(s).[8] The patent owner can then set higher drug prices than they could if they had to compete with other sellers of the same drug.[9]

Patent law provides an economic incentive to innovate: if you come up with an invention and share the details of it with the

---

2 Sonal Parasrampuria & Steven Murphy, U.S. Assistant Sec'y for Plan. and Evaluation, Off. of Sci. & Data Pol'y, Issue Brief on Trends in Prescription Drug Spending, 2016–2021, at 1 (2022).

3 *See* Nisha Kurani, Dustin Cotliar & Cynthia Cox, *How Do Prescription Drug Costs in the United States Compare to Other Countries?*, Peterson-KFF Health Sys. Tracker (Feb. 8, 2022), https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries [https://perma.cc/A9VL-CQBK]; *see also* Letter from Elizabeth Warren, U.S. Sen., et al. to Hon. Xavier Becerra, Sec'y of the Dep't of Health & Hum. Servs. (June 23, 2022).

4 Dan Witters, *In U.S., Large Racial Divide in COVID-19 Cost Concerns*, Gallup News (July 29, 2020), https://news.gallup.com/poll/316052/large-racial-divide-covid-cost-concerns.aspx [https://perma.cc/7ZVR-ESL3]; *see also* Letter from Elizabeth Warren, U.S. Sen., et al. to Hon. Xavier Becerra, Sec'y of the Dep't of Health & Hum. Servs. (June 23, 2022).

5 *See* Sarah C. Van Alsten & Jenine K. Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014*, 17 Preventing Chronic Disease 1, 1 (2020) (finding that patients skipping or delaying doses of medication due to their not being able to afford prescriptions is linked to a "15% to 22% higher all-cause mortality rates for all [medical] conditions").

6 *See* Andrew M. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield & Alejandro U. Becerra-Ornelas, RAND Corp., International Prescription Drug Price Comparisons 20 (2021).

7 *See* Frazer A. Tessema, Aaron S. Kesselheim & Michael S. Sinha, *Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs*, 71 Hastings L.J. 1019, 1021–23 (2020); *see also* Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, 51 IIC Int. Rev. Intell. Prop. Competition. L. 1062 (2020).

8 *See infra* notes 89–90 and accompanying text; *see also* Tessema et al., *supra* note 7, at 1021–23.

9 *See infra* Section I.A; *see also* Tessema et al., *supra* note 7, at 1021.

public, the government will grant you a monopoly on your invention for a twenty-year term.[10] This quid pro quo creates a binding contract between the inventor and the public whereby the inventor gains the right to exclude competitors from the market for their invention.[11] This power to exclude competitors leads to higher prices for patented goods.[12] The basic rationale for patent law is that innovation is worth the premium consumers pay for it.[13] This Note seeks to ascertain just how far that rationale extends.

Specifically, this Note considers how patents on lifesaving medicines for which there are no close substitutes would fare if challenged as unreasonable restraints of trade in violation of section 1 of the Sherman Antitrust Act ("Section 1").[14] This Note argues patents on lifesaving medicines for which there are no close substitutes might be illegal "contract[s] . . . in restraint of trade" under Section 1 because consumers are exceptionally vulnerable to high prices when their lives depend on whether they can access patented medicines.[15] The Section 1 action described in this Note could be brought by a state attorney general on grounds that competitive failures in prescription drug markets have resulted in exorbitant prices that overburden their state's public health insurance programs.[16]

If the Section 1 action described herein were successful, the defendant patent owner would likely have to pay damages to the state bringing the suit, license their patents to generic drugmakers,[17] and ultimately lower their prices.[18] For now, the Section 1 action described herein may be little more than a thought experiment, as its viability relies on the assumption that patents are eligible to be challenged under

---

10 *See infra* notes 89–90 and accompanying text.

11 *See* Martin J. Adelman, Randall R. Rader & John R. Thomas, Patent Law 411 (5th ed. 2019); *see also infra* note 96 and accompanying text.

12 *See infra* Part I.

13 *See infra* Section II.A.

14 15 U.S.C. § 1 ("Every contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."); Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007) ("[T]he Court has repeated time and again that § 1 'outlaw[s] only unreasonable restraints.'" (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997))).

15 15 U.S.C. § 1; *see infra* Sections III.B–.C.

16 *See* 15 U.S.C. § 15c(a)(1) ("Any attorney general of a State may bring a civil action in the name of such State . . . in any district court of the United States having jurisdiction of the defendant, to secure monetary relief as provided in this section for injury sustained by such natural persons to their property by reason of any violation of sections 1 to 7 of this title.").

17 *See infra* Section III.C (discussing patent licensing for a reasonable royalty as a less restrictive alternative to patent enforcement).

18 *See* IMS Inst. for Healthcare Informatics, Price Declines after Branded Medicines Lose Exclusivity in the U.S. (2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf [https://perma.cc/6WET-DVNJ] (discussing how increased competition results in lower drug prices).

Section 1 in the first place. Federal courts may be reluctant to entertain a Section 1 challenge to patent rights because Supreme Court precedents imply that patents are immune from Section 1 antitrust enforcement.[19] However, the Supreme Court has not definitively decided whether patents are immune from Section 1 challenges,[20] and in any case, such policy questions are best left to Congress.[21] Congress should proactively resolve the issue by amending federal law to clarify the extent to which plaintiffs may challenge patent rights under Section 1.

Part I of this Note examines the prices of patented medicines and identifies the entities that pay those prices.[22] Part II provides necessary background on patent law, antitrust law, and the fraught relationship between them.[23] Part III, proceeding from the assumption that patents are not immune to Section 1 challenges, explains why patents on lifesaving medicines for which there are no close substitutes are problematic under Section 1.[24] Part IV explains that, for now, patents are likely immune to Section 1 challenges and suggests statutory amendments that would permit the Section 1 action described herein to proceed on the merits.[25]

I. High Prices of Patented Medicines

Patent-protected medicines can have extraordinarily high prices. For example, Zolgensma, a patent protected biologic medicine discussed in Part I.A, costs $2.1 million per dose.[26] Upon its release, it was the most expensive drug in the world,[27] and its patent protection[28] enables its high price.[29] High prescription drug prices are paid by several entities including private and public insurers; but, whether directly or indirectly, high prescription drug prices ultimately land on the American public,

---

19 *See* cases cited *infra* notes 262–67 and accompanying text.

20 *See infra* notes 262–67 and accompanying text.

21 Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc., 435 U.S. 519, 558 (1978) ("[F]undamental policy questions [are] appropriately resolved in Congress . . . .").

22 *See infra* Part I.

23 *See infra* Part II.

24 *See infra* Part III.

25 *See infra* Part IV.

26 *See infra* note 33 and accompanying text.

27 Rebecca Robbins & Stephanie Nolen, *A Dilemma for Governments: How to Pay for Million-Dollar Therapies*, N.Y. Times (Jan. 25, 2023), https://www.nytimes.com/2023/01/24/health/gene-therapies-cost-zolgensma.html [https://perma.cc/6FZW-4XWP].

28 *See* U.S. Patent No. 7,906,111 (filed Sept. 30, 2004); Determination of Regulatory Review Period for Purposes of Patent Extension; ZOLGENSMA, 86 Fed. Reg. 33307, 33308 (June 24, 2021).

29 *See* Gurgula, *supra* note 7, at 1063.

who, along with politicians on both sides of the aisle, demand lower drug prices.[30]

A. Setting a Price: Zolgensma

Without a Zolgensma treatment, type one spinal muscular atrophy ("SMA"), a rare birth defect, is usually fatal within a patient's first two years of life.[31] However, a single dose of Zolgensma, a patented biologic medicine sold by Novartis, can extend an SMA patient's life for several years.[32] Novartis decided to set the price for one Zolgensma treatment at $2.1 million.[33] How did they determine that price? Zolgensma was surely costly to develop, but Novartis has not said *how* costly,[34] and the price is not necessarily based on the cost of research and development ("R&D").[35] Because Zolgensma is patent protected[36] and no other medicines on the market treat SMA nearly as well as Zolgensma,[37] the only limit on the price of Zolgensma is what insurers are willing to pay for SMA patients to live.[38] When Novartis brought Zolgensma to

---

30 *See infra* Sections I.B–.C.

31 *See generally A Deeper Look into SMA*, Zolgensma, https://www.zolgensma.com/sma-progression [https://perma.cc/49UR-2WSP] (providing an overview of typical SMA progression without Zolgensma treatment).

32 *See Novartis Shares Zolgensma Long-Term Data Demonstrating Sustained Durability Up to 7.5 Years Post-Dosing; 100% Achievement of All Assessed Milestones in Chrildren Treated Prior to SMA Symptom Onset*, Novartis (Mar. 20, 2023), https://www.novartis.com/news/media-releases/novartis-shares-zolgensma-long-term-data-demonstrating-sustained-durability-75-years-post-dosing-100-achievement-all-assessed-milestones-children-treated-prior-sma-symptom-onset [https://perma.cc/Y63D-YNV6] (discussing study that showed that even "up to 7.5 years post-dosing, children who were treated [with Zolgensma] after presenting symptoms of SMA maintained all previously achieved motor milestones").

33 Robbins & Nolen, *supra* note 27 (mentioning "Zolgensma's list price of $2.1 million").

34 *See* Mark Nuijten, *Pricing Zolgensma—the World's Most Expensive Drug*, 10 J. Mkt. Access & Health Pol'y 1, 3 (2022) (stating "[t]he . . . costs for R&D . . . are derived from published literature" where the cited literature was not specific to Zolgensma).

35 *See* Nicola Davies, *Putting a Price on Life: Is the Answer Outside Pharma?*, Reuters Events (Nov. 4, 2019), https://www.reutersevents.com/pharma/access-and-evidence/putting-price-life-answer-outside-pharma# [https://perma.cc/LTV2-PQ6R] (discussing that many factors—such as patent protection, economies of scale, uncertainty about benefits and side effects, short-term budget impacts, long-term cost offsets, and other considerations of what a "fair price" would be—all impact the cost of a drug, and providing commentary on Zolgensma from Dan Ollendorf, Director of Value Measurement and Global Health Initiatives at the Center for the Evaluation of Value and Risk in Health, who states, "Ultimately, by putting a value on a cure, we put a value on a human life").

36 *See* U.S. Patent No. 7,906,111 (filed Sept. 30, 2004).

37 The closest substitute is Spinraza, which is not exceptionally close. *See generally Zolgensma vs Spinraza: What Are the Key Differences?*, Drugs.com (Dec. 11, 2023), https://www.drugs.com/medical-answers/zolgensma-spinraza-key-differences-3555030 [https://perma.cc/7V8H-CS27] (comparing Zolgensma with Spinraza).

38 *See* Emma Court, *'Like We Were Being Forced to Gamble with Our Son's Life': Health Insurers Won't Pay for a $2.1 Million Drug for Kids, and Parents Say They're Running Out of*

market in 2019, the drug held the title of the most expensive medicine in the world,[39] but its pricing model is not unique, and it has since lost the title to other lifesaving medicines.[40] Virtually all patent protected lifesaving medicines for which there are no close substitutes are priced in the same way, where the only cap on price is what people, through their insurers, will pay to live.[41]

B. Resulting Financial Burdens

No matter how a patient pays for a prescription drug, the burden of high drug prices inevitably lands on the American public.[42] The most straightforward—but least common—payment method is payment out of pocket.[43] Given how expensive prescription drugs can be, most people would prefer not to pay out of pocket.[44] When someone cannot afford a prescription drug out of pocket and also does not have insurance, they are often forced to go without the drug,[45] risking catastrophic health consequences.[46] To avoid this scenario, they can enroll in a public insurance program such as Medicare or Medicaid, which are described below.[47] Sometimes, drug manufacturers give prescription drugs to uninsured people for free or at a substantially reduced price[48]—and they must presumably factor these losses into their drug prices.

Time, Bus. Insider (July 26, 2019, 9:36 AM), https://www.businessinsider.com/health-insurance-companies-deny-kids-with-sma-gene-therapy-zolgensma-2019-7 [https://perma.cc/K96G-ULBW] (highlighting the lack of alternative treatments for Zolgensma, the inability of patients to pay out of pocket, and the short window to treat patients to show that insurance companies hold significant power over whether someone receives treatment).

39 *See* Robbins & Nolen, *supra* note 27.

40 *See id.*

41 Steven G. Morgan, Hannah S. Bathula & Suerie Moon, *Pricing of Pharmaceuticals Is Becoming a Major Challenge for Health Systems*, 368 BMJ 67, 67 (2020).

42 *See infra* text accompanying notes 44–66. *See generally* Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 Seton Hall L. Rev. 385, 389 (2021) (discussing how prescription drug prices often result in great personal costs for patients and place a strain on states' public funding).

43 *See* Kurani et al., *supra* note 3 (explaining that out of pocket expenses accounted for about 15% of drug spending in the U.S.).

44 *See id.*; Wolitz, *supra* note 42, at 389–90; Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 11 (2022).

45 *See* Witters, *supra* note 4; Wolitz, *supra* note 42, at 394–95.

46 *See* Van Alsten & Harris, *supra* note 5.

47 *See infra* note 61 and accompanying text.

48 *See generally* Janet Nguyen, *Why Do Pharmaceutical Companies Give Away Some Expensive Drugs for Free?*, Marketplace (Mar. 31, 2023), https://www.marketplace.org/2023/03/31/why-do-pharmaceutical-companies-give-away-some-expensive-drugs-for-free [https://perma.cc/7NZK-RF3K]; *Pharmaceutical Manufacturer Patient Assistance Program Information*, Ctrs. for Medicare & Medicaid Servs. (Sept. 6, 2023, 4:51 PM), https://www.cms.gov/medicare/coverage/prescription-drug-coverage/patient-assistance-program [https://perma.cc/5RZQ-49AB].

Alternatively, patients can pay for a prescription drug through their insurance.[49] Insurance can be provided by either a private insurance company or by state governments through programs including Medicare and Medicaid.[50] This Section discusses private and public insurance separately because there are significant differences between them. Private insurance companies spread individual medical expenses out over large groups of insured people.[51] These people generally pay an annual lump sum (i.e., a "premium") to their insurance company, and in exchange, their insurance company agrees to pay some portion of their medical expenses.[52] Some people (e.g., those who incur minimal medical expenses) pay more for insurance coverage than their insurer ends up paying for their medical expenses.[53] Their overpayment covers medical expenses of people who incur more in medical expenses than they pay for insurance coverage.[54] So if someone with private insurance undergoes a $2.1 million Zolgensma treatment, a large group of insured people, rather than just the one patient receiving the treatment, will pay the bill.[55]

Additionally, private insurers often bargain with healthcare providers, drug manufacturers, and pharmacies to negotiate lower prices for their patients.[56] This business model works inasmuch as it generally enables insured people to incur enormous medical expenses without going broke.[57] Yet individual savings become collective burdens as insurance companies pass ever-increasing healthcare costs onto insured people by raising premiums, reducing coverage, or both.[58] While insured

---

49 *See generally How U.S. Health Insurance Works*, Stanford Vaden Health Servs., https://vaden.stanford.edu/insurance-referral-office/health-insurance-overview/how-us-health-insurance-works [https://perma.cc/TDB7-73BA].

50 *See* Katherine Keisler-Starkey & Lisa N. Bunch, U.S. Census Bureau, P60-274, Health Insurance Coverage in the United States: 2020, at 3 (2021), https://www.census.gov/content/dam/Census/library/publications/2021/demo/p60-274.pdf [https://perma.cc/B3SM-ECEG] ("In 2020, private health insurance coverage continued to be more prevalent than public coverage at 66.5 percent and 34.8 percent, respectively."); *see also infra* note 61.

51 *See generally How U.S. Health Insurance Works*, *supra* note 49.

52 *See generally id.*

53 *See generally id.*

54 *See generally id.*

55 *See generally id.*

56 *See generally id.*

57 *See id.*

58 *See* Ann Carrns, *Expect Higher Health Insurance Premiums, but Not A Lot Higher*, N.Y. Times (Nov. 4, 2022), https://www.nytimes.com/2022/11/04/your-money/health-insurance-premiums-employer-plans.html [https://perma.cc/8772-FVNC]; Wolitz, *supra* note 42, at 398–99. *See generally How U.S. Health Insurance Works*, *supra* note 49.

people generally will not go bankrupt from a $2.1 million treatment,[59] that financial burden still makes its way back to members of the public.[60]

Public insurance works similarly, but it tends to be far less expensive than private insurance as it is heavily subsidized by the federal government.[61] Public insurance options include, most notably, Medicare (generally for people at least sixty-five years old)[62] and Medicaid (for low-income people).[63] While most Medicare and Medicaid funding comes from federal tax revenue, Medicare and Medicaid are administered by the states.[64] A key difference between public and private health insurance is that it is difficult—and was, until recently, forbidden—for public insurance programs to negotiate prescription drug prices with manufacturers and pharmacies.[65] Just as private insurance companies pass the financial burdens of high drug prices onto members of the public via higher premiums and reduced coverage, states and the federal government pass the burdens of high drug prices on to members of the public via higher taxes.[66]

C. Demand for Lower Prices

Prescription drug price reform is one of the few areas in American politics where almost everyone seems to agree on what the problem

---

59 *See generally* Carrns, *supra* note 58; *How U.S. Health Insurance Works*, *supra* note 49.

60 Often, there are more steps involved than indicated here. For example, where employers pay for their employees' health insurance, the financial burden of higher premiums may fall on employers. *See* Carrns, *supra* note 58. Even then, employers pass the burden onto their employees (by, e.g., reducing compensation or firing people), clients (by, e.g., raising prices), or both. *See id.*; Matthew Rae, Rebecca Copeland & Cynthia Cox, *Tracking the Rise in Premium Contributions and Cost-Sharing for Families with Large Employer Coverage*, Peterson-KFF Health Sys. Tracker (Aug. 14, 2019), https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage [https://perma.cc/WH42-MMXS].

61 Depending on a person's income, Medicare or Medicaid coverage may be free. *See Costs*, Medicare.gov, https://www.medicare.gov/basics/costs/medicare-costs [https://perma.cc/KX2L-H2KK]; *Medicaid & CHIP Coverage*, HealthCare.gov, https://www.healthcare.gov/medicaid-chip [https://perma.cc/H54H-MCBF].

62 *When Can I Sign Up for Medicare?*, Medicare.gov, https://www.medicare.gov/basics/get-started-with-medicare/sign-up/when-can-i-sign-up-for-medicare [https://perma.cc/5RTC-Z5XW].

63 *About Us*, Medicaid.gov, https://www.medicaid.gov/about-us/index.html [https://perma.cc/B4BE-7FVS].

64 Note that state governments also cover some of the costs of Medicare and Medicaid. *See How Do States Pay for Medicaid?*, Peter G. Peterson Found. (June 2, 2023), https://www.pgpf.org/budget-basics/budget-explainer-how-do-states-pay-for-medicaid [https://perma.cc/6E63-7K3N].

65 *See* Memorandum on Medicare Drug Price Negotiation Program from Chiquita Brooks-LaSure, Adm'r for Ctrs. for Medicare & Medicaid Servs. (Jan. 11, 2023) (explaining that the 2022 Inflation Reduction Act authorized Medicare to negotiate the price of prescription drugs and was the first time this negotiating power was given to U.S. public insurance programs).

66 *See How Do States Pay for Medicaid?*, *supra* note 64; Danial E. Baker, *High Drug Prices: So Who Is to Blame?*, 52 Hosp. Pharmacy 5, 5 (2017).

is: prices are too high.[67] Consumers across the board want lower drug prices,[68] and federal legislators from both major parties purport to champion this cause.[69] The executive branch appears to be in agreement.[70] President Biden spent nearly six minutes of his 2023 State of the Union address speaking about Americans' need for lower drug prices, receiving raucous applause from a bipartisan audience.[71] And under the guidance of Lina Khan, President Biden's appointee for Chair of the Federal Trade Commission ("FTC"),[72] the FTC has taken a special interest in antitrust enforcement in the pharmaceutical industry.[73]

The entities with the strongest incentives to reduce the prices of patented medications include, of course, those who shoulder the burdens of high drug prices: insurance companies, the federal government, state governments, and the public at large.[74] Seeking to lower prescription drug prices, representatives of these groups have brought, and will presumably continue to bring, antitrust enforcement actions against drug companies.[75]

II. Patent & Antitrust Law: Unresolved Tension

Patent and antitrust law share a complicated relationship.[76] Both areas of law seek to promote consumer welfare, and, in a sense, both

---

67 *See A Political Rarity: Almost Everyone Agrees We Need to Change Drug Prices*, KFF Health News (Oct. 13, 2021), https://kffhealthnews.org/morning-breakout/a-political-rarity-almost-everyone-agrees-we-need-to-change-drug-prices [https://perma.cc/FHX9-HNA7].

68 *See* Rosenthal, *supra* note 1.

69 *See* Joseph Choi, *House Republicans Open Investigation into Role of Intermediaries in Prescription Drug Prices*, The Hill (Mar. 1, 2023, 3:39 PM), https://thehill.com/policy/healthcare/3879512-house-republicans-open-investigation-into-role-of-intermediaries-in-prescription-drug-prices [https://perma.cc/C8SL-5DBC]; Sheryl Gay Stolberg & Rebecca Robbins, *Democrats' Long-Sought Plan for Lowering Drug Costs Is at Hand*, N.Y. Times (Aug. 5, 2022), https://www.nytimes.com/2022/08/05/us/politics/medicare-drug-costs.html [https://perma.cc/JZZ8-LJEE].

70 *See infra* notes 71–73 and accompanying text.

71 *See* C-SPAN, *President Biden Delivers 2023 State of the Union & Republican Response*, YouTube, at 00:53:54–00:59:40 (Feb. 7, 2023), https://www.youtube.com/watch?v=sfe2sOi-apk [https://perma.cc/4HUG-Q3WB].

72 Press Release, FTC, Lina M. Khan Sworn in as Chair of the FTC (June 15, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/06/lina-m-khan-sworn-chair-ftc [https://perma.cc/U6HH-CR7Y].

73 For example, in 2022 the FTC hosted a two-day workshop "to explore new approaches to enforcing the antitrust laws in the pharmaceutical industry." *The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers*, Fed. Trade Comm'n, https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers [https://perma.cc/4V8F-DQ52].

74 *See supra* text accompanying notes 44–66.

75 *See, e.g.*, FTC v. Actavis, Inc., 570 U.S. 136 (2013); Mayor of Balt. v. AbbVie Inc., 42 F.4th 709 (7th Cir. 2022).

76 *See generally* FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy 1–2 (2003) [hereinafter FTC Innovation Rep.] (explaining the

seek to promote competition.[77] But they work in fundamentally different ways. Patent law promotes competition between innovators by awarding a limited monopoly to the first inventor to file a patent application for a new invention,[78] while antitrust law promotes competition by preventing the accumulation and exercise of monopoly or market power.[79] This Part explains principles of patent law[80] and antitrust law[81] before discussing the tension between them[82]—tension that could be addressed by the Section 1 litigation proposed in Part III.[83]

A. The Purpose and Function of Patent Law

The purpose of the patent system is "To promote the Progress of . . . useful Arts[] by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[84] A patent is essentially a prize the government awards to an inventor for meeting the legal requirements of the patent application process.[85] The main legal requirement is to file a patent application[86] demonstrating that the inventor has genuinely invented a new and useful product or process.[87] Patent applications are typically published eighteen months after they are filed with the U.S. Patent and Trademark Office ("USPTO"), thereby availing the claimed invention to the public.[88]

---

interaction between patent and antitrust law, the two fields' similar goals, and their competing interests).

77 *See id.*

78 *See* U.S. Const. art. I, § 8, cl. 8; *New Patent Cover*, U.S. Pat. & Trademark Off., https://10millionpatents.uspto.gov/newpatentcover.html [https://perma.cc/C5VG-L6CZ].

79 *See infra* Section II.B.

80 *See infra* Section II.A.

81 *See infra* Section II.B.

82 *See infra* Section II.C.

83 *See infra* Part III.

84 U.S. Const. art. I, § 8, cl. 8.

85 The appearance of a patent cover bears resemblance to that of a prize, as does the language used to grant patents. *See New Patent Cover*, *supra* note 78 ("The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law. Therefore, this United States Patent grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . .").

86 *See* 35 U.S.C. § 111(a).

87 A patent application must satisfy four criteria before a patent may issue. Specifically, the application must demonstrate that the claimed invention is (1) patent-eligible subject matter, (2) novel, (3) nonobvious to a person of ordinary skill in the art, and (4) enabled by the teaching provided in the patent specification. *See* 35 U.S.C. §§ 101–103, 112(a).

88 *See* 35 U.S.C. § 122(b). There are limited exceptions where national security mandates secrecy and where the applicant certifies that they will seek a patent for the claimed invention only in the United States. 35 U.S.C. §§ 181, 122(b)(2)(B)*; see* Files Open to the Public, 37 C.F.R. § 1.11(a) (2023) ("The specification, drawings, and all papers relating to the file of: A published application; a patent; or a statutory invention registration are open to inspection by the public . . . .").

The prize for meeting the applicable legal requirements is "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States"[89] for twenty years from the time the patent application was filed.[90] Anyone who violates a patent owner's rights by, for example, manufacturing and selling the patented invention, has infringed the patent[91] and may be held liable to the patent owner for damages.[92] But perhaps the most valuable remedy for patent infringement is an injunction preventing the defendant from continuing to infringe.[93] An injunction—and the threat of obtaining one—is particularly valuable because it enables the patent owner to enforce a monopoly on their invention.[94] Alternatively, a patent owner may agree to refrain from seeking or enforcing an injunction in exchange for a handsome licensing fee from an infringer.[95]

Importantly for the purposes of this Note, patents are agreements (i.e., contracts) between inventors and the public.[96] Under the patent laws, the public agrees to grant inventors temporary monopolies over their inventions in exchange for, inter alia, inventors' public disclosure of their inventions.[97] These agreements usually confer substantial benefits on both parties. Inventors, for their part, gain assurance that if their patent rights are violated by infringers, they have powerful legal remedies available to them.[98] This assurance makes it worthwhile for people to invest their time, energy, and money in the R&D required to develop

89 35 U.S.C. § 154(a)(1); *New Patent Cover*, *supra* note 78.

90 *See* 35 U.S.C. § 154(a)(2).

91 *See id.* § 271(a).

92 *See id.* § 284.

93 *See id.* § 283. But injunctive relief is sometimes unavailable even where the patent owner prevails, especially where the patent owner is a nonpracticing entity—i.e., an entity that does not make or sell the patented invention—or the patented invention is a small component of a larger product. *See* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (holding an injunction may issue only if (1) the patent owner would suffer irreparable harm absent an injunction, (2) money damages alone are inadequate, (3) the balance of hardships between the patent owner and the infringer warrants equitable relief, and (4) an injunction would not harm the public interest); *see also id.* at 396–97 (Kennedy, J., concurring) (arguing that nonpracticing entities and owners of patents on small components are generally less deserving of injunctions).

94 *See* FTC, The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition 5 (2011) [hereinafter FTC Evolving IP Marketplace Rep.].

95 *See id.*

96 *See infra* notes 155, 177–78 and accompanying text.

97 *See* 35 U.S.C. §§ 154(a)(2), 271 (codifying patent rights); *see also supra* note 88 and accompanying text (discussing the public disclosure requirement).

98 *See supra* notes 89–95 and accompanying text.

a new invention.[99] In turn, entire industries are catalyzed.[100] And in exchange, the public gains the knowledge of how to "make and use" new inventions.[101] At the end of a patent term, members of the public may thus make, use, or sell the invention without having invested any of the time, energy, or money required to develop it.[102]

B. The Purpose and Function of Antitrust Law

Antitrust law has a wide variety of purposes, the most prominent of which is to promote consumer welfare.[103] Antitrust law promotes consumer welfare by inducing and maintaining competition in product markets, as competition among sellers keeps prices low, which is good for consumers.[104] Antitrust law generally disfavors monopolized markets as monopolists do not have to compete with other sellers and can, therefore, maximize profits by reducing their output below competitive levels and raising prices above competitive levels.[105] Monopolized markets are economically inefficient and reduce consumer welfare.[106]

Of course, the real-world economy is more nuanced than economic models,[107] and antitrust laws attempt to account for this nuance.[108] Some firms that do not have monopoly power nonetheless violate antitrust

---

99 *See* Miriam Marcowitz-Bitton & Yotam Kaplan, *Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution*, 12 U.C. Irvine L. Rev. 423, 425–26 (2022).

100 *See, e.g.*, *id.* (discussing incentives presented by patents for COVID-19 vaccine development); *see also* Nathan Yates, *I Have Spinal Muscular Atrophy. Critics of the $2 Million New Gene Therapy Are Missing the Point*, STAT (May 31, 2019), https://www.statnews.com/2019/05/31/spinal-muscular-atrophy-zolgensma-price-critics [https://perma.cc/BL75-S7RE] (arguing the high prices of patented medicines such as Zolgensma—the SMA treatment—enable their development); Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383–84 (Fed. Cir. 2006) (discussing "the importance of the patent system in encouraging innovation" in the pharmaceutical industry).

101 35 U.S.C. § 112(a) (requiring that a patent application disclose how to "make and use" the patented invention); *see supra* note 88 and accompanying text (discussing the public disclosure requirement for patents).

102 60 Am. Jur. 2d *Patents* § 633, Westlaw (database updated Mar. 2023).

103 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application § 100a, Lexis (database updated May 2023) ("[T]he principal objective of antitrust policy is to maximize consumer welfare by encouraging firms to behave competitively . . . .").

104 *See id.* §§ 401, 402b2. *See generally id.* § 402 (providing a detailed explanation of how a perfectly competitive market promotes consumer welfare).

105 *See id.* § 403a–b.

106 *See id.* § 403b.

107 *See id.* § 406a (explaining that "conditions in real markets never satisfy the assumptions of the model perfectly").

108 *See generally id.* ch. 4B (explaining several ways in which U.S. antitrust policy departs from the basic principles discussed above).

laws,[109] and some firms that do have monopoly power are perfectly within the law.[110] Rather than strictly targeting monopolists, antitrust laws generally target firms that have "market power."[111] Under antitrust law, "market power is the abilities (1) to price substantially above the competitive level *and* (2) to persist in doing so for a significant period without erosion by new entry [by competitors] or expansion [of the relevant market]."[112]

There is no agreed upon method for determining whether a defendant has market power, but courts routinely look to a few key indicators: the defendant's share of the product market at issue,[113] the price elasticity of demand for the product (i.e., the extent to which the quantity demanded of the product decreases in response to price increases),[114] and the ease with which potential competitors may enter the product market.[115] For purposes of this Note, it suffices to understand that if a defendant holds a high share of the market for a product that has a low price elasticity of demand and high barriers to entry, that defendant likely has market power, if not full-blown monopoly power.[116] For instance, recall Zolgensma, which is made and sold by pharmaceutical giant Novartis.[117] Due to Zolgensma's patent protection,[118] Novartis can maintain a 100% share of the market for Zolgensma, as patent enforcement is an insurmountable barrier to entry for potential competitors.[119] And since patients who need Zolgensma will likely die without it, as the drug has no close substitutes,[120] demand for Zolgensma likely does not diminish as price increases—that is, demand for Zolgensma is *inelastic*.[121] But to be clear, market power is only illegal if obtained or

---

109 *See, e.g.*, United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 220 (1940) (upholding convictions under Section 1 where defendants had neither monopoly nor oligopoly power).

110 *See* Verizon Commc'ns, Inc. v. L. Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.").

111 Ohio v. Am. Express Co., 585 U.S. 529, 541 (2018) (quoting Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 768 (1984)).

112 Areeda & Hovenkamp, *supra* note 103, § 501.

113 *See generally id.* § 532.

114 *See generally id.* § 507.

115 *See generally id.* § 420.

116 *See id.* § 532b ("[A] firm with a large market share may lack monopoly power because of highly elastic demand, ready expansion, or entry by others.").

117 *See supra* Section I.A.

118 *See* U.S. Patent No. 7,906,111 (filed Sept. 30, 2004).

119 *See supra* notes 78, 89 and accompanying text.

120 *See supra* note 37 and accompanying text.

121 *See* Morgan et al., *supra* note 41.

exercised in some impermissible way,[122] such as through an agreement that unreasonably restrains trade.[123]

A court's analysis of whether and to what extent a defendant has market power plays a crucial role in many actions brought under Section 1.[124] Under Section 1, "every contract" that unreasonably restrains trade is illegal.[125] The paradigmatic example of such a contract is a price fixing agreement between companies that purport to compete with one another in the same product market.[126] But in Section 1 cases that do not involve conduct as obviously egregious as price fixing, courts perform "rule of reason" analyses to determine liability.[127]

Under the antitrust rule of reason,[128] the standard burden shifting process is as follows. The plaintiff bears the initial burden of proving the existence of a prima facie anticompetitive agreement, which can be done by demonstrating (1) the defendant has market power and (2) the defendant is party to "an agreement whose likely effect in the presence of [the defendant's market] power is an increase in price or a reduction in output."[129] The burden then shifts to the defendant to show that the allegedly anticompetitive agreement "in fact furthers some procompetitive objective."[130] If the defendant succeeds, the court must determine whether the same "procompetitive objective" could be achieved by some alternative means that would be less harmful to competition than the agreement at issue.[131] If the court finds there is no viable, less restrictive alternative to the agreement at issue, the court decides antitrust liability by simply weighing the anticompetitive harms of the agreement against its procompetitive benefits.[132]

---

122 Areeda & Hovenkamp, *supra* note 103, § 502 n.8 ("[A]ntitrust law generally requires improper conduct before condemning market power.").

123 *See infra* note 125 and accompanying text.

124 *See infra* note 129 and accompanying text.

125 15 U.S.C. § 1; Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 877, 885 (2007) ("[T]he Court has repeated time and again that § 1 'outlaw[s] only unreasonable restraints.'" (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997))).

126 *See, e.g.*, *In re* Broiler Chicken Antitrust Litig., 290 F. Supp. 3d 772, 772 (N.D. Ill. 2017) (alleged price fixing scheme in the chicken industry involving Tyson Foods, Pilgrim's Pride, and several other chicken suppliers).

127 *See State Oil Co.*, 522 U.S. at 10.

128 The analysis provided herein is for horizontal restraints only—i.e., restraints on competition between direct competitors. Vertical restraints—e.g., a restraint imposed by a supplier on a retailer—are analyzed under a modified rule of reason framework. *See, e.g.*, *Leegin*, 551 U.S. at 907.

129 Areeda & Hovenkamp, *supra* note 103, § 1914b (alteration added).

130 *Id.* § 1914c (citing United States v. Brown Univ., 5 F.3d 658, 669 (3d Cir. 1993)).

131 *Id.* § 1914c (At this juncture, "[s]ome courts give the plaintiff the burden of showing that some workable less restrictive alternative is available . . . others give the defendant the burden of showing that no such alternative exists.").

132 *Id.* § 1912i (citing Sullivan v. Nat'l Football League, 34 F.3d 1091, 1111 (1st Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995)).

C. *Perpetual Tension Between Patent and Antitrust Law*

While patent and antitrust law do not necessarily contradict each other, their purposes and functions are in tension with one another.[133] Patents convey market power to some patent owners,[134] and antitrust law makes some forms of market power illegal.[135] Patent law temporarily insulates some patent owners from competition, and antitrust law seeks to promote competition.[136] But in another sense, the goals of patent law and antitrust law are in harmony.[137] Both areas of law seek to increase the variety of products available to consumers, and both promote competition insofar as patent law incentivizes competitors to race to be the first to invent the next big invention, and antitrust law explicitly targets anticompetitive behavior.[138] Moreover, antitrust law does not illegalize market power itself.[139] It merely illegalizes market power achieved by or exercised through agreements that unreasonably restrain trade[140] and market power achieved or maintained through anticompetitive means.[141]

This tension is best explained by comparing the long-term policy objectives of patent law with the short-term policy objectives of antitrust law. Patent law is premised on the notion that short-term economic inefficiency is a small price to pay for a system that, in the long term, reliably

---

133 *See* Hannah M. Lasting, Note, *Big Pharma, Big Problems: COVID-19 Heightens Patent-Antitrust Tension Caused by Reverse Payments*, 44 SEATTLE U. L. REV. 591, 592 (2021) (explaining that "antitrust law aims to prevent monopolies," while patent law aims to permit limited monopolies where there is some greater public interest).

134 *See* AREEDA & HOVENKAMP, *supra* note 103, § 518 ("[I]f strong demand for a good or process creates the possibility of market power, the patent laws serve to protect that power by forbidding others from duplicating what the patent covers." (emphasis omitted)).

135 *See* Ohio v. Am. Express Co., 585 U.S. 529, 541 (2018) (explaining that antitrust law seeks to distinguish restraints that benefit competition from those that harm it).

136 *See* Lasting, *supra* note 133, at 592.

137 *See* FTC INNOVATION REP., *supra* note 76, at 1–2 (discussing how both areas of law seek to promote innovation that will benefit the public); FTC v. Qualcomm Inc., 969 F.3d 974, 988 (9th Cir. 2020) ("'[A] central goal of both patent and antitrust law is the promotion of the public benefit through a competitive economy.' . . . '[P]atent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition.'" (first quoting Int'l Wood Processors v. Power Dry, Inc., 792 F.2d 416, 427 (4th Cir. 1986); and then quoting Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1362 (Fed. Cir. 1999))).

138 *See* FTC INNOVATION REP., *supra* note 76, at 1–2.

139 *See* Verizon Commc'ns, Inc. v. L. Offs. of Curtis v. Trinko, LLP, 540 U.S. 398, 407 (2003) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system."); AREEDA & HOVENKAMP, *supra* note 103, § 502 n.8 ("[A]ntitrust law generally requires improper conduct before condemning market power.").

140 *See* 15 U.S.C. § 1; Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 877, 885 (2007).

141 *See* 15 U.S.C. § 2; *Trinko*, 540 U.S. at 407.

produces innovative products and processes.[142] The argument goes, even though patents enable sellers to temporarily charge supracompetitive prices, the patent system is well worth it because a steady stream of patent-protected inventions inspires investment in technology-based industries and enables the United States to compete with other highly innovative countries in the international marketplace.[143]

By comparison, antitrust law focuses on shorter-term realities for consumers.[144] From the antitrust perspective, it is problematic for sellers to charge prices that far exceed their costs (i.e., supracompetitive prices) because at the end of the day, this leaves consumers with less money in their pockets and a constrained supply of products.[145] Thus, despite the long-term procompetitive focus of the patent system, individual patents can harm competition in the short term. Section 1's rule of reason provides a framework for weighing short-term competitive harm against long-term procompetitive benefits to determine legality.[146]

FTC v. Actavis, Inc.,[147] a case the Supreme Court decided in 2013, provides an example of how courts can evaluate patent-related conduct in the pharmaceutical industry under the rule of reason. In *Actavis*, the Court evaluated the legality of a settlement agreement reached between Solvay, the patent owner, and a group of generic drugmakers that had allegedly infringed, and sought to invalidate, Solvay's patent.[148] Under the settlement agreement, the generic drugmakers promised to refrain from (1) challenging the validity of Solvay's patent and (2) entering the market for the patented product, a testosterone gel,[149] until the patent expired in exchange for payments totaling about $250 million.[150] The Court held that such agreements, termed "reverse payment" agreements, where patent owning plaintiffs pay generic drugmaker defendants to refrain from challenging the validity of their patents, may violate Section 1 and should be analyzed under the rule of reason.[151]

---

142 *See* Paul Morinville & Terry Fokas, *The U.S. Patent System, Not China's IP Policies, Is the Reason Behind America's Decline in Global Competitiveness*, IPWatchdog (Mar. 1, 2018, 7:15 AM), https://ipwatchdog.com/2018/03/01/u-s-patent-system-americas-decline-competitiveness/id=94249 [https://perma.cc/BNB3-8699]; Wolitz, *supra* note 42, at 401.

143 *See* Morinville & Fokas, *supra* note 142.

144 *See* United States v. Apple, Inc., 791 F.3d 290, 334–35 (2d Cir. 2015) (finding that long-term competitive benefits did not justify short-term price fixing).

145 *See generally* Areeda & Hovenkamp, *supra* note 103, § 502.

146 *See supra* note 132 and accompanying text.

147 570 U.S. 136 (2013).

148 *See id.* at 136–37, 140.

149 *See* Mike Leonard, *AbbVie Wins Preliminary Antitrust Ruling in AndroGel Litigation*, Bloomberg L. (Mar. 24, 2022, 11:48 AM), https://news.bloomberglaw.com/antitrust/abbvie-wins-preliminary-antitrust-ruling-in-androgel-litigation [https://perma.cc/XDA5-QNJS] (describing the patented product as a "testosterone booster").

150 *See Actavis*, 570 U.S. at 145.

151 *See id.* at 159.

The Court decided to subject reverse payment agreements to rule of reason analysis because the agreements could improperly extend the term of Actavis's patent monopoly, thereby preventing money from "flow[ing] . . . to consumers in the form of lower prices."[152] This holding demonstrates the Court's willingness to apply the rule of reason to patent-related agreements like the reverse payment agreements at issue. But the Court stopped short of evaluating patents *themselves* under the rule of reason.[153]

Indeed, it does not appear that a patent has ever been challenged as an agreement that in and of itself unreasonably restrains trade under Section 1. If such an action were to proceed on the merits, it would provide an opportunity for a court to address the tension between patent law and antitrust law head-on by determining whether the patent is justified under the rule of reason. Part III imagines how such an action might proceed on the merits, and Part IV explains why, absent statutory changes recommended in this Note, a defendant could likely avoid litigation on the merits.

III. On the Merits: Analyzing Patents Under the Rule of Reason

This Part considers how a patent could be challenged as an agreement that unreasonably restrains trade and thereby violates Section 1 of the Sherman Act. It also clarifies that precious few patents would actually be vulnerable under the Section 1 rule of reason analysis, and the remedy in such an action would *not* be to invalidate the patent at issue. Instead, it would be to compel licensing of the challenged patent to generic drugmakers for a reasonable royalty.

A. Patents Are Contracts

Under the rule of reason, the plaintiff bears the initial burden of demonstrating that the defendant is party to a prima facie anticompetitive agreement, which, for present purposes, requires a showing that a patent is an agreement.[154] Patents are commonly referred to as contracts,[155]

---

152 *See id.* at 154.

153 *See id.* at 158–59 (holding limited to reverse payment agreements).

154 *See supra* note 129 and accompanying text.

155 *See, e.g.*, FTC v. Actavis, Inc., 570 U.S. 136, 149 (2013) ("'[T]he public is given a novel and useful invention' in 'consideration for its grant [of a patent].'" (quoting United States v. Singer Mfg. Co., 374 U.S. 174, 199 (1963) (White, J., concurring))); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l Inc., 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974))); Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."); Adelman et al.,

but since antitrust precedents generally do not describe them as such,[156] this Section argues that they indeed are contracts. As explained above,[157] a patent is an agreement between the public and an inventor wherein the public gains the knowledge of an invention via its public disclosure, and in exchange, the inventor receives a limited right to exclude others from making, selling, offering for sale, or importing their invention.[158]

Basic principles of contract law support the proposition that patents are contracts. A contract is usually formed by offer and acceptance.[159] In the case of a patent, the offer is the federal law, codified in Title 35 of the U.S. Code, promising that a patent "shall" be awarded to any person who meets the requirements of law for a patent to issue.[160] To be a legitimate offer, an offer must empower the offeree to create a contract by accepting the offer.[161] An offer can be accepted by either promise or performance, as specified in the offer.[162] An inventor is empowered to accept the offer codified at Title 35 by performing in accordance with the mandates of that Title (e.g., filing an adequate patent application to be published after eighteen months and paying the requisite fees).[163] Inventors are empowered to accept the offer in that, if their patent application meets the requirements of law, then the contract is made—the patent "shall" issue without the need for further action on the applicant's part.[164]

Although the agreement is not in effect the moment the filer accepts the offer of Title 35 by performance, as the patent does not immediately issue,[165] the acceptance is still valid.[166] The government has

---

supra note 11, at 411 ("Analogized to the contract law, the Patent Act permits the formation of binding agreements between inventors and the public. Under these agreements, inventors receive exclusive rights in exchange for full disclosure of their inventions.").

156 *See, e.g.*, Mayor of Balt. v. AbbVie Inc., 42 F.4th 709 (7th Cir. 2022) (discussing patents at length in the context of antitrust law but not acknowledging that they are agreements).

157 *See generally supra* Section II.A.

158 *See supra* note 89 and accompanying text.

159 Restatement (Second) of Conts. § 17 cmt. b (Am. L. Inst. 1981) ("The typical contract is a bargain, and is binding without regard to form."); *id.* § 3 cmt. d ("A bargain is ordinarily made by an offer by one party and an acceptance by the other party . . . .").

160 *See* 35 U.S.C. § 102(a) (providing that a person who meets the legal requirements "shall be entitled to a patent"); *id.* § 131.

161 *See* Restatement (Second) of Conts. § 24 (Am. L. Inst. 1981) ("An offer is the manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that *his assent to that bargain . . . will conclude it*." (emphasis added)).

162 *Id.* § 30 ("An offer may invite or require acceptance to be made by an affirmative answer in words, or by performing or refraining from performing a specified act . . . [u]nless otherwise indicated by [its] language . . . .").

163 *See* 35 U.S.C. §§ 102(a), 131; *supra* notes 86–88 and accompanying text.

164 *See* 35 U.S.C. §§ 102(a), 131.

165 *Id.* § 131 (providing that a patent application must be examined and approved before a patent issues).

166 *See infra* note 167 and accompanying text.

permissibly, in its offer, reserved the right to verify that the inventor's performance in acceptance of the offer accords with the requirements of Title 35.[167] By examining the inventor's patent application in accordance with USPTO procedures, the government is simply verifying that the inventor has accepted the offer codified in Title 35.

In addition to offer and acceptance, there is an exchange of valuable consideration between the government, representing the public, and the applicant: "'the public is given a novel and useful invention' in 'consideration for its grant [of a patent].'"[168] In publicly disclosing how to "make and use" their invention,[169] the applicant is giving away valuable knowledge that the applicant could have kept to themselves as a trade secret.[170] This is valuable to the public because it contributes to the body of scientific knowledge and enables the development of follow-on innovations.[171] The inventor also agrees to forfeit their patent rights after the twenty-year patent term, at which time anyone in the public may make and use the patented invention without fear of liability.[172] The government's consideration—the patent, which conveys the "right to exclude"[173]—is valuable to the applicant because it insulates them from competition.[174]

Due to the valid offer and acceptance and the exchange of consideration,[175] it is clear that a patent is a contract. Moreover, the notion that a patent is an agreement is well established, albeit not often acknowledged in the antitrust context.[176] Patents are often described as agreements in scholarship,[177] textbooks,[178] and cases.[179]

---

167 *See* RESTATEMENT (SECOND) OF CONTS. § 30 cmt. a (AM. L. INST. 1981) ("The offeror is the master of his offer.").

168 FTC v. Actavis, Inc., 570 U.S. 136, 149 (2013) (quoting United States v. Singer Mfg. Co., 374 U.S. 174, 199 (1963) (White, J., concurring)).

169 35 U.S.C. § 112(a); *see supra* note 101 and accompanying text.

170 Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 376–77 (2002).

171 Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 91 (2004).

172 *See supra* notes 100–02 and accompanying text.

173 35 U.S.C. § 154(a)(1); *see supra* note 89 and accompanying text.

174 *See supra* notes 93–94 and accompanying text.

175 *See supra* Section II.A.

176 *See supra* note 155.

177 *See, e.g.*, Rachel Marie Clark, Note, *Collateral Estoppel of Claim Interpretation After* Markman, 86 MINN. L. REV. 1581, 1583 (2002) ("A patent is an agreement between an inventor and the federal government."); R. Oosterlinck, *The Intergovernmental Space Station Agreement and Intellectual Property Rights*, 17 J. SPACE L. 23, 26 (1989) ("A patent is an agreement between a State and an inventor.").

178 *See, e.g.*, ADELMAN ET AL., *supra* note 11, at 411 ("Analogized to the contract law, the Patent Act permits the formation of binding agreements between inventors and the public. Under these agreements, inventors receive exclusive rights in exchange for full disclosure of their inventions.").

179 *See, e.g.*, cases cited *supra* note 155.

B. Which Patents Raise Concerns Under the Rule of Reason?

Very few of the approximately three million active U.S. patents[180] would raise serious concerns under a Section 1 rule of reason analysis. To meet their initial burden under Section 1, a plaintiff—for example, a state attorney general representing their state's public insurance programs—would need to demonstrate (1) the defendant has market power and (2) the defendant is party to "an agreement whose likely effect in the presence of [the defendant's market] power is an increase in price or a reduction in output."[181] For present purposes, these two elements logically merge into the sole inquiry of whether the defendant patent owner has gained market power from their patents.

The Supreme Court used to presume that all patents conferred market power on their owners.[182] But in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*,[183] the Court abandoned this presumption, agreeing with "Congress, the antitrust enforcement agencies, and most economists . . . that a patent does not necessarily confer market power upon the patentee."[184] Patents do not necessarily confer market power for antitrust purposes because some patents cover products for which comparably priced substitutes are widely available.[185] If the owner of such a patent attempted to raise the price of their product above competitive levels, consumers would simply start buying substitute products instead.[186] Consider the now expired patent on a Gillette safety razor

---

180 *See U.S. Patent Statistics Chart: Calendar Years 1963–2020*, U.S. Pat. & Trademark Off., https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm [https://perma.cc/G2XS-T56N]; *Statement of Commissioner for Patents Andrew Hirshfeld Before the United States Senate Subcommittee on Intellectual Property Committee on the Judiciary*, U.S. Pat. & Trademark Off. (Oct. 30, 2019), https://www.uspto.gov/about-us/news-updates/statement-commissioner-patents-andrew-hirshfeld-united-states-senate [https://perma.cc/H7VZ-H5VF] (mentioning that there are "approximately 3 million patents currently in force" in the U.S.); Press Release, World Intell. Prop. Org., World Intellectual Property Indicators Report: Worldwide Trademark Filing Soars in 2020 Despite Global Pandemic, U.N. Press Release PR/883 (Nov. 8, 2021), https://www.wipo.int/pressroom/en/articles/2021/article_0011.html [https://perma.cc/C87F-8LWH] (stating that there are approximately 3.3 million U.S. patents currently in force).

181 *See* Areeda & Hovenkamp, *supra* note 103, § 1914b.

182 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 16 (1984) ("[I]f the Government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.").

183 547 U.S. 28 (2006).

184 *Id.* at 45–46.

185 *See infra* notes 186–88 and accompanying text.

186 *See* Areeda & Hovenkamp, *supra* note 103, § 501 ("[F]orbidding everyone else from a [sic] making a patented product brings the defendant patentee no market power when consumers have little use for it or can buy adequate substitutes from others."); Kenneth J. Burchfiel, *Patent Misuse and Antitrust Reform: 'Blessed Be the Tie?'*, 4 Harv. J.L. & Tech. 1, 74 (1991) ("[I]n an economic sense, the essential element of market power is negated if there are acceptable substitutes for the tying product available from others at comparable prices.").

with three blades.[187] Indeed, Gillette's patent entitled it to a "monopoly" on the specific safety razors that fell within the protection of its patent,[188] but Gillette's razor still had to compete with all the other razors on the market that did not fall within its patent protection.[189] If Gillette had attempted to set prices above competitive levels, their customers presumably would have switched to a competitor's razor.[190] Accordingly, the many patents covering inventions that are either economically inviable[191] or too easily replaced with comparably priced substitutes[192] do not confer market power and thus could not be the subject of the Section 1 action proposed in this Note.

Nonetheless, "A patent may control an important market. For example, it was once impossible to project a motion picture film or make a lightbulb or plain-paper copier without access to patents that dominated those markets."[193] For any market-controlling patent, a plaintiff could easily demonstrate that the patent confers market power, if not full-blown monopoly power.[194] Such patents definitionally confer market power on their owners because the patents themselves define a market; accordingly, there are no adequate substitutes for consumers to turn to if prices rise above competitive levels[195]—which they inevitably will, assuming an economically rational patent owner.[196] Patents in this category are initial candidates for the Section 1 action proposed in this Note.

Under rule of reason analysis, the burden would then shift to the defendant to advance a procompetitive justification for its patent.[197] In most cases, the defendant would be able to advance strong, but not necessarily decisive, procompetitive justifications.[198] The defendant

---

187 U.S. Patent No. 6,212,777 (filed Sept. 22, 1994).

188 Interestingly, as construed by the Federal Circuit, this patent covered safety razors with three *or more* razors. *See* Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1371 (Fed. Cir. 2005).

189 *See, e.g.*, Randal C. Picker, *The Razors-and-Blades Myth(s)*, 78 U. Chi. L. Rev. 225, 239–43 (2011) (explaining that Gillette's patented disposable razors from the early 1900s, U.S. Patent Nos. 775,134 and 775,135, still had to compete with other noninfringing razors, such as the Ever-Ready razor and Gem Junior razor, which were priced low enough that "Gillette shavers could switch easily if Gillette blade prices were too high").

190 *See id.*

191 *See, e.g.*, Apparatus for Facilitating the Birth of a Child by Centrifugal Force, U.S. Patent No. 3,216,423 (filed Jan. 15, 1963).

192 *See supra* notes 184–187 and accompanying text.

193 Areeda & Hovenkamp, *supra* note 103, § 1737c.

194 *See id.* § 533.

195 *See id.*

196 *See id.* § 403.

197 *See supra* note 129 and accompanying text.

198 *See* Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 101 (1984) (explaining that it can be a compelling justification to show that the product market at issue would not even exist without the challenged restraint on trade).

patent owner would be able to point to the Court's holding in *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*[199] that agreements in restraint of trade can be justified on the grounds that they make something available to consumers that would otherwise be unavailable, i.e., that they bring new inventions and efficiencies to the market, or new value to consumers.[200] Using this decision, owners of market-defining patents may simply point to the evidence of their market power and say, "Look at what people are willing to pay for the product we invented. This new patented product is what we bring to consumers, and we know how much people value it because we see what they will pay for it." The patent owner would explain, "The only reason we felt comfortable investing time and money to develop such a wonderful invention is because we knew that if we succeeded, our patent protection would permit us to set high prices that recoup our initial investment."[201]

The burden would then shift back to the plaintiff to prove the existence of a less restrictive alternative, i.e., to prove that the same procompetitive objective advanced by the defendant could be achieved in a way that is less harmful to competition.[202] This Note assumes that in *almost* every case, the plaintiff would not be able to meet this burden because most patents—even most market-defining patents—are limited in the harm they can inflict on competition.[203] The reason is that patent owners' ability to set supracompetitive prices is usually limited by the fact that as prices increase, fewer consumers will purchase the product.[204] In other words, demand for most products is somewhat elastic.[205] Since consumer willingness to go without a product limits how harmful most patents can be to competition,[206] it is unlikely that a plaintiff could demonstrate a convincing, less restrictive alternative to most patents.

---

199 441 U.S. 1 (1979).

200 *See id.* at 21–22; *see also* AREEDA & HOVENKAMP, *supra* note 103, § 1504 ("The clearest and most legitimate benefit is that which makes possible the very activity that is allegedly restrained.").

201 *See* Morinville & Fokas, *supra* note 142; Wolitz, *supra* note 42, at 401; FTC EVOLVING IP MARKETPLACE REP., *supra* note 94, at 1 ("The patent system plays a critical role in promoting innovation across industries from biotechnology to nanotechnology, and by entities from large corporations to independent inventors.").

202 *See* Nat'l Collegiate Athletic Ass'n v. Alston, 594 U.S. 69, 97–91 (2021) (discussing the "less restrictive alternative" rule).

203 *See* Morgan et al., *supra* note 41, at 67 (explaining that demand for most patented goods is somewhat elastic because consumers either do not really need the goods or are willing to delay consumption until prices fall due to, e.g., increased competition after expiration of a market controlling patent).

204 *See supra* notes 114–21 and accompanying text.

205 *See* AREEDA & HOVENKAMP, *supra* note 103, § 507.

206 *See id.*

But lifesaving medicines for which there are no close substitutes are unique because consumers cannot simply go without them.[207] Thus, patents on such medicines are extremely restrictive and leave more room for a plaintiff to prove the existence of a less restrictive alternative. Patents on lifesaving pharmaceuticals are uniquely restrictive because of the sheer magnitude of the market power such patents confer on their owners.[208] Relevant attributes of the pharmaceutical industry that contribute to that market power can be summarized as follows:

> The pharmaceutical sector can potentially abuse market power because of the inelasticity of demand for necessary medicines. Unlike consumers of ordinary goods, consumers of patented medicines—also known as patients with medical needs—may not be in a position to defer consumption until prices fall. Also, unlike ordinary consumers, patients are often insulated from the cost of the treatments owing to various forms of collective financing—most notably, public or private health insurance. Companies can exploit the vulnerability of patients and collective financing schemes by asking for prices that far exceed standard definitions of value for money.[209]

A state attorney general challenging a patent on a lifesaving medicine for which there are no close substitutes could argue that consumers' (i.e., patients') unique economic vulnerabilities in the pharmaceutical industry put them at the mercy of patent owners. The resulting economic inefficiencies—prices that far exceed costs and overburden consumers, insurers, and the public at large—outweigh procompetitive justifications for the patent. The next Section explains in more detail the arguments a plaintiff could advance in their rule of reason analysis of a patent on a lifesaving medicine.

C. Magnitude of Competitive Harm and Viability of Compulsory Licensing for a Reasonable Royalty as a Less Restrictive Alternative

The Supreme Court has already acknowledged that consumer vulnerability in healthcare can ring antitrust alarm bells.[210] In particular,

---

207 *See* Morgan et al., *supra* note 41, at 67 (explaining that consumption of lifesaving medicine is often urgent, in contrast to consumption of many ordinary goods, which consumers can afford to delay); Wolitz, *supra* note 42, at 394 (arguing lifesaving medicines are necessities rather than luxuries, which differentiates them from many other valuable goods).

208 *See* Morgan et al., *supra* note 41, at 67.

209 *Id.*

210 *See* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 461–62, 464 (1986) (holding that an agreement among dentists to refuse to provide patient x-rays to the patients' insurers, thereby preventing the insurers from evaluating the fairness of treatment costs, violated Section 1).

the Court has recognized that where consumers are uninformed about the goods or services they are purchasing, "the proper functioning of the price-setting mechanism of the market [is likely to be disrupted]."[211] Consumers of lifesaving medicines are particularly vulnerable in two unique ways: first, their demand for medicines is completely inelastic, and second, they are systemically deprived of price information that they could otherwise use to negotiate lower prices.[212] Elasticity of demand is a key concept in measuring market power.[213] If demand for a product is highly elastic, meaning the quantity of the product demanded declines sharply in response to price increases, then even a firm with a very high market share for that product may not have market power.[214]

The two reasons why demand for a product would be elastic are (1) there are widely available close substitutes for the product, or (2) consumers are willing to simply go without the product.[215] The patents this Note imagines plaintiffs challenging are patents on medicines for which there are no close substitutes, so reason (1) for elasticity does not apply. And reason (2) does not apply because, due to the lifesaving nature of the medicines, consumers are unwilling—or unable—to go without them.[216] Accordingly, the demand for lifesaving medicines for which there are no close substitutes is highly inelastic. In such inelastic markets, where consumers are vulnerable and have no real choice about whether to purchase goods, the extent of a patent owner's market power is exorbitant.

This market power is enhanced by the lack of price transparency in the pharmaceutical industry.[217] Consumers are often unaware of just how much their medicines cost, and they are therefore unable to properly negotiate those prices.[218] One reason for price obscurity is the prevalence of middlemen in the pharmaceutical industry.[219] Consumers may know what they pay out of pocket for a medicine, but since

---

211 *Id.*; *see* New York v. Actavis PLC, 787 F.3d 638, 645–47 (2d Cir. 2015).

212 *See* Morgan et al., *supra* note 41, at 67 (explaining that people with life-threatening medical needs often cannot defer consumption of lifesaving medicine until prices fall and that health insurance insulates them from knowing the true cost of their medicine).

213 *See* Areeda & Hovenkamp, *supra* note 103, § 507 (noting market power varies with the rate at which buyers substitute products).

214 When consumers are simply unwilling to pay supracompetitive prices for a product, even a monopolist will have to keep prices at competitive levels. *See id.* § 532b ("When very elastic demand is not captured in the market definition, we can have a 'monopolist' without any market power.").

215 *See id.* § 507.

216 *See* Morgan et al., *supra* note 41, at 67; *see, e.g.*, *supra* note 31 and accompanying text (explaining that without a Zolgensma treatment, type one spinal muscular atrophy is usually fatal within a patient's first two years of life).

217 *See* Morgan et al., *supra* note 41, at 67.

218 *See id.*

219 *See id.*

most consumers have insurance, they are not aware of the true price of the medicine.[220] Indeed, the actual cost of a medicine generally varies depending on who a patient's insurer is and which insurance plan they are on.[221] Additionally, since insurance companies spread costs across large groups of insured people, only some of whom require the most expensive medicines, consumers are doubly removed from the costs of the medicines they consume.[222]

Consequently, for insured people, would-be outrage over price is likely diminished because the economic harm caused by unfair pricing is spread out over many people rather than concentrated on just the few people who consume the medicines.[223] However, the aggregate amount of economic harm done by supracompetitive prices is the same as if those prices were paid by individuals—it is just spread out.[224] In this way, pharmaceutical suppliers are able to keep consumer complaints to a minimum without actually reducing prices.[225] This is unique to the healthcare industry; in most industries, people know how much the products they consume cost as they review the prices and then decide whether to buy them.[226] But in healthcare, people, by and large, do not know the prices of their medicines; they are simply following their doctors' advice and hoping that insurance will cover the costs.[227] A result of this price obscurity is that consumers are unsure whether they should complain to drug manufacturers about prices or to insurers about prescription drug benefits.[228]

The procompetitive justifications for patents on lifesaving medicines are strong, as defendant patent owners can emphasize that they

---

220 *See id.*

221 *See supra* Section I.B.

222 *See* Morgan et al., *supra* note 41, at 67; *supra* Section I.B.

223 *See* Morgan et al., *supra* note 41, at 67.

224 *See generally id.*

225 *See* Wolitz, *supra* note 42, at 416 (explaining that consumers generally direct their outrage at insurers who refuse to cover certain treatments rather than at sellers who charge exorbitant prices for those treatments). But note that this is only true for insured people. Uninsured people, who are not insulated from the true prices of medications, are often financially decimated by the costs. *See generally* Karen Davis, *The Costs and Consequences of Being Uninsured*, 60 MED. CARE RSCH. & REV. 89S (2003), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_in_the_literature_2003_jun_the_costs_and_consequences_of_being_uninsured_davis_consequences_itl_663_pdf.pdf [https://perma.cc/2YGK-ZV82].

226 *See* New York v. Actavis PLC, 787 F.3d 638, 645 (2d Cir. 2015); Gregory Day, *The Necessity in Antitrust Law*, 78 WASH. & LEE L. REV. 1289, 1322 (2021) (stating that, for most goods, consumers are presumed to have options of buying a substitute item or nothing at all).

227 *See Actavis PLC*, 787 F.3d at 645–46 (discussing the "price disconnect" between patients and doctors; noting that "the doctor may not know or even care about the price [of medicine] and generally has no incentive to take the price into account"). *See generally* Court, *supra* note 38.

228 *See* Wolitz, *supra* note 42, at 416 (explaining that consumers are misled by the invisibility of drug price regulation: they only see rising insurance costs and thus a conflict between them and their insurers, rather than the true conflict, which is between consumers and drug sellers).

will have less incentive to invest in the development of lifesaving medicines if they cannot rely on patent protection for the medicines they develop.[229] Thus, a sufficient less restrictive alternative would have to preserve incentives to invest in drug R&D while preventing defendant patent owners from maintaining profit-maximizing prices. Such an alternative could likely be achieved because the gulf between pharmaceutical innovators' R&D costs and their enormous profits indicates that R&D would still be incentivized even if its profitability were substantially reduced.[230]

A less restrictive alternative could be compulsory licensing of the defendant's patent to a generic drugmaker for a reasonable royalty. To be clear, this would deprive a defendant patent owner of the right to absolutely exclude others from making and using their invention.[231] The upshot would be increased generic competition in markets for lifesaving medicines, resulting in not just greater supply and lower prices, but also lives saved. Reasonable royalties are often awarded to patent owners who prevail in patent infringement cases.[232] The Supreme Court has already upheld compulsory patent licensing for a reasonable royalty as an appropriate remedy in antitrust cases brought under section 2 of the Sherman Act.[233]

A reasonable royalty award would work as a less restrictive alternative to the absolute right to enjoin competition because reasonable royalties are calculated based on what royalty a patent owner could command in a hypothetical negotiation with a licensee, which would of course account for the patent owner's R&D costs.[234] Requiring defendants to license the patents covering their medicine for a reasonable royalty would preserve incentives to invest in R&D by permitting defendants to continue earning a profit from their patents.[235] Because the award of a reasonable royalty has been a workable remedy in

---

229 *See supra* note 201 and accompanying text.

230 *See* Wolitz, *supra* note 42, at 404–05 (From 2009 to 2019, pharmaceutical companies had higher returns on invested capital than any other sector, with an average return of 17.3%; for every $1 spent on cancer drug R&D, making the median return $14.50).

231 *See* 35 U.S.C. §§ 154(a)(2), 271 (patent owners' right to exclude).

232 *See, e.g.*, Vectura Ltd. v. GlaxoSmithKline LLC, 981 F.3d 1030, 1045 (Fed. Cir. 2020) (affirming award of a reasonable royalty for infringement of a pharmaceutical patent); Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (providing a list of factors for courts to consider when determining a reasonable royalty in an infringement case). The statutory basis for awarding a reasonable royalty in patent infringement cases is 35 U.S.C. § 284.

233 *See, e.g.*, United States v. United Shoe Mach. Corp., 110 F. Supp. 295, 351 (D. Mass. 1953), *aff'd per curiam*, 347 U.S. 521 (1954).

234 *See, e.g.*, Wright v. United States, 53 Fed. Cl. 466, 470 (2002) (factoring a patent owner's R&D costs into a reasonable royalty calculation).

235 *See Georgia-Pacific*, 318 F. Supp. at 1120 (the eighth factor directs courts to account for the profitability and commercial success of the patented product).

infringement cases,[236] it could also be a workable less restrictive alternative in an antitrust action.

Consider how compulsory licensing for a reasonable royalty could work for Zolgensma, the $2.1 million SMA medicine discussed in Section I.A. An attorney general of a state whose Medicaid program covers Zolgensma for its members—Colorado, for example[237]—could file a lawsuit against Novartis alleging a violation of Section 1.[238] The theory of harm would be that Colorado taxpayers are harmed by Novartis's exclusion of competitors from the market for Zolgensma.[239] Colorado could meet its initial Section 1 burden by alleging the existence of a contract that gives Novartis market power in the market for Zolgensma.[240] The contract in this case would be the Zolgensma patent.[241] Novartis could defend by raising the procompetitive justification that without patent protection, it would not have invested in developing Zolgensma and bringing it to market, the theory being that consumers benefit from patent protection of new medicines like Zolgensma.[242] Colorado could respond that a less restrictive alternative to absolute patent protection would be generic[243] licensing for a reasonable royalty.[244] Colorado could argue Novartis would have still had the incentive to develop and

---

236 *See, e.g.*, *id.*

237 *See* Marc Williams, *Colorado Medicaid Executes Its First Pharmaceutical Value-Based Contracts*, Colo. Dep't of Health Care Pol'y & Fin. (Mar. 22, 2022), https://hcpf.colorado.gov/colorado-medicaid-executes-its-first-pharmaceutical-value-based-contracts [https://perma.cc/7H2R-KCN6].

238 *Supra* note 16 and accompanying text.

239 *See supra* Section I.A; *supra* notes 50–55 and accompanying text (explaining how, because private insurance companies spread individual medical expenses out over large groups of insured people, those who incur minimal medical expenses pay more for insurance coverage than their insurer pays for their medical expenses, and that this overpayment rises as the price of medicine rises, culminating in situations such as the $2.1 million Zolgensma treatment, where a large group of insured people pay the high price derived from a high need and lack of competition).

240 *See supra* notes 128–29, 193–96 and accompanying text. Patents on lifesaving medicines can grant control of important markets if the medicine is novel and there are no adequate substitutes for consumers.

241 *See* U.S. Patent No. 7,906,111 (filed Sept. 30, 2004); *supra* Section III.A.

242 *See supra* notes 197–201 and accompanying text; *see also* Yates, *supra* note 100.

243 Zolgensma is a type of medicine called a "biologic." *See How ZOLGENSMA Works*, Zolgensma, https://www.zolgensma.com/how-zolgensma-works [https://perma.cc/CFU9-7RK5] (Zolgensma "is a type of medicine called gene therapy."); *What is Gene Therapy?*, U.S. FDA (July 25, 2018), https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy [https://perma.cc/L8U9-3MA2] ("Gene therapy products are biological products regulated by the FDA's Center for Biologics Evaluation and Research."). "Generic" versions of biologics are usually called "biosimilars" rather than "generics," but because both "generic" and "biosimilar" refer to imitations of branded drugs, this Note uses "generics" broadly to include both traditional generics and biosimilars. *See Biological Product Definitions*, U.S. FDA, https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf [https://perma.cc/PGK5-95NU].

244 *See supra* notes 229–36 and accompanying text.

market Zolgensma if Novartis were entitled to a reasonable royalty from competitors.[245]

If the court were convinced of the less restrictive alternative, Novartis would be liable for a Section 1 violation, and the court could fashion an appropriate compulsory licensing remedy.[246] An appropriate remedy would first, forbid Novartis from seeking to enjoin generic drugmakers from developing and marketing a Zolgensma generic, and second, establish a reasonable royalty based in part on the costs of developing Zolgensma, which Novartis could permissibly solicit from any infringing generic drugmaker. The court would likely have to retain continuing jurisdiction over the case to ensure Novartis's compliance with the remedy and then adjudicate any future issues that may arise regarding, for example, whether a generic attempting to come to market is actually infringing the Zolgensma patent and, therefore, required to pay the reasonable royalty.[247]

The result would be that a generic version of Zolgensma could be developed and brought to market without liability for patent infringement beyond the reasonable royalty. If the reasonable royalty is low enough, generic drugmakers will be incentivized to try their hand at developing a generic.[248] After securing Food and Drug Administration ("FDA") approval for the generic, the generic drugmakers would be able to come to market and compete with brand-name Zolgensma.[249] Price competition would do the rest; lower prices would lessen the burden on insurers and patients and improve access to Zolgensma.[250] As a result, more SMA patients could survive.[251]

Plaintiffs could use this Section 1 theory to introduce competition into markets for several other patent-protected medicines. The theory could work for any medicine that (1) is protected by one or more patents, (2) is medically necessary to save patients' lives, and (3) has no

---

245 *See generally supra* note 230 and accompanying text. But this argument would depend on facts specific to Novartis's business, which Colorado could obtain through discovery.

246 *See supra* note 131 and accompanying text (discussing liability where the court finds there is a less restrictive alternative to the defendant's conduct); 15 U.S.C. § 4 (statutory authority for injunctive relief).

247 *See, e.g.*, United States v. United Shoe Mach. Corp., 110 F. Supp. 295, 351, 354 (D. Mass. 1953), *aff'd per curiam*, 347 U.S. 521 (1954) (establishing continuing jurisdiction to enforce the court's remedy of compulsory patent licensing for a reasonable royalty where the defendant violated antitrust law).

248 The lower the royalty, the more likely it is for generics to enter the market. *See* Areeda & Hovenkamp, *supra* note 103, § 421c ("One is much readier to invest $1 than $20 for a 10 percent chance of reaping $100 annually.").

249 "Federal law requires all new drugs in the U.S. be shown to be safe and effective for their intended use prior to marketing." *Unapproved Drugs*, U.S. FDA (June 2, 2021), https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/D7CU-UKNJ].

250 *See generally supra* Section I.B.

251 *See supra* note 38 and accompanying text.

close substitutes. A complete list of medicines fitting these criteria is beyond the scope of this Note,[252] but the list would likely include several of the most expensive biologic[253] and small molecule medicines.[254]

IV. Off the Merits: The Case for Antitrust Immunity and Other Considerations

The antitrust action proposed in this Note, while plausible on the merits, would likely fail before proceeding to the merits due to a defendant's strong case for implied immunity from antitrust liability. The main flaw with the action proposed in this Note is that it relies on the premise that a patent owner could be forbidden from exercising their rights under a valid patent, granted by operation of federal statutory law, on grounds that the exercise of those rights would violate another federal law.[255] Congress deliberately crafted the patent laws[256] and presumably did not intend for the rights granted to inventors under those laws to violate other laws, such as Section 1,[257] that were also deliberately crafted by Congress.[258] Nonetheless, the rule of reason analysis conducted in Part III reveals that the policy rationales for robust and absolute patent protection wear thin in markets for lifesaving medicines for which there are no close substitutes.[259] Accordingly, Congress

---

252 The bounds of such a list would be difficult to demarcate. Consider, for instance, the issues that might arise in determining what exactly counts as a drug that is "medically necessary to save patients' lives" for present purposes. But note that extremely high prices of certain drugs provide a strong indication that those drugs fit the criteria, as these criteria enable extremely high drug prices in the first place. *See, e.g.*, *supra* Section I.A (discussing how Zolgensma's price came to be so high and why other lifesaving medicines also have such high prices).

253 "[Biologics] are generally large, complex molecules. [They] may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs." *Biological Product Definitions*, *supra* note 243. Biologics tend to be more expensive than small molecules. Favour D. Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, Med. in Drug Discovery, Mar. 2021, at 4–7. Zolgensma is an example of a biologic that could be challenged under the Section 1 theory in this Note. *See supra* notes 238–52 and accompanying text.

254 Small molecule medicines are "drugs made by chemical synthesis . . . . Most patented drugs in the market and their generics are small molecules." Makurvet, *supra* note 253, at 1. A small molecule medicine that could be challenged under the Section 1 theory in this Note is Trikafta, a cystic fibrosis treatment that costs "roughly $326,000 per patient per year." Fraiser Kansteiner, *Vertex Pricing Under Fire—Again—as Activists Press 4 Governments for Trikafta Generics*, Fierce Pharma (Feb. 7, 2023, 10:59 AM), https://fiercepharma.com/pharma/vertexs-trikafta-pricing-under-pressure-again-patients-and-activists-press-4-governments [https://perma.cc/WL6K-6EKC].

255 *See supra* Part II.

256 35 U.S.C. §§ 1–390.

257 15 U.S.C. § 1.

258 *See* United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., 484 U.S. 365, 371 (1988) (standing for the proposition that statutory provisions should be read so that they "produce[] a substantive effect that is compatible with the rest of the law").

259 *See supra* Part III.

should consider amending Chapter 1 of Title 15 of the U.S. Code to abrogate patents' implied immunity from antitrust enforcement to the extent such immunity exists.

Statutory and common law rules establish various antitrust immunities.[260] For example, under 15 U.S.C. § 17, workers who agree to collectively negotiate via a labor union are immune from antitrust enforcement against legitimate union activities.[261] In addition to these explicit immunities, the Supreme Court has recognized some implicit immunities to antitrust enforcement for various activities related to federal and state government action.[262] In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,[263] the Court made the broad comment that "it has been held that where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the [Sherman] Act can be made out."[264] But in that case, the comment was dicta,[265] and in the cases cited to support the comment, the holdings were limited to the particular government actions challenged, not government action generally.[266] While the Court has not explicitly held that implied antitrust immunity protects the exercise of one's absolute right to exclude under a valid patent, it has assumed as much.[267] Accordingly, it is unlikely that the Section 1 action described in this Note would succeed in court if brought under current federal law.

The likelihood that such an action would not succeed in court merely highlights an opportunity for Congressional intervention. Prescription drug prices, especially for patent-protected lifesaving medicines for which there are no close substitutes, are exorbitant and

---

260 *See, e.g.*, 15 U.S.C. §§ 13c, 17, 37, 37b; United States v. Rock Royal, 307 U.S. 533, 559–60 (recognizing implied immunity for federal statutory and regulatory scheme permitting price fixing in the milk industry).

261 *See* 15 U.S.C. § 17.

262 *See, e.g.*, *Rock Royal*, 307 U.S. at 559–60 (recognizing implied immunity for federal statutory and regulatory scheme permitting price fixing in the milk industry where milk producer associations had "a vital interest in the establishment of an efficient marketing system"); Parker v. Brown, 317 U.S. 341, 352, 362–63 (1943) (antitrust immunity for certain state regulatory schemes permitting price fixing due to state sovereignty, where state schemes did not "substantially impair[] the national interest in the regulation of commerce"); E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961) (antitrust immunity for people who successfully petitioned their state government to establish a monopoly).

263 365 U.S. 127 (1961).

264 *Id.* at 136.

265 *See id.* at 127–28, 136.

266 *See Rock Royal*, 307 U.S. at 559–60; *Parker*, 317 U.S. at 352, 363.

267 *See* FTC v. Actavis, Inc., 570 U.S. 136, 148 (2013); United States v. Line Material Co., 333 U.S. 287, 305 (1948) (listing among uncontested issues in the case, "[w]ithin the limits of the patentee's rights under his patent, monopoly of the process or product by him is authorized by the patent statutes").

place an unjustified burden on the public.[268] The antitrust rule of reason provides a suitable framework for identifying patents that are not justified under the usual innovation-incentivization rationale for patents.[269] While the Supreme Court has narrowed the reach of antitrust law with the implied immunity doctrine, perhaps it is time for a return to the century old principle that "[patent rights] are indeed very definite and extensive, but they [are not] a[] universal license against positive prohibitions. The Sherman law is a limitation of . . . rights which may be pushed to evil consequences and therefore restrained."[270]

To avail the Section 1 action proposed in this Note to state attorneys general, Congress should amend Title 15, Chapter 1 of the U.S. Code by adding the following section setting forth the circumstances under which a plaintiff could bring a Section 1 action challenging a patent as an unreasonable restraint of trade[271]:

* * *

15 U.S. Code § 39 - Antitrust laws applicable to patents on lifesaving medicines

(a) Patents are contracts

For purposes of determining liability under section 1 of this title, a valid United States patent is a "contract."[272]

(b) Persons who may bring an action under section 1 alleging a patent unreasonably restrains trade

Only a state attorney general may bring an action against a patent owner on the theory that a patent unreasonably restrains trade.[273]

(c) Patent subject matter limitation

A patent is subject to challenge under Section 1 as an unreasonable restraint of trade only if it covers a lifesaving medicine.

(d) Definition of "lifesaving medicine"

(i) As used in subsection (c), "lifesaving medicine" means any drug or biological product that, if properly administered, is reasonably likely to prevent death for a substantial portion of patients having the condition the drug treats.[274]

(ii) "Life-saving medicine" shall be construed broadly.

---

268 *See* discussion of Zolgensma *supra* Sections I.A, III.B–.C.

269 *See supra* Section III.B.

270 Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 49 (1912).

271 Note that the footnotes in this proposed code section are intended as substantiation for the purposes of this Note, not additional proposed statutory language.

272 *See supra* Section III.A.

273 *See* 15 U.S.C. § 9.

274 *See, e.g.*, *supra* note 32 and accompanying text (Zolgensma, when properly administered, can extend the lives of those with SMA for up to several years).

(iii) The applicable definition of "drug" is provided in section 321(g)(1) of title 21, and the applicable definition of "biological product" is provided in section 262(i)(1) of title 42.[275]

(e) Applicable remedies

(i) Where a patent is proven to unreasonably restrain trade under section 1, the district court shall issue a decree-

(A) forbidding the defendant from seeking, in any United States forum, injunctive relief against alleged patent infringers whose alleged infringement results from the alleged infringer's good faith attempt to develop and market a medicine that is bioequivalent or biosimilar to the medicine covered by the challenged patent;[276]

(B) permitting the defendant to solicit a reasonable royalty from patent infringers whose infringement results from a good faith attempt to develop and market a medicine that is bioequivalent or biosimilar to the medicine covered by the challenged patent;[277]

(C) establishing the district court's continuing jurisdiction, for a reasonable time, over the matter to oversee enforcement of the decree and resolve any issues that arise as to, for example, whether a third party has actually infringed the defendant's patent, or the reasonableness of a royalty.[278]

(ii) For purposes of this section, a reasonable royalty is a royalty substantially likely to result in the defendant's recovery of costs the defendant incurred for the research and development of the medicine in question. A royalty is reasonable only if it preserves, to some extent, innovators' incentives to invest in the development of new lifesaving medicines. The reasonableness of a royalty is within the district court's discretion.[279]

---

275 This provision defines drugs and biologics consistently with the definitions used by the FDA. *See* 21 U.S.C. § 321(g)(1); 42 U.S.C. § 262(i)(1).

276 *See* 15 U.S.C. § 1 (granting district courts some discretion in deciding how to punish antitrust violations); 15 U.S.C. § 9 (providing for district courts to be "invested with jurisdiction to prevent and restrain violations" in context of other antitrust violations).

277 *See supra* notes 233–36 and accompanying text (explaining why a reasonable royalty is a viable remedy).

278 *See supra* note 247 and accompanying text.

279 *See supra* notes 230, 248 and accompanying text (discussing reasonableness of royalties and R&D).

(iii) A finding of liability under Section 1 has no effect on the validity of the challenged patent.
(iv) Monetary damages may not be awarded where a defendant is liable under Section 1 only for ownership of a patent that unreasonably restrains trade.[280]

* * *

The main consequence of this proposed new section is that, where a violation is proven, the defendant may no longer use their patent to fully exclude competitors from the market; they may use it only to solicit a reasonable royalty from generic competitors.

Conclusion

The long-term global economic supremacy envisioned by patent law and day-to-day economic efficiencies championed by antitrust law are, in some respects, irreconcilable. However, Congress should not sit idly by in the face of this tension while patients' access to lifesaving medicine hangs in the balance. Upholding a patent owner's absolute right to exclude infringers is, in most circumstances, reasonable and justified by the strong incentive to innovate that the U.S. economy relies on.[281] But that justification only carries so much weight, and it may not sufficiently justify the right to exclude competitors from markets for lifesaving medicines. Under a rule of reason analysis, some patents on lifesaving medicines could be found to unreasonably restrain trade,[282] but due to patents' probable immunity from antitrust law, that rule of reason analysis is likely unreachable absent congressional intervention.[283] By amending federal antitrust law as recommended in this Note, Congress could preserve the incentives of patent law, lift an enormous financial burden off the public, and improve patients' access to lifesaving medicines.[284]

---

280 This provision is intended to avoid a chilling effect on R&D by limiting defendants' potential liability.

281 *See supra* notes 197–206 and accompanying text.

282 *See supra* Sections III.B–.C.

283 *See supra* Part IV.

284 *See id.*