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**PATENTED BRAND DRUGS ARE
ESSENTIAL FACILITIES AND
REGULATORY COMPACTS**

Clovia Hamilton & Gerald Stokes



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PATENTED BRAND DRUGS ARE ESSENTIAL FACILITIES AND REGULATORY COMPACTS

Clovia Hamilton & Gerald Stokes†*

ABSTRACT—The COVID-19 health pandemic highlighted the need for more readily affordable patented drugs. Brand drug companies argue that they need to recuperate their research and development (“R&D”), marketing and advertising expenses. The incentive to innovate also needs to be preserved. Drug companies are entitled to a profit and a return on their investment, just as afforded to utility monopolies. Intellectual property and human rights clash relative to access to patented drugs. We provide several proposed approaches to resolve this dilemma and conclude with an argument that patented drugs should be considered a public utility. A model based on the public utility approach has a great deal of merit as a model for setting prices for essential drugs and treatments. The price, however, setting should not be the province of back-room discussions between drug companies and insurers. Prices should be negotiated in public with full transparency just as electricity rates. Investor-owned utilities are profitable essential facilities that are of great benefit to consumers and provide reasonable and regular return on investment for their owners. This can happen for manufacturers of essential drugs as well.

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I. BACKGROUND

The COVID-19 pandemic health crisis highlighted the need for more readily affordable patented brand drugs. Prior to the pandemic, worldwide spending on prescription drugs was \$1.3 trillion and \$350 billion in the United States. Prescription drugs are costly and “[a]pproximately 25% of Americans find it difficult to afford prescription drugs due to high out-of-pocket costs.”¹ High costs threaten individual patients’ wellness.² More than thirteen percent of American adults have reported knowing at least one person in the past five years who died after not receiving needed medical treatment due to inability to pay for the treatment.³ Further, the lockdowns during the pandemic also caused business closures and an increase in unemployment. Once some individuals lost their jobs, they lost their health care insurance.⁴

The United States grants patent holders twenty years of exclusivity beginning with the patent application filing date for new drug patents.⁵ This is also granted by member countries to the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) agreement.⁶ The twenty-year market exclusivity granted to drug patent holders drives up drug prices. This yields a natural monopoly.⁷ The rationale for the lengthy twenty years of exclusivity

¹ S. Vincent Rajkumar, *The High Cost of Prescription Drugs: Causes and Solutions*, 10 BLOOD CANCER J. 71, 71 (2020).

² *Id.*

³ Dan Witters, *Millions in U.S. Lost Someone Who Couldn’t Afford Treatment*, GALLUP (November 12, 2019), <https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx> [<https://perma.cc/4F99-6J6Q>].

⁴ See Jessica Schorr Saxe, *The Other Epidemic: Lack of Health Insurance for all Americans*, THE CHARLOTTE POST, May 27, 2020.

⁵ 35 U.S.C. § 154(a)(2) (2013).

⁶ Info. and Media Rel. Div. of the World Trade Organization [WTO] Secretariat, *TRIPS and Pharmaceutical Patents: Fact Sheet*, (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf [<https://perma.cc/R5MU-GZVB>].

⁷ See EUR. COMM’N. DIRECTORATE-GEN. FOR INTERNAL MKT., INDUS., ENTREPRENEURSHIP AND SMES, *STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE: FINAL REPORT* (2018); Shubha Ghosh, *Decoding*

is to help brand drug companies recuperate their research and development (“R&D”) expenses and have an incentive to continue to invest in R&D.⁸ Less profits result in less attractiveness to investors and less research.⁹ So, any proposed solution for the lowering of drug prices needs to preserve the incentive for drug companies to innovate.¹⁰ Some believe that facilitating broad use of new medications may “choke off this research” resulting in less innovation and fewer treatments.¹¹

Brand drug manufacturers also argue that they need the lengthy twenty years of exclusivity in order to cover their hefty marketing and advertising costs. While the prescription medicine demand ought to be inversely related to drug costs and directly related to marketing expenditures, patent expirations should reduce the price of a drug and the marketing expenditures. Law professor Rena Conti and management professor Frank Berndt (2018) studied loss of U.S. patent exclusivity and use for specialty drug prices with data from 2001 to 2007.¹² They observed a decline in prices after generic entry.¹³ The largest decline was physician administered drugs compared to oral drugs.¹⁴ They found that brand drugs increased in price over time and the generic drugs fell upon loss of exclusivity.¹⁵

Professors Gautier Duflos and Frank Lichtenberg (2012) noted that “[p]rice and marketing expenditure both decline by about 50-60% in the years immediately following generic entry, but the number of prescriptions remains essentially constant during those years.”¹⁶ The two consequences of

and *Recoding Natural Monopoly, Deregulation, and Intellectual Property*, 2008 U. ILL. L. REV. 1125, 1126-84 (2008).

⁸ See MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS & HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW 34 (1998).

⁹ See Sarah Kliff, *The True Story of America’s Sky-High Prescription Drug Prices*, VOX (May 10, 2018, 9:19 AM), <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> [<https://perma.cc/ZE5T-XQ4H>]. See also CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 22 (Feb. 11, 2020) (citing Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, 17 MINN. J.L. SCI. & TECH. 663, 688–92 (2016)).

¹⁰ See Eric Lamm, *Keeping Consumers out of the Crossfire: Final-Offer Arbitration in the Pharmaceutical Market*, 65 UCLA L. REV. 926 (2018).

¹¹ LAURENCE R. HEIFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 90 (2011).

¹² Rena M. Conti & Ernst R. Berndt, *Specialty Drug Prices and Utilization After Loss of U.S. Patent Exclusivity, 2001-2007*, in MEASURING AND MODELING HEALTH CARE COSTS 273 (Ana Aizcorbe, Colin Baker, Ernst R. Berndt & David M. Cutler ed., 2018).

¹³ See *id.*

¹⁴ *Id.* at 294.

¹⁵ *Id.*

¹⁶ Gautier Duflos & Frank Lichtenberg, *Does Competition Stimulate Drug Utilization? The Impact of Changes In Market Structure on US Drug Prices, Marketing and Utilization*, 32 INT’L REV. L. & ECON. 95, 95 (2012).

more competition from generics are lower prices and lower marketing expenses.¹⁷ In contrast, Conti and Berndt's (2018) found that 2001-2007 drug sales and sales revenues for both brand and generic drugs increased. Thus, with sales being indicative of consumption. These two almost exactly offset one another, so the net effect of patent expiration on drug use is zero.¹⁸ Yet, in 2017, management professor Ernst Berndt, law professor Rena Conti, and economics research Stephen Murphy found evidence that generic drug prices are dramatically rising over time "particularly following the implementation of the 2010 Affordable Care Act and the 2012 Generic Drug User Fee Amendments."¹⁹ Drug prices decrease significantly after patents expire due to generic entry, but the extent to which drug prices decrease differed between countries.²⁰

Harvard University professors of medicine Richard Frank and Andrew Hicks, along with management professor Ernst and Berndt noted in 2019 that generic price increases need to be put in context because "on balance in the U.S. consumers have experienced substantial price declines for generic drugs," but consumers are burdened by more cost sharing.²¹ Generic price increases can be attributed to mergers and acquisitions.²² Markets for generic drugs get consolidated which leave them open to shortages which increase prices.²³ Non-patent and generic drug prices in the United States are four times greater than in comparable English-speaking, high-income countries.²⁴ Researchers attribute price markups to the market power of drug suppliers rather than wholesale intermediaries or pharmacies.²⁵

In the United States, the cost of anticancer drugs surpasses \$100,000 annually for a single course of treatment.²⁶ Multinational pharmaceutical companies such as the brand name company Pfizer enjoy extremely large

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Ernst R. Berndt, Rena M. Conti & Stephen J. Murphy, *The Landscape of US Generic Prescription Drug Markets, 2004-2016* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 23640, 2017).

²⁰ See Gerard T. Vondeling, Qi Cao, Maarten J. Postma & Mark H. Rozenbaum, *The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review*, 16 APPLIED HEALTH ECON. & HEALTH POL'Y 653, 656-59 (July 17, 2018).

²¹ Richard G. Frank, Andrew Hicks & Ernst R. Berndt, *The Price To Consumers of Generic Pharmaceuticals: Beyond the Headlines* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 26120, 2019).

²² Berndt, *supra* note 19, at 29-31.

²³ 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, 1022-24 (2020).

²⁴ Sharat Ganapati & Rebecca McKibbin, *Markups and Fixed Costs in Generic and Off-Patent Pharmaceutical Markets* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 29206, 2021).

²⁵ *Id.*

²⁶ Sham Mailankody & Vinay Prasad, *Five Years of Cancer Drug Approvals, Innovation, Efficacy and Costs*, 1 JAMA ONCOLOGY 539, 539 (2015).

profits from their blockbuster drugs and earn margins up to 90%.²⁷ The top 20 most expensive drugs range from \$27,421 to \$71,305 a month. Insurance covers most of these hefty prices.²⁸ However, 5.4 million American workers are thought to have lost their health insurance between February and May of 2020 due to COVID layoffs.²⁹ Further, in developing countries “[i]t does not matter if the cost of a drug is \$100 or \$180 a year if the average salary in a particular country is \$560 a year.”³⁰ As a result, many people cannot afford to buy their medications.³¹

In 2010, the pharmaceutical industry experienced a “patent cliff” when a number of best-selling drugs had patents that would expire between 2010 and 2015.³² In 2011, Lipitor, Caduet, Combivir and Solodyn patents expired.³³ After patents expire, generic competition brings drug prices close to marginal production cost.³⁴ Economic policy researcher Dean Baker estimated that drug patents raise prices by an average of 300-400% over those found in the open, competitive market.³⁵ When prices exceed marginal cost, there is a deadweight loss imposed on the economy.³⁶ The prices may be higher than marginal cost because of trade restrictions or rules.³⁷ Baker noted that “the gaps between price and marginal cost that result from most trade barriers or regulations are trivial compared to the gaps that are created by patent protection in the pharmaceutical industry.”³⁸ The associated

²⁷ Jack DeRuiter & Pamela L. Halston, *Drug Patent Expirations and the “Patent Cliff,”* 37 U.S. PHARM. 12 (June 20, 2012), <https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff> [https://perma.cc/SXP2-GRRG].

²⁸ Samantha McGrail, *GoodRx Names Top 20 Most Expensive Prescription Drugs in 2020*, PHARMA NEWS INTELLIGENCE (Feb. 18, 2020), <https://pharmanewsintel.com/news/goodrx-names-top-20-most-expensive-prescription-drugs-in-2020> [https://perma.cc/PDX2-3ZXT].

²⁹ Sheryl Gay Stolberg, *Millions Have Lost Health Insurance in Pandemic-Driven Recession*, N.Y. TIMES (July 13, 2020), <https://www.nytimes.com/2020/07/13/us/politics/coronavirus-health-insurance-trump.html> [https://perma.cc/FV8H-LXYG].

³⁰ Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK J. INT’L L. 363, 387 (2017).

³¹ *Id.*

³² DeRuiter & Halston, *supra* note 27.

³³ *Id.*

³⁴ See Julio Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries* 27–28 (The World Bank, Working Paper No. 502, 1990); see also Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 383, 385, 389–90 (1994) (conducting empirical studies illustrating the 1984 Hatch-Waxman Act’s impact on generic competitors’ ease of entry upon patent expiration as a driver of price competition).

³⁵ Dean Baker, *Financing Drug Research: What Are The Issues?*, CTR. FOR ECON. & POL’Y RSCH. 2 (Sept. 22, 2004).

³⁶ *Id.* at 6.

³⁷ *Id.*

³⁸ *Id.*

deadweight efficiency loss due to drug patent protection was estimated to surpass \$100 billion annually by the end of 2014.³⁹

In addition to the excessive profit noted above for patented drugs, there are cases where a dominant market player engages in predatory pricing. There are three well known cases of predatory drug pricing. The first is where the hedge fund manager Martin Shkreli formed Turing Pharmaceuticals and acquired the drug Daraprim.⁴⁰ He raised the price from \$13.50 to \$750 per pill.⁴¹ The second case involved Valeant Pharmaceuticals' acquisition of Medicis Pharmaceuticals in 2013. Valeant acquired intellectual property rights to the Calcium ethylene-diamine tetraacetate ("EDTA") lead poisoning treatment which had a price of \$950.⁴² Once Valeant took ownership, the price was increased to \$26,927 in the United States.⁴³

The third well-known case is when brand name company Mylan increased the price of EpiPens from \$57 to \$500 after it acquired the auto injector in 2007.⁴⁴ By 2016, Mylan was charging \$700 for an auto-injector two pack. A generic reached the market in 2016 and that twin pack sold for \$400.⁴⁵ In 2017, Mylan settled with the U.S. Department of Justice for \$465 million over charging excessively for the EpiPens.⁴⁶ Mylan sold both until the U.S. Food and Drug Administration ("FDA") approved of the Teva Pharmaceutical generic version in 2018.⁴⁷ Generic competition forces the original patent holders to reduce their prices.⁴⁸ More recent research,

³⁹ *Id.* at 25.

⁴⁰ See Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone is Missing the Point*, THE NEW YORKER (Feb. 5, 2016), <https://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point> [<https://perma.cc/GT7H-CNGA>].

⁴¹ 'Pharma Bro' Martin Shkreli is Ordered to Return \$64M, Barred from Drug Industry, NPR (Jan. 14, 2022, 3:13 PM), <https://www.npr.org/2022/01/14/1073161736/pharma-bro-martin-shkreli-barred#:~:text=Shkreli%20was%20CEO%20of%20Turing,decades%2Dold%20drug%20in%202015> [<https://perma.cc/Y7RZ-TENW>].

⁴² Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, J.L. & THE BIOSCIENCES, 205, 205 (2017).

⁴³ *Id.*

⁴⁴ Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016), <https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=362c0dee280c> [<https://perma.cc/D5SW-X7RS>].

⁴⁵ Tori Marsh, *2 Years After the EpiPen Price Hike, Here's What's Changed*, GOODRX (Aug. 16, 2018), <https://www.goodrx.com/epinephrine-epipen/epipen-price-change-since-mylan-released-generic-epinephrine> [<https://perma.cc/M5NZ-6LB7>].

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ See Nogués, *supra* note 34, at 26–27; *see generally* Conti & Berndt, *supra* note 12 (examining the impact of generic competition on drug prices and administration of prescription drugs through empirical studies).

however, suggests that even the generic drug prices are significantly increasing.⁴⁹

The drug Humira can cost a consumer \$2,669 per month in the United States, \$1,362 in the United Kingdom (“U.K.”) and \$822 in Switzerland.⁵⁰ Three million people suffer from Hepatitis C in the United States.⁵¹ The cost of the three-month course of Solvadi for Hepatitis C is \$84,000.⁵² Interestingly, in India, a generic version costs \$200.⁵³ Furthermore, “[n]et prices for brand-name prescription drugs in the United States rose by 60% from 2007 to 2018.”⁵⁴

The United States allows pharmaceutical companies to determine their own pricing.⁵⁵ In other countries, however, government agencies meet with pharmaceutical companies to haggle and negotiate prices.⁵⁶ Due to price negotiations between their governments and the pharmaceutical industry, other wealthy countries spend much less on prescription pharmaceuticals than the United States does.⁵⁷ Drug manufacturers are not allowed to set their own prices.⁵⁸ It is important to note that “[o]ther countries regulate the price of drugs because they see them as a public utility.”⁵⁹ Professors François Lévêque and Shubha Ghosh have compared public utilities and patents as a

⁴⁹ Berndt et al., *supra* note 19, at 25; Frank et al., *supra* note 21, at 3. *See also* Ganapati & McKibbin, *supra* note 24, at 2–3 (demonstrating through empirical analysis that generic and off-patent drugs are significantly more expensive in markets with limited supplier competition).

⁵⁰ Kliff, *supra* note 9.

⁵¹ Dean Baker, Co-Director, Ctr. for Econ. and Policy Research, *Remarks at Uppsala University’s Svedberg Seminar: Drugs are Cheap: Why Do We Let Governments Make Them Expensive?* (Feb. 13, 2017), in CEPR PUBL’NS., Mar. 2, 2017, at 2.

⁵² *Id.* at 1.

⁵³ *Id.* at 2; *but cf.* Amy Kapczynski & Aaron S. Kesselheim, ‘Government Patent Use’: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFFS. 791, 791 (2016) (asserting Solvadi is produced by generic manufacturers in India for \$1,000 per course of treatment, which is still well below \$84,000 per course in the United States).

⁵⁴ Liam Bendicksen, Benjamin N. Rome, Jerry Avorn & Aaron S. Kesselheim, *Pursuing Value-Based Prices for Drugs: A Comprehensive Comparison of State Prescription Drug-Pricing Boards*, THE MILBANK Q, 1162, 1163 (2021).

⁵⁵ *See* DEAN BAKER, REDUCING WASTE WITH AN EFFICIENT MEDICARE PRESCRIPTION DRUG BENEFIT 2 (2013).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*; *see also* Amir Attaran, Tim Mackey & Reed Beall, *Lowering the High Cost of Cancer Drugs—III*, 91 MAYO CLINIC PROCS, 399, 399 (2016) (discussing how new cancer medicines in the U.S. are priced above those in other countries). However, the authors warn that buying drugs from those countries such as Canada may be risky because they may be fake and have no active ingredients, and when Americans purchase from other countries they may be draining a small country’s small supply of drugs.

⁵⁹ Kliff, *supra* note 9.

type of natural monopoly.⁶⁰ To assure profitability, “industry-specific regulation law and intellectual property law have an impact on dynamic economic efficiency.”⁶¹ Ghosh pointed out that the intellectual property policy debates twelve years prior paralleled the 1970s and 1980s deregulation movement which defined intellectual property as a regulated natural monopoly.⁶²

II. AMERICAN DRUG PRICE REDUCTION EFFORTS

A. Medicare Prescription Drug Improvement and Modernization Act

Medicare is a government health insurance program that the Centers for Medicare and Medicaid Services (“CMS”) oversees which is designed for all Americans at least 65 years of age. Part B covers outpatient prescription drugs which are typically “large molecule, injectable or infused biologics” for treating conditions such as arthritis or cancer. Part D is a standard pharmacy benefit plan covering small molecule drugs.⁶³ Medicaid is a joint federal–state health care program for Americans with low-income and disabilities. All states cover outpatient prescription drugs, and the majority of drug makers have voluntary rebate deals with the CMS.⁶⁴

In the United States, consumer drug prices are “decided each year at a negotiating table, where insurance companies leverage price concessions from drug companies by threatening to limit coverage for a certain drug.”⁶⁵ Congress debated this in 2003. The noninterference provision in the 2003 Medicare Prescription Drug Improvement and Modernization Act (“MMA”), which was supported by pharmaceutical lobbyists, forbids Medicare from negotiating drug prices.⁶⁶ Medicare was anticipated to bargain for lower prices with the pharmaceutical industry by using its market dominance. Instead, they must buy insurance from for-profit, private companies that receive government subsidies.⁶⁷ With many insurers acting

⁶⁰ See generally François Lévêque, *Pharmaceutical Regulation and Intellectual Property: The Third Side of the Triangle*, (Centre D’Économie Industrielle at Mines ParisTech, Working Paper No. 2009-03, 2009); see Ghosh, *supra* note 7, at 1140, 1151–1160.

⁶¹ Lévêque, *supra* note 60.

⁶² Ghosh, *supra* note 7.

⁶³ Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 82–83 (2020).

⁶⁴ *Id.*

⁶⁵ Lamm, *supra* note 10, at 926.

⁶⁶ Hagop Kantarjian, Donald W. Light & Vivian Ho, *The “American (Cancer) Patients First” Plan to Reduce Drug Prices—A Critical Assessment*, 93 AM. J. HEMATOLOGY 1444 (2018).

⁶⁷ BAKER, *supra* note 55, at 1.

as buyers, Medicare is less likely to be able to negotiate lower prescription drug prices.⁶⁸

Medicare does not negotiate drug prices in the United States because within the Medicare Modernization Act, Pharmacy Benefit Managers (“PBMs”) working in private corporations were put in charge of acquiring drugs through Medicare’s Part D plan. The PBMs comprise an industry of professionals that act as middlemen to negotiate pricing with hospitals or insurers and drug companies at a significant discount from the list prices. The uninsured, however, do not benefit from this and might have to pay the full list price.⁶⁹ On behalf of health insurance providers, PBMs oversee prescription drug coverage, determine how much pharmacies are paid and influence which medications are prescribed the most frequently. PBMs get paid from fees from payers, fees from the maintenance of pharmacy networks, and a part of the financial savings from drug companies’ rebates they negotiate.⁷⁰

PBM managed drug plans are used by 266 million Americans, so the bulk of prescription medications are distributed by PBMs around the United States. Yet, one problem is that the PBM operations are hidden and the lack of transparency could be hiding the possibility of them profiting too much and not passing savings on to consumers.⁷¹ There is a need for transparency since “PBM practices are largely opaque, raising questions about whether PBMs contribute to rising drug prices.”⁷² The Medicare Negotiation and Competitive Licensing Act, H.R. 4811 was to serve to put Medicare in charge of negotiations and of acquiring the lowest drug prices possible.⁷³ H.R. 4811 was introduced by Congressman Lloyd Doggett of Texas and referred to the Committee on Health in July 2021. It was referred to the Subcommittees on Health in the Committees of Ways and Means and Energy

⁶⁸ KANTARJIAN et al., *supra* note 66, at 1446.

⁶⁹ BAKER, *supra* note 51, at 5.

⁷⁰ Cole Werble, *Pharmacy Benefit Managers*, 12 HEALTH AFFAIRS 1 (Sept. 14, 2017).

⁷¹ See MERRILL MATTHEWS, INST. FOR POL’Y INNOVATION, A GUIDE TO UNDERSTANDING PRESCRIPTION DRUG PRICING 4, (2020). See also Michael Ollove, *Drug-Price Debate Targets Pharmacy Benefit Managers*, STATELINE (Feb. 12, 2019), <https://stateline.org/2019/02/12/drug-price-debate-targets-pharmacy-benefit-managers/#:~:text=By%3A%20Michael%20Ollove%20%2D%20February%2012%2C%202019%2012%3A00%20am&text=In%20the%20bipartisan%20drive%20to,known%2C%20are%20big%20businesses%20themselves> [https://perma.cc/N3E8-22E9].

⁷² JOHN O’SHEA, TX. PUB. POL’Y FOUND., *ADDRESSING COST DRIVERS IN U.S. HEALTHCARE THROUGH TRANSPARENCY, COMPETITION AND VALUE* 8 (2021).

⁷³ John F. Wasik, *Why Medicare Can’t Get the Lowest Drug Prices*, FORBES 2018. (Aug 10, 2018), <https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices/?sh=153f7882302b> [https://perma.cc/9MR2-BQBD].

and Commerce. In September 2021, it was also referred to the Committee on Veterans Affairs Subcommittee on Health. No further action was taken.⁷⁴

As a 2020 Presidential candidate, President Joe Biden proposed to lift this restriction.⁷⁵ This bill was introduced in the U.S. House of Representatives in February 2019. It was referred to the Subcommittees on Health in the Committee on Energy and Commerce and Ways and Means. A subcommittee hearing was held on September 25, 2019. No further actions were taken.⁷⁶

B. Section 340B of the Veterans Health Care Act

During the COVID-19 pandemic, drug manufacturers raised the list prices of hundreds of medicines. The manufacturers have argued that tracking increases in list prices do not consider discounts, rebates and other concessions.⁷⁷ In 1990, the Omnibus Budget Reconciliation Act (“OBRA”) established the Medicaid Drug Rebate Program requiring drug manufacturers to provide state Medicaid programs with their best market prices.⁷⁸ This program was developed to provide lower-income Americans with prescription drug expenses assistance. Once the rebate program was implemented, drug manufacturers scaled charitable discounts back. So, the 340B discount program was created in 1992 as Section 340B of the Veterans Health Care Act.⁷⁹ The 340B program is administered by the Health Resources and Services Administration (“HRSA”) in the U.S. Department of Health and Human Services (“DHHS”).⁸⁰

The original intention of the 340B program was to reduce costs for facilities serving disadvantaged, low-income patients. Eligible hospitals ‘outpatient medications’ from drug producers which means that patients get the drugs from a hospital after treatment but do not spend the night in the hospital. While dispensing or providing these drugs, the facility can still

⁷⁴ Medicare Negotiation and Competitive Licensing Act of 2021, H.R. 4811, 117th Cong. (2021-2022).

⁷⁵ Karen Andersen & Damien Conover, *What a Biden Presidency Could Mean for Drug Pricing*, MORNINGSTAR (Jul. 17, 2020), <https://www.morningstar.com/stocks/what-biden-presidency-could-mean-drug-pricing> [https://perma.cc/8WR4-67QX].

⁷⁶ Medicare Negotiation and Competitive Licensing Act of 2019, H.R. 1046, 116th Cong. (2019-2020).

⁷⁷ Sarah Owerhohle, *Drug Prices Steadily Rise Amid Pandemic Data Shows*, POLITICO (July 7, 2020, 7:55 PM), <https://www.politico.com/news/2020/07/07/drug-prices-coronavirus-351729> [https://perma.cc/E4FQ-VMQE].

⁷⁸ Samuel Thomas & Kevin Schulman, *The Unintended Consequences of the 340B Safety-Net Drug Discount Program*, 55 HEALTH SERVS. RSCH. 153 (2020).

⁷⁹ See Jarrett Gerlach, Sarah McSweeney, Angela Swearingen & Alberto Coustasse, *Examining the Benefits of the 340b Drug Discount Program*, 37 THE HEALTH CARE MANAGER 225 (2018). See also *id.*

⁸⁰ See O’Shea, *supra* note 72, at 8.

charge insurers full price. The rationale for this policy is that the facility could use the funds to provide additional services to low-income patients.⁸¹ The expected 340B profits were \$2.5 million which were minor in comparison to facilities' operating budgets but substantial compared to their uncompensated care expenses. In 2020, the White House attempted to improve the 340B program enforcement by compelling hospitals to report their program earnings and their use of the program savings. The State of California imposes this reporting requirement.⁸² There are limited restrictions on how the proceeds from the discounts are to be used.⁸³

The 340B program is currently very controversial because large, well-financed hospitals now dominate and qualify for the discounts. These hospitals use their funds to expand by acquiring new outpatient offices through mergers and acquisitions.⁸⁴ In 2010, the Affordable Care Act ("ACA") considerably enlarged the program's eligibility to include *critical access hospitals*, sole community hospitals, rural referral facilities, and free-standing children's and free-standing cancer hospitals.⁸⁵ The number of enrolled hospitals doubled between 2009 and 2012.⁸⁶

By 2014, the 340B program covered 45 percent of all Medicare acute care hospitals. As per the HRSA April 5, 2010, guidance, 340B eligible companies were permitted to use an unlimited number of contract pharmacies. Before this, contract pharmacies were only available to 340B program entities that did not have an on-site pharmacy. This resulted in more than 12,000 covered entities participating in the 340B program by 2017.⁸⁷ Conti and Bach found that compared to hospitals that joined the 340B program prior to 2004, the 340B eligible hospitals were more likely to be in higher-income communities.⁸⁸ Professors Sunita Desai and J. Michael

⁸¹ Peter B. Bach & Rachel E. Sachs, *Expansion of the Medicare 340B Payment Program Hospital Participation, Prescribing Patterns and Reimbursement, and Legal Challenges*, 320 JAMA 2311, 2311 (2018).

⁸² Rena M. Conti & Sayeh S. Nikpay, *Revenues and Profits from Medicare Patients in Hospitals Participating in the 340B Drug Discount Program, 2013-2016*, 2 JAMA NETWORK OPEN 10 (2019).

⁸³ O'SHEA, *supra* note 72, at 9. *See also* MEDICARE PAYMENT ADVISORY COMMISSION, MEDICARE PAYMENT POLICY (Mar. 2020).

⁸⁴ Bach, *supra* note 81, at 2311.

⁸⁵ O'SHEA, *supra* note 72.

⁸⁶ Conti, *supra* note 82. *See also* GERLACH, *supra* note 79. (Research points out that the expansion of hospitals has expanded access to health care services). Isha Rana et al., *A Comparison of Medication Access Services at 340B and Non-340B Hospitals*, RESEARCH IN SOCIAL AND ADMINISTRATIVE PHARMACY (2021). According to Vandervelde & Blalock (2017), by 2016, 340B sales only represented only 2 percent of US drug sales and almost 8 percent of the overall market. *See* Measuring the relative size of the 340B Program: 2012-2017. pt. 1-7 (2017).

⁸⁷ O'SHEA, *supra* note 72.

⁸⁸ Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals generate profits by expanding to reach more affluent communities*, 33 HEALTH AFFS. (2014).

McWilliams found that larger hospitals movement into using the 340B is associated with higher numbers of parenteral drug claims billed for hematology-oncology and ophthalmology patients; and the hospital's program eligibility "was associated with lower proportions of low-income patients in hematology-oncology and ophthalmology."⁸⁹

C. State government drug pricing review boards

1. Value-based pricing

Business law professor Rena Conti, health policy professor Stacie Dusetzina and law professor Rachel Sachs argue that the so-called "Affordable" Care Act was a missed opportunity when it comes to making prescription drugs affordable. They commented that "keeping not just innovation but also its value for all Americans at the forefront of policy discussions is critical for decision makers who seek to improve prescription drug affordability ten years after the ACA's passage."⁹⁰ Value based pricing, "[the] use of research data—typically from clinical trials—to estimate a treatment's expected clinical outcomes, value, and equitable retail price for a population of patients. In contrast, outcomes-based pricing rewards actual clinical outcomes. . . ."⁹¹

There is also a movement by a few state governments to form prescription drug pricing boards focused on data driven determinations of value. Six state boards in five U.S. states. Board review of drug pricing is triggered by a health department's inability to reach a desired rebate agreement with a manufacturer; if a prescription drug spending limit under Medicaid would be surpassed or if a drug's annual cost exceeds some limit such as \$20,000-\$30,000. New York's board determines a value-based price after reviewing publicly available pricing information and the availability of alternative drugs. If a manufacturer does not agree with the recommended target rebate, the state Medicaid office may be required to remove the drug from its list of treatments. The state of New York was successful in getting their rebate. New York's Medicaid drug review body was successful in obtaining rebate deals for the drugs Infliximab and Lumacaftor/Ivacaftor.⁹² Further, drug manufacturers are reluctant to disclose confidential

⁸⁹ S. Desai & J. M. McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 NEW ENG. J. MED. 539, 539 (2018).

⁹⁰ Rena M. Conti, Stacie B. Dusetzina & Rachel Sachs, *How the ACA Reframed the Prescription Drug Market and Set the Stage for Current Reform Efforts*, 39 HEALTH AFFS. 445,450 (2020).

⁹¹ Daniel M. Blumenthal, Dana P. Goldman & Anupam B. Jena, *Outcomes-Based Pricing as a Tool to Ensure Access to Novel But Expensive Biopharmaceuticals*, 166 ANNALS OF INTERNAL MED. 219, 220 (2016).

⁹² Liam Bendicksen et al., *Pursuing Value-Based Prices for Drugs: A Comprehensive Comparison of State Prescription Drug-Pricing Boards*, THE MILBANK Q. 1162, 1163 (2021).

information about their negotiated rebate, international prices, R&D costs, marketing budgets and production expenses.

2. Outcome-based pricing

Although outcome-based pricing is also called value-based drug pricing, it differs from the aforementioned review board objectives because outcome-based pricing applies “when a drug is rejected by a government health agency for failing to meet standards for clinical or cost-effectiveness, manufacturers will often reduce its price to increase its relative value.”⁹³ Government-run health care plans in the United Kingdom, Norway and Canada evaluate drugs under this outcome-based framework.⁹⁴ Prasad (2017) offers this compelling argument for considering value:

“In no business sector is the cost of the product based entirely on the manufacturing cost or the cost of failed research but, rather, the cost is largely based on what a person is willing to pay for the value that the product provides in the presence of alternative choices.”⁹⁵

In practice, outcome-based pricing involves negotiating contracts that make payments to drug manufacturers reliant on the drug’s effectiveness. These outcome-based contracts may contain rebates and discounts for expensive pharmaceuticals that are conditioned on outcomes.⁹⁶ For example, in 1998, if the product Zocor plus dieting did not help patients lower their low-density lipoprotein cholesterol, Merck guaranteed to repay up to six months of treatment expenditures. Johnson & Johnson similarly committed to refund the U.K. National Health Services in 2006 if multiple myeloma patients did not respond after four cycles of its medicine Velcade. In 2017, Amgen agreed to compensate patients who had a heart attack or stroke while taking its cholesterol medicine Repatha and Novartis agreed to refund the CMS if patients did not respond to its leukemia drug Kymriah within a month.⁹⁷

⁹³ Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, J.L. & THE BIOSCIENCES 205, 208 (2017).

⁹⁴ *Id.*

⁹⁵ Vinay Prasad, Kevin De Jesus & Sham Mailankody, *The High Price of Anticancer Drugs: Origins, Implications, Barriers, Solutions*, 14 CLINICAL ONCOLOGY 381, 383 (2017) (recuperating R&D outlays is a common justification for high anticancer drugs. Yet, the cost of developing medication “is irrelevant to the price”) (citing M. Herper, *The Truly Staggering Cost Of Inventing New Drugs*, FORBES 2012.; and A. Sarpatwari, J. Avorn & A. S. Kesselheim, *State Initiatives to Control Medication Costs - Can Transparency Legislation Help?*, 374 NEW ENG. J. MED. (2016).

⁹⁶ Michael Fralick, Joshua J. Gagne, Elisabetta Patorno, Raisa Levin & Aaron S. Kesselheim, *Using Data from Routine Care to Estimate the Effectiveness and Potential Limitations of Outcomes-Based Contracts for Diabetes Medications*, 23 VALUE IN HEALTH (REAL-WORLD EVIDENCE)434, 434 (2020).

⁹⁷ Elodie Adida, *Outcome-Based Pricing for New Pharmaceuticals via Rebates*, 67 MGMNT. SCI. 1, 2 (2021) (citing J.J. Carlson, L.P. Garrison Jr & S.D. Sullivan, *Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals*, 15 J. MANAGED CARE PHARMACY 683 (2009); P.J.

In 2016, medical doctor Daniel Blumenthal, health policy and economics researcher Dana Goldman, and health care policy professor Anupam Jena reported that insurers were increasingly tying reimbursements to outcomes. For example, Spark Therapeutics agreed that if a patient did not experience vision gains within thirty to ninety days after using their Luxturna treatment for a rare form of blindness, or if gains were not maintained thirty months following the treatment, the corporation would reimburse insurance for a portion of the cost to insurers. Luxturn costs \$425,000 per eye.⁹⁸ Outcome-based pricing promotes accountability and incentivizes competition and price setting based on a treatment's actual value.⁹⁹ A study on outcome-based pricing contracts for diabetes medications concluded that these contracts "are unlikely to meaningfully reduce drug expenditures even if significant refunds were provided by the manufacturers, mainly because of their high cost and the low cost of drugs in another widely effective class of cholesterol-lowering medications."¹⁰⁰ In 2020, Assistant Editor of the BMJ health care journal, Gareth Iacobucci recommended that the British NHS would pay the entire cost of a cancer medicine only if it provided the expected benefits. In order to engage in indication-based or outcome-based pricing, however, the NHS would need to acquire precise data and the digital infrastructure and personnel to do so. Iacobucci recommends that a private public partnership could accomplish this goal.¹⁰¹

Outcome-based pricing involves the use of modeling. Some value-based pricing models use quality-adjusted life year ("QALY") and/or incremental cost-effectiveness ratio ("ICER") terms. There is a four-step assessment to computing value: (1) comparing two drugs in clinical trials and measuring the benefit of one over the other; (2) considering the comparative effectiveness from real life data on the use of the medicine; (3) calculating cost-effectiveness by comparing the effectiveness benefit against the cost consequences such as QALY or some other measure; (4) considering if this opportunity is going to be at least cost-effective as the one it displaced

Neumann, J. D. Chambers, F. Simon & L.M. Meckley, *Risk Sharing Arrangements that Link Payment for Drugs to Health Outcomes are Proving Hard to Implement*, 30 HEALTH AFFAIRS 2329 (2011); P. Loftus, *Drug Companies Tie Costs to Outcomes*, Wall Street Journal (Sept. 12, 2017, 10:07 PM), <https://www.wsj.com/articles/drug-companies-tie-costs-to-outcomes-1505268421> [<https://perma.cc/X5WE-B76N>].)

⁹⁸ Laura Entis, *Cost Over Sight? Spark's Blindness Cure Has the Industry Talking*, MEDICAL MKTG & MEDIA (Feb. 2, 2018, 10:00 AM), <https://www.mmm-online.com/home/channel/features/cost-over-sight-sparks-blindness-cure-has-the-industry-talking/> [<https://perma.cc/52KV-CG4N>].

⁹⁹ Blumenthal, *supra* note 91.

¹⁰⁰ Fralick, *supra* note 96, at 438.

¹⁰¹ Gareth Iacobucci, *NHS Should Vary Price It Pays for Cancer Drugs to Improve Access*, *Say Experts*, BMJ (Nov. 09, 2020), <https://www.bmj.com/content/371/bmj.m4322> [<https://perma.cc/3JKA-4UJJ>].

when new interventions are introduced to displace an available one; and (5) determining if the intervention is affordable in the current budget.¹⁰²

In countries that already use these models to reduce costs, there is disagreement on how much the QALY should cost and whether a country should continue with QALY appraisal tools. Meanwhile, since drug companies can employ QALY and ICER criteria strategically to increase profitability, governments should be careful when using sophisticated compensation models.¹⁰³ In 2017, Optum and Merck entered into a collaboration to develop and simulate the performance of contractual reimbursement models in which payment for prescription drugs is aligned to patient outcomes. This multi-year collaboration is called a *Learning Laboratory*, and studies value-based pricing and outcomes-based risk sharing agreements.¹⁰⁴ Toon Van der Gronde, Global Development Science Director for AstraZeneca, and his coauthors warned in 2017 that although outcome-based pricing is a viable short term policy option, for precision drugs, there has been no systematic research on the usefulness of these instruments. As a result, *ad hoc* decisions have been taken that have had a negative impact on the supply of essential drugs.¹⁰⁵

3. Indication-based pricing

Indication-based pricing is used in Europe and implementation in most European countries “appears difficult” with regard to legalities, data collection and billing.¹⁰⁶ Many drugs are used for a variety of indicators. For example, diabetes medications can treat other conditions including asthma, osteoporosis, cancer, and cardiovascular disease.¹⁰⁷ The cancer drug nab-Paclitaxel (Abraxane) can treat pancreatic, metastatic breast, and non-small cell lung cancer. These are FDA approved *indications*. The value of a treatment in relation to its expenses varies. The monthly price of a medicine based on the most valuable indications can be determined, as can the monthly

¹⁰² MONDHER TOUMI, *INTRODUCTION TO MARKET ACCESS FOR PHARMACEUTICALS* 24 (CRC Press, 1st ed. 2017) (noting that “cost per QALY seems to have been increasingly adopted over the recent years in most HTA organizations”).

¹⁰³ Toon van der Gronde, Carin A. Uyl-de Groot & Toine Pieters, *Addressing the Challenge of High-Priced Prescription Drugs in the Era of Precision Medicine: A Systematic Review of Drug Life Cycles, Therapeutic Drug Markets and Regulatory Frameworks*, 12 PLOS ONE 1, 25 (2017).

¹⁰⁴ Optum Inc., *Optum and Merck to Collaborate on Outcome-Based Pricing Strategy* (May 31, 2017), <https://www.pharmaceuticalprocessingworld.com/optum-and-merck-to-collaborate-on-outcome-based-pricing-strategy/> [<https://perma.cc/NQ5V-38QC>].

¹⁰⁵ Van der Gronde, *supra* note 103, at 1.

¹⁰⁶ Matthias Flume, Marc Bardou, Stefano Capri, Oriol Sola-Morales, David Cunningham, Lars-Ake Levin, & Nicolas Touchot, *Feasibility and Attractiveness of Indication Value-Based Pricing in Key EU Countries*, 4 J. MKT. ACCESS & HEALTH POL’Y 1, 6 (2016) (Flume et al. studied Germany, France, Italy, Spain, England and Sweden).

¹⁰⁷ Fralick, *supra* note 96.

price based on meeting a goal value per year of life gained. Thus, indication-based pricing can be used to rationalize drug prices.¹⁰⁸

Sachin Kamal-Bahl, Head of the Global Health and Value Innovation Center at Pfizer, et al. found that although indication-based pricing may increase payer expenses, increased pricing rivalry at the indication level has the potential to lower drug prices.¹⁰⁹ Legal scholar Ryan Knox (2019) points out that indication-based pricing models suggest that more effective treatment should be priced higher. This raises the ethical concern about what should be done when a patient cannot afford the most effective treatment. Access and high prices are still an issue.¹¹⁰ Life science researcher Ryan Lawlor and his team of researchers from Charles Rivers Associates and Merck states that another access challenge is the administrative costs borne by drugs that have numerous indications since the number of assessments increase. This delays access.¹¹¹ As Peter Bach, Director of the Sloan Kettering Cancer Center's Center for Health Policy and Outcomes notes, this pricing scheme rationalizes the drug prices. It does not lower the prices unless, as Kamal-Bahl argues, this results in increased price competition.

D. Hatch-Waxman Act for generic drug market entry

When a firm controls the majority of a pharmaceutical market, they have a natural monopoly. Advantages of competition include: 1) improved consumer choice, 2) price reduction, and 3) quality improvement.¹¹² In 1984, the Drug Price Competition and Patent Term Restoration Act, more commonly called the Hatch-Waxman Act, was enacted in the United States to allow generic drug companies to enter the marketplace, increase competition and drive drug prices down.¹¹³ However, “the fact that any potential competitor would have to complete a lengthy approval process before selling a generic version” means that patent holders have a natural monopoly for an indefinite period of time.¹¹⁴ Thus, a patent holder such as Martin Shkreli of Turing Pharmaceutical who was engaged in the predatory

¹⁰⁸ Peter B. Bach, *Indication-Specific Pricing for Cancer Drugs*, 312 JAMA 1629, 1629 (2014).

¹⁰⁹ Sachin Kamal-Bahl, Adrian Towse, Liz Spurgin & Patricia M. Danzon, *Specific Value Assessment Considerations*, 22 VALUE IN HEALTH S24, S24 (2019).

¹¹⁰ Ryan Knox, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 191, 191–224 (2019).

¹¹¹ Ryan Lawlor, Tim Wilsdon, E. Darquennes, D. Hemelsoet, J. Huisman, R. Normand & A. Reodiger, *Accelerating Patient Access to Oncology Medicines with Multiple Indications in Europe*, 9 J. OF MKT. ACCESS & HEALTH POL'Y 1, 1 (2021).

¹¹² Jorge Contreras & Liza Vertinsky, *Pre-Competition*, 95 N.C. L. REV. 67, 123 (2016).

¹¹³ Hatch-Waxman Act, 21 U.S.C. § 355-1 (2013).

¹¹⁴ Lamm, *supra* note 10, at 941.

pricing of the drug Daraprim would have a natural monopoly for an indefinite period of time.

Further, the Federal Trade Commission (“FTC”):

“has not forced manufacturers who wish to leave the market once it is no longer profitable to continue producing a drug in order to keep generic prices low in natural monopolies. Yet the FTC has in effect created a duty for brand name manufacturers to aid competitors by requiring them to continue producing drugs that are no longer profitable until generics can be introduced into the market to stimulate competition.”¹¹⁵

It is also vital to highlight that there are problems associated with reduced competition among generic manufacturers. A three-prong strategic framework has been proposed to balance dynamics and maximize competition among generic makers. First, it was recommended that the 2012 Generic Drug User Fee Act (“GDUFA”) be reauthorized. Second, it was recommended that the FDA collaborate with other national regulatory agencies to create a single electronic application window for generic medicine approvals. Third, with a quarter of the United States pharmaceuticals being imported, the FDA needs “a pathway for granting reciprocal drug approval to approved generic versions of U.S. medications without patent protection or other forms of exclusivity, but lacking insufficient generic competition.”¹¹⁶ The 2012 GDUFA, now referred to as the GDUFA I, was reauthorized in 2017 as part of the Food and Drug Administration’s Safety and Innovation Act (“FDASIA”) and is currently referred to as the GDUFA II.¹¹⁷

III. MECHANISMS FOR BRAND DRUG POST-PATENT EXTENSIONS

The patent system is impervious to efforts to manipulate the system and government regulations are supposed to encourage more R&D and inventions of cures.¹¹⁸ There are at least three mechanisms by which brand drug companies extend the life of their patents beyond twenty years. It is worth noting that, in time, these extensions strengthen the monopolies. They are no longer “natural” but rather devised through market manipulation. These mechanisms have been in practice prior to the patent cliff and include reverse payment settlements, evergreening, and product hopping.

¹¹⁵ Chelsea E. Ott, *The Evolution of Pharmaceutical Regulatory Gaming Practices*, 47 SETON HALL L. REV. 849, 878 (2017).

¹¹⁶ THOMAS J. BOLLYKY & AARON S. KESSELHEIM, HUTCHINS CENTER, CAN DRUG IMPORTATION ADDRESS HIGH GENERIC DRUG PRICES??. 29 WORKING PAPER 1, 12 (May 2017).

¹¹⁷ Ernst R. Berndt et al., *The Generic Drug User Fee Amendments: An Economic Perspective*, J.L. & BIOSCIENCES 103 (2018). See also *Generic Drug User Fee Amendments*. (2017).

¹¹⁸ Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1, 2 (2016).

A. Reverse payment settlements

High drug prices are part of a growing trend of patent dispute settlement agreements between brand and generic medicine businesses. When a generic drug company attempts to market a drug before the patent rights of a brand manufacturer expire, the generic drug manufacturer could challenge the validity of the brand company's patents. In some of these cases, a generic company may file an Abbreviated New Drug Application ("ANDA"), and the brand company sues them for patent infringement.¹¹⁹ With reverse payment settlements, the brand medicine companies pay generic drug businesses millions of dollars in order to settle, drop their lawsuits, and avoid market entry. Despite protests, courts have upheld these agreements on the premise that these result in cost reductions and increased innovation.¹²⁰

These agreements are also called "exit payments." Courts have upheld these payments¹²¹ and "pay for delay" settlement deals.¹²² The payments ranged from \$10-60 million dollars per year between 2001 and 2012.¹²³ Payment for delay settlements frequently include payment in the form of brand businesses committing not to release Authorized Generics ("AGs") that compete with generics. So, this is a coercive tool.¹²⁴ AGs are drugs produced by brand drug makers at generic prices; or the brand drug maker gives a generic drug maker the intellectual property and helps them enter the market ahead of competition. During the first filing generic company's 180-day exclusivity period, Hatch-Waxman allows brand firms to create their own AG versions of medications. It reduces the generic companies' revenues by forty to fifty-two percent during this period and by fifty-three and sixty-two percent in the following thirty months. The related payment for delay settlements "are collusive and lower consumer welfare by maintaining

¹¹⁹ Congressional Research Service. *Drug Pricing and Pharmaceutical Patenting Practices* (R46221), Prepared by Kevin T. Richard et al. February 11, 2020.

¹²⁰ Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Liability*, 108 MICH. L. REV. 37, 62 (2009).

¹²¹ Christina Bohannon & Herbert J. Hovenkamp, *IP and Antitrust: Reformation and Harm*. 51 B.C. L. REV. 905, 933 (2010).

¹²² Fiona S. Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 16 (Hutchins Center Working Paper No. 30, 2017).

¹²³ Tracey Toll, *Pharmaceutical Reverse Payment Settlement Agreements and a Proposal for Clarifying the Application of Antitrust Law Rule of Reason Analysis to These Agreements*, 15 HOUS. J. HEALTH L. & POL'Y 281, 316 (2015).

¹²⁴ Gregory H. Jones et al., *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1399 (2016).

monopoly prices after patents should have expired, while proponents argue they reinforce incentive for innovation.”¹²⁵

In *in re Cardizem*, the Sixth Circuit found these pay for delay payments to be per se illegal. Yet, in the *in re Ciprofloxacin Hydrochloride* antitrust case, the U.S. Court of Appeals for the Federal Circuit found against the per se treatment of pay for delay payments as illegal if they did not restrict competition beyond the exclusionary scope of the patent themselves and held that courts should examine patent enforceability and validity when deciding reverse payment settlement cases.¹²⁶

Reverse payments create an antitrust concern because they discourage future entry and lead to higher prices. In addition, they are inefficient with regard to the impact on innovation.¹²⁷ In *F.T.C. v. Actavis, Inc.*, the United States Supreme Court held that reverse payment settlements are unlawful when made to delay compensation or to avoid the risk of competition.¹²⁸ The rule of reason approach acknowledges that not all reverse payments are anticompetitive since some have legitimate justifications such as avoiding litigation expenses or compensating for services rendered by an alleged infringers. However, the Court wonder[ed] skeptically what those might be.”¹²⁹

The number of Pay-for-Delay transactions declined dramatically in the first year following the *Actavis* ruling.¹³⁰ They later increased, and the FTC stopped publishing reports. See Table 1.

¹²⁵ ERIC HELLAND & SETH A. SEABURY, ARE SETTLEMENTS IN PATENT LITIGATION COLLUSIVE? EVIDENCE FROM PARAGRAPH IV CHALLENGES (Nat’l Bureau of Econ. Rsch., Working Paper No.22194, 2016).

¹²⁶ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1340 (Fed. Cir. 2008).

¹²⁷ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1612 (2006).

¹²⁸ *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

¹²⁹ Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 21 (2013).

¹³⁰ Press Release, Fed. Trade Comm’n, FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court’s *Actavis* Decision (Jan. 13, 2016), <https://www.ftc.gov/news-events/news/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay-deals-decreased-substantially-first> [https://perma.cc/679S-GEJC]; BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 OVERVIEW OF AGREEMENTS FILED IN FY 2014 (2016), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf> [https://perma.cc/4A53-XBNQ].

Year	Agreements of patent battles between brand and generic pharmaceutical producers	No. of agreements in which a brand manufacturer compensated a generic manufacturer for preventing the generic from entering the market
2014	160	21
2015	170	14
2016	232	30
2017	226	20

TABLE 1: AGREEMENTS BETWEEN BRAND AND GENERIC DRUG MANUFACTURERS.¹³¹

Post-*Actavis*, several courts determined whether provisions that delayed generic market entry were the type of payments consistent with *Actavis*. These courts held that the payments need not be cash-only in order for *Actavis* to apply. ‘No-AG’ provisions may give rise to an inference of risk to competition.¹³²

¹³¹ Press Release, Fed. Trade Comm’n, FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court’s *Actavis* Decision (Jan. 13, 2016), <https://www.ftc.gov/news-events/news/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay-deals-decreased-substantially-first> [https://perma.cc/679S-GEJC]; Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2015 Report on Branded Drug Firms’ Patent Settlement with Generic Competitors (Nov. 1, 2017), <https://www.ftc.gov/news-events/news/press-releases/2017/11/ftc-staff-issues-fy-2015-report-branded-drug-firms-patent-settlements-generic-competitors> [https://perma.cc/456T-J8AD]; Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2016 Report on Branded Drug Firm’s Patent Settlements with Generic Competitors (May 22, 2019), <https://www.ftc.gov/news-events/news/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent-settlements-generic-competitors> [https://perma.cc/H462-KW2G]; Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2017 Report on Branded Drug Patent Settlements with Generic Competitors (Dec. 3, 2020), <https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent-settlements-generic-competitors> [https://perma.cc/J8BE-KEJK].

¹³² *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 241-247 (D. Conn. 2015); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *18-23 (D.N.J. Oct. 6, 2014), *rev’d and remanded sub nom. In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017)2014; *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 542-545 (D.N.J. 2014), *rev’d and remanded*, 868 F.3d 231 (3d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 192-193 (D.R.I. 2014), *vacated and remanded*, 814 F.3d 538 (1st Cir. 2016)); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 390-392 (D. Mass. 2013); *In re Niaspan Antitrust Litigation*, 42 F. Supp. 3d 735, 750-753 (E.D. Pa. 2014); *King Drug Co. of Florence v. SmithKline Beecham Corp.*, 791 F.3d 388, 403-405 (3d Cir. 2015); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-710 (E.D. Pa. 2014); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 069-071 (N.D. Cal. 2014).

GlaxoSmithKline (“GSK”) manufactures the anti-epileptic brand drug Lamictal. The generic company, Teva Pharmaceuticals, and GSK were in a legal challenge. Teva entered into a settlement agreement with GSK which had a no-AG provision that stated GSK would refrain from introducing its own AG. This allowed Teva to capture generic sales for six months.¹³³ In 2019, the FTC entered into a global settlement to resolve reverse-payment charges against Teva. The agreement forbids Teva from entering collusive deals that restrict price competition. It prohibits two forms of reverse payments: “(1) a side deal, in which the generic company receives compensation in the form of a business transaction entered at the same time as the patent litigation settlement; and (2) a no-AG commitment, in which a brand company agrees not to compete with an authorized generic version of a drug for a period of time.”¹³⁴ It is also important to note that there are state laws in the United States that outlaw illegal antitrust activities, monopolies, illegal trade constraints, unfair commerce, and deceptions.

It has been recommended that state attorney generals should litigate cases involving pay for delay agreements that influence intrastate transactions.¹³⁵ It has also been recommended that the United States Congress should define what an impermissible reverse payment agreement is. Recall that reverse settlement payments ranged from \$10-60 million dollars per year between 2001 and 2012. Therefore, an example definition of an impermissible reverse payment that the U.S. Congress can consider could be if it:

“(1) contains a payment from the patentee to the generic manufacturer in the settlement of a patent infringement suit totaling ten million dollars or more (this figure includes money designated for licenses, backup manufacturing, and other benefits, and will be adjusted annually for inflation); and (2) restrains the generic manufacturer from marketing its medication for over a year when there is no available bioequivalent substitute on the market as of the time of the settlement.”¹³⁶

¹³³ *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 561-562 (D.N.J. 2014), vacated and remanded sub nom. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

¹³⁴ Press Release, Fed. Trade Comm’n, FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva (Feb. 19, 2019), <https://www.ftc.gov/news-events/news/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges-against-teva> [<https://perma.cc/75PX-FPDP>].

¹³⁵ Raymond J. Prince, *Pay-for-Delay: How Brand-Name and Generic Pharmaceutical Drug Companies Collude and Cost Consumers Billions*, 68 S.C. L. REV. 689, 719-727 (2017).

¹³⁶ Tracey Toll, *Pharmaceutical Reverse Payment Settlement Agreements and a Proposal for Clarifying the Application of Antitrust Law Rule of Reason Analysis to These Agreements*, 15 HOUS. J. HEALTH L. & POL’Y 281, 315 (2015).

Further, in 2017, law professor Erik Hovenkamp and economics professor Jorge Lemus noted that the Patent Trial and Appeal Board (“PTAB”) commonly executes delayed entry settlements.¹³⁷ A reform attempt in 2019 with the Preserve Access to Affordable Generics and Biosimilars Act (“PAAGBA”) was aimed to limit the ability of brands to pay generic or biosimilar manufacturers to delay entry. This proposed legislation would establish a presumption of illegality rather than the current rule of reason analysis based on the Actavis holding.¹³⁸

B. Evergreening

Evergreening is the technique used by brand drug companies to extend the life of their patent protection beyond twenty years, by filing new patents containing minor product updates.¹³⁹ Since the later filed patents often include claims other than active ingredients, they are sometimes called *secondary patents*. Proponents of evergreening have argued that the ability to engage in this practice incentivizes drug developers to use the secondary patent to address problems with the original drug formulations, such as side effects that result in the discontinued use of drugs. They also argue that the extension of patent protection enables them to recoup R&D expenses.¹⁴⁰

In 2004, an Australia court revoked a Merck drug patent for gastrointestinal issues for this reason. In that case, GlaxoSmithKline’s antidepressant paroxetine expired in the late 1990s, but with attempts to evergreen the patent, the resulting ancillary patents did not expire until 2006-2018.¹⁴¹ Another high-profile evergreening case is where the Supreme Court of India refused to grant Novartis a patent for a new version of Glivec. Novartis argued that the new version could be more easily absorbed into the blood, but the India Supreme Court held it was evergreening.¹⁴²

¹³⁷ Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 54 INT’L REV. OF L. AND ECON. 30, 37-38 (2017).

¹³⁸ KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 40-41 (2020). See *F.T.C. v. Actavis*, 570 U.S. at 159.

¹³⁹ Roger Collier, *Drug Patents: the Evergreening Problem*, 185 CAN. MED. ASS’N J. 385, 385-386 (2013). See also Thomas Faunce, *Australian Competition and Consumer Commission v. Pfizer: Evergreening and Market Power as a Blockbuster Drug Goes Off Patent*, 22 MED. L. REP. 771, 774-775 (2015).

¹⁴⁰ RICHARDS, HICKEY & WARD, *supra* note 138, at 16-19, 32-35.

¹⁴¹ Robert Chalmers, *Evergreen or Deciduous? Australian Trends in Relation to the ‘Evergreening’ of Patents*, 30 MELB. U. L. REV. 29, 3333 (2006).

¹⁴² Roger Collier, CMAJ, *Drug Patents: the Evergreening Problem*, 185 CAN. MED. ASS’N J. 385, 385-386 (2013).

One solution to evergreening is to strengthen patent examination.¹⁴³ Pharmaceutical companies must demonstrate evidence of safety and efficacy before releasing a new medicine into the market. Once the company gets approval, the drug gets listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations book (the "Orange Book").¹⁴⁴ A proposed solution is to subject all Orange Book listed patents to immediate re-examination by the United States Patent and Trademark Office ("USPTO").¹⁴⁵

No laws currently forbid evergreening except for the patent examination requirement that patent claims can be rejected on the basis of obviousness. The Congressional Research Service ("CRS") noted in 2020 that "[p]roposals targeting evergreening primarily aim to make it harder for companies to receive later-filed or secondary patents, reduce the impact of later-filed patents, or incentivize challenges to patents." These proposals include: (1) increasing patent examination resources so that examiners prevent the issuance of low-quality patents; (2) requiring that secondary patents have increased proven improvement rather than minor changes; (3) requiring that a secondary patent expire on the date of the earlier patent (i.e., the proposed Terminating the Extension of Rights Misappropriated Act)¹⁴⁶; (4) limiting secondary patents to only those that relate to a drug's active ingredient (i.e., the proposed Reforming Evergreening and Manipulation that Extends Drug Years Act¹⁴⁷; and (5) requiring notification to the USPTO when adding patents to the Orange Book provisionally. After adding patents to the Orange Book, the USPTO requests intellectual property rights filings from entities that challenge the patent or simply provide a period of time for which it waits until no challenges are filed. If a challenge is filed, the USPTO

¹⁴³ Jorge Lemus & Olgu Ozkul, *Product Hopping and Innovation Incentives*, 14-15 (Sept. 30, 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3275815#paper-citations-widget [<https://perma.cc/X8BS-BFGG>]. See also Scott Parker & Kevin Mooney, *Is 'Evergreening' a Cause for Concern? A Legal Perspective*, 13 J. COM. BIOTECHNOLOGY 235, 240-243 (2007).

¹⁴⁴ Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 32-33 (Stan. L. Sch. John M. Olin Program L. and Econ. Working Paper No. 367, 2008), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1287221 [<https://perma.cc/8277-VTS2>].

¹⁴⁵ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 337 (2012).

¹⁴⁶ Terminating the Extension of Rights Misappropriated Act of 2019, H.R. 3199, 116th Cong. (2019). Note that this legislation was referred to the Subcommittee on Courts, Intellectual Property, and the Internet by the Committee on the Judiciary. No further action was taken, however.

¹⁴⁷ Reforming Evergreening and Manipulation that Extends Drug Years, H.R. 3812, 116th Cong. (2019). Note that this legislation was referred to the Subcommittee on Health by the Committee on Energy and Commerce in July 2019. No further action was taken.

can affirm patentability. This is the proposed Second Look at Drugs Patents Act)¹⁴⁸.

C. *Product hopping*

As opposed to evergreening, which relates to patent application filing, product hopping occurs when one creates new products similar to the original and encourages patients to upgrade to the newer version.¹⁴⁹ The new version may be an extended release, altered dosage, or new method of administering the drug.

An example is where Pfizer sells the antidepressant venlafaxine marketed as Effexor. Since Effexor has major side effects that can be alleviated with drug's time release, Pfizer filed patent applications to add time release. Pfizer obtained two new patents and an extension of exclusivity in the market. The time released version was sold as Effexor-XR. Selling these products is an example of product hopping (i.e., from Effexor to Effexor-XR).¹⁵⁰ Product hopping is a method for drug companies to manipulate the regulatory system. It is important to note that regulators cannot substitute for antitrust courts, nor replace their role in guaranteeing competitive markets.¹⁵¹

The drug company Warner Chilcott allegedly engaged in product hopping by releasing three successive medical reformulations for their antibiotic Doryx. The problem was that the FTC and plaintiff Mylan Pharmaceutical believed that the reformulations provided little or no medical value to consumers. The reformulations were merely designed to impede meaningful generic competition. Warner wanted to dismiss the lawsuit, claiming that the introduction of a new product could not be anticompetitive. The FTC and American Antitrust Institute filed amicus briefs explaining how minor, non-therapeutic changes to branded products is anti-competitive.¹⁵² A

¹⁴⁸ Second Look at Drug Patents Act of 2019, S. 1617, 116th Cong. (2019). Note that this legislation was referred to the U.S. Senate Committee on Health, Education, Labor, and Pensions in May 2019. No further action was taken.

¹⁴⁹ Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, § 15.3c1 (1st ed. 2002). Hovenkamp et al. coined the phrase "product hopping." A brand influences a hop from one product to another in order to maintain its market dominance.

¹⁵⁰ Hazel Moir & Deborah Gleeson, *Explainer: Evergreening and How Big Pharma Keeps Drug Prices High*, THE CONVERSATION, (Nov. 5, 2014, 2:27 PM), <https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> [<https://perma.cc/FR9H-PS8S>].

¹⁵¹ Dogan & Lemley, *supra* note 144.

¹⁵² Richard Brunell, *AAI Supports Scrutiny of Drug "Product Hopping" in Doryx case (Mylan Pharmaceuticals v. Warner Chilcott)*, (Sept. 28, 2015), <https://www.antitrustinstitute.org/work-product/aa-i-supports-scrutiny-of-drug-product-hopping-in-doryx-case-mylan-pharmaceuticals-v-warner-chilcott/> [<https://perma.cc/Y2MJ-35AU>]; U.S. FED. TRADE COMM'N, OVERVIEW OF FTC

unanimous three-judge panel in the Third Circuit Court of Appeals ruled that while Warner Chilcott Co., which was bought by New Jersey-based Actavis PLC in 2013, and Mayne Pharma Group Ltd. may have warded off generic competition, Mylan failed to show that they broke the law in doing so.¹⁵³

As aforementioned, the generic drug must be a bioequivalent. Thus, a hop can prevent automatic substitution by a generic manufacturer since the brand drug change may significantly differ from the generic version. The generic may not obtain an AB rating from the FDA. While there is no law forbidding product hopping, these incidents get challenged on the grounds of being alleged monopolistic violations of antitrust laws. The 2019 proposed Affordable Prescriptions for Patients Act would make product hopping an antitrust violation.¹⁵⁴ This proposed legislation was introduced by Senator John Cornyn on May 9, 2019, and placed on the legislative calendar on June 27, 2019, but no other action was taken.¹⁵⁵

Recollect that the rationale for twenty years of exclusivity is to help brand drug companies recuperate their R&D expenses and continue investment in R&D. Less profits result in less attractiveness to investors and less research.¹⁵⁶ Any proposed solution for lowering drug prices must preserve the incentive for drug companies to innovate.¹⁵⁷ Product hopping reduces consumer welfare because drug prices rise. Further, “product hopping may increase the value of incumbency which increases the ex-ante incentive to innovate.” Policies that prevent firms from product hopping include tightening patentability standards to not allow new patent issues on very minor and obvious improvements. It has been proposed that if firms are simply allowed to pay a fee to renew patent terms, this would preserve incentives to innovate and reduce the welfare-reducing effects of product hopping.¹⁵⁸

Professor of law and medicine Kerstin Vokinger and her medical research collaborators note several policy reforms proposed to counter

ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (June 2019), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf [<https://perma.cc/YAT4-MT55>].

¹⁵³ Brendan Pierson, *Mylan Loses Appeal of Product-Hopping Case Over Acne Drug*, REUTERS, (Sept. 29, 2016, 5:51 AM), <https://www.reuters.com/article/health-doryx/mylan-loses-appeal-of-product-hopping-case-over-acne-drug-idUSL2N1C50DA> [<https://perma.cc/49NE-Z6CU>].

¹⁵⁴ VALERIE C. BRANNON, CONG. RSCH. SERV., LSB10298, DRUG PRICE DISCLOSURES AND THE FIRST AMENDMENT (2019), <https://sgp.fas.org/crs/misc/LSB10298.pdf> [<https://perma.cc/C2DT-QPXM>].

¹⁵⁵ Affordable Prescriptions for Patients Act of 2019, S. 1416, 116th Cong. (2019).

¹⁵⁶ Sarah Kliff, *The True Story of America’s Sky-High Prescription Drug Prices*, VOX, (May 10, 2018, 9:19 AM), <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> [<https://perma.cc/MF6C-PLZK>].

¹⁵⁷ Lamm, *supra* note 114.

¹⁵⁸ Lemus & Ozkul, *supra* note 143.

strategies by brand drug manufacturers' plans for extending market exclusivity. They include stricter interpretation of patenting rules, secondary patent challenges, prohibitions on reverse payment settlements, and the misuse of restricted distribution programs and REMs.¹⁵⁹

IV. RARELY USED MECHANISMS FOR COMPELLING BRAND DRUG PRICE REDUCTIONS

A. TRIPS Agreement's Compulsory Licensing

Requiring the owner of a patented brand drug to compulsorily license to manufacturers and sell the drug at reasonably affordable prices is one solution to the issue of addressing the affordability of patented drugs. The patent laws of the United States do not mandate compulsory licensing. Real property law, for example, permits some maximum price restrictions. Municipal rent control laws limit the lessor to a reasonably fair rate of return even if that return is less than the rate of return that could be gained in an unregulated market.¹⁶⁰ If these practices were applied in intellectual property and patented brand drugs specifically, the approaches would likely be viewed as a highly intrusive, anticompetitive marketplace interference. Compulsory licensing provides the same benefits, but would be less intrusive in the marketplace.¹⁶¹

There is precedent for the compulsory licensing of drugs. Under the TRIPS agreement, the owner of a patented brand drug would be required to license the right to make and sell the drug to a developing country. Articles 27.1 and 33 of the TRIPS agreement provide that World Trade Organization ("WTO") member countries are required to grant patent protection for pharmaceutical medicines or processes for at least twenty years from the date the patent application was filed. In order to promote access to existing drugs and promote drug R&D, Article 31 of the TRIPS agreement allows compulsory licensing as "other use without authorization of the right

¹⁵⁹ Kerstin Noelle Vokinger et al., *Strategies that Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MEDICINE 1665 (2017).

¹⁶⁰ RALPH E. BOYER ET AL., THE LAW OF PROPERTY (1991). Note that Rutschman (2021) also considered if intellectual property were treated as real property for which in the public interest, a government could exercise eminent domain and engage in a taking in exchange for fair compensation. Rutschman notes that the Federal Circuit has applied the three-prong test that the Supreme Court developed in *Penn Central* to identify regulatory takings of real property to cases involving patents. Ana Santos Rutschman, *Property and Intellectual Property in Vaccine Markets*, 7 TEX. A&M J. PROP. L. 110, 129-30 (2021) (citing Dolin & Manta (2016) who argue that the 2015 *Horne vs. Department of Agriculture* decision subjects patents to the Takings Clause. Gregory Dolin & Irena D. Manta, *Taking Patents*, 73 WASH. & LEE L. REV. 719, 771-72 (2016)).

¹⁶¹ Andrew Beckerman-Rodau, *Patent Law - Balancing Profit Maximization and Public Access to Technology*, 4. COLUM. SCI. & TECH. L. REV. 1, 1 (2001).

holder.”¹⁶² It permits member countries to impose compulsory licensing in restricted circumstances and under specified conditions. An appropriate royalty rate for the license can be set by a neutral third-party government entity or the WTO.¹⁶³

Compulsory licensing authorizes the production of generic versions of patented medicines that treat mostly Type II diseases – diseases that are found primarily in poor, developing countries.¹⁶⁴ In countries that exercise compulsory licensing, the government requires patent holders to relinquish their patent rights to a government institution or a licensee in exchange for a predetermined fee.¹⁶⁵ It is debated whether compulsory licenses result in significantly cheaper prices in underdeveloping countries because there is evidence that copied products that result from compulsory licensing sell at high prices. This phenomenon occurs despite R&D expenses being minimized overall.¹⁶⁶ Sapna Kumar, Professor of Law, notes that the United States has opposed compulsory licensing for many decades.¹⁶⁷

In 2004, economics professor Aidan Hollis proposed compulsory licensing of patents at no cost. The patent holders would be rewarded based on the drug’s rated quality of life improvement and the extent to which it is used. Hollis called this outcome-based approach an efficient reward system for pharmaceutical innovation. A government agency would reimburse the patent holder each year based on a usefulness rating and annual sales.¹⁶⁸

Under the Hollis proposal, drug developers would receive an income from government payments based on the drug sales, frequency of drug use, and a usefulness rating of the drugs. Drug assessments required for the ratings would need to be performed on an ongoing basis.¹⁶⁹

Like the dominance of brand drug manufacturers, the phone utility company AT&T maintained a dominant position in the telephone industry with aggressive patenting, restrictive cross licensing, and lawsuits against

¹⁶² WTO, *supra* note 5.

¹⁶³ Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AMER. UNIV. INT’L. L. REV. 941, 958–61 (2000).

¹⁶⁴ LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 141 (2011).

¹⁶⁵ Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT’L L. 363, 390 (2000).

¹⁶⁶ Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and The Reality*, 33 IDEA 349, 352 (1993).

¹⁶⁷ Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CTRLR 57, 57 (2022).

¹⁶⁸ Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* 1 (2004). [<https://perma.cc/W9EW-BRLR>].

¹⁶⁹ Dean Baker, *Financing Drug Research: What are the Issues?*, CTR. FOR ECON. & POL’Y RSCH. (Sept. 22, 2004).

patent infringers. AT&T eventually submitted to government regulation and price caps in order to allow smaller telephone companies to break into the marketplace. Compulsory licensing was required in U.S. antitrust decrees. There were warnings that this would bring an end to patent protection and the beginning of making everyone's patents everybody else's. The actual impact was not this dire. Harvard Business School students asked companies subjected to compulsory licensing if the United States antitrust decrees affected their motivations for investing in R&D

Law professor Sapna Kumar notes that in October 2020, in response to the COVID-19 pandemic, India and South Africa petitioned the WTO to let governments give up intellectual property rights. Waivers must be agreed to by all WTO member states, and many were opposed. Some critics that opposed IP waivers favored helping low-income countries get COVID-19 vaccines.¹⁷⁰ Professor of bioethics, humanities and philosophy Nancy Jecker and Caesar Atuire, professor of philosophy, opined that temporary IP waivers are useless since drug shortages are not a temporary problem.¹⁷¹ In May 2021, the Biden administration supported giving up IP protection for COVID-19 vaccines. U.S. Trade Representative Katherine Tai called the pandemic an extraordinary circumstance requiring special measures. The European Union ("EU") called for WTO members to recognize the exceptional, emergency nature of the pandemic and that "compulsory licensing should expand to exports to countries lacking manufacturing capacity, and the level of remuneration due should be affordable."¹⁷²

Kumar further notes that Section 1498's march-in-rights for federal government funded research that results in the development of intellectual property (discussed in Part IV(b) below) could be a valuable tool. It is a lengthy bureaucratic process, however, since the patent holder is afforded appeals. Section 1498 cannot be used unless the federal government sponsored the research. Kumar opines that the current law is not sufficient for dealing with drug shortages because "third parties cannot petition for a compulsory license for inventions that were not government-funded."¹⁷³

The question that this research proposes to answer is whether it is possible to revise law and institutions with a reform plan that "maximizes *both* medical innovation and access to medicines."¹⁷⁴ To answer this

¹⁷⁰ Pinelopi Koujianou Goldberg, *Forget the Vaccine Patent Waiver*, JOONG ANG DAILY, May 27, 2021.

¹⁷¹ Nancy S. Jecker & Caesar A. Atuire, *What's Yours is Ours: Waiving Intellectual Property Protections for COVID-19 Vaccines*, 47 J. MED. ETHICS (2021).

¹⁷² Kumar, *supra* note 167, at 89.

¹⁷³ *Id.* at 100.

¹⁷⁴ Helfer & Austin, *supra* note 164, at 91.

question, a number of alternative strategies have been proposed over the past two decades.

B. *March-in-rights*

The United States heavily subsidizes the pharmaceutical industry with research funding and tax breaks.¹⁷⁵ Critics call the phenomenon of high drug pricing “paying twice.” The idea is that the United States federal government pays for the research and then a second pay out occurs through the purchase of market priced resulting drug products. This phenomenon is also called the privatization of federally funded research.¹⁷⁶

The 1980 Bayh-Dole statute grants recipients of federal funds exclusive rights to inventions created with that funding, subject to federal government “march-in rights.” A right to march-in means that a federal agency may award itself a license to practice the invention if it is essential to alleviate public safety or health demands that a contractor, assignee or licensee of federally sponsored research funding cannot properly meet. There has to be a public use and the goal must be to achieve a practical application of the invention.¹⁷⁷ One problem with implementing this provision is that the contractor, assignee, or licensee can appeal the government’s decision to march-in. Law professor Robert Field advocated having only the patent holder be able to appeal the judgment, and encouraging Congress to make it easier for federal funding agencies to march-in. Furthermore, march-in-rights have never been exercised.¹⁷⁸

One problem is that in developing an FDA approved drug product, a manufacturer may file for additional patents which are unrelated to government sponsored research. Multiple patents may protect a single medicine. In 2016, the consumer advocacy groups Knowledge Ecology International and Union for Affordable Cancer Treatment petitioned the United States DHHS for Section 202 of the Bayh-Dole Act to be invoked to allow a generic version of the prostate cancer medicine enzalutamide, or

¹⁷⁵ Shyam Goswami, *Windfall Profits and Failed Goals of the Bayh-Dole Act*, 19 J. GENDER RACE & JUST. 375, 376 (2016) (citing Robert I. Field, *How the Government Created and Sustains the Private Pharmaceutical Industry*, 6 ST. LOUIS U.J. HEALTH L. & POL’Y 11 (2012)).

¹⁷⁶ Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177, 181-182 (2019).

¹⁷⁷ 35 U.S.C. § 203(a)(1)-(4) (2011). *See also Id.* at 181.

¹⁷⁸ Goswami, *supra* note 175, at 392. *See also* Alfred B. Engelberg & Aaron S. Kesselheim, *Use the Bayh-Dole Act to Lower Drug Prices for Government Healthcare Programs*, 22 NATURE MED. 576, 576 (2016) [<https://perma.cc/UPJ9-ULGG>]; and Zoe Haggerty, *Patentability of COVID-19 Vaccines*, 2021 B.C. INTEL. PROP. & TECH. F. 1, 13 (2021) (noting that the fact that march-in-rights have never been invoked suggests that it is not an obvious solution to the COVID-19 pandemic because the government is hesitant to overstep its bounds in relation to the private marketplace).

Xtandi. The government was paying \$42.38 per pill and received an offer of \$3 per pill for the generic version.

Legal scholar Alfred Engelberg and Aaron Kesselheim, professor of medicine opined that “a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose of producing enzalutamide for sale to the government.”¹⁷⁹ One reason the government does not exercise the march-in right is because critics argue that doing so devalues private rights and reduces private industry’s desire and willingness to invest in commercializing innovations resulting from federally-funded sponsored research.¹⁸⁰ Critics also argue that this would have a chilling effect on public private partnerships.¹⁸¹

In 1989, the DHHS’ National Institute of Health (“NIH”)’s Patent Policy Board adopted a reasonable pricing clause policy motivated by the 1987 FDA approval of the drug azidothymidine (“AZT”) for the treatment of the Human Immunodeficiency Viruses (“HIV”). The Burroughs Wellcome Company launched AZT for \$8,000 to \$10,000 per patient per year. Burroughs received government sponsored research funding from the National Cancer Institute to develop AZT. Since this price was too expensive for patients suffering from HIV, the NIH responded. To exclusive licenses sought by contractors, assignees or licensees under Cooperative Research and Development Agreements (“CRADAs”), the NIH implemented a reasonable pricing condition.

The reasonable pricing clause states that the DHHS “has a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.” It stated that “exclusive commercialization licenses granted for NIH/Alcohol, Drug Abuse, and Mental Health Administration (“ADAMHA”) intellectual property rights may require that this relationship be supported by reasonable evidence.” One problem with this clause is the lack of an enforcement mechanism.¹⁸² The industry response was negative, and private industry withdrew from entering into CRADAs since they did

¹⁷⁹ Engelberg & Kesselheim, *supra* note 178, at 576.

¹⁸⁰ *Id.*

¹⁸¹ Amy C. Madl, *Using Value-Agnostic Incentives to Promote Pharmaceutical Innovation*, 71 STAN. L. REV. 1305, 1347 (2019).

¹⁸² Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. MED. 177, 194 (citing OFF. TECH. TRANSFER NAT’L INSTS. HEALTH, 1992 PHS TECHNOLOGY TRANSFER DIRECTORY NIH/ADAMHA/CDC/FDA, *Policy Statement on Cooperative Research and Development Agreements and Intellectual Property Licensing* § 16 “Pricing,” 311 (Oct. 1992), <https://archive.org/details/1992phstechnolog00nati> [<https://perma.cc/6UAV-RQCW>]; see also NIH/ADAMHA Patent Policy Board V-13, Cooperative Research and Development Agreement, Article 8.3 “Pricing,” (Apr. 24, 1989).

not want to be subject to price constraints. By 1995, the NIH revoked the policy.¹⁸³

In 2001, letters containing Anthrax spores were mailed and the drug Cipro could counter its effects. There was not enough ciprofloxacin (“Cipro”) to fill the emergency demand, however. Senator Chuck Schumer “suggested that the government allow generic manufacturers infringe the Cipro patent to increase the government’s stockpile of the drug.” This march-in was not necessary because Bayer agreed to supply 100 million tablets at a discounted rate. In 2015, Senator Bernie Sanders requested the exercise of Section 1498 for the drug Sovaldi to lower Hepatitis C medication. His request resulted in no action.¹⁸⁴

In 2017, U.S. House of Representatives member Henry Waxman proposed, using the threat of march-in-rights, to set prices for drugs developed with government funds.¹⁸⁵ According to Kuan, the NIH received at least twelve march-in petitions when a company’s production was not meeting demand needs or when a company set a high drug price. In all cases, the companies’ production plans were deemed satisfactory, and the NIH declared that controlling drug prices was outside of their authority. The mere threat of a march-in during the AIDS epidemic, however, enticed Abbott Laboratories to lower the price of the HIV drug ritonavir.¹⁸⁶

C. Patent buyouts

Patent buyouts date back to 1837 when the French government compensated Louis Jacques Mande Daguerre for the daguerreotype imaging process.¹⁸⁷ While the exercise of march-in-rights engages pharmaceutical companies in an involuntary manner, a voluntary patent buyout is a one-time

¹⁸³ Amy C. Madl, *Using Value-Agnostic Incentives to Promote Pharmaceutical Innovation*, 71 STAN. L. REV. 1305, 1347 (2019) (citing *Nat’l Insts. Of Health, Dep’t Of Health & Human Servs., NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interests are Protected* 10-11 (2001), [<https://perma.cc/F3MZ55N6>]); Madl, *supra* note 181, at 1347.

¹⁸⁴ Brittany S. Bruns, Note, *The Pharmaceutical Access Act: An Administrative Eminent Domain Solution to High Drug Prices*, 106 CALIF. L. REV. 2023, 20492048-49 (2018). See also Amy Kapczynski & Aaron S. Kesselheim, ‘Government Patent Use’: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFFAIRS 1, 2 (2016) [<https://perma.cc/VKM7-6WU9>]. For more history on the use of §1489 march-in-rights see also Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 301 (2016).

¹⁸⁵ Nicholas Florko & David Lim, *House GOP Tax Plan Would Repeal Orphan Drug Tax Credit*, 23 INSIDEHEALTHPOLICY.COM’S FDA WEEK; ARLINGTON 1 (Nov. 3, 2017).

¹⁸⁶ Roger Kuan & Joan Wang, *Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19*, 33 INTELL. PROP. & TECH. L.J. 11, 12 (2021).

¹⁸⁷ See Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1144 (1998). Kremer warns that to thwart unlimited government decisions and discretion related to patent buyouts, perhaps an auction system should be employed.

payment made in return for using a patent. A buyout allows generic manufacturers to enter the market before patents expire. The buyout price is negotiated between patent holders and the United States government.¹⁸⁸ Patent buyouts would not have the same chilling effect as march-in rights because “no price controls attach – the government can only buy a federally-funded therapy at market price from a willing seller, and firms that purchase rights at auction can develop and price the acquired therapies subject only to marketing and regulatory constraints.”¹⁸⁹

A patent buyout has been recommended for the opioid crisis. Alternatively, Yale Law School student, Alex Wang and Harvard Professor of Medicine Aaron Kesselheim recommended that the government buy and stockpile the Evzio naloxone auto-injector produced by Kaleo in response to the Opioid crisis. Naloxone functions as an overdose reversal agent and opioid antagonist and is essential to the public health response to this crisis.¹⁹⁰

Further, law professor Christopher Morten and intellectual property law researcher Charles Duan advocate for the use of Section 1498 march-in rights rather than patent buyouts.¹⁹¹ This is because Section 1498 has four features: (1) employment of an impartial judge, (2) use scope flexibility, (3) determination of post crisis of recompense and (4) speed of innovation.

D. Defense Production Act

The 1950 Defense Production Act (“DPA”) was enacted during the Korean War.¹⁹² The DPA allows the executive branch to require that federal contracts with private companies get prioritized over that companies accept and perform contracts in order to ensure that the United States government can meet production needs required for national defense.¹⁹³ During the COVID-19 pandemic, United States hospitals “faced shortages of critical drugs, including sedatives and neuromuscular blocking agents needed to intubate patients and maintain ventilatory support, opioids for pain control and sedation, antibiotics to address secondary bacterial infections, and bronchodilators to open airways.”¹⁹⁴

¹⁸⁸ See Amy Kapczynski, *Government Patent Use: A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFAIRS 791, 794 (2016).

¹⁸⁹ Madl, *supra* note 181, at 1347.

¹⁹⁰ See Alex Wang & Aaron S. Kesselheim: *28 U.S.C. 1498 and Evzio*, 46 J.L., MED. & ETHICS 472, 472 (2018).

¹⁹¹ See Christopher J. Morten & Charles Duan, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 Fall YALE J.L. & TECH. 1, 2 (2020).

¹⁹² Brooke L. Raunig et al., *Drug Shortages and the Defense Production Act*, 110 AJPH 1504, 1504 (2020) (citing Defense Production Act, Pub L No. 81–774, 50 USC §4501 et seq. (Sept. 8, 1950)).

¹⁹³ Kuan, *supra* note 186, at 12.

¹⁹⁴ Raunig, *supra* note 192, at 1504.

Knowledge of COVID-19 drug shortages were reported in February 2020. By October 2020, the DPA was not invoked for drugs due to government hesitancy.¹⁹⁵ In January 2021, the Biden administration announced the use of the DPA to launch a full-scale wartime effort to ramp up vaccine production and distribution during the COVID-19 pandemic.¹⁹⁶ Critics argue that use of the DPA could limit incentives for the pharmaceutical industry to invest in improvements to avert future shortages “such as strengthening contractual supply-assurance provisions, engaging with multiple suppliers, preparing alternative treatment protocols and other contingency plans, and holding larger inventories in reserve.”¹⁹⁷ Law professor Brooke Raunig, medical professor Aaron Kesselbein, and legal researcher Jonathan Darrow with the Program on the Regulation, Therapeutics and Law (“PORTAL”) at Brigham and Women’s Hospital advise that in order to explain the potential extent the DPA could be used, it is important to have knowledge of production capabilities.

V. DRUG PRICING REFORM PROPOSALS

A. *Essential Facility Doctrine & Regulatory Compacts*

Drug R&D costs and exclusive patent rights make duplication by other companies difficult for competitors such as generic drug manufacturers. Exorbitant drug costs deny access to many consumers. Drug patent holders have a monopoly until the patent expires. Exorbitant drug costs deny access to many consumers. Once patents expire, the generics can take as much as 90% of patent holders’ sales, which result in cost savings to consumers.¹⁹⁸ Patented brand drug manufacturers can provide the drugs under a regulated scheme. The Essential Facilities Doctrine provides such a regulatory scheme.

¹⁹⁵ See *id.* at 1505 stating that “[s]uch hesitancy to use the DPA could render its authorities futile if critical drugs are not produced in time to address patient needs.”

¹⁹⁶ See Janice Hopkins Tanne, *Covid-19: Biden Launches National Plan Based on “Science and Public Health Alone”*, 372 *BMJ* (2021); see also Beth Wang, *Govt. Will Buy 200M More Vaccine Doses to be Delivered by Summer*, *INSIDE CMS*, 1/28/2021. (2021); see also Emma Bowman & Ashish Valentine, *Biden Backs Waiving International Patent Protections for COVID-19 Vaccines*, *NPR*, 5/5/2021. 2021; see also Z. Junfeng, *U.S. backs waiving international Patent Protections for COVID-19 Vaccines*, *CGTN*, 2021. Note that Germany opposed the waiver of IPR. The WTO advocated for a negotiated compromise. There is a need to protect global supply chains and do technology transfer simultaneously; see also Dharshini David, *COVID: US Backs Waiver on Vaccine Patents to Boost Supply*, *BBC NEWS*, 5/6/2021. (2021); see also Davide Rigo, *Global Value Chains and Technology Transfer: New Evidence from Developing Countries*, 157 *REV. OF WORLD ECON.* (2021).

¹⁹⁷ Raunig, *supra* note 192, at 1505.

¹⁹⁸ Jack DeRuiter & Pamela L. Halston, *Drug Patent Expirations and the “Patent Cliff,”* 37 *U.S. PHARM.* 12, 12 (June 20, 2012), <https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff> [<https://perma.cc/SXP2-GRRG>].

The Essential Facilities Doctrine has historical roots. In *Munn v. Illinois* (1876) the United States Supreme Court confirmed the state commissions' right to oversee a range of commercial activities that had a public interest.¹⁹⁹ This was followed by the 1912 case *U.S. v. Terminal R.R. Ass'n of St. Louis*, which set out the Essential Facility Doctrine.²⁰⁰ It called on the owners of all river crossings in St. Louis, Missouri to sell access to railroad companies. This paper argues that the river crossings are analogous to brand drugs. Brand drug manufacturers provide an essential facility to consumers and need to be regulated in this manner. The six elements of essential facilities which must be met are: (1) difficulty of the competitor to practically or fairly reproduce the essential facility; (2) the fact that duplicating the facility would be economically unviable; (3) the fact that preventing competitors from using it would severely disadvantage any new entrants to the market; (4) established control of the essential facility by a monopolist; (5) denied use of the facility to competitors; and (6) feasible to provide the facility.

Today, there are Regulatory Compacts for water, electric and natural gas utility commissions. Utility commissions provide Certificates of Public Convenience and Necessity ("CCN"s), rate regulation, and financing regulation. The CCNs provide market entry control and keep out utility providers that should not have the right to provide the services. It is proof that the utility provider has been vetted. The three elements of regulatory compacts include: (1) the utility must provide necessary services for a vast majority of customers; (2) if the utility service does not exist, it must be created by the government to satisfy the needs and convenience of consumers; and (3) a close relationship to a public interest must exist.²⁰¹

Natural monopolies only permit one rival. Electric power distribution provides an example in that it "requires the construction of an elaborate wired network. Creating duplicate networks to permit competition would inefficiently increase overall costs to consumers."²⁰² Thus, it is a natural monopoly. Besides electricity and water utility regulatory compacts, the phone company Bell also secured a natural monopoly. Bell successfully argued that a private company with a vast scale could manage the phone service efficiently. Bell entered into a quid pro quo deal with authorities.

¹⁹⁹ Charles M. Davidson & Michael J. Santorelli, *Federalism in Transition: Recalibrating the Federal-State Regulatory Balance for the All-IP Era*, 29 BERKELEY TECH. L.J. 1131, 1140 (2014); see also *Munn v. Illinois*, 94 U.S. 113 (1876).

²⁰⁰ *United States v. Terminal R.R. Ass'n of St. Louis*, 224 U.S. 383 (1912).

²⁰¹ Robert L. Swartwout, *Current Utility Regulatory Practice from a Historical Perspective*, 32 NAT. RES. J. 289, 289-290 (1992).

²⁰² Steven Semeraro, *Property's End: Why Competition Policy Should Limit the Right of Publicity*, 43 CONN. L. REV. 753, 793 n.200 (2011).

Prior to this, Bell was in a heated competition with Western Union.²⁰³ Bell was required to break up its monopoly and AT&T resulted. This is an example of how utilities can become just as monopolistic as brand drug manufacturers. Regulators need to be careful.

In addition, there is a debate over whether the United States Supreme Court adopted or completely repudiated the Essential Facilities Doctrine.²⁰⁴ Antitrust scholar Phillip Areeda expressed concern about expanding the Essential Facilities Doctrine outside the scope of physical infrastructure because such a doctrine needs boundaries.²⁰⁵ Areeda advocated that the Essential Facilities Doctrine is not a doctrine but rather an epithet.²⁰⁶ He proposed some limitations that would make it so this so-called epithet would not eliminate freedom to contract. In addition, requiring a truly ‘essential’ facility, should substantially improve competition by reducing prices, increasing production, or increasing innovation; and the holder of the essential facility should have the ability to justify why they refuse to deal.²⁰⁷ This means that there exist limiting boundaries for the application of the Essential Facilities Doctrine. The current limiting boundaries are the elements of the doctrine listed in Table 1 herein. Further, when applying the Essential Facilities Doctrine to Areeda’s proposed limits, patented brand drugs meet most of these proposed boundary constraints. We propose that the brand drug patent holders be regulated in such a manner that they do not have an opportunity to justify why they refuse to deal. Currently, they do not refuse to deal. Instead, their exorbitant prices make it difficult for many consumers to afford the drugs like when Martin Shkreli of Turing Pharmaceuticals raised the Daraprim drug price from \$13.50 to \$750 per tablet.

Further, with respect to pricing, in the 1990s, the Federal Communications Commission (“FCC”) adopted an incentive regulation for the telephone industry with the basic price-cap structure. There was a movement away from cost-based regulation toward systems of regulation that provide incentives for increasing efficient production. The goal was to allow firms to share the social gains earned from ‘efficiency’ and increased profits. The price-cap structure allowed telephone companies like Bell to

²⁰³ ROBERT B. HORWITZ, *THE IRONY OF REGULATORY REFORM: THE DEREGULATION OF AMERICAN TELECOMMUNICATIONS* 97 (1989).

²⁰⁴ Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential General Competitors*, 67 *FLA. L. REV.* (2015); *See also* *Verizon Commc’ns Inc. v. Law Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

²⁰⁵ Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 *ANTITRUST L.J.* 841, 841-854 (1990).

²⁰⁶ *Id.* at 841.

²⁰⁷ *Id.* at 853.

choose a set of prices for designated services so that an index of the price would not exceed some level.²⁰⁸ As a means of controlling natural monopolies, it is not clear what the value of price caps is.²⁰⁹

There were discussions between the CMS and the FDA about setting up a joint office to assess the affordability of pharmaceuticals. In 2004, this was held awaiting the economic study “relegated to a bit part in the setting of reimbursement by the CMS.”²¹⁰ In a study of the imposition of regulatory instruments on reimbursements (i.e., public subsidies) for pharmaceutical products in the European Union (“EU”) on R&D, health economics professor Alistair McGuire and his research collaborators discussed the cost effectiveness analysis implemented in the EU. Setting a price makes it possible to judge the economic efficiency of new products. Although price regulation attempts to set a price compatible with incentives to innovate:

“it may be argued that cost-effectiveness attempts to evaluate the relative value-for-money provided by a new health care technology through explicitly linking treatment costs to health outcomes. The implication is that formal adoption of cost-effectiveness evidence ties reimbursement to a consideration of the cost of acquiring a new product, which increases health status. Cost-effectiveness analysis establishes the comparative costs and health outcomes under review. Used in conjunction with reimbursement regulation, this amalgamates information on treatment costs with relative effectiveness. This relates reimbursement to comparative effectiveness in a manner that is explicit. Moreover, in highlighting effectiveness, this regulatory instrument also aids the definition of the indications or patient groups where the new therapy will be of greatest value.”²¹¹

Legal scholars Nicholson Price and Arti Rai have argued that government-imposed price caps are not the solution in the pharmaceutical industry. They argue that it is a mistake to view the problem as a natural monopoly, where there is only one rival, and price caps will do nothing to foster disclosure.

There is a need for both the recognition that there is a natural monopoly and a need for information sharing. Secrecy and information sharing are real

²⁰⁸ Ronald R. Braeutigam & John C. Panzar, *Effects of the Change from Rate-of-Return to Price-Cap Regulation*, 83 THE AM. ECON. REV. 191, 191 (1993).

²⁰⁹ Eshref Trushin, *Evaluation of incentives for R&D in the pharmaceutical industry with applications for neglected diseases* (Apr. 2011) (Ph.D. thesis, Queen Mary University of London) (on file with Queen Mary University of London).

²¹⁰ Alistair McGuire, Michael Drummond & Frans Rutten, *Reimbursement of pharmaceuticals in the European Union*, in REGULATING PHARMACEUTICALS IN EUROPE: STRIVING FOR EFFICIENCY, EQUITY & QUALITY EUROPEAN OBSERVATORY ON HEALTH SYSTEMS & POLICIES 130, 138 (Elias Mossialos, Monique F. Mrazek & Tom Walley eds., 2004).

²¹¹ *Id.* at 136.

problems. Consider biosimilars. Biosimilars are follow-up biologics which are highly similar to approved biologics. In addition to patent protection, there are trade secrecy issues involving biosimilars. In Europe, in order to enter the market, a generic company might need \$100-250 million and seven to eight years to reverse engineer biosimilars.²¹² Further, it is worth noting that the FDA regulates biologics and biosimilars slightly different from small molecule drugs. Enacted in 2009, the “Biologics Price Competition and Innovation Act (“BPCIA”) provides an abbreviated path to approval for biosimilars that is analogous to the ANDA process.” Biosimilar drug manufacturers use the Abbreviated Biologics License Application (“ABLA”) to demonstrate similarity or interchangeability with the approved biologic drug. The FDA cannot approve a biosimilar until after a 12-year period of exclusivity afforded to the biologic.²¹³

To understand how biosimilars, small molecule drugs and biologics differ in relation to R&D expenses and ultimately pricing, small molecule drugs are like aspirin. Biologic drugs are produced by living cells. Small molecule drugs are getting harder for brand manufacturers to discover. Thus, pharmaceutical companies have shifted away from R&D spending on small molecule drugs and toward biologics. Biologic R&D is very expensive - twenty-two times the cost of developing small molecule drugs, but “represent[s] many of the most prominent and promising new treatments for cancer and other major diseases.”²¹⁴ Biologics are used to treat patients with autoimmune disorders and various forms of cancer. Biologics are also more challenging to generate in large quantities than small molecule drugs because of their complicated structural makeup.²¹⁵

Again, there is a need for both the recognition that there is a natural monopoly and a need for information sharing. Consumers with health ailments need the drugs to improve their health. If patented brand drugs did not exist, they would have to be created by the government to satisfy consumers’ needs. Access to the highest caliber medicines to improve all

²¹² W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition & Innovation*, 101 IOWA L. REV. 1023, 1028 (2016).

²¹³ JOSEPH ADAMCZYK, ADRIENNE LEWIS & SHIVANI MORRISON, § 1498: A GUIDE TO GOVERNMENT PATENT USE, A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS 35 (2021).

²¹⁴ Price & Rai, *supra* note 212, at 1026. According to the FDA, biologics “can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources – human, animal, or microorganism.” Gene-based and cellular biologics can be used to treat a variety of medical conditions. While most drugs are chemically synthesized and their structure are known, biologics are complex mixtures that are not easily identified or characterized. See *generally*, FDA, *What are “Biologics” Questions and Answers*, FDA (Feb. 2, 2018), [fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers](https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers). [<https://perma.cc/XTT9-NZ95>]

²¹⁵ See Kumar, *supra* note 167, at 98.

citizens' health is in the public interest. Take, for example, the COVID-19 pandemic. The elements of the Essential Facilities and Regulatory Compacts are provided in Table 2. We show how drug patents meet the elements for either option.

Essential Facilities	Patented Drugs
(1) the facility could not be economically duplicated	Drug R&D and regulatory process costs and exclusive patent rights make duplication by other companies difficult
(2) denying its use has a severe negative impact on new or existing market entrants	Exorbitant drug costs deny access to many consumers
(3) a monopolist has established control of the essential facility	Drug patent holders have a monopoly until the patent expires.
(4) competitors must be unable to practically or opportunistically imitate the essential facility	Drug R&D costs, regulatory process and exclusive patent rights make duplication by other companies difficult for competitors such as generic drug manufacturers.
(5) denied use of the facility to competitors	Exorbitant drug prices are equivalent to the denial of access to many consumers.
(6) feasible to provide the facility	Patented brand drug manufacturers can provide the drugs under a regulated scheme.
Regulatory Compacts	
(1) a necessity for the vast majority of customers	Consumers with health ailments need the drugs to improve their health.
(2) if the utility service did not exist, it would have to be created by government to satisfy the needs and convenience of consumers	If patented brand drugs did not exist, they would have to be created by government to satisfy the needs and convenience of consumers.
(3) a close relationship to public interest.	It is in the public interest to provide access to the best quality drugs to all citizens that need to improve their health.

TABLE 2. ELEMENTS OF THE ESSENTIAL FACILITIES AND REGULATORY COMPACTS

When their drug patents are active, brand-name pharmaceutical companies enjoy monopoly revenues. According to the Drug Price

Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”), generic drug producers can rely on the comprehensive clinical research that brand drug companies have already conducted in order to satisfy the United States FDA requirements for their generic products.²¹⁶ The generic drug companies have to verify that their product is a bioequivalent to the previously approved brand-name medicine. Hatch-Waxman provides for ANDAs that allow generic drug companies to circumvent the stringent FDA clinical trial testing if the bioequivalent has the same active ingredients in the same therapeutic or pharmaceutical class as the brand manufacturer’s product.²¹⁷ Typically pharmacists will only substitute a brand drug with the generic if the FDA gives the generic an AB-rating. All 50 states have enacted drug product selection (DPS) laws allowing and sometimes requiring the use of generics in order to lower consumer drug prices.²¹⁸

In addition, in an effort to join the market before brand drug patents expire, an ANDA is the primary way a generic drug company might contest brand drug patents.²¹⁹ For high-risk drugs, the FDA requires drug manufacturers to comply with the Risk Evaluation and Mitigation Strategies (“REMS”). REMS are enhanced labeling, packaging, and restricted distribution safety measures.²²⁰ For the purpose of conducting bioequivalence tests, brand-name pharmaceutical companies must sell their medicines to generic drug manufacturers. The purpose of this testing is to show that a generic formulation is medically equivalent to the brand drug. In 2007, the House of Representatives included language that these product sales to generic drug companies be at market price, but the Senate never addressed this bill.²²¹

The REMS restricted distribution safety measures have been used by brand drug developers as an excuse to not provide generic manufacturers

²¹⁶ Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355-1 (2018).

²¹⁷ *Id.*; see also Craig Garthwaite, *The Economics of Drug Development: Pricing and Innovation in a Changing Market*, REPORTER (Sept. 2018), [<https://perma.cc/QDW4-PNZR>] (With respect to the 1983 Orphan Drug Act, providing R&D tax credits and extended periods of market exclusivity for drug manufacturers that develop products aimed to treat medical diseases which are rare and afflict fewer than 200,000 people. These precision medicines and orphan drugs have higher prices because they are bought for a smaller patient population. Garthwaite notes that 50% of small-molecule non-orphan drug products faced generic competition from ANDA filings; and only 33% of small-molecule orphan drug product manufacturers have an ANDA filed against them).

²¹⁸ KEVIN T. RICHARDS, KEVIN J. HICKEY, ERIC WARD, CONG. RSCH. SERV., R46221, DRUG PRICING & PHARMACEUTICAL PATENTING PRACS. 1, 22 (2020), [<https://crsreports.congress.gov/product/pdf/R/R46221>] [<https://perma.cc/L4EL-V7YL>].

²¹⁹ See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUDS. 613 (2011).

²²⁰ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

²²¹ H.R. 2900, 110th Cong. § 901(f)(6) (2007); see also S. 3187, 112th Cong. § 1131(k) (2012).

with sufficient sample amounts. This occurred when Mylan tried to develop generics of Celgene’s Thalomid and Revlimid brand cancer drugs. The REMS restricted distribution program. Celgene also allegedly imposed voluminous and unnecessary requests for information to delay Mylan. Celgene contended that it is completely up to their company to decide whom to do business with and most of the vertical agreements between manufacturers and distributors are not anticompetitive. The FTC filed an *Amicus Curiae* brief stating that Mylan’s antitrust claims were not barred as a matter of law because a monopolist’s refusal to sell to potential competitors may be illegal as a violation of Section 2 of the Sherman Act.²²²

The REMS restricted distribution safety measure was also invoked by Actelion, the brand manufacturer of Tracleer for hypertension and Zavesca for Type 1 Gaucher disease. Actelion prevented Actavis Apotex and Roxane from obtaining samples of the brand drugs by imposing the REMS distribution restrictions. Actelion also refused to sell their brand drugs directly to these generic drug manufacturers. Actelion argued that it had no obligation to sell its products to its competitors. The FTC filed an *Amicus Curiae* brief stating that the Hatch-Waxman Act cannot function as Congress intended it to if generics could not get the samples for bioequivalence testing. Again, the unwillingness of a monopolist to sell to potential rivals may constitute an antitrust violation of the Sherman Act.²²³

Product hopping is also an issue. Patent owners switch formulations for their drug to take advantage of multiple thirty-month (“30-month”) stays. The FDA’s generic approval procedure has inherent delays. Because the product might be protected by a patent, bioequivalence certification does not guarantee that the generic will be allowed to reach and enter the market. The generic manufacturer has to identify any patents that are relevant to their ANDA. If there is an unexpired patent, the generic has to attest that the patent is not violated, that their product does not infringe the patent, and notify the patentee. There are forty-five days for the patentee to sue for infringement and if the patentee sues, it gets a 30-month stay of the ANDA application.²²⁴ Lemus proposes policy changes that include relaxing generic substitution

²²² Markus H. Meier, Bradley S. Albert & Kara Monahan, Overview of FTC Actions in Pharmaceutical Products and Distribution (2019) https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf [<https://perma.cc/Z9V3-44ZY>].

²²³ *Id.* at. 84–85.

²²⁴ 21 U.S.C. § 355(j)(5)(B)(iii); *see also* Adamczyk, *supra* note 213, at 35 (“[T]he 30-month provision from the Hatch-Waxman Act does not apply to biologics. This is because the 30-month stay is only triggered by [the] filing of a small molecule ANDA, and biosimilars follow a different approval process”).

laws. The 30-month stay delays generic entry for years.²²⁵ In 2003, antitrust law professor Herbert Hovenkamp noted that:

“The existence of a single 30-month stay materially affects the bargaining calculus between pioneer and generic in a patent infringement suit, because it is the equivalent of an automatic preliminary injunction that courts would be reluctant to issue in a normal patent suit. Further, existing law under the Hatch-Waxman provision creates the potential for a pioneer to invoke multiple 30-month stays, by successively listing new patent information in the Orange Book relevant to a given drug product. The prospect of multiple thirty-month stays presents an opportunity for anticompetitive behavior that does not exist in ordinary patent infringement litigation.”²²⁶

The 2019 Orange Book Transparency Act (“OBTA”) would modify the Orange Book’s patent listing requirements. According to the OBTA, only the following sorts of patents may be listed in the Orange Book: (1) method claims for drug usage or (2) drug claims and drug substances such as active ingredients or drug product formulation patents. The 30-month stay of approval of a generic would be less available if the categories were restricted because the stay is only available if the brand sues on one of the patents for which the generic made a Paragraph (IV) certification.²²⁷

It has been argued that when brand drug manufacturers decline to give sufficient samples to generic drug manufacturers for bioequivalence testing, “courts should use the essential facilities doctrine to presume such refusals to deal are anticompetitive absent a legitimate business reason.”²²⁸ The argument that REMS-restricted drug patents should not qualify as essential facilities is that the decision to restrict access is not anti-competitive because drug patents are not essential facilities. There has to be a competitive relationship between the parties when courts apply the essential facilities doctrine. There also needs to be a sound commercial basis or business justification for the brand drug manufacturers’ conduct in dealing with generic manufacturers.²²⁹ It has also been argued that essential facilities are

²²⁵ Lemus & Ozkul, *supra* note 143.

²²⁶ Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1754 (2003).

²²⁷ Richards et al., *supra* note 218.

²²⁸ Christopher Megaw, *Reviving Essential Facilities to Prevent REMS Abuses*, 47 COLUM. J.L. & SOC. PROBS. 104, 133 (2013); *see also* Darren S. Tucker et al., *REMS: The Next Pharmaceutical Enforcement Priority?*, 28 ANTITRUST 74 (2014).

²²⁹ Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential General Competitors*, 67 FLA. L. REV. 977 (2016).

rare in the healthcare industry and if the doctrine is applied, it solely applies to hospital facilities and resources.²³⁰

Pyrimethamine, the active ingredient in Daraprim, is used to treat malaria and was found in 1952. In addition to treating many parasitic diseases, it is used to treat HIV/AIDS in combination with other drugs. There is a moderately sized market for Daraprim with only 8,000 to 12,000 prescriptions filled each year. Turing used a REMS restricted distribution system to prevent potential generic entrants from obtaining supply of Daraprim needed to perform the necessary bio-equivalency trials, despite the fact that there are no intellectual property hurdles preventing other generic manufacturers from joining the market. The employment of the REMS method indicates that they were concerned about the entry of competing generics. Some generic drug markets, however, are too small to support a second generic. Such a generic is a natural monopoly and may be able to substantially raise prices without luring entry.²³¹

Further, law professor Rachel Sachs argues that since the generic FDA approval process is too lengthy, generic pre-clearances under certain conditions is a solution. The idea is that “the FDA could preclear generics from particular active pharmaceutical ingredients (“API”s) and permit companies to market their competing product now and obtain FDA approval later.” This would shorten the time for generic competitors to enter the market.²³²

Utility services are essential. They are a necessity and the Regulatory Compact supports regulation of these services. Opponents to the regulation of electric, gas and water utilities argue that when regulators are ill-prepared and inexperienced, this has resulted in utility rate increases. They argue that this tarnishes regulators’ reputations and results in a high turn-over of utility service regulators. When this occurs, there is a decrease in continuity in decision making. As of the early 1990s, however, there was no evidence that these shortcomings could not be overcome.²³³

What has been said about the state of utility commissions 1990-2020? In 2017, attorneys Charles Read, Joseph Seliga, Mitch Holzrichter, and Noelle Coates addressed these questions. These lawyers acknowledged that it would be an onerous task to review all 50 states’ utility regulations. Instead, they summarized the 100-year histories of three states in an effort to

²³⁰ Scott D. Makar, *The Essential Facility Doctrine and the Health Care Industry*, 21 FLA. ST. U. L. REV. 913 (1994).

²³¹ Morton & Boller, *supra* note 122.

²³² Rachel E. Sachs, *Addressing Pharmaceutical Price Spikes Through Generic Preclearance*, 39 J. LEGAL MED. 169, 174 (2019).

²³³ Swartwout, *supra* note 201, at 290.

highlight recurring patterns in state regulations. They reviewed the California Public Utilities Commission, the Illinois Commerce Commission, and the State Corporation Commission of Virginia.²³⁴ A summary of their findings is provided in Table 3.

	Founding Year	Utilities regulated	Legislative Body	Problems	Praise
California Public Utilities Commission (“CPUC”)	1850	The CPUC first set max rates a RR could charge for passengers and freight; prohibited rate discrimination and extortion. It now regulates privately owned electric, natural gas, telecom, water, RR, rail transit, and passenger transportation.	Governor appoints commissioners subject to state senate approval; 6-year terms; legislature can remove a commissioner with a 2/3 vote	Beholden to the RR’s and rarely refused requests to raise rates. Deregulation in the 1990s led to a year 2000 blackout as third party produced energy could not meet peak demand created due to a cold winter, warm summer, and drought that adversely impacted hydro- electric power.	Independence from the judicial, legislative, and executive branches. Derives power from state constitution.
Illinois Commerce Commission (“ICC”)	1913	Established to negotiate utility supply contract supply, rate, and duration terms. Supervises all	Governor appoints 5 commissioners with the advice and consent of the state senate;	In 2006, the ICC approved utility plans to conduct reverse auctions. This	The state created a separate Illinois Power Agency (“IPA”) to

²³⁴ Charles C. Read, Joseph Seliga, Mitch Holzrichter & Noelle Coates, *One Hundred Years of State Utility Regulation*, 2017 A.B.A. INFRASTRUCTURE & REG. INDUS. SEC. 3.

		public utility companies including transportation, telephone, water, gas, heating, lighting and electric.	original 6-year terms is now 5-years	resulted in rate increases as much as 50%. ICC reliance on utility taxes and fees present significant challenges.	broker the supply of electricity through competitive auctions. Retailers are to procure their electricity supplies pursuant to a procurement plan developed by the IPA and approved by the ICC.
State Corporation Commission of Virginia	1816	Control over water transportation, road, and RR. Now approves transmission facilities and sets electric utility rates that are owned by investors, established prices for fuel, energy production facility and energy efficiency.		Subordinate to the state General Assembly	

TABLE 3 SUMMARY OF HISTORY OF CALIFORNIA, ILLINOIS, AND VIRGINIA STATE UTILITY COMMISSIONS²³⁵

If the regulatory compact is applied to patented brand drugs, a commission would be formed to CCN, rate regulation and financing regulation. The regulators working in this commission would need to be prepared, experienced, and have employment contracts for terms that are terminable for cause. These regulators should also be required to have mandatory training about the pharmaceutical industry and about sound, impartial decision making.

Again, utility commissions provide CCN, rate regulation and financing regulation. The CCNs provide market entry control and keep out utility providers that should not have the right to provide the services. It is proof that the utility provider has been vetted. They also serve to avoid duplication of facilities, avoid economic waste, protect the significant investment in the utility, avoid ruinous and destructive competition and avoid public inconvenience when there is duplication and waste.²³⁶ If this model is applied to patented brand drugs, it will require that only one brand drug company be allowed to manufacture one type of drug or drugs in only one category. While this could be viewed as anticompetitive, it would be welcomed as a mechanism to avoid waste for this essential service that addresses a grave public interest.

B. Other reform proposals

Economics professor Michael Kremer suggested a system of auction at fair market values in which the government purchases the majority of drug patents at auctions and transfers them into the public domain so that generic versions are produced.²³⁷ Recall that any proposed solution for the lowering of drug prices must preserve the incentive for drug companies to innovate.²³⁸

In the proposed Kremer auction system, most patents would be placed in the public domain, thereby reducing payments to drug developers. Drug prices would likely be lower since the “value that bidders place on a new patent will be drastically reduced if patented drugs must compete with newly developed drugs that are being sold as generics.” It is not clear how this plan impacts developers’ research funding, but the drug developers would not have the marketing costs that they currently have. The drug companies

²³⁵ *Id.* at 4-5, 9-10, 12.

²³⁶ Swartwout, *supra* note 201, at 306.

²³⁷ Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECONS. 1137 (2018).

²³⁸ Eric Lamm, *Keeping Consumers Out of the Crossfire: Final-Offer Arbitration in the Pharmaceutical Market*, 65 UCLA L. REV. 926, 958 (2018).

research costs would be reduced because “the Kremer system would eliminate most of the incentive to research copycat drugs (there would be little market for copycats, when breakthrough drugs are selling at generic prices).”²³⁹

In September of 2004, House Representative Dennis Kucinich proposed H.R. 5155, the Free-Market Drug Act. This was a proposal whereby the government would publicly support pharmaceutical research in order to eliminate big pharma’s justification for high prices and the need for the lengthy 20-year long period of patent protection. Kucinich proposed that a Director of a new National Institute for Biomedical Research and Development would “(1) grant non-exclusive licenses for the commercial marketing of FDA-approved candidate discoveries; (2) establish Federal laboratories to carry out this Act; and (3) establish a fund to provide cash awards for making significant advances in knowledge regarding a disease, disorder, or other health condition.”²⁴⁰ This would likely result in less incentive to carry out R&D of duplicative drugs because the research corporations would have to evaluate the results of their spending at regular intervals; and would need to disclose their research findings to competitors.²⁴¹ H.R. 5155 was referred to the House Committee on Energy and Commerce, then to the Subcommittee on Health. No further action was taken.²⁴²

In 2011, law professors Laurence Helfer and Graeme Austin proposed that a reform plan needs to include: “(1) reframing public perceptions of morally and legal behavior, (2) providing a mechanism to compel governments to provide access to lifesaving drugs, and (3) revising national health care systems and social safety nets in which access to medicine regimes are embedded.”²⁴³ They describe differential pricing and public good reform strategies. Differential pricing requires pharmaceutical firms to offer their proprietary drugs to different customers at different prices. They would still likely profit from sales to the more affluent buyers. This scheme is problematic and has been deemed unworkable. Helfer and Austin argue that the public good scheme is more promising. Drugs would be provided as a public good that pharmaceutical companies can use free of charge.

²³⁹ Dean Baker, *Financing Drug Research: What are the Issues?*, CENTER FOR ECONOMIC AND POLICY RESEARCH, (2004), [<https://perma.cc/3TUP-GN8E>]

²⁴⁰ Free Market Drug Act, H.R. 5155, 108th Congress (2003), [<https://www.congress.gov>. [<https://perma.cc/L648-6728>]

²⁴¹ *Baker*, *Supra* note 210.

²⁴² Free Market Drug Act, H.R. 5155, 108th Congress (2003), [<https://www.congress.gov>. [<https://perma.cc/L648-6728>]

²⁴³ Laurence Helfer & Graeme Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* 142 CAMBRIDGE UNIVERSITY PRESS (2011), [<https://perma.cc/SAR5-MVXC>]

Competition among companies would bring prices down closer to the cost of production. With the public good reform plan, poor populations would get a free ride on pharmaceutical research that benefits developing countries which builds goodwill.

Economic policy researcher Dean Baker proposed a similar radically transformative public good reform plan. He proposed that when the federal government funds research that results in drug patents, the patents should be put into the public domain without exclusivity to the intellectual property holders. All research findings and patents would be freely available for use by anyone. The federal government can commit a bulk of funding to private firms under long term contracts for drug research.²⁴⁴ Baker argues that relying on patent monopolies is too costly and thus needs to be eliminated. Baker later argued that since state governments support research at public universities, they could fund pharma research and make the developed drugs available to state residents at generic prices. A group of states could also act collectively in this manner.²⁴⁵

In 2014, in a policy brief and panel discussion, Scott Gotlieb, M.D., of the American Enterprise Institute proposed drug mortgages to finance high priced drug treatments. Drug mortgages are the amortization of an expensive drug over time.²⁴⁶ For example, if someone wants the Harvoni treatment for Hepatitis C which costs \$84,000, they could “take out a health care loan with a nine-year term at an annual interest rate of about 9 percent.” Repayment would only be required if the treatment works. Andrews describes a debate between Economics Professor Andrew Lo of the Massachusetts Institute of Technology, David Weinstock, an oncologist at the Dana Farber Cancer Institute, and Professor Mark Fendrick, M.D., of the University of Michigan School of Public Health. Lo and Weinstock advocate for drug mortgages. Dr. Fendrick argues that some patients do not finish their course and the treatment would not work in that event. If a person follows a doctor’s instructions, then that person would have to repay their loan, but the other patient would not. Dr. Fendrick argues that if a person follows through and does as expected, they should not be held liable for the loans.²⁴⁷

²⁴⁴ Baker, *supra* note 51.

²⁴⁵ Dean Baker, *The Future of the Pharmaceutical Industry: Beyond Government-Granted Monopolies*, 49 J.L., MED. & ETHICS 25 (2021).

²⁴⁶ J.D. Kleinke & Nancy McGee, *Breaking the Bank: Three Financing Models for Addressing the Drug Innovation Cost Crisis*, 8 AM. HEALTH & DRUG BENEFITS (2015).

²⁴⁷ See Michelle Andrews, *Is Paying A ‘Mortgage’ the Answer to Expensive Prescriptions?*, KAISER HEALTH NEWS (Mar. 29, 2016), <https://kffhealthnews.org/news/mortgages-for-expensive-health-care-some-experts-think-it-can-work/> [<https://perma.cc/ZS94-4NC4>]. See also Andrew Smith, *Renting Health vs Buying Cures: How New Financing Tools can Boost Cancer Therapy Development*, 24 EVIDENCE-

Two potential problem areas with implementing drug mortgages include: (1) clear clinical milestones for each drug candidate would need to be created and (2) the requirement of a milestone tracking tool integrated in electronic medical record systems that would trigger payment if the milestone is not achieved.²⁴⁸ In addition, Professor Lo notes that “health plans are not set up to be part of subscription models,” and there is a need for changes in state legislation to allow state Medicaid plans to engage in these types of contractual arrangements.²⁴⁹

In 2019, Senate Finance Committee Chair Senator Chuck Grassley of Iowa and Senator Ron Wyden of Oregon proposed making drug companies rebate drugs when prices rise faster than inflation. This proposal was enacted in August 2022 when President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law.²⁵⁰ Senator Grassley also advocates for drug mortgages in Medicaid “which Medicaid directors dislike because they say it would let drug companies set high launch prices.”²⁵¹

Besides these five proposed policy options, Caleb Alexander and his Johns Hopkins medical research collaborators provide a more exhaustive list, including 52 proposals. The proposals fall into categories: (1) modifying the patent system; (2) promoting research to increase the creation of new drugs; (3) amending pharmaceutical regulations; (4) reducing market demand; and (5) creating alternative pricing policies. We echo Alexander’s notes that they may have missed some policies, and that not all policies include implementation or enforcement details.²⁵²

Notwithstanding these 57 proposals, countless additional proposals continue to be put forth. For example, Legal scholar Brittany Bruns recommends a Pharma Access Act (“PAA”) requiring that an independent agency be formed in the United States to exercise compulsory licensing. This is recommended since the Section 1498 march-in-rights have not been used, with the exception of Senator Chuck Schumer’s suggestion to exercise it in response to the Anthrax threat in 2001.²⁵³

BASED ONCOLOGY (Dec. 24, 2018); and Bapu Jena, FREAKONOMICS RADIO (2023), <https://freakonomics.com/series-full/bapu/> [<https://perma.cc/9Z2M-UF2T>].

²⁴⁸ Kleinke, *supra* note 246, at 122.

²⁴⁹ Jena, *supra* note 247.

²⁵⁰ CMS, *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Initial Guidance*, INFLATION REDUCTION ACT & MEDICARE (Feb. 2023).

²⁵¹ John Wilkerson, *Senate Finance Members to Meet July 9 to Go over Drug-Price Package*, INSIDE HEALTH POLICY, (Jul. 2, 2019).

²⁵² Caleb G. Alexander et al., *Reducing Branded Prescription Drug Prices: A Review of Policy Options*, 37 PHARMACOTHERAPY PUBL’NS, INC. 79 (Oct. 17, 2017).

²⁵³ Bruns, *supra* note 184.

Netherlands Cancer Institute researcher Nora Franzen, et al. conducted a systematic review of drug pricing reduction proposals that involved screening 4,775 articles. Nine intellectual property proposals were identified, focusing on increasing competition, delinking innovation rewards from the production of pharmaceuticals, and controlling prices. These researchers concluded that “delinkage, transparency, 2-part pricing, public drug discovery, orphan drug reform, and public clinical trials” merit further analysis. They advocate that further research on the effects of policies is needed.²⁵⁴

For the COVID-19 pandemic, legal researcher Zoe Haggerty notes that since compulsory licensing and march-in-rights are not likely to be exercised by the federal government, she advocates for the Generic Open License that law professor Kevin Outterson and Aaron Kesselheim, Harvard professor of medicine, proposed in 2008.²⁵⁵ With the General Open License, once a drug is patented, it needs to be immediately available to outside developers who are allowed to manufacture it only in underdeveloped countries in order to preserve the incentive to further engage in R&D and to recuperate R&D expenses.²⁵⁶

None of the proposals in this Section V. include viewing drugs as an essential facility such as a utility similar to the electric or natural gas utilities.

VI. DISCUSSION

The downside of the 20-year exclusivity period for drug patents is that it drives up drug prices. Pricing regulatory solutions need to preserve drug companies’ ability to recuperate their R&D expenses and incentives to further invest in innovation. There is double dipping when the federal government funds R&D, however. There is also the issue of keeping not only innovation but also value at the forefront to these debates. Value is the worth of a drug with regard to its cost in terms of its benefits.

Several tools and proposals for reducing drug prices are available or have been proposed. First, there is the Hatch-Waxman Act to promote the entry of generic drugs. Generic drug entry has a lengthy approval process, however, and brands extend their period of exclusivity with reverse payment settlements, evergreening and product hopping. Generic drug companies are exposed to generic medicine shortages and price increases caused by generic market consolidations through mergers and acquisitions. The cost of generic

²⁵⁴ Nora Franzen et al., *Evidence Underlying Policy Proposals for Sustainable Anticancer Drug Prices a Systematic Review*, 6 JAMA ONCOLOGY 909 (Jun. 1, 2020).

²⁵⁵ Haggerty, *supra* note 178.

²⁵⁶ *Id.* at 2 (citing Kevin Outterson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines in Developing Countries*, 27 HEALTH AFFAIRS (2008)).

drugs is rising, and prescription prices in the United States are greater than those in other countries.

Medicare, Medicaid and Section 340B have limited eligibility for aging and low-income populations. Drug price negotiations are riddled with problems of transparency. PBMs that negotiate prices are possibly profiting too much and not passing savings on to consumers. The Section 340B program is being gamed and, although the original intention was to serve low-income communities, this program is being used by health facilities in higher income communities. Further, there is a need for universal access to drugs for the poor, middle class, wealthy, young and old.

There are several proposed drug pricing schemes: (1) value-based pricing, (2) outcome-based pricing, and (3) indication-based pricing. Data that drug manufacturers are reluctant to share is relied on heavily by value-based pricing. Information about rebates, international prices, R&D costs, marketing costs, and production costs are all proprietary business information that need to be held confidential in order for these companies to remain competitive. Outcome-based pricing uses models for which there is a lack of research on their effectiveness and there is concern that QALY and ICER thresholds can be strategically used by drug companies to increase their earnings. With indication-based pricing, drug accessibility of the high priced most effective treatments for the poor is still problematic. In other words, indication-based pricing rationalizes drug prices but does not lower the prices.

The limited, restricted use of compulsory licensing does not necessarily result in lower prices. There is also push back in the use of march-in-rights. The NIH has declared that controlling drug prices is outside of its authority. A single medicine may have several patents protecting it. Some of these patents may have resulted from federally funded research, and others privately funded. Critics also argue that government march-ins will undermine the value of commercial private rights and will have a chilling effect on public private partnerships. In contrast, patent buyouts do not have the same chilling effect as march-in-rights since they are not viewed as price controls.

Critics argue that the use of the Defense Production Act also restricts the pharmaceutical industry's incentives to spend money on advancements that prevent drug shortages. The needed investments include: (1) working with several suppliers, (2) creating alternative treatment regimens, (3) having backup plans, and (4) holding extended reserve inventory. There is a need for the government to have access to knowledge about production capacities and capabilities.

This need for information and knowledge sharing is also imperative for exercising the Essential Facilities Doctrine or Regulatory Compacts. Critics, such as legal scholars Nicholson Price and Arti Rai, argue that using these tools will do nothing to foster disclosure.²⁵⁷ Legal scholar Phillip Areeda's concern is when applying the essential facilities doctrine outside of physical infrastructure, the issue becomes how to establish boundaries.²⁵⁸

There are countless proposals for reducing drug prices including but not limited to an auction system, government supported R&D with non-exclusive licensing in exchange, differential pricing, and drug mortgages. We propose that drugs should be viewed as an essential public utility.²⁵⁹

VII. CONCLUSION

The goal of this study is to shed light on the tension between patented pharmaceutical affordability and access and intellectual property rights. Several alternatives to the current legal systems and institutions have been proposed and are described herein. The challenge is to expand access with affordability while maintaining incentives that reward research, development, and medical innovation. We recommend that the following strategy be applied:

(1) Recognize drugs and treatments as an essential public facility and natural monopoly requiring government regulation.

(2) Establish a regulatory process that:

a. determines and establishes certain classes of drugs or treatments as "essential public facilities" when they cure diseases, alleviate chronic conditions, and extend lives.

b. determines the price of the drug or treatment that fairly compensates the developer and manufacturer of the drug or treatment with a fair return on investment and equity.

c. acknowledges the global value of modern medications and treatments, eventually establishing this regulatory process under international organizations such as the WTO and World Intellectual Property Organization (WIPO).

(3) Mandate compulsory information sharing between brand companies and generics for all drugs and treatments, essential public facilities, and production capacities and capabilities.

(4) Establish and maintain strong contractual supply-assurances which involve engaging with multiple suppliers, preparing alternative treatment

²⁵⁷ Price & Rai, *supra* note 212.

²⁵⁸ Areeda, *supra* note 205.

²⁵⁹ Kliff, *supra* note 9.

protocols, keeping longer inventories in reserve when possible, and having contingency plans.

(5) The regulatory authority over utilities is about the natural monopoly arising from infrastructure and customers within a state, so the impact is arguably at the state level. With drugs, however, the monopoly is created by the USPTO and the benefit is national. Further, drug distribution is a retail distribution within the states and globally. Thus, there is a need to engage the WTO in an advisory capacity. The patenting and view of United States drug patents as an essential facility would remain at the national level.

We believe that there are collateral benefits from this strategy. It will obviate the need for more than mere “cosmetic changes” by drug developers to achieve patent extensions for brand drugs. In addition, negotiations between health insurance companies and drug companies on pricing will no longer be the dominant mechanism of price control.

The drug industry has come a long way since the days of traveling snake oil salesmen hawking patent medicines from town to town. Modern drugs and medicines cure diseases, alleviate chronic conditions, and extend lives with quality for tens of millions of people. In the United States, the patent system has supported that progress and helped to create a remarkable and robust economic and scientific engine.

These drugs are no longer the province of the few, however, they are the means by which countries maintain the health of their labor force and provide essential quality of life. It is not unlike the transformation of the utility industry that took electric lights from the living space of the rich and democratized them into an essential part of life. Modern medicine is no less an essential service than electricity and appropriately benefits from the natural monopoly status that patenting affords it. Just as in the case of electricity and other essential services, however, it is in the best interest of the government and the people it serves to ensure that these monopolies do not turn into predatory businesses preying on the sick and infirm.

Our thesis here has been that certain classes of drugs, such as those that preserve life and mitigate the effects of chronic diseases, should be regulated differently. Drug companies are entitled to a profit and a return on their investment, just as the utility monopolies. Price setting should not, however, be the province of back-room discussions between drug companies and insurers. Prices should be negotiated in public with full transparency, just as electricity rates are. In fact, a model based on a public utility approach has a great deal of merit for setting prices for essential drugs and treatments. Public utilities in the United States have been beneficial because they are reliable and affordable. Public utilities are essential facilities because they are essential for businesses and homes that rely on these operations. Since public

utilities are regulated by government to ensure that rates are fair and affordable for customers, these essential facilities provide for accessibility to citizens of different income groups. If essential drugs were regulated in the same manner as essential facilities, they can be more affordable and accessible too.

