States, Preemption, and Patented Drug Prices

*Rebecca E. Wolitz**

The enormous cost of patented medications is severely straining state budgets. Covering a single treatment might cost a state upwards of half a billion dollars, and states therefore confront difficult choices between restricting access to life-saving treatments and defunding other important health services or even schools and infrastructure programs. In light of federal regulatory abdication, states are experimenting with a diversity of cost-containment and fair-pricing efforts. State-level reform, however, confronts the headwinds of patent preemption. As patent rights are federally conferred, how—if at all—may states regulate excessively priced patented medications?

This Article begins from the premise that the federal patent system is best understood as being charged with sufficiently incentivizing innovation. Thus, excessively rewarding patent holders is not among its aims. From this premise, I advance three main arguments. First, excessively priced patented medications are at odds with the public purposes of the patent system. They are further unfair to patients and health systems against the background of their widespread unaffordability. For these reasons, drug price regulation is warranted.

Second, the federal government should be the one to comprehensively address the problem of excessively priced patented medications, but congressional action has been politically stalled and uncertain. State-level interventions offer the possibility of second-best solutions. Yet, though states are the locus of drug pricing reform, their degrees of regulatory

* Assistant Professor of Law, The Ohio State University Moritz College of Law. Former Postdoctoral Fellow, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and Harvard Medical School, with support from Arnold Ventures which provides funding for PORTAL research, but had no role in the conception, design, drafting, or revision of this manuscript. Many thanks to Doni Blumfeld, Erin Fuse Brown, Zack Buck, Mike Carrier, Jonathan Darrow, Bill Eskridge, Ari Glogower, Abbe Gluck, Paul Gugliuzza, Yair Listokin, Daniel Markovits, Michelle Mello, Elizabeth McCuskey, Lisa Larrimore Ouellette, Efthimios Parasidis, Guy Rub, Ana Santos Rutschman, Rachel Sachs, Jake Sherkow, and participants in the Fifth Annual Health Law Works-in-Progress Retreat at Seton Hall Law School for helpful feedback on this project at various stages. Any errors are my own.

freedom are constrained by misguided Federal Circuit precedent. Consequently, federal regulatory failure is compounded by neutered state regulation.

Third, states should not be preempted by federal patent law from addressing the urgent problem of excessively priced patented medications. Their exclusion is neither doctrinally required nor desirable public policy. Unfettered by patent preemption, state regulation holds the promise of improving physical and fiscal health as well as manifesting an overwhelming bipartisan preference for drug pricing reform.

States further have valuable contributions to make to federal pharmaceutical innovation policy. States have an underappreciated role to play in recalibrating federal patent policy away from the privileging of private interests and aligning it with its intended public-serving purpose. They have important contributions to make to national conversations about innovation incentives and fair drug pricing. To the extent states are patent preempted from regulation reaching patented drug prices, this is a significant and unwarranted missed opportunity both to meet the urgent needs of Americans and to pursue the best version of our federal pharmaceutical innovation policy.

I. INTRODUCTION 388
II. DRUG PRICING, PATENT RIGHTS, AND FEDERAL REGULATORY FAILURE 394
A. The Moral Case for Government Intervention 394
B. The Public Purpose of Patent Rights 397
C. Excessive Compensation and Federal Abdication 401
III. STATES AS SECOND-BEST SOLUTIONS 409
A. Looking Beyond the Federal Government 409
B. State Experimentation: Price and Payment Regulation 417
1. Price Regulation of Patented Medications 417
2. Payment Regulation: Out of Pocket Caps and Drug Affordability Review Boards 421
C. Patent Preemption and State Excessive Price Regulation 425
D. Patent Preemption Revisited 431
1. The Presumption Against Preemption 432
2. Congressional Purpose 436
IV. AVOIDING PREEMPTION AND REIMAGINING STATE PARTICIPATION IN FEDERAL PATENT POLICY 440
A. Congressional Amendment 441
B. The Shield of Sovereign Immunity 442
C. Excessive Patented Drug Price Regulation 2.0 444
D. Tax Penalties 450
E. Payment Regulation 453
F. Reimagining States as Participants in Federal Patent Policy 457
V. CONCLUSION 459

I. INTRODUCTION

Expensive prescription drugs are imposing seemingly needless hardship and sorrow on American patients, families, and health systems.[1] The origins of specific drug pricing controversies differ, but extremely expensive patented prescription drugs present a recurrent problem for patients and health systems alike.[2] New drugs account for a dramatically disproportionate share of drug spending.[3] More broadly, patented medications comprise the bulk of prescription spending despite being a minority of prescriptions.[4] In 2019, for instance, 80 percent of U.S. prescription drug spending was on branded medications.[5] Yet, branded medications represented only 9.8 percent of prescriptions dispensed.[6] In brief, patented medications are expensive, and many believe that they are excessively, unfairly so.

Given the federal nature of patents, one might reasonably expect the federal government to craft careful, comprehensive, and powerful solutions to the problem of excessively priced patented medications. A national policy solution is preferable morally and doctrinally. Yet, despite federal bipartisan support for drug pricing reform, to date, Congress and the executive branch have largely failed to act. Federal drug pricing reform remains underpowered and uncertain, and with multiple crises spanning political insurrection, climate change, immigration, and an ongoing pandemic, it is unclear whether reform will occur in the near future, let alone be meaningful. This state of affairs necessitates a search for interim second-best solutions.

---

[1] *See, e.g.*, *Our Stories*, PATIENTS FOR AFFORDABLE DRUGS, https://patientsforaffordable drugs.org/our-stories/ (last visited Sept. 23, 2021) (collecting patient narratives describing the impact of expensive medications).

[2] Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859 (2016).

[3] Although specialty drugs accounted for approximately 1 percent of Medicare Part D and Medicaid prescriptions, they account for 30 percent of net spending. *See* Huseyin Naci & Aaron S. Kesselheim, *Specialty Drugs—A Distinctly American Phenomenon*, 382 NEW ENG. J. MED. 2179, 2179 (2020) (citing CONGRESSIONAL BUDGET OFFICE, PRICES FOR AND SPENDING ON SPECIALITY DRUGS IN MEDICARE PART D AND MEDICAID 1 (2019)).

[4] BLUE CROSS BLUE SHIELD, HEALTH OF AMERICA REPORT, RISING COSTS FOR PATENTED DRUGS DRIVE GROWTH OF PHARMACEUTICAL SPENDING IN THE U.S. 1 (2017), https://www.bcbs.com/ the-health-of-america/reports/rising-costs-patented-drugs-drive-growth-pharmaceutical-spending-us (finding that single-source patented drugs make up less than 10 percent of filled prescriptions, but a staggering 63 percent of drug spending).

[5] IQVIA INST., MEDICINE SPENDING AND AFFORDABILITY IN THE UNITED STATES 33 (2020), https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us. Branded drugs commonly coincide with patented drugs.

[6] *Id*.

In a federal system, the possibility of state-level intervention offers a promising alternative in light of politically stalled and limited federal reform. States, in fact, have been experimenting with various tools to address the problem of excessively priced medications. Further, in contrast to the federal government, states have the demonstrated political ability to enact a variety of drug pricing reforms.

States have a particular interest in the pricing of patented medications. High prescription drug prices impose great personal costs on constituents and systemic costs on state budgets.[7] In 2016, for instance, Louisiana was grappling with how to pay for Hepatitis C medications.[8] The state would need to spend an estimated $760 million to treat all infected Medicaid enrollees and its uninsured, which was more than Louisiana's expenditures on "K-12 education, Veteran's Affairs, and Corrections combined."[9] Paying for these medications would mean defunding other important programs.[10] More recently, given its low clinical value, high price, and potentially sizable patient population, the FDA's controversial accelerated approval of Aduhelm (an Alzheimer's drug) is raising significant concerns about its costs for Medicaid programs.[11] Outside of Medicaid, states experience significant drug spending through correctional facilities as well as through employee and retiree health benefits.[12] State legislators, further,

---

[7] *See* Trish Riley & Sarah Lanford, *States on the Front Line: Addressing America's Drug Pricing Problem*, 39 J. LEG. MED. 81, 82 (2019).

[8] Rebekah E. Gee, *Louisiana's Journey Toward Eliminating Hepatitis C*, HEALTH AFFS. BLOG (Apr. 1, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190327.603623/full.

[9] *Id.*

[10] Sarah Jane Tribble, *Louisiana Proposes Tapping a Federal Law to Slash Hepatitis C Drug Prices,* KAISER HEALTH NEWS (May 4, 2017), https://khn.org/news/louisiana-proposes-tapping-a-federal-law-to-slash-hepatitis-c-drug-prices/; *Louisiana Budget Allocator*, DRUG PRICING LAB, https://drugpricinglab.org/tools/louisiana-budget-allocator/ [hereinafter LOUISIANA BUDGET ALLOCATOR].

[11] *See* Rachel Dolan & Elizabeth Williams, *How Might the FDA's Approval of a New Alzheimer's Drug Impact Medicaid?*, KAISER FAM. FOUND. (July 13, 2021), https://www.kff.org/medicaid/issue-brief/how-might-the-fdas-approval-of-a-new-alzheimers-drug-impact-medicaid/.

[12] PEW CHARITABLE TRS., PHARMACEUTICALS IN STATE PRISONS 1, 3 (2017), https://www.pewtrusts.org/-/media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf (noting twenty-one departments of corrections "named drug costs as one of their agency's primary health cost drivers" and showing, e.g., 32 percent of NY's 2015 prison health care spending on prescription drugs); Anne C. Spaulding et al., *Funding Hepatitis C Treatment in Correctional Facilities by Using a Nominal Pricing Mechanism*, 25 J. CORR. HEALTH CARE 15, 16 (2019) (observing that HCV medications "can still outstrip prison budgets"); Jon Lender, *Prescription Drug Spending for State Employees Runs Wild, Despite Cost-Saving Efforts*, HARTFORD COURANT (Dec. 6, 2015, 7:56 AM), https://www.courant.com/politics/hc-lender-prescription-drug-costs-1206-20151205-column.html; TEX. COMPTROLLER, TEXAS HEALTH CARE SPENDING REPORT FISCAL 2015, at 13, 17,

frequently hear from their constituents about affordability challenges stemming from the costs of their prescription medications.[13]

State budget shortfalls and challenges are likely to be exacerbated in light of the COVID-19 pandemic. At the beginning of the pandemic, states were facing "unprecedented" levels of lost revenue.[14] Moreover, millions of Americans lost their jobs,[15] and "the employment rate remains below pre-pandemic levels" with "millions still report[ing] that their households did not get enough to eat or are not caught up on rent payments."[16] As they lost their jobs due to COVID-19, many Americans became vulnerable to losing their health insurance as well.[17] Between February 2020 and April 2021, total Medicaid/CHIP enrollment grew by 11 million, or 15.5 percent.[18] Thus, the expense of patented medications remains an issue of significance, if not urgency, for individuals and states alike.

33, 36 (2017); *CalPERS Delays Launch of Two Programs to Lower Drug Costs*, CHIEF INV. OFFICER (Apr. 13, 2020), https://www.ai-cio.com/news/calpers-delays-launch-two-programs-lower-drug-costs/; Chad Terhune, *CalPERS Taps UnitedHealth to Run Its Prescription Drug Business,* CAL. HEALTHLINE (May 18, 2016), https://californiahealthline.org/news/calpers-taps-unitedhealth-to-run-its-prescription-drug-business/; Chad Terhune, *Specialty Drugs Costs Soar 30% for California Pension Fund*, KAISER HEALTH NEWS (Sept. 28, 2016), https://khn.org/news/specialty-drug-costs-soar-30-for-california-pension-fund/; Erin Alberty, *Prescriptions from Mexico? Utah is Paying Public Employees to Make the Trip*, SALT LAKE TRIB. (Jan. 5, 2020), https://www.sltrib.com/mexico-pharmacy-tourism/.

13 *See, e.g.*, Dana Gentry, *Prescription Drug Prices Make Americans Sick, Regardless of Politics*, NEV. CURRENT (Aug. 21, 2019), https://www.nevadacurrent.com/2019/08/21/prescription-drug-prices-make-americans-sick-regardless-of-politics/.

14 Allan Smith, *'Unprecedented': States Face Hundreds of Billions in Lost Revenue, NBC News Finds*, NBC NEWS (May 17, 2020), https://www.nbcnews.com/politics/politics-news/unprecedented-states-face-hundreds-billions-lost-revenue-nbc-news-finds-n1206316.

15 CENTER ON BUDGET AND POLICY PRIORITIES, STATES GRAPPLING WITH HIT TO TAX COLLECTIONS (2020), https://www.cbpp.org/research/state-budget-and-tax/states-grappling-with-hit-to-tax-collections.

16 CTR. ON BUDGET & POL'Y PRIORITIES, TRACKING THE COVID-19 ECONOMY'S EFFECTS ON FOOD, HOUSING, AND EMPLOYMENT HARDSHIPS, https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-economys-effects-on-food-housing-and (last updated Oct. 21, 2021).

17 Approximately 5.4 million workers became uninsured due to loss of employment between February and May of 2020. FAMILIES USA, THE COVID-19 PANDEMIC AND RESULTING ECONOMIC CRASH HAVE CAUSED THE GREATEST HEALTH INSURANCE LOSSES IN AMERICAN HISTORY 3 (2020), https://www.familiesusa.org/wp-content/uploads/2020/07/COV-254_Coverage-Loss_Report_7-17-20.pdf.

18 Bradley Corallo & Avirut Mehta, *Analysis of Recent National Trends in Medicaid and CHIP Enrollment,* KAISER FAM. FOUND. (Sept. 21, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/.

State-level reform, however, confronts the headwinds of patent preemption. As patent rights are federally conferred, how—if at all—may states regulate excessively priced patented medications?

This Article analyzes state excessive drug pricing reforms at the intersection of federal patent law. It advances three main arguments. First, excessively priced patented medications are at odds with the public purposes of the patent system. Further, against a background of their widespread unaffordability, excessively priced patented medications are unfair to patients and health systems. For these reasons, drug price regulation is warranted.

Second, the federal government should address the problem of excessively priced patented medications, but congressional action continues to face significant political challenges. State-level interventions therefore offer the possibility of second-best solutions.[19] Although states are the locus of drug pricing reform, their degrees of regulatory freedom are constrained by misguided Federal Circuit precedent. Consequently, federal regulatory failure is compounded by neutered state regulation.

Third, states should not be preempted on the grounds of federal patent law from addressing the urgent problem of excessively priced patented medications. Their exclusion is neither doctrinally required nor desirable public policy. Unfettered by patent preemption, state regulation holds the promise of improving physical and fiscal health as well as manifesting an overwhelming bipartisan preference for drug pricing reform.

States further have valuable contributions to make to federal biopharmaceutical innovation policy. States have an underappreciated role to play in recalibrating federal patent policy away from the privileging of private interests and aligning it with its intended public-serving purpose. They have important contributions to make to national conversations about innovation incentives and fair drug pricing. Under present circumstances, to the extent states are patent preempted from regulation reaching patented drug prices, this is a significant and unwarranted missed opportunity both to meet the urgent needs of Americans and to pursue the best version of our federal pharmaceutical innovation policy.

This Article proceeds in three parts. Part II establishes the underlying public purpose of federal patent law. It begins from the

[19] The phrase "second-best" is not intended to confer a meaning of "not very good." To quite the contrary, the second-best solutions discussed herein are thoughtful attempts to implement important and meaningful policies in light of federal inaction.

premise that patents serve a public purpose.[20] Their purpose is not the accretion of private wealth or the enrichment of inventors, but rather the promotion of inventions.[21] As such, the federal patent system is best understood as being charged with *sufficiently* incentivizing innovation. A purpose to *excessively* reward patent holders is not among the aims of federal patent policy. I argue that excessiveness can be defined by reference to the goals of federal patent law itself, suggesting a model of cost-plus pricing. As such, excessive pricing is not identical to supra-competitive pricing. Overcompensation of patent holders is unwarranted by reference to the aims of federal patent law and morally problematic when such overcompensation further renders important medications unaffordable. I make a prima facie case that overcompensation of drug manufacturers occurs and conclude that such situations are ripe for regulation. This section further observes that present federal limits placed on high drug prices, facilitated by drug manufacturers' patent rights, are nearly nonexistent.

Part III presents the possibility of state regulation as a second-best solution. This Part discusses second-best solutions and argues both for a preference for federal intervention over state intervention and for a preference for price regulation over payment regulation. This Part further discusses state experimentation with excessive price and payment legislation. It then turns to the doctrinal issue of patent preemption. It analyzes the practical barrier to state regulation posed by Federal Circuit precedent in *BIO v. D.C.*[22] and argues that this precedent is misguided. State excessive price regulation should not be preempted. Patent preemption is neither doctrinally required nor good public policy.

Part IV then considers how states may move forward in light of this precedent. This Part considers five options available to states: (1) congressional amendment; (2) the shield of sovereign immunity; (3) reformulated excessive price regulations; (4) tax penalties on excessive price increases; and (5) payment regulation. It ultimately argues that payment regulation, at this time, is likely the least risky and most expedient comprehensive option for state-level drug pricing reform that avoids patent preemption. This Part concludes by considering the broader themes at issue in conceptualizing the role of states as participants in federal patent innovation policy through the vehicle of drug pricing reform. States have valuable roles to play as participants in federal patent policy and national conversations on fair drug pricing.

---

[20] *See infra* Section II.B.

[21] U.S. CONST. art. I, § 8, cl. 8.

[22] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007).

Two caveats to this article's arguments and discussions are in order. First, this discussion focuses exclusively on the issue of patent preemption. This focus does not mean that other issues are unimportant or even non-dispositive. For instance, in addition to surviving patent preemption, state-level price or payment regulations will also need to survive the dormant Commerce Clause. In light of Maryland's generic anti-price-gouging law's failure in the Fourth Circuit on these grounds,[23] there is credible reason to think that such challenges may not be insignificant.

Second, this Article primarily contemplates state reform efforts outside the context of Medicaid. Yet, there is considerable change occurring within state Medicaid programs with regard to prescription drug payment. Many states are experimenting with value-based contracting or cost review to secure supplemental rebates.[24] As state reforms made internal to a state-federal program raise separate considerations, their discussion and evaluation are deferred.

As already emphasized, this Article contemplates state-level drug pricing reform largely as a second-best solution. State-level regulation is instrumentally valuable in achieving the desired policy goals of fairer and less excessive patented drug prices. State participation in federal pharmaceutical patent policy is also inherently valuable in its expression of traditional values of federalism, such as local experimentation and accountability. Yet, stemming the tide of excessively high patented drug prices merits a national solution and not a patchwork of varied responses. Resource-strapped states should not have to take on one of the world's most powerful industries so that their constituents have reasonably affordable access to one of life's necessities. The federal government qua federal government is far better placed to address these issues of national significance. The problem of excessively priced patented medications is not the unique problem of Californians or Virginians: it is a problem for Americans. In the absence of comprehensive federal reform, however, states are not waiting.[25]

---

[23] *See* Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 667–74 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

[24] *See infra* Section III.B.2.

[25] *See* Riley & Lanford, *supra* note 7, at 93.

II. DRUG PRICING, PATENT RIGHTS, AND FEDERAL REGULATORY FAILURE

A. *The Moral Case for Government Intervention*

This Article's arguments for the examination and implementation of excessive drug price regulation builds on a larger background theory that supports the moral desirability of targeted price regulation.[26] Targeted government regulation of excessively high prescription drug prices can be justified on the basis of efficiency and fairness: the overcompensation of patent holders is unsupported by reference to the goals of federal patent law, and when patient affordability is further at issue, such overcompensation is unfair.

Moral argument for excessive drug price regulation relies on the assumption that prescription drugs are necessary goods. Though it can be challenging to define the precise parameters of what is or is not a necessity, necessary goods encompass—at the very least—those items fundamental to survival, and arguably, good health.[27] Even if not all prescription medications are necessities, many are, and I shall leave that assumption undisturbed.[28]

That prescription drugs are necessities means that we care about their access and affordability in a way that we do not regarding luxuries.[29] As necessary goods, unaffordable prescription medications can seem unfair.[30] Their unaffordability appears to serve as a moral inflection point.[31] It might be thought of as a proxy for the imposition of sacrifices that appear deeply unfair: the compelled sacrifice of other necessities.[32] In the case of prescription medications, unaffordability

---

[26] *See* Rebecca E. Wolitz, Drug Manufacturers, Pricing, and Ethical Obligations 171 (July 26, 2021) (Ph.D. dissertation, Yale University) (on file with author); Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 NW. U. L. REV. 859, 863–64 (2020) (putting forward five commonsense assumptions regarding a workable excessive drug price regulation).

[27] *Cf.* Ezekiel J. Emanuel, *When Is the Price of a Drug Unjust? The Average Lifetime Earnings Standard*, 38 HEALTH AFFS. 604, 604 (2019) (arguing that many health care goods are "necessary to live a decent human life").

[28] *See, e.g.*, *id.*; *see also* Richard A. Spinello, *Ethics, Pricing and the Pharmaceutical Industry*, 11 J. BUS. ETHICS 617, 621 (1992). For brevity, I will refer to prescription medications as if all are necessities, with the caveat that particular instances may merit closer inspection of this assumption.

[29] *See* Emanuel, *supra* note 27.

[30] *Id.*

[31] Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 173.

[32] Currently, no consensus view—either normative or empirical—exists as to what it means to be an affordable medication. A few proposals have been made, including the "average lifetime earnings standard" offered by Dr. Ezekiel Emanuel. *See* Emanuel, *supra* note 27, at 604. The Institute for Clinical and Economic Review has also generated a methodology for setting affordability and budgetary impact thresholds for the drugs it

suggests that a patient must give up her medication itself or a necessity of another kind. For instance, a patient may be compelled by the high price of a prescription drug to choose between her medication and rent when it is not possible to pay for both.[33] In such a case, the patient faces a tradeoff she ought not have to make. This idea has parallels with institutions. A state, for instance, should not have to decide whether to cover a single, yet important, medication or defund educational programs or social services for vulnerable children.[34]

As the unaffordability of prescription medications can have many causes, however, one cannot automatically conclude that *if* unaffordability is unfair, the *price* of a medication is unfair.[35] Yet, for a category of cases, the conceptualization of unaffordability as indicative of price unfairness is compelling. These are cases in which the price of a medication already appears excessive by reference to independent criteria. As argued in more detail below, in the case of patented medications, the goals of the federal patent system can provide this criterion: patent rewards that exceed those necessary to effectuate the goals of federal patent law are excessive and overcompensate patent holders.

Thus, when affordability challenges are overlaid upon excessive patented drug pricing, additional justifications for regulation become available. If the overcompensation of patent holders occurs, not only

evaluates. Steven D. Pearson, *The ICER Value Framework: Integrating Cost Effectiveness and Affordability in the Assessment of Health Care Value*, 21 VALUE IN HEALTH 258, 259 (2018). Different conceptions of "affordable" have been offered in the adjacent literature on affordable health insurance, but again there is no consensus view. Of those accounts, a more plausible account offered by Carla Saenz, the "reasonable tradeoffs" view, argues that health insurance is affordable if the purchaser need not forgo a benefit of comparable value. She argues that a decent minimum of benefits from within each of the categories of education, housing, nutrition, employment, safety, and affiliation offers comparable benefits to health insurance. Carla Saenz, *What is Affordable Health Insurance? The Reasonable Tradeoff Account of Affordability*, 19 KENNEDY INST. ETHICS J. 401, 408 (2009). Applying this account to prescription drug pricing, medications would be deemed unaffordable if the costs of a patient's medications forced her to give up the benefits of a decent minimum of a comparable benefit in one of the identified categories.

33 Michael Sainato, *'Medication or Housing': Why Soaring Insulin Prices Are Killing Americans*, GUARDIAN (Sept. 23, 2019, 2:00 AM), https://www.theguardian.com/society/2019/sep/23/diabetes-americans-soaring-insulin-prices; Jo Ann Jenkins, *Prescription Drug Prices Are Out of Control*, CNN (Mar. 17, 2019), https://www.cnn.com/2019/03/17/opinions/prescription-drug-pricing-out-of-control-jenkins/index.html ("[T]oo often older people face the grim reality of having to choose between paying for their medicines and paying for food or rent.").

34 *See* LOUISIANA BUDGET ALLOCATOR, *supra* note 10.

35 Wolitz, *supra* note 26, at 166–68; *see* NAT'L ACADS. OF SCIS., ENG'G, & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 1 (Norman R. Augustine et al. eds., 2018) ("*Affordability*, however, is a complex function of factors, including not just the prices of the drugs themselves[] . . . .").

would regulation be justified as a countermeasure to inefficiency by reference to the purposes of federal patent law and policy, but government regulation would be justified as a correction to unfairness. When actual prices for patented medications exceed both the affordable price and the non-excessive price, those prices are not simply utterly unwarranted, they are also unfair.[36] Patients should not have to choose between necessities, such as medicine and housing or food (nor states between coverage of a single drug and programs for children). Further, it is unjustified for the government to permit, through a lack of regulation, the imposition of these bleak circumstances if manufacturers are *already* overcompensated by reference to the goals of the federal patent scheme that facilitates this ability to overcharge in the first instance. Regulation of prices down to the affordable price is therefore justified on the basis of unfairness to patients and institutions. Regulation down to the non-excessive price is justified on grounds of efficiency, and in some cases, unfairness as well.[37]

Whether government regulation in cases of excessively priced patented medications is justified on grounds of efficiency or fairness, however, two showings must be made. First, it must be demonstrated that overcompensation of patent holders is not among the purposes of federal patent law. This issue becomes of particular importance doctrinally for a patent preemption analysis. If federal patent law aims to provide patent holders with wholly unrestricted rewards, normative arguments against this position are preserved, but doctrinal arguments will flounder. Second, to justify governmental intervention, at least a prima facie case must be made that the overcompensation of patent

[36] Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 204; *see also* Suerie Moon, Stephanie Mariat, Isao Kamae & Hanne Bak Pedersen, *Defining the Concept of Fair Pricing for Medicines*, 368 BMJ 1 (2020) (proposing a fair drug pricing framework where a drug price floor fair to sellers is dictated by costs and a fair profit, and a drug price ceiling fair to buyers is defined by reference to affordability).

[37] When the affordable price is less than the price at which sufficient incentives are provided through patent rewards, it would appear unfair to price in excess of the "sufficient" price. Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 171, 191 (making a similar argument). A further wrinkle is how we ought to think about regulation of the surplus between the "sufficient" price (that is, the non-excessive price of a patented drug) and the affordable price, when the affordable price exceeds the sufficient price. Unless the affordable price is also the non-excessive patented price, this leaves a gap between the non-excessive patented price and the affordable price. It is tempting to think that any price above the sufficient price is unfair. On such a view, government regulation down to the sufficient price is not merely justified on the basis of efficiency, but also unfairness. As I argue elsewhere, however, defending such an argument is more difficult that one might expect. Prices above the sufficient price but below the affordable price are not obviously unfair, and an additional allocative principle is required. *Id.* at 192.

holders occurs. If patented drug prices are not excessive, justification of government regulation on the basis of patent law efficiency or price unfairness grounded in unaffordability are attenuated.

B. *The Public Purpose of Patent Rights*

Patent rights are temporally limited rights of exclusion granted by the federal government in exchange for the public disclosure of an invention. Congressional authority to grant patents derives from the Intellectual Property Clause of the United States Constitution. This Clause provides: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[38] Congress created a statutory scheme implementing this Constitutional power. By statute, patent holders may exclude "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . ."[39]

Despite being rights of *exclusion*, patent rights are often confused with rights to an economic monopoly.[40] Yet, patent rights are not monopoly rights.[41] The difference is subtle, but its implications vast. Patents can, and do, *enable* monopolies when market conditions permit, but the rights themselves are not rights to an economic monopoly. Rights to an economic monopoly suggest affirmative rights to occupy a marketplace and further the absence of competition.[42] But "a patent does not grant the right to make, use, and sell the invention."[43] A patent right, as an exclusive right, merely allows a patent holder to prevent

[38] U.S. CONST. art. 1, § 8, cl. 8.

[39] 35 U.S.C. § 271(a).

[40] *See* Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 VAND. L. REV. 1727, 1729 (2000); *see also* Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws - Part II*, 14 FED. CIR. B.J. 21, 32 (2004).

[41] Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1010–11 (2014); Robin Feldman, *Patent and Antitrust: Differing Shades of Meaning*, 13 VA. J.L. & TECH. 1, 4 (2008).

[42] The difference between FDA marketing and data exclusivity might prove a helpful analogy. Marketing exclusivity, for example, provided by the Orphan Drug Act prevents competition from "the same drug for the same disease or condition" by preventing approval during the exclusivity period. 21 U.S.C. § 360cc(a). By contrast, with data exclusivity, generic competitors are precluded from seeking FDA approval during the data exclusivity term if they rely on the originator's data. *See, e.g.*, Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 103 (2016) (discussing this distinction).

[43] Feldman, *supra* note 41, at 8.

others from undertaking activities that fall within the scope of a patent.[44]

Consequently, patents do not guarantee their holders any particular economic benefits, let alone any economic benefits at all.[45] For instance, there may be no market for a patented product.[46] Or, despite the existence of patents, the market might be competitive in light of non-infringing products.[47] In the prescription drug context, the recent competition between hepatitis C treatments illustrates this point.[48] Though Gilead Sciences was first to market, AbbVie eventually offered a competing treatment.[49]

Nevertheless, particularly in the absence of non-infringing competition,[50] patents create opportunities for monopoly pricing.[51] Monopoly pricing comes at a predictable cost: "some people who would be willing to pay more than the marginal cost of a copy of the idea will not be able to access it."[52] When the patented goods involved are necessities, as many patented medications arguably are,[53] the human consequences are significant. At the individual level, a patent holder's

---

[44] Rich, *supra* note 40, at 27–29, 31 (collecting cases articulating patent rights as rights of exclusion).

[45] *See* Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1537 (2017) ("But the Patent Act does not guarantee a particular price."); Feldman, *supra* note 41, at 11; Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu & Katherine Gudiksen, *The Patent Act and the Constitutionality of State Pharmaceutical Regulation*, 45 RUTGERS COMPUT. & TECH. L.J. 40, 45 (2019); Joshua D. Sarnoff, BIO v. DC *and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation*, 2007 PATENTLY-O PAT. L.J. 30, 33–34 (2007).

[46] *See* Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 287 (2016) (noting that originator pricing is subject to demand).

[47] *See* FTC v. Actavis, Inc., 570 U.S. 136, 147 (2013) ("And even a valid patent confers no right to exclude products or processes that do not actually infringe."); Abbott, *supra* note 46, at 286–87.

[48] Kesselheim et al., *supra* note 2, at 861.

[49] *Id.*

[50] Even with competition between patented medications, downward pricing pressure is often modest. *Id.*; Jonathan J. Darrow & Aaron S. Kesselheim, Policy Options Paper, *Promoting Competition to Address Pharmaceutical Prices*, HEALTH AFFS. (Mar. 15, 2018), https://www.healthaffairs.org/do/10.1377/hpb20180116.967310/full/. Moreover, in many instances there may be no close substitutes. Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 285 (2016).

[51] *See, e.g.*, Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L.J. 1, 44–45 (2004).

[52] Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 131 (2004).

[53] *See, e.g.*, Emanuel, *supra* note 27, at 606; Richard A. Spinello, *Ethics, Pricing and the Pharmaceutical Industry*, 11 J. BUS. ETHICS 617, 619 (1992).

decision to charge what the market will bear can literally be the difference between life and death.[54] At the state level, it can compel officials to confront a tragic set of choices: does one defund education and infrastructure or restrict access to a life-saving treatment?[55]

These tragic choices imposed on individuals and states by the existing federal statutory scheme raise significant questions about the purpose of this regime in the first instance. One could be forgiven for thinking that patents are merely tools for promoting private wealth. Consider, as but one example, the "best-selling drug" in the United States, AbbVie's Humira.[56] Humira treats many different kinds of autoimmune diseases, and from 2012 to 2018, this drug generated in excess of $56 billion in the United States alone.[57] Humira is protected by more than one hundred patents, and this "make[s] it difficult (if not impossible) to sell competing drugs."[58] AbbVie's executives have acknowledged that the company's patent strategy is to stall competitors for as long as possible.[59] Meanwhile, "when it comes to Humira, Abbvie [sic] sales have paid off the research and development costs multiple times over with plenty leftover for billions of dollars in profits."[60] A recent congressional investigation of Humira estimates that AbbVie's anti-competitive conduct involving this single drug has cost the U.S. health care system $19 billion.[61]

Yet while patent holders can and do make extraordinary returns off their ability to exclude others, the accretion of private wealth is *not*

---

[54] *See, e.g.*, Shraddha Chakradhar, *'Maisie's Army': How a Grassroots Group Is Mobilizing to Help Toddlers Access a Lifesaving Drug*, STAT NEWS (Aug. 20, 2019), https://www.statnews.com/2019/08/20/maisies-army-zolgensma-access-spinal-muscular-atrophy/; Emma Court, *'Like We Were Being Forced to Gamble with Our Son's Life': Health Insurers Won't Pay for a $2.1 Million Drug for Kids, and Parents Say They're Running out of Time*, BUS. INSIDER (July 26, 2019), https://www.businessinsider.com/health-insurance-companies-deny-kids-with-sma-gene-therapy-zolgensma-2019-7.

[55] *See, e.g.*, LOUISIANA BUDGET ALLOCATOR, *supra* note 10.

[56] *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020).

[57] *Id.*

[58] *Id.* at 819.

[59] *Id.* at 823–24.

[60] Bruce Japsen, *Why Abbvie May Have a Tough Time Defending Humira's Price Before Congress*, FORBES (Feb. 26, 2019, 7:00 AM), https://www.forbes.com/sites/brucejapsen/2019/02/26/why-abbvie-may-have-a-tough-time-defending-humiras-price-before-congress/?sh=3bec5b852fd3; *see also* Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWEEK (Sept. 7, 2017), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

[61] STAFF OF H.R. COMM. ON OVERSIGHT & REFORM, 117TH CONG., DRUG PRICING INVESTIGATION: ABBVIE—*HUMIRA AND IMBRUVICA*, at v (2021).

the purpose of patent law.[62] Rather, federal patent law's purpose is dominantly public,[63] and its fundamental objectives are well established.[64]

Patent law as an instrumental tool in the service of public ends is evidenced by the text of the Constitution,[65] United States Supreme Court precedent, and academic consensus. The purpose of the Intellectual Property Clause "on its face . . . is to promote the public interest through an increase of the public domain or commons of intellectual ideas and thought."[66] Likewise, the Supreme Court stated that the "limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."[67] Patents by their "very nature" are "affected with a public interest" and "a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'"[68]

The Court more specifically articulated that federal patent law serves three objectives: (1) to foster and reward innovation, (2) to promote the disclosure of inventions to stimulate further creation, and (3) to assure that innovations in the public domain stay there.[69] Each of these purposes are public-minded; they do not reflect a purpose to promote private gain, though private gain occurs along the way. Private gains to inventors (and their investors), facilitated by patent protection, are a means and not an end of the federal patent system.

---

62 Edward C. Walterscheid, *The Nature of the Intellectual Property Clause: A Study in Historical Perspective (Part 1)*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 763, 764 (2001); Feldman et al., *supra* note 45, at 47.

63 Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665 (1944).

64 Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979); *see also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law,* 89 VA. L. REV. 1575, 1576 (2003).

65 U.S. CONST. art. I, § 8, cl. 8.

66 Walterscheid, *supra* note 62, at 764.

67 Kendall v. Winsor, 62 U.S. 322, 327–28 (1858); *see also* Motion Picture Pats. Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) (quoting *Kendall*, 62 U.S. at 327–28) (Further observing that the Court "has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is 'to promote the progress of science and the useful arts.'"); Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984) (Intellectual property "privileges" are not "primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved."). Note that *Sony* is a copyright case, but discusses the constitutional clause and refers to "authors and inventors." *Id.* at 429–30.

68 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 815–16 (1945); *see also* Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found., 402 U.S. 313, 344 (1971) (stating that a patent "is a privilege . . . conditioned by a public purpose"); Feldman et al., *supra* note 45, at 47.

69 *Aronson*, 440 U.S. at 262; *see also* Burk & Lemley, *supra* note 64, at 1576.

Further, the public purpose and instrumental nature of the patent system is, by far, the "predominant" justification among commentators.[70] The "embarrassment"[71] of a patent—that is, the social costs imposed upon the public by rights of exclusion—is primarily justified by reference to an incentive theory of patent law.[72] Patent rights purportedly play a necessary role in bringing forth new knowledge goods, ultimately placed in the public domain, that might not have existed in their absence.[73] This role is the logic of having *patented* prescription medications. Patent policy "tolerates" the allocative inefficiencies of patients being priced out of their medications on the assumption that "[t]he prospect of monopoly profits" offered by patent protection is necessary to "create [a] drug in the first place. In other words, the development of the drug is necessary to provide any access at all."[74]

Why emphasize the public purpose of federal patent law? If the private reward of patent holders as an end in and of itself is *not* among the purposes of federal patent law, claims that the potential rewards offered by patent protection are untouchable—that they must be wholly unlimited and unregulated—are weakened. Regulation of potential patent rewards, consistent with the public objectives of the patent system, is not only possible, but plausible. Such regulation is not necessarily at odds with the purposes of patent law.

C. *Excessive Compensation and Federal Abdication*

Price regulation of patented medications raises a palpable worry: won't regulation of the potential rewards offered by patent protection undermine the ability of patents to incentivize innovation? In the pharmaceutical context—where the industry is both largely privatized and financed through patent rents—this could negatively impact new drug discovery.[75] Claims that lower prices today will inevitably yield

---

[70] Carrier, *supra* note 51, at 31–32 ("The utilitarian justification of providing incentives to innovate, however, is the predominant justification for IP, one that is consistent with the Constitution, that the courts have recognized, and that the academic literature has tested.").

[71] Graham v. John Deere Co., 383 U.S. 1, 9 (1966) (quoting Thomas Jefferson and discussing the purpose of the patent system).

[72] Lemley, *supra* note 52, at 131; Roin, *supra* note 41, at 999.

[73] *See, e.g.*, Lemley, *supra* note 52, at 129–30.

[74] Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 108–09 (2020).

[75] *Id.* at 121 (noting that the United States "alone among developed countries" allocates drugs mostly based on price); *see* Rahul K. Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, 367 BMJ (2019); *see also* Kesselheim et. al., *supra* note 2, at

less innovative therapies tomorrow, is a well-worn mantra.[76] If this were true, patented price regulation could undermine the constitutional goals of patents "[t]o promote the [p]rogress of [s]cience and the useful [a]rts."[77]

Yet, the public purposes of patent law suggest that its goals are best understood as including a purpose to *sufficiently* incentivize innovation. Excessive compensation of patent holders is notably absent from the purposes of federal patent law, and consequently there is neither a constitutional nor congressional mandate to compel users of patented products to overpay through excessive pricing. To the contrary, "the goal of intellectual property is only to provide the 'optimal incentive,' not the largest incentive possible."[78] The excessive compensation of pharmaceutical patent holders through extraordinarily high prices, therefore, ought not be beyond legal reproach. All the more so, given their imposition of tragic costs.

What, then, counts as an excessive reward? This is a complicated question. Nevertheless, the internal logic of federal patent law offers a definition: patent rewards excessively compensate patentees when they exceed those rewards necessary to incentivize the underlying invention into existence.[79] More specifically, benchmarking excessive pricing to the purposes of the patent system is highly suggestive of a cost-plus model of excessive drug pricing.[80] When drug pricing exceeds a manufacturer's costs plus a reasonable profit, the price charged is excessive.[81] The aims of the patent system help define what constitutes

861–62 (stating that the industry is largely, but not exclusively privatized, and that interactions between public and private financing for drugs are complex).

[76] *See, e.g.*, Rebecca E. Wolitz, *A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications,* 94 IND. L. J. 1163, 1212–13 (2019); Michael A. Carrier & Genevieve Tung, Opinion, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019), https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry/; Alex M. Azar II, Sec'y, Health & Hum. Servs., Remarks on Drug Pricing Blueprint (May 14, 2018).

[77] U.S. CONST. art. I, § 8, cl. 8.

[78] Mark A. Lemley, *Beyond Preemption: The Law and Policy of Intellectual Property Licensing*, 87 CAL. L. REV. 111, 125 (1999).

[79] *Cf.* Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. BIOSCIENCES 1, 2 n.15 (2017) (defining "'excessive' rewards for knowledge-good producers" as occurring when "the reward exceeds the amount needed to induce a potential innovator to pursue a project").

[80] While some might subscribe to the view that cost-plus pricing serves as a benchmark for determining fair or unfair drug pricing, here I adopt the language of "excessive pricing" to distinguish such views from my own as laid out in Section II.A.

[81] Drug development costs can be understood to include the cost of capital as well as costs surrounding compound failures.

a reasonable profit. A reasonable profit is one that, sufficiently, but not excessively, incentivizes innovation.

This definition permits an important distinction. Excessive pricing is *not* identical to supra-competitive pricing.[82] Just because the necessary incentives require supra-competitive pricing does not mean such pricing is excessive. The concerns motivating justified government intervention are not about patented medications simply being expensive or priced above what one might expect in a competitive market. The concerns that motivate and justify regulation pertain to excessiveness and unfairness. Excessive patent holder compensation defined by reference to the patent system is unnecessary to the achievement of federal patent law's objectives and may additionally be morally condemnable as unfair. *Regulation* of excessive patented drug prices, therefore, on this understanding of excessive, is compatible with the purposes of federal patent law; it need not be at odds with patent law's goals of incentivizing innovation. Further, as argued above, when affordability challenges also exist, price regulation can be morally justified on fairness grounds.

A cost-plus perspective on excessive patented prescription drug pricing furthermore, and incidentally, helps account for several dominant themes in drug pricing debates. With respect to research and development costs, it explains why the drug industry, at least historically, has perpetuated the often questionable (yet chronic) argument that high prices for prescription medications are necessary to cover the costs of researching and developing important new medications.[83] While these arguments present foremost as a threat ("If you cut *our* prices, you won't have *your* new drugs"), they also can be read as an attempt at price justification ("Our prices cannot be excessive since they are related to our costs—and we just have a lot of costs").[84]

The cost-plus perspective further helps explain concerns about expensive medications in light of those drugs' public financing.[85] A prevailing sentiment in public discourse is that the American public

---

[82] "Excessive" pricing in this sense is somewhat agnostic as to the "value" of a new invention. *See generally* Nicholson Price, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 771 (2020) (discussing how patent law promotes innovation that is "new purely for the sake of being new, and not better at all").

[83] Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 178–79; Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/.

[84] Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 178–79.

[85] *Id.* at 179.

unfairly "pays-twice" when privatized expensive patented medications benefited from government funding.[86] While this is fundamentally an issue about the fair allocation of benefits relative to the contributions of collaborators, it is also a complaint about excessive drug pricing on the basis of costs.[87] Part of these objections, arguably, is the thought that drug manufacturers should not get to charge for costs paid by others; when drug prices are higher because they *do* reflect such charges, those prices are excessive.[88]

Even so, regulatory intervention premised on excessive pricing and the overcompensation of patent holders requires a showing that the antecedent condition of overcompensation occurs. Are pharmaceutical patent holders overcompensated through patent facilitated monopoly pricing? If patent holders are not excessively compensated, excessive patented price regulation is a solution without a problem.

Broad generalizations about a varied and complex industry are imprudent. The pharmaceutical industry, despite the existence of patents, has clear market failures; in some cases, patents on their own are insufficient to sustain or bring forth certain kinds of innovation. Therapies for neglected diseases or those predominantly plaguing low income populations are well-known examples.[89] Antibiotics[90] and vaccines, paradoxically, offer others.[91]

Nevertheless, using cost recoupment as a benchmark suggests that excessive drug manufacturer compensation by reference to the goals of federal patent law are prima facie plausible.[92] To begin with, a study of returns on invested capital ("ROIC") for large pharmaceutical companies from 2009 to 2019 found that these companies had returns exceeding those of all other sectors.[93] Large pharmaceutical companies

---

[86] Rebecca E. Wolitz, *The Pay Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177, 190 (2019).

[87] Wolitz, *Drug Manufacturers, Pricing, and Ethical Obligations*, *supra* note 26, at 179.

[88] *Id.*

[89] Roin, *supra* note 41, at 1030; *see also* Lemley, Ouellette & Sachs, *supra* note 74, at 121 (discussing Chagas disease).

[90] *See* Thomas J. Hwang, Daniel Carpenter & Aaron S. Kesselheim, *Paying for Innovation: Reimbursement Incentives for Antibiotics*, 7 SCI. TRANSLATIONAL MED., 1, 2 (Feb. 25, 2015).

[91] *See* Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019).

[92] *Cf.* Lemley, Ouellette & Sachs, *supra* note 74, at 117 (noting "[f]or at least some drugs, patent-owner returns for pharmaceuticals seem to far exceed the risk-adjusted R&D costs").

[93] SEAN DICKSON & JEROMIE BALLREICH, WEST HEALTH POL'Y CTR., HOW MUCH CAN PHARMA LOSE? A COMPARISON OF RETURNS BETWEEN PHARMACEUTICAL AND OTHER INDUSTRIES 6, 9, 13 (2019).

had an average ROIC of 17.3 percent.[94] To achieve parity with the next highest sector's return of 15.3 percent, large pharmaceutical companies would need to reduce their total profits by approximately $127 billion.[95] Thus, these large companies could undergo significant profit reductions and still be as or more lucrative than other industries. The study's authors therefore found that even with lower ROIC, "manufacturers could still maintain a revenue level that is attractive to institutional investors without reducing current expenditures for research and development."[96]

Other recent studies are further suggestive of the prima facie case. Cancer drugs, for instance, are routinely priced in excess of $100,000 per year of treatment.[97] Yet one study of such drugs found that while the median cost of development was $648 million, median revenues post-approval were $1658.4 million with a range up to $22,275 million.[98] In aggregate, total revenue from the drugs studied was $67 billion compared with total research and development ("R&D") spending of $7.2 billion.[99] The authors concluded that development costs were "more than recouped" over a short period of time, and that some companies saw revenue in excess of ten times their R&D costs, representing "a sum not seen in other sectors of the economy."[100] Another study of ninety-nine FDA-approved cancer drugs likewise found that every $1 spent on R&D generated a median of $14.50 in sales income (with a range up to $55.10) for originator companies.[101] These authors likewise noted that these "supernormal returns . . . are much higher than what would be considered a justifiable return required for rewarding and incentivizing innovation, both in economic terms and by reasonableness."[102] The authors were particularly concerned given the lack of access globally to affordable cancer medications.[103]

Yet another analysis of the world's twenty top-selling drugs demonstrates that premium pricing in the U.S. market *alone*—the

94 *Id.* at 6.

95 *Id.* at 10.

96 *Id.* at 13.

97 Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERNAL MED. 1569, 1570 (2017).

98 *Id.* at 1572.

99 *Id.* at 1569, 1572.

100 *Id.* at 1574.

101 Kiu Tay-Teo, André Ilbawi & Suzanne R. Hill, *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, JAMA NETWORK OPEN, Jan. 4, 2019, at 1, 5, 7.

102 *Id.* at 7.

103 *Id.*

difference between U.S. prices and those paid in other countries for the same drug—averaged 163 percent of drug manufacturers' global R&D expenditures.[104] This analysis "counters the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development. Rather, there are billions of dollars left over even after worldwide research budgets are covered."[105] An even more recent comparative country study found that U.S. prices for brand-name originator drugs are 344 percent more expensive than those in thirty-two comparison Organisation for Economic Co-operation and Development countries.[106] There are other examples.[107] Further, regular price increases by name brand companies, far in excess of inflation, remain a common practice,[108] with some companies even continuing this practice during the current global pandemic.[109]

While broad claims of drug manufacturer overcompensation may be unwarranted, the evidence suggests that this phenomenon exists. To the extent it does exist, the situation is ripe for regulatory intervention. Yet existing federal law is inadequate to meet the challenge.

The United States does not have a general scheme for regulating drug prices. Rather, it has a patchwork of laws pertinent to prescription drug pricing through existing patent law safeguards, laws facilitating competition, and laws pertaining to drug pricing within federal payment

---

104 Nancy L. Yu, Zachary Helms & Peter B. Bach, *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFS. BLOG (Mar. 7, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/.

105 *Id.*

106 Andrew E. Mulcahy et. al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND CORP., at vii, xii (2021), https://www.rand.org/pubs/research_reports/RR2956.html.

107 *See, e.g.*, Brennan et al., *supra* note 50, at 328 (noting Gilead's returns on its hepatitis C medications amounting to forty times the cost of producing the drugs and three times the purchase price of Pharmasset, in less than 2.5 years).

108 *See* Michelle M. Mello & Trish Riley, *To Address Drug Affordability, Grab the Low-Hanging Fruit*, 325 JAMA HEALTH F. 1599, 1599 (2021); STAFF OF U.S. S. OF HOMELAND SEC. & GOVERNMENTAL AFFS. COMM., MINORITY OFF., MANUFACTURED CRISIS: HOW DEVASTATING DRUG PRICE INCREASES ARE HARMING AMERICA'S SENIORS, at 1–2 (2018), https://www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf.

109 Sarah Owermohle, *Drug Prices Steadily Rise Amid Pandemic, Data Shows*, POLITICO (July 7, 2020), https://www.politico.com/news/2020/07/07/drug-prices-coronavirus-351729; *see also* STEPHEN W. SCHONDELMEYER & LEIGH PURVIS, AARP, TRENDS IN RETAIL PRICES OF BRAND NAME PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS, 2006 TO 2020, at 1 (2021) ("Between 2019 and 2020, retail prices for 260 widely used brand name prescription drugs increased by 2.9 percent, more than two times faster than general inflation (1.3 percent)."); Mello & Riley, *supra* note 108, at 1599 (noting "large price increases continue to be a major driver of prescription drug costs.").

or purchasing programs. Within patent law itself, safeguards within the Bayh-Dole Act applicable to federally funded inventions could be used to address excessively priced patented medications,[110] but in practice have lain fallow.[111] Similarly, 28 U.S.C. § 1498, applicable to *all* patented inventions, regardless of funding source, limits plaintiffs' recovery for government use of patents to reasonable compensation and does not allow injunctions. Again, however, in recent memory government patent use has remained largely dormant as a tool to improve drug accessibility.[112] The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act")[113] and the Biologics Price Competition and Innovation Act ("BPCIA")[114] facilitate competition in prescription drug markets, which drive down drug prices, but do not regulate excessive pricing.

Finally, federal programs involving prescription drug coverage and procurement (e.g., Medicare, Medicaid, and the Federal Supply Schedule) regulate, to some extent, the price of medications, including those that are patented. On the whole, however, with limited exceptions for regulation of certain price increases,[115] these laws are generally ineffective at counteracting overall trends, and none currently regulate patented medications for price excessiveness. Drug manufacturers

---

110 35 U.S.C. § 202(c)(4) (providing the federal government with a "nonexclusive, nontransferrable, irrevocable, paid-up license to practice" (or have practiced on its behalf) the subject invention throughout the world); 35 U.S.C. § 203(a) (empowering the federal government to "march-in" on patent rights under certain conditions and grant a license to others).

111 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); Wolitz, *The Pay Twice Critique, supra* note 86, at 183; Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 794 (2016) (noting the NIH's aversion to exercising march-in rights and interpreting "reasonable terms" to only refer to "product availability"); NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., IN THE CASE OF NORVIR® MANUFACTURED BY ABBOTT LAB'YS, INC. 5–6 (2004), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

112 *See* Christopher Morten & Charles Duan, *Who's Afraid of Section 1498?: Government Patent Use as Versatile Policy Tool*, WRITTEN DESCRIPTION (Apr. 24, 2020), https://writtendescription.blogspot.com/2020/04/whos-afraid-of-section-1498-government.html.

113 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

114 Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 804-21 (2010) (codified as amended at 42 U.S.C. § 262 (2012)).

115 42 U.S.C. § 1396r-8(c)(2)(A) (Medicaid provision limiting price increases); Lemley, Ouellette, & Sachs, *supra* note 74, at 89 (noting that more than half of Medicaid rebates are estimated to be due to a provision limiting price increases in excess of inflation). Yet, price increases—even modest ones—on an already excessively priced medication still leaves an excessive price paid.

interacting with these programs are still free to initially price their products as they wish. Moreover, given that Medicare and Medicaid must cover certain drugs as a matter of law, this weakens their bargaining position.[116]

The Constitution empowered Congress to create a patent scheme to incentivize novel inventions, including new medications. Yet, Congress has done so without addressing pricing abuses. In so doing, it has privileged private interests over the physical health of its citizens and the financial health of both citizens and states. Its failure to act is further contrary to the country's democratic wishes.[117] Addressing prescription drug prices is a bipartisan priority. Eighty-five percent of Democrats and 69 percent of Republicans ranked lowering prescription drug prices as the most important priority for Congress and the former administration, just behind lowering health care costs more generally.[118]

Yet, patented drug prices remain largely unregulated, and a prima facie case can be made that Americans needlessly pay more for their medications than serves the existing ends of federal patent policy. While rights of exclusion under conditions of scarce resources could mean a tradeoff of access by present patients for the existence of new therapies for future patients, drugs are necessities. Congress and the executive branch have thus far failed to execute laws that treat this potential tradeoff with the gravitas it deserves. They have further privileged private interests beyond the purposes imposed by the Constitution at the expense of states and individuals' financial and physical health. Despite the tragic costs imposed by this federal scheme *and* the chronic, overwhelming, bipartisan consensus that drug prices need to be addressed, the federal government has neither enacted nor implemented meaningful reform. While Congress has again been contemplating federal drug pricing reform,[119] and one cannot predict

---

116 Lemley, Ouellette, & Sachs, *supra* note 74, at 86 (discussing Medicare Part D's six protected classes and the impact this can have on negotiations); *id*. at 88 (noting that because all state Medicaid programs cover prescriptions, this "requires them to cover all FDA-approved drugs with a few exceptions . . . .").

117 *See* Isaac D. Buck, *The Drug (Pricing) Wars: States, Preemption, and Unsustainable Prices*, 99 N.C. L. REV. 167, 215–216 (2020).

118 POLITICO AND HARVARD T.H. CHAN SCH. OF PUB. HEALTH, AMERICANS' DOMESTIC PRIORITIES FOR PRESIDENT TRUMP AND CONGRESS IN THE MONTHS LEADING UP TO THE 2020 ELECTION 1, 3 (2020).

119 Rachel Cohrs, *Moderate Democrats Sink Pelosi's Aggressive Drug Pricing Bill in Key Committee Vote*, STAT NEWS (Sept. 15, 2021), https://www.statnews.com/2021/09/15/moderate-democrats-sink-pelosis-aggressive-drug-pricing-bill-in-key-committee-vote/.

the future, presently, federal abdication continues to leave a significant regulatory vacuum.

III. STATES AS SECOND-BEST SOLUTIONS

A. *Looking Beyond the Federal Government*

Given the federal nature of patents, one might reasonably expect well-crafted solutions to problems of excessively priced patented medications by the federal government. A national policy solution is preferable morally, pragmatically, and doctrinally. Affordability challenges pertaining to excessively priced patented medications are a problem for Americans. They are not a problem just for Californians, or Utahns, or Floridians. If regulation is motivated by a desire to stamp out unfairness, piecemeal regulation at the sub-national level runs the substantial risk of leaving many behind. Unfair pricing will persist for some and not others because of the arguably morally insignificant distinction of intranational geographic boundaries.

Likewise, for regulation justified on the basis of correcting for inefficiencies. In the context of expensive patented medications, the sanitized vocabulary of efficiency obscures its import: assuming price and access are largely inversely correlated under conditions of scarce resources, preventing the overcompensation of patent holders means more patients will have access to important medications. Lives and health are on the line.

Doctrinally and pragmatically, a national solution would avoid legal challenges that, while perhaps not necessarily insurmountable, have plagued state drug pricing reform efforts.[120] The pharmaceutical and biotechnology industries are incredibly well-resourced, organized, and litigious. As mentioned at the outset, states do not merely need to grapple with and litigate problems of patent preemption. They also have to contend with the dormant Commerce Clause. Federal regulation sidesteps these potential doctrinal impediments entirely.[121] Moreover, to the extent states struggle with budget shortfalls, the federal government is far better placed financially to address these problems of national significance.

Federal proposals, however, even when they exist, have historically come up short. The United States currently does not have a general scheme regulating drug prices, let alone excessive patented

120 *See* Mello & Wolitz, *supra* note 26, at 862–863.

121 *Id.* at 957.

drug prices.[122] And, despite bipartisan support in Congress and an explicit commitment by the prior Administration to address the problem of excessively priced medications, federal solutions have been largely stalled or ineffective. Over the past few years, the most prominent legislative proposals for drug pricing reform have focused on Medicare.[123] Yet, these efforts in both the Senate and the House went nowhere.[124] Further, former President Trump's Executive Orders—which, for the most part, focused on federal programs—were generally met with great skepticism by experts.[125]

Federal drug pricing reform is again a priority for President Biden and Congress. President Biden's recent Executive Order to Promote Competition in the American Economy explicitly supports "aggressive

[122] *See, e.g.*, *Why Does the US Pay the Highest Prices in the World for Prescription Drugs?: Hearing Before the Subcomm. on Primary Health and Retirement Security of the S. Comm. on Health, Educ., Labor, and Pensions*, 117th Cong. 3 (2021) (statement of Aaron S. Kesselheim, Prof. of Medicine, Harvard Medical School) ("[I]n the US we allow brand-name pharmaceutical manufacturers to charge whatever they want during their periods of government-granted market exclusivity—a condition not seen in any other developed nation."); S. Vincent Rajkumar, *The High Cost of Prescription Drugs: Causes and Solutions*, 10 BLOOD CANCER J. 1, 1 (2020) ("Unregulated monopoly over an essential product can lead to unaffordable prices that threaten the life of citizens. This is the case in the United States, where there are no regulations to control prescription drug prices . . . ."); 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 ("The United States is exceptional in that it does not regulate or negotiate the prices of new prescription drugs when they come onto market.").

[123] *See, e.g.*, Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong. (2019); *Description of the Chairman's Mark*, *The Prescription Drug Pricing Reduction Act (PDPRA) of 2019* (as reported by S. Comm. on Finance, July 25, 2019), https://www.finance.senate.gov/download/description-of-the-chairmans-mark-for-the-prescription-drug-pricing-reduction-act-of-2019; Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (as passed by the House, Dec. 12, 2019).

[124] *Id*. H.R. 3, however, as discussed below, was reintroduced, Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong., https://www.congress.gov/bill/117th-congress/house-bill/3?r=8&s=1, and a version of it was being considered through the Biden spending plan before the House Budget Committee.

[125] On July 24, 2020, President Trump issued four Executive Orders related to drug pricing. These orders permitted drug re-importation from Canada, alterations to the handling of discounts in Medicare Part D, passing on 340B savings to underserved patients, and use of an international pricing index within Medicare Part B. *Trump Administration Announces Historic Action to Lower Drug Prices for Americans*, U.S. DEP'T OF HEALTH & HUM. SERVS., NEWS RELEASE (July 24, 2020), https://www.hhs.gov/about/news/2020/07/24/trump-administration-announces-historic-action-lower-drug-prices-americans.html. The response to these orders was underwhelming. Sydney Lupkin, *Trump Signs Executive Orders On Drug Prices*, NPR (July 24, 2020), https://www.npr.org/2020/07/24/895290378/trump-signs-executive-orders-on-drug-prices.

legislative reforms that would lower prescription drug prices."[126] The Secretary of Health and Human Services, Xavier Becerra, was tasked with generating a plan to "combat excessive pricing of prescription drugs."[127] Recently released, this plan identifies both legislative and administrative levers for improving drug affordability, promoting competition, and fostering scientific innovation.[128] Legislative proposals include reforms to Medicare to permit drug price negotiation and cap out-of-pocket costs, legislation to address price increases, and legislation to improve generic and biosimilar competition.[129] Administrative reforms include testing the use of "value-based payments in Medicare Part B," efforts to improve transparency and competition, and the development of drug importation programs.[130] Meanwhile, Congress has been re-considering the ability of Medicare to negotiate maximum fair prices for certain single source drugs[131] enforced through the imposition of not insignificant civil monetary penalties.[132] In earlier iterations, individuals enrolled in commercial plans could also benefit from these negotiations, unless their plans opted out.[133]

The federal drug pricing reform landscape has been more dynamic than in recent memory. But barriers to federal-level reform are dominantly political[134] and comprehensive federal level reform to

126 Exec. Order No. 14,036, 86 Fed. Reg. 36,987 (July 9, 2021).

127 *Id.* at 36,997.

128 XAVIER BECERRA, U.S. DEP'T OF HEALTH & HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES 2 (2021), https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.

129 *Id.*

130 *Id.* at 2–3.

131 Build Back Better Act, S. Con. Res. 14, 117th Cong., at 2343 (as passed by H. Budget Comm., 2021), https://docs.house.gov/meetings/BU/BU00/20210925/114090/BILLS-117pih-BuildBackBetterAct.pdf.

132 *Id.* at 2386.

133 *Id.* at 2383–2384.

134 Consider, for instance, that pharmaceutical industry spending on lobbying and congressional campaign contributions is notoriously strategic and generous. Among other examples, these dynamics were on display with the 2020 Senate races. A blue wave across the executive branch and both houses of Congress was deemed "a nightmare scenario for drug companies," and their political spending therefore reflected their "clear stake in keeping the Senate in Republican hands." Lev Facher & Kaitlyn Bartley, *Pharma Is Showering Congress with Cash, Even as Drug Makers Race to Fight the Coronavirus*, STAT NEWS (Aug. 10, 2020), https://www.statnews.com/feature/prescription-politics/prescription-politics/. Senate Majority Leader Mitch McConnell, for instance, according to one analysis, received more drug industry campaign contributions "than any other lawmaker"; McConnell has demonstrated little interest in advancing drug pricing reforms. *Id.*; *see* Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United*

address excessive patented drug pricing remains unlikely; the most likely reform outcome, if any, is Medicare reform, but passage of even more limited measures remains far from certain. As Rachel Sachs has written of the HHS plan to address high drug prices, "what is needed is not necessarily new ideas, but the legal and political ability to implement existing proposals."[135]

The specific proposal for Medicare negotiation has been contentious with "three key democrats" announcing earlier this fall that they would not vote in its favor.[136] Given background politics, it was speculated that these no votes would likely "put drug-pricing reform in mortal jeopardy" and threaten President Biden's overarching spending plan, which these reforms would help finance.[137] Aaron Kesselheim and Jerry Avorn opined that these democrats' opposition to drug pricing reform "is probably explained by the scale of pharmaceutical spending to block reform."[138]

The situation surrounding President Biden's spending package is highly fluid. The White House had announced that the spending package would move forward without any drug pricing reform provisions.[139] Despite the President spending "countless hours with members of Congress," there was not enough support for government drug price negotiation—"every single policy idea aimed at lowering prescription drug prices" was going to be "abandon[ed]."[140]

As of this writing, however, it appears that a revised drug pricing deal is again under consideration.[141] This compromise currently includes an out-of-pocket cap for Medicare Part D beneficiaries, a restructuring of Part D's catastrophic coverage phase, Medicare Part B and Part D drug manufacturer rebates to the government for drug price

States, 1999-2018, 180 JAMA INTERNAL MED. 688, 688 (2020) (but also noting siginificant state-level contributions).

135 Rachel Sachs, *Biden Drug Pricing Plan Seeks To Balance Access and Innovation*, HEALTH AFFS. BLOG (Sept. 13, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210909.434045/full/.

136 Aaron S. Kesselheim & Jerry Avorn, *Letting the Government Negotiate Drug Prices Won't Hurt Innovation*, WASH. POST (Sept. 22, 2021), https://www.washingtonpost.com/outlook/2021/09/22/drug-pricing-negotiation-biden-bill/.

137 *Id.*

138 *Id.*

139 Rachel Cohrs, *Biden Abandons His Push to Lower Drug Prices*, STAT NEWS (Oct. 28, 2021), https://www.statnews.com/2021/10/28/biden-abandons-his-push-to-lower-drug-prices/.

140 *Id*.

141 Rachel Sachs, *Understanding The New Drug Price Reform Deal*, HEALTH AFFS. BLOG (Nov. 4, 2021), https://www.healthaffairs.org/do/10.1377/hblog20211104.184553/full/.

increases in excess of inflation (which would impact private insurers as well), and authority (scaled back relative to previous proposals) for direct Medicare drug price negotiation.[142] Under this deal, the Secretary of Health and Human Services would only be permitted to negotiate the prices of up to ten drugs in the program's first year and a maximum of twenty drugs in the future.[143] Negotiated prices further would not be operative until an initial post-approval market period had passed.[144] Reactions to this draft compromise have, on the one hand, noted its significance relative to the status quo,[145] and, on the other hand, observed that it "'seems designed to let legislators claim an achievement while granting pharma protection.'"[146] It remains to be seen what the final text will be as well as whether these compromise Medicare reforms ultimately become law.

Against a background of continued federal gridlock, uncertainty, and proposals predominantly targeting specific federal programs, a search for "second-best solutions" is compelling. A second-best solution, as the phrase is used here, represents a policy that might be non-ideal in some respects, yet in light of real-world imperfections is the most desirable of available options to achieve a policy goal.[147] This Article argues that we can look to state level excessive pricing regulation for the *who* and *how* of a second-best solution to the problem of excessively priced patented prescription medications. Further, as even this second-best solution faces doctrinal and pragmatic barriers on the basis of patent preemption precedent, a second-second best solution—payment regulation or payment regulation in tandem with penalties on excessive price increases—should be considered.

Regarding the *who* of a second-best solution, a national solution is not our only option for addressing the unfairness and inefficiency of excessively priced patented medications. States offer an alternative.

---

142 *Id*.

143 *Id*. Build Back Better Act, H.R. 5376, 117th Cong. § 1192(a) (as reported by the H. Budget Comm., with modifications, Nov. 3, 2021).

144 Sachs, *supra* note 141; Build Back Better Act, H.R. 5376, 117th Cong. § 1192(e)(1)(A)–(B) (as reported by the H. Budget Comm., with modifications, Nov. 3, 2021).

145 Sachs, *supra* note 141.

146 Bob Herman, *Pharmaceutical Industry May Avoid Big Losses in Drug Pricing Deal* (Nov. 3, 2021) (quoting Ronny Gal, Bernstein pharmaceutical analyst), https://www.axios.com/pharmaceutical-industry-may-avoid-big-losses-in-drug-pricing-deal-bea3ada1-30b7-412b-b094-b9d6a950934f.html.

147 *Cf.* Robert E. Goodin, *Political Ideals and Political Practice*, 25 BRIT. J. POL. SCI. 37, 52 (1995) (explaining the economic theory of second best where a "second-best state of affairs is not necessarily one in which your ideal conditions are realized more rather than less completely").

For the reasons discussed above, however, state-level intervention to curb excessive patented drug pricing is less preferable to federal reform. In virtue of their jurisdictional limitations, state reform efforts will be necessarily geographically constrained to particular populations. Further, the legal maneuvers available to states are more restricted; they must navigate regulating in the shadow of avoiding preemption, which can impose additional limitations on the reach of reforms. Thus, if the achievement of a particular health policy outcome—widespread fairer and more efficient prices for patented medications for all Americans—is the goal, states as the implementers of reform face inherent limitations that the federal government does not.

Yet, in the world of second-best scenarios, reformers who operate with additional constraints appear preferable to a lack of reformers at all. States have been experimenting with a number of different proposals to address excessive pricing, to control costs, and to improve the affordability of prescription medications for their constituents. In contrast to the federal government, states are both motivated to implement drug pricing reform and, perhaps more importantly, have the demonstrated political ability to pass a variety of new legislation.[148]

States stepping into the role of excessive patented drug price reformers, because the federal government has been politically incapacitated, further offers the prospect of ancillary benefits by way of values traditionally associated with federalism. While state drug pricing reform largely appears motivated by ideals of instrumental federalism—that is, federalism in the service of a particular policy goal—some state efforts do exude qualities consistent with "federalism for federalism's own sake."[149] These qualities include increased accountability to constituents, experimentation, and expression of local preferences and values.[150] For instance, in the adjacent arena of drug pricing transparency legislation, Nevada's new laws focus specifically on medicines for health conditions of particular salience to the state—diabetes and asthma.[151] In the present context, state regulation involving determinations of excessive pricing schemes exemplifies local experimentation with difficult moral and policy considerations regarding unfair and excessive drug pricing.

---

148 *See, e.g.*, Mello & Wolitz, *supra* note 26, at 873–87 (discussing state-level price gouging and rate-setting laws).

149 *See* Abbe R. Gluck & Nicole Huberfeld, *What Is Federalism in Healthcare For?*, 70 STAN. L. REV. 1689, 1787 (2018) (drawing distinction between valuing federalism as a means to an end as opposed to an end in itself).

150 *Id.*

151 NEV. REV. STAT. §§ 439B.630, 439B.635, 439B.640, 439B.645, 439B.650 (West 2021).

That states—subject to avoiding or overcoming preemption headwinds—*can* be excessive patented drug pricing reformers does not yet address the issue of *how* such a second-best solution might be implemented. To answer this question, two *primary* kinds of policy tools are available: price regulation and payment regulation. Price regulation sets the prices that drug manufacturers (or, perhaps additionally, others within the supply chain) can charge for the sale of patented prescription medications.[152] Payment regulation, by contrast, regulates the amount that payors or purchasers can pay for patented prescription medications.[153] It does not restrict how much a drug manufacturer can charge. The former type of regulation focuses on seller conduct, the latter on buyer conduct.

Price regulation and payment regulation tackle the problem of excessively priced medications from different angles, but could yield similar results. Suppose, for instance, a drug ought to be priced at $100. A state, conceivably, can achieve a $100 purchase price either through prohibiting a drug manufacturer from charging in excess of $100 for the drug or by prohibiting reimbursement for the drug in excess of $100.

While price and payment regulation could theoretically achieve similar results, there are moral and political reasons to favor price regulation.[154] From a moral perspective, the primary aim of government regulation in this space is to prohibit unfair and excessive patented drug pricing. This is exactly what price regulation does. It identifies the problematic conduct and directly prohibits the responsible actor from treating others in morally problematic ways. It prevents patent holders from charging unfair prices and charging more than necessary in furtherance of the goals of federal patent law. Payment regulation, by contrast, does not prohibit unfair or problematic conduct; drug manufacturers remain free to price their drugs unfairly and excessively. Payment regulation puts the onus of preventing unfair or excessive pricing on those who would be overcharged, and its protective value

152 *See* Mello & Wolitz, *supra* note 26, at 948.

153 *Id.*

154 *See* Govind Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 973–977 (2021) (arguing in favor of price regulation). Considerations of ERISA preemption could offer an additional reason to prefer price regulation. Payment regulatory schemes designed to avoid ERISA preemption could be of more limited reach than a comparative price regulation. *See, e.g.*, Rachel E. Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, NAT'L ACAD. FOR ST. HEALTH POL'Y (Aug. 10, 2020), https://www.nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/#toggle-id-3 (discussing ERISA complications with upper payment limits incorporating international reference pricing).

extends only to buyers covered by the law. It makes drug manufacturer participation in non-excessive and fair pricing voluntary.

Political reasons also suggest a preference for price regulation over payment regulation. Price regulation reflects the true conflict at issue regarding *excessively* priced patented medications as one between patients and payors on the one hand and drug manufacturers on the other. Payment regulation reframes the terms of the debate in an unhelpful way.[155] The debate about access and expensive medications becomes a conflict between patients and payors.[156] It refocuses the debate from excessive and unfair pricing to potentially ungenerous spending. Payment regulation poses the political problem of potentially restricting access to drugs already in use by beneficiaries if drug manufacturers are not willing participants.[157]

As one example of how this reframing can alter the terms of the debate, consider the plight of parents whose toddlers suffer from the debilitating, if not fatal, genetic disorder of spinal muscular atrophy. Novartis' Zolgensma has been hailed as a miracle drug.[158] It requires just a single infusion to be administered before a patient reaches her second birthday and can be potentially curative.[159] The drug's price, however, is $2.1 million which has led to highly publicized battles between parents and insurers, with many patients being, at least prior to public shaming campaigns, denied coverage for the drug.[160] As parents observe, it is not feasible to find a job with different insurance or to come up with the $2.1 million themselves. Yet, one has to wonder: why must this drug be so expensive?[161] News coverage has appeared to

155 *See* Persad, *supra* note 154, at 976.

156 *Id.*

157 *Id.*

158 Linda Carroll & Lauren Dunn, *$2.1 Million Drug to Treat Rare Genetic Disease Approved by FDA*, NBC (May 24, 2019), https://www.nbcnews.com/health/health-news/2-1-million-drug-treat-rare-genetic-disease-approved-fda-n1009956; Shraddha Chakradhar, *'Maisie's Army': How a Grassroots Group is Mobilizing to Help Toddlers Access a Lifesaving Drug*, STAT NEWS (August 20, 2019), https://www.statnews.com/2019/08/20/maisies-army-zolgensma-access-spinal-muscular-atrophy/; Emma Court, *'Like We Were Being Forced to Gamble With Our Son's Life': Health Insurers Won't Pay for a $2.1 Million Drug for Kids, and Parents Say They're Running Out of Time*, BUSINESS INSIDER (July 26, 2019), https://www.businessinsider.com/health-insurance-companies-deny-kids-with-sma-gene-therapy-zolgensma-2019-7.

159 *See, e.g.*, Court, *supra* note 158.

160 *Id.*

161 The company defended the price on the basis of the drug's value relative to the estimated $6 million in long-term care costs that would otherwise be spent during the first ten years of these children's lives. *See* Faith Karimi, *She's 14 Months Old and Needs a Drug that Costs $2.1 Million to Save Her Life,* CNN (Mar. 31, 2021), https://

focus on challenges between patients and insurers as opposed to this underlying question.[162]

While there are moral and political reasons to favor state level price regulation over state level payment regulation, a key feature of second-best solutions is that they must offer pragmatic and workable policy options.[163] A pressing question, therefore, is can states even serve as our second-best solution when it comes to excessively priced patented medications? What reforms are states exploring?

B. *State Experimentation: Price and Payment Regulation*

1. Price Regulation of Patented Medications

States, in general, regulate the prices of goods in a variety of ways.[164] To date, the District of Columbia's ("D.C.") Prescription Drug Excessive Pricing Act of 2005 ("the Act")[165] offers the most prominent example of an enacted excessive price statute that specifically targeted patented drug prices.[166] The Act begins by finding that excessive drug prices were "threatening the health and welfare of residents of the District" and that "[t]he traditional police powers of the District of Columbia include protecting and promoting the health, safety, and welfare of its residents . . . ."[167]

In light of these findings, the Act therefore made it "unlawful" for drug manufacturers and licensees "to sell or supply for sale" any patented prescription medications for an excessive price within D.C.[168] Though the Act did not define "excessive," it created a rebuttable presumption of excessiveness for wholesale prices 30 percent or greater than those medications' prices in certain high-income countries: "A prima facie case of excessive pricing shall be established where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in

www.cnn.com/2021/03/31/health/toddler-expensive-drug-zolgensma-wellness/index.html.

162 *Id.*

163 *Cf.* Mello & Wolitz, *supra* note 26, at 864 (discussing five commonsense assumptions of workable excessive price regulation).

164 *Id*. at 859.

165 D.C. CODE ANN. §§ 28-4551-28-4555.

166 For purposes of preemption principles, the District of Columbia was treated as a state in litigation. Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1371 (Fed. Cir. 2007).

167 D.C. CODE ANN. § 28-4551 (West 2021).

168 *Id.* § 28-4553.

which the product is protected by patents or other exclusive marketing rights."[169]

"High income county" was specifically defined to refer to the United Kingdom, Germany, Canada, and Australia.[170] As a rebuttable presumption, a defendant could try to justify its "excessive" prices.[171] To rebut the prima facie case of excessiveness, defendant drug manufacturers or licensees would need to demonstrate that the price was not excessive in light of the drug's costs of invention, development, and production; the company's global profits; any government support for the drug's development; and the price's impact on access to the drug.[172] The Act was broad both in terms of who could sue to enforce the Act's provisions and the range of available remedies.[173]

The two major industry trade organizations—Biotechnology Industry Organization ("BIO") and Pharmaceutical Researchers and Manufacturers of America ("PhRMA")—sued alleging, among other claims, patent preemption.[174] Ultimately, the Federal Circuit ruled that the D.C.'s Act was conflict preempted on the basis of federal patent law in the case of *BIO v. D.C.*[175] As this ruling is of great practical importance for states in crafting their policy interventions impacting excessively priced patented medications, its discussion and analysis are reserved for a detailed discussion below.

This adverse ruling regarding patent preemption, however, has inspired states over the years to shift their focus in drafting excessive pricing laws to generics and inspired increased interest in payment regulation.[176] Among anti-price gouging proposals in the 2021 legislative session, a focus on generics predominates.[177] States, however, over the past few years have still put forward proposed legislation with the ability to reach patented medications.

Minnesota's HF 4 provides an example.[178] This bill prohibited the unconscionable price gouging of "essential prescription drugs sold in

169 *Id.* § 28-4554(a).

170 *Id.* § 28-4552 (2).

171 *Id.* § 28-4554(b).

172 *Id.*

173 *See* D.C. CODE ANN. § 28-4555.

174 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1366 (Fed. Cir. 2007).

175 *Id.* at 1374.

176 Mello & Wolitz, *supra* note 26, at 877.

177 *See 2021 State Legislative Action to Lower Pharmaceutical Costs Tracker*, NAT'L ACAD. FOR STATE HEALTH POL'Y, https://www.nashp.org/rx-legislative-tracker/ (see "Price Gouging" tab) (last visited Oct. 28, 2021).

178 *See generally* H.R. 4, 2020 Leg., 91st Sess. (Minn. 2020).

Minnesota" by drug manufacturers or wholesalers.[179] Finding that essential prescription drugs are necessities, the bill stated:

> Abuses in the pricing of various essential prescription drugs are well-documented, jeopardize the health and welfare of the public, and have caused the death of patients who could not afford to pay an unconscionable price for these drugs. . . . This section is intended to address such abuses, but allow drug manufacturers and wholesale drug distributors a fair rate of return with respect to their sale of essential prescription drugs in the state of Minnesota.[180]

Crucially, among other conditions, the bill defined an essential prescription drug to be "a patented (including an exclusivity-protected drug), off-patent, or generic drug . . . ."[181] The bill targeted medications that have a wholesale acquisition cost of greater than $80 per month or per treatment and defined an "unconscionable" price by reference to a drug's costs.[182] An unconscionable price is one that "is not reasonably justified by the actual cost of inventing, producing, selling, and distributing the essential prescription drug, and any actual cost of an appropriate expansion of access to the drug to promote public health . . . ."[183] This legislation further required that the Attorney-General be notified of "any price increase of 15 percent or more" for any essential drug sold in Minnesota.[184]

Other recent price gouging bills that reach patented medications have narrower applications. For instance, a New York bill sought to focus exclusively on price increases above the cost of living for "critical prescription drugs," defined as those drugs that are "necessary to prevent or treat a disease or state in which death is possible or imminent."[185] By contrast, a bill in New Jersey focused exclusively on "prohibit[ing] any person from charging excessive prices for drugs developed by publicly funded research."[186] Excessive pricing is determined by reference to the lowest price charged in certain foreign jurisdictions.[187] Still other excessive drug pricing bills have limited their reach to times of emergency and market shortages. A bill in Rhode Island, for instance, would reach patented medications sold for an

179 *Id.* § 4, subdiv. 1.
180 *Id.*
181 *Id.* § 4, subdiv. 2(b).
182 *Id.* § 4, subdiv. 2(b)(2)(i).
183 *Id.* § 4, subdiv. 2(d)(1).
184 *Id.* § 4, subdiv. 5.
185 S. 320, 2020–2021 Leg., Reg. Sess. §§ 346(a), (f) (N.Y. 2021).
186 Assemb. B. 2671, 219th Leg. Sess. (N.J. 2020).
187 *Id.*

"unreasonably excessive" price during an emergency.[188] An "unreasonably excessive" price, however, is defined by reference to the price of the drug thirty days prior to the declaration of an emergency.[189]

States have further begun to experiment with an adjacent approach that—rather than regulate drug prices directly—levies a fine or tax penalty on state revenue generated from unsupported or excessive price increases taken on a drug.[190] These proposals operate by selecting a baseline reference price (for instance, keyed to a particular calendar date or launch date), but if a drug manufacturer subsequently decides to increase prices, increases deemed "unsupported" or "excessive" would be subject to a penalty.[191] Existing proposals reach patented medications.

Massachusetts Bill H.1, the Governor's proposed budget, for instance, included provisions applicable to any FDA approved drug.[192] Under these provisions, drug manufacturers would have to pay a penalty equal to 80 percent of that portion of a price increase deemed excessive per unit "of the drug ultimately dispensed or administered in the commonwealth."[193] Excessive price increases are determined by starting with the reference price of the drug which is defined to be the wholesale acquisition cost ("WAC") of the drug, per unit, as of January 1, 2021, or if a drug was not yet on the market, the date it was first marketed.[194] Using this reference price as a baseline, drug manufacturers are permitted to increase a drug's price by the consumer price index plus an additional 2 percent of the reference price annually.[195] Price increases beyond this are deemed excessive, and drug

188 *See* H.R. 7040, 2020 Gen. Assemb., Jan. Sess. 6-13.4-3 (2) (R.I. 2020) (defining "Drug").

189 *Id*. at 6-13.4-3(6).

190 *See 2021 State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y, https://www.nashp.org/rx-legislative-tracker/ (noting five unsupported price hike bills) (last visited Oct. 28, 2021).

191 These proposals have features in common with payment regulation insofar as they permit a drug manufacturer to charge whatever it wants. Unlike payment regulation, however, unsupported price increase legislation regulates not what payers can pay, but how much sellers can increase their prices without consequence. *See* Mello & Dusetzina, *infra* note 390; NAT'L ACAD. FOR STATE HEALTH POL'Y, *Q&A: An Act to Protect Consumers from Unsupported Prescription Drug Price Increases* (July 28, 2020), https://www.nashp.org/qa-an-act-to-protect-consumers-from-unsupported-price-increases-on-prescription-drugs/.

192 B.H.1, 192nd Gen. Ct., § 28 ch. 63E(1) (Mass. 2021).

193 *Id.* § 28 ch. 63E(2(a)).

194 *Id.* § 28 ch. 63E(1).

195 *Id.*

manufacturers must file a return with the Commissioner of Revenue paying the 80 percent per unit excessive price increase tax penalty.[196]

2. Payment Regulation: Out of Pocket Caps and Drug Affordability Review Boards

Rather than regulate patented drug *prices* for excessiveness, *payment* regulation offers an alternative. One recent permutation of payment reform is out-of-pocket caps for patients taking insulin. U.S. prices for insulin have been a particularly fraught subject in controversies over drug pricing. Insulin prices have risen dramatically; the same $1,487 vial of insulin in 2019 might have only cost $175.57 fifteen years earlier.[197] Between 2012 and 2016, prices nearly doubled.[198] Patients can end up paying thousands of dollars for this necessary medication even with insurance.[199] There have been numerous examples of patients rationing their medications, with some losing their lives as a result.[200] Consequently, Colorado became the first state to pass legislation limiting insulin co-pays to no more than $100 per month for state-regulated health plans.[201] Several other states have recently passed similar legislation.[202] Importantly, the legislation does not limit what drug manufacturers can charge insurers. Rather, it limits patients' cost-sharing with their insurers, and raises the possibility that insurers can pass on such costs by raising premiums.

The National Academy for State Health Policy ("NASHP") has advocated for a different approach to payment regulation. It provided model legislation for Drug Affordability Review Boards ("DABs") that

196 *Id.* §§ 28 Ch. 63E(1–2).

197 Nicholas Florko, *'Everyone Is at Fault': With Insulin Prices Skyrocketing, There's Plenty of Blame to Go Around*, STAT NEWS (Feb. 19, 2019), https://www.statnews.com/2019/02/19/no-generic-insulin-who-is-to-blame/.

198 Ed Silverman, *Insulin Costs for U.S. Patients Nearly Doubled from 2012 Through 2016, but Usage Was Flat*, STAT NEWS (Feb. 19, 2019), https://www.statnews.com/pharmalot/2019/01/22/insulin-drug-prices-diabetes/.

199 *See* Anna Staver, *Colorado Becomes First State in Nation to Cap Price of Insulin*, DENVER POST (May 23, 2019), https://www.denverpost.com/2019/05/23/colorado-insulin-price-cap/.

200 Amy Martyn, *States Are Trying to Cap the Price of Insulin. Pharmaceutical Companies Are Pushing Back.*, NBC NEWS (Aug. 15, 2020), https://www.nbcnews.com/news/us-news/states-are-trying-cap-price-insulin-pharmaceutical-companies-are-pushing-n1236766.

201 Meg Wingerter, *Lawmaker Looks to Close "Loophole" in Colorado's First-in-the-Nation Insulin Price Cap*, DENVER POST (Jan. 10, 2020), https://www.denverpost.com/2020/01/10/colorado-insulin-price-cap-loophole/.

202 *See* Nicholas Florko, *State Legislatures Are Lapping the Federal Government On Drug-Pricing—Even Amid The Coronavirus*, STAT NEWS (April 14, 2020), https://www.statnews.com/2020/04/14/states-drug-pricing-policies/.

has informed many state proposals.[203] The basic idea is that a government body is endowed with the authority to set payment ceilings for specified payers within a state regarding particular drugs that are deemed excessively priced or pose affordability challenges.

Maryland's passage of HB 768 is perhaps the most high-profile example of this idea's realization.[204] In 2019, Maryland created its Prescription Drug Affordability Board ("Board") with the purpose "to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products."[205] Comprised of members with expertise in medicine and health economics,[206] the Board is charged with identifying prescription drugs that pose affordability challenges.[207] For brand drugs and biologics, these are drugs that launch with a WAC of greater or equal to $30,000 annually or per course of treatment; or drugs that have a WAC increase of greater or equal to $3,000 annually or per course of treatment, if shorter.[208] The Board will also identify biosimilars that are not at least 15 percent cheaper than the referenced biologic at launch, and generic drugs that are $100 or more meeting certain criteria.[209] A catchall clause permits the identification of any "other prescription drug[s] that may create affordability challenges."[210]

After identifying drugs that may be unaffordable, the Board determines which drugs merit a cost review.[211] In conducting a cost review, the Board considers many factors. For instance, it considers the cost of the drug to health plans, the price of competitors (if any), average concessions made to health plans, and the impact on patient access due to cost, among other factors.[212] Its lens is affordability for state payers and patient out-of-pocket costs.[213] It is only *after* consideration of these factors, if the Board cannot determine whether the drug has or will

203 *See* Nat'l Acad. for State Health Pol'y, *supra* note 177 (showing sixteen affordability review proposals as of October 14, 2021, for 2021 state legislation); for more details on DABs see Mello & Wolitz, *supra* note 26, at 883–888, 948–950.

204 Mello & Wolitz, *supra* note 26, at 883–84.

205 MD. CODE ANN., HEALTH-GEN. § 21-2C-02(b).

206 *Id.* § 21-2C-03(a)(1).

207 *Id.* § 21-2C-08(b)(2).

208 *Id.* § 21-2C-08(c)(1).

209 *Id.* § 21-2C-08(c)(2)-(3).

210 *Id.* § 21-2C-08(c)(4).

211 MD. CODE ANN., HEALTH-GEN. § 21-2C-09.

212 *Id.* § 21-2C-09(b)(2).

213 *Id.* § 21-2C-09(b); *see also* Mello & Wolitz, *supra* note 26.

create affordability challenges, that the Board *may* consider certain drug manufacturer financial information, such as R&D costs.[214]

The Board is currently tasked with creating a report on its findings and recommendations regarding whether setting upper payment limits on drugs posing affordability challenges is in the state's best interests.[215] If the Board thinks the state ought to move forward, it shall draft a plan for implementation.[216] It is not until January 1, 2022, at the earliest—and subject to plan approval—that the Board may set upper payment limits for drugs posing affordability challenges.[217] These limits would apply to state and local plans and purchasers.[218] By December 1, 2023, the Board must then report to specified legislative committees whether it recommends expanding the Board's authority to set upper payment limits for all payors.[219]

Given that the implementation of upper payment limits is yet to occur, Maryland has not experienced litigation over its Prescription Drug Affordability Board. The Board, however, hit an unexpected speedbump. In May 2020, the legislature passed a bill authorizing funding for the Board through fee collection from drug manufacturers, pharmacy benefit managers, insurers, and wholesale distributers not to exceed $2,000,000 annually.[220] Yet Governor Hogan vetoed the bill, calling it "unconscionable" to "raise taxes and fees on Marylanders at a time when many are already out of work and financially struggling."[221] In light of previous appropriations, the Board was able to continue with its work,[222] but a lack of sustained funding would undermine its ability to achieve its objectives. In February 2021, the Maryland House of Delegates voted to override the Governor's veto—a testament to the state's commitment to address drug pricing.[223]

---

214 MD. CODE ANN., HEALTH-GEN. § 21-2C-09(b)(3).

215 *Id.* § 21-2C-07, -13.

216 *Id.* § 21-2C-13(a).

217 *Id.* § 21-2C-14(a).

218 *Id.*

219 *Id.* § 21-2C-16.

220 S.B. 669, 2020 Gen. Assemb., Reg. Sess. (Md. 2020), http://mgaleg.maryland.gov/2020RS/bills/sb/sb0669T.pdf.

221 Letter from Governor Hogan, Maryland Off. of the Governor, to Hon. Bill Ferguson & Hon. Adrienne A. Jones, Maryland State House, (May 7, 2020), https://governor.maryland.gov/wp-content/uploads/2020/05/Taxes-Fees-Veto.pdf.

222 Ed Silverman, *Maryland Governor Vetoes Funding for a Prescription Drug Affordability Board*, STAT NEWS (May 8, 2020), https://www.statnews.com/pharmalot/2020/05/08/maryland-governor-vetoes-funding-for-a-prescription-drug-affordability-board/ (noting $750,000 in previous appropriations).

223 Ed Silverman, *With a Legislative Vote, Maryland's Prescription Drug Affordability Board Moves Forward*, STAT NEWS (Feb. 11, 2021), https://www.statnews.com/pharmalot/2021/02/11/maryland-drug-prices-veto-hogan/.

Drug payment regulation reform is also occurring within Medicaid. Medicaid is a federal-state program that receives significant rebates and supplemental rebates from drug manufacturers. Nevertheless, state Medicaid programs have found that the cost of prescription drugs—particularly new specialty drugs—have become increasingly unsustainable. Paying for prescription medications has become an increasing share of overall state Medicaid expenditures.[224] Thus, as with non-Medicaid state proposals for DABs, a main motivation for payment reform is to control excessive costs.

Though trends change, an interesting historical feature of some state experimentation with Medicaid reform is the comparative emphasis in DABs on "value-based pricing" when contrasted with non-Medicaid DAB cousins.[225] The meaning of value-based pricing is notoriously variable.[226] The basic distinguishing idea, however, is that drugs should be renumerated on the basis of their benefits and harms. It is an approach to fair drug pricing that focuses on value for money.

Themes of value-based pricing are working their way into state Medicaid reform in at least two ways. First, consideration of a drug's value is being incorporated into new DAB structures in New York and Massachusetts as the basis for negotiating increased supplemental rebates on high-cost drugs.[227] Second, several states—with Oklahoma being the first—have amended their state plans or received waivers to incorporate "[v]alue-based purchasing agreements" to lower costs on the front end through negotiation.[228]

---

224 N.Y. PUB. HEALTH LAW § 280(1) (McKinney 2020).

225 Of course, one cannot draw a bright line. Non-Medicaid DABs can incorporate this approach. Maryland's DAB law, for instance, includes consideration of "relative financial impacts to health…compared to baseline effects of existing therapeutic alternatives" as well as "any other factors as determined by the Board…." MD. CODE ANN., HEALTH-GEN. §§ 21-2C-09 (b)(2)(ix), (xi).

226 Anna Kaltenboeck & Peter B. Bach, *Value-Based Pricing for Drugs: Theme and Variations*, 319 JAMA 2165, 2165 (2018).

227 Thomas J. Hwang, Aaron S. Kesselheim & Ameet Sarpatwari, *Value-Based Pricing and State Reform of Prescription Drug Costs*, 318 JAMA 609, 609 (2017); Priyanka Dayal McCluskey, *Pharmaceutical Industry Mounts Opposition to State's Effort to Curb Drug Costs*, BOS. GLOBE (Dec. 23, 2019), https://www.bostonglobe.com/business/2019/12/23/pharmaceutical-industry-mounts-opposition-state-effort-curb-drug-costs/OlQA-jYYeiJ7v5Zv7vkGbiN/story.html.

228 John Armstrong & Colleen Becker, *Value-Based Pricing to Address Drug Costs*, NAT'L CONF. STATE LEGISLATURES (Apr. 2019), https://www.ncsl.org/research/health/value-based-pricing-to-address-drug-costs.aspx.

C. *Patent Preemption and State Excessive Price Regulation*

Moral and political reasons warrant a preference for state-level price regulation over payment regulation, yet a second-best solution must be pragmatic and workable. State excessive price regulation of patented medications faces several practical challenges. Most significantly, excessive price regulation confronts the doctrinal barrier of unfavorable Federal Circuit precedent in *BIO v. D.C.* As already noted, this case ruled that at least one version of an excessive drug pricing statute was patent preempted. This precedent is flawed, and arguments in support of the District of Columbia, and state level excessive price regulation more generally, ought to be revived and revisited.[229] The alternative is rather bleak: federal regulatory failure compounded by neutered state regulation.

Preemption of state law can take different pathways.[230] Preemption can be express. This occurs when federal law explicitly preempts state law.[231] Neither the Intellectual Property Clause nor federal statutory patent law expressly preempt state law.[232] Indeed, the Federal Circuit acknowledged that "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods."[233]

Yet, if not express, preemption can be implied. There are several different kinds of implied preemption.[234] Obstacle preemption—a kind of conflict preemption—occurs when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives

[229] Sarnoff, *supra* note 45, at 35; Brief for the Nat'l Legis. Ass'n on Prescription Drug Prices et al. as Amicus Curiae Supporting Defendant-Appellant., Biotechnology Indus. Org. v. District of Columbia 496 F.3d 1362 (Fed. Cir. 2007), (No. 2006-1593), 2006 WL 3846637 (submitted by Professors Sean Fiil-Flynn and Joshua Sarnoff).

[230] Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461, 1480 (2018) (noting three types of preemption).

[231] The Copyright Act, for instance, has an express preemption provision. *See* 17 U.S.C. § 301.

[232] Jeanne C. Fromer, *The Intellectual Property Clause's Preemptive Effect, in* INTELL. PROP. & COMMON L. 265 (Shram Rrishna Balganesh ed., 2013); Camilla A. Hrdy, *State Patents as a Solution to Underinvestment in Innovation*, 62 U. KAN. L. REV. 487, 525–26 (2013); Sharon K. Sandeen, Kewanee *Revisited: Returning to First Principles of Intellectual Property Law to Determine the Issue of Federal Preemption*, 12 MARQ. INTELL. PROP. L. REV. 299, 335 (2008).

[233] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

[234] Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203–04 (1983); *see also Murphy*, 138 S. Ct. at 1480; Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142, (1963).

of Congress."[235] Obstacle preemption is the kind of conflict preemption that the Federal Circuit found in *BIO v. D.C.*[236]

The district court in this litigation agreed with the trade associations' argument that the federal patent laws, and in particular, the Hatch-Waxman Act, "reflect Congress' considered judgment of the economic incentives and protections necessary to best promote the development of new medications."[237] The D.C. Act, according to the court, therefore impermissibly interfered with Congress's considered incentive scheme. The district court wrote:

> How then does the D.C. Act's thinly veiled effort to force manufacturers to limit the wholesale price of those drugs to less than 30% more than the wholesale price of the same patented drugs sold in four designated "high income" countries square with the congressional purpose and objectives inherent in the Patent Term Restoration Act? It doesn't![238]

The district court further observed that drug manufacturers would be "caught between a rock and a hard place."[239] If manufacturers wanted to continue selling their patented products in D.C. without being tied up in litigation over what counts as excessive, they would need to price to avoid triggering the rebuttable presumption. This was described by the court as both a punishment and antithetical to Congress's intentions.[240]

The Federal Circuit Court of Appeals affirmed. According to the appellate court, patent rights are valuable "because the ability to foreclose competitors . . . may allow . . . an opportunity to obtain above-market profits during the patent's term."[241] Moreover, the court argued that this prospect of above-market profits plays a "central role" in patent

---

235 Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

236 For those wondering about field preemption—when the federal regulatory scheme is so pervasive as to infer that Congress left no room for state regulation—it is unlikely in this context. Field preemption is a "rarer form" of preemption. Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMP. L. REV. 95, 103 (2016). Further, as others observe, it is not "likely that field preemption exists" in the case of patents and price regulation. Feldman et al., *supra* note 45, at 45; *see also* Christopher Lea Lockwood, Biotechnology Industry Organization v. District of Columbia*: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 178–79 (2009).

237 Pharm. Rsch. & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 65 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org.*, 496 F.3d at 1362.

238 *Id.* at 66.

239 *Id.*

240 *Id.* at 66–67.

241 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

law's scheme to encourage invention,[242] and is of particular importance for medications. As evidence, the court cited approvingly to part of the Hatch-Waxman Act's legislative history stating that profits are higher in the absence of competition, and "'[t]hese profits act as incentives for innovative activities.'"[243] In the court's view, the only restriction on economic rewards offered by a patent ought to be "the dictates of the marketplace."[244]

While the Federal Circuit recognized a "dialectic tension" between patent rights and patient needs and state budgets, it explained that such hardships are balanced by the limited duration of patent rights—over which Congress has exclusive authority.[245] "Congress, as the promulgator of patent policy," is the final arbiter of how that balance between exclusive rights and the public domain is struck.[246] In light of this authority and Congress's purportedly explicit consideration of these issues in the Hatch-Waxman Act, the court deemed D.C.'s law to impermissibly alter this balance.[247] The Act penalized manufacturers, "limiting the full exercise of the exclusionary power that derives from a patent" and "shift[ing] the benefits of a patented invention from inventors to consumers."[248] Furthermore, the court stated that D.C.'s law was problematic in part because, by singling out just patented medications for excessive price regulation, it was "in no way general."[249]

In the denial of the petition for rehearing en banc, Judge Dyk and Judge Gajarsa, the latter being the author of the underlying ruling, had a spirited exchange.[250] Judge Dyk, dissenting from the denial of rehearing, argued that, far from "determin[ing] what price is necessary to spur innovation" (which he thinks *would* be preempted),[251] the Act actually regulates price discrimination.[252] Regulating for pricing parity "presents no conflict with the purpose of the federal patent law."[253] Patents confer only an exclusive right and are not "designed . . . to allow

---

242 *Id.* at 1373.

243 *Id.* (citing H.R. REP. NO. 98-857, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650).

244 *Id.* at 1372 (citing King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995)).

245 *Id.* at 1373.

246 *Id.* at 1373.

247 *Biotechnology Indus. Org.*, 496 F.3d at 1374.

248 *Id.*

249 *Id.* at 1373.

250 Biotechnology Indus. Org. v. District of Columbia, 505 F.3d 1343, 1344 (Fed. Cir. 2007).

251 *Id.* at 1348–49 (Dyk, J., dissenting).

252 *Id.* at 1349.

253 *Id.*

the patent holder to exploit the grant for the maximum profit that the market will bear."[254] Patents do not confer antitrust immunity, do not prevent the regulation of patented products, and thus if a state law does not interfere with the grant of *exclusivity*—which price discrimination regulation does not—it does not conflict.[255] Judge Dyk further noted that the panel, in his opinion, did not give adequate attention to state police powers.[256]

In response, Judge Gajarsa's concurrence accused the dissent of "sophistry."[257] Whatever the purported purpose of the Act, it "was a direct attempt 'to change federal patent policy' within the District of Columbia."[258] Judge Gajarsa reasoned that while patents do not provide affirmative rights, a right of exclusion "is not granted in a vacuum or for its own sake."[259] Exclusionary rights are instrumental and fulfill their Constitutional purpose to promote innovation through the opportunity for above-market profits.[260] According to Judge Gajarsa, the Hatch-Waxman Act underscored the particular importance of these rights for medications by restoring patent terms in light of the FDA approval process.[261] Moreover, he argued, because the Hatch-Waxman Act facilitates competitive markets upon patent expiration due to concern for medications' costs, Congress clearly identified how it thinks the balance between innovation and access should be set.[262]

Thus, according to Judge Gajarsa, states need to stay in their lane. States exceed their power not just by direct interference with an exclusive right (e.g., interfering with a patent holder's ability to prevent others from using or selling a patented product), but by interfering with the anticipated rewards derived from an exclusionary right. Since the value of an exclusionary right is its prospect of above-market rewards, and the prospect of above-market rewards is Congress's mechanism for promoting innovation, this purpose is "obstructed . . . by systematically preventing a patentee from reaping the increased profits that would otherwise come from its exclusionary rights."[263]

---

254 *Id.* at 1350.

255 *Id.* at 1350–51.

256 *Biotechnology Indus. Org.*, 505 F.3d at 1351 (Dyk, J., dissenting).

257 *Id.* at 1344–45 (Gajarsa, J., concurring).

258 *Id.* (quoting Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007)).

259 *Id.* at 1346.

260 *Id.*

261 *Id.*

262 *Biotechnology Indus. Org.*, 505 F.3d at 1347 (Gajarsa, J., concurring).

263 *Id.* at 1346 (footnote omitted).

For all that, however, Judge Gajarsa argued that his statement is not as broad as it first seems. In his view, not *all* state regulation impacting patent-derived profits is preempted if that regulation only does so "incidentally" and does not "significantly and directly impede[] Congress's purpose in providing the federal patent right."[264]

> This does not mean that any state regulation that affects a patentee's profits so undermines the goals of the patent system as to be preempted. It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent. But that states have broad leeway to regulate patented products does not mean that they have unlimited ability to do so in situations in which the regulation significantly and directly impedes Congress's purpose in providing the federal patent right.[265]

Judge Gajarsa concluded his concurrence by asserting that the dissent "overstates the breath" of the opinion.[266] It does not "require the preemption of 'any state law regulating the prices of patented pharmaceutical products.'"[267] The opinion is specific to the facts of the D.C. Act, and a different state law regulating drug prices might avoid preemption if it "did not only target patent [sic] drugs or did not as significantly or directly undermine the balance of the federal patent right."[268]

As previously mentioned, *BIO v. D.C.* has seemingly had a chilling effect on state efforts to regulate excessively priced patented medications. No state has enacted direct patented drug price regulation for unconscionably high prices in the intervening years since *BIO v. D.C.* While some recent prescription drug anti-price-gouging bills implicitly or explicitly cover patented medications, the focus for this kind of legislation has generally shifted to generic, off-patent medications.[269]

Even though addressing the excessive costs of patented medications is urgent for both patients and health systems, with limited resources and litigious adversaries, states likely have been wary of triggering claims of patent preemption. Maryland's failed antigouging law, for instance, only applied to essential off-patent medications "[f]or

---

264 *Id.* at 1346 n.1 (citation omitted).

265 *Id.* (citation omitted).

266 *Id.* at 1348.

267 *Id.* (citation omitted).

268 Biotechnology Indus. Org. v. District of Columbia, 505 F.3d 1343, 1348 (Fed. Cir. 2007).

269 *See supra* Section III.B.1.

which all federal exclusive marketing rights . . . ha[d] expired."[270] It was criticized for this focus by Governor Hogan: "This oversight, whether inadvertent or deliberate, is troubling since the patented or brand-name pharmaceuticals make up a significant amount of the market and are often times the most expensive and essential pharmaceuticals."[271] Yet, the focus on generics was likely deliberate in order to avoid patent preemption.

Further, at least one district court has expansively interpreted *BIO v. D.C.*'s ruling.[272] In *Southeastern Pennsylvania Transportation Authority v. Gilead Sciences, Inc.* ("*SEPTA*"), patients and an employee health plan sued Gilead over its use of price discrimination and the high U.S. costs of its hepatitis C drugs Sovaldi and Harvoni.[273] At the time of the litigation, Sovaldi cost $84,000 and Harvoni cost $94,500 for a twelve-week course of treatment.[274] The plaintiffs alleged that, despite Gilead selling the active ingredient in these drugs (sofosbuvir) for much less in other countries and giving discounts to certain federal agencies, the pricing of their hepatitis C drugs thwarted domestic access through insurer rationing.[275] In light of these "bogus" and "exorbitant prices," plaintiffs sued Gilead "to stop this unconscionable and unfair conduct, and to secure appropriate relief for consumers and third party payers who have been victimized by Gilead's price gouging scheme."[276] Plaintiffs put forward a number of state law claims including unjust enrichment, breach of the duty of good faith and fair dealing, and prohibitions against unfair competition.[277]

---

[270] MD. CODE ANN., HEALTH–GEN. § 2-801(b)(1)(i) (West, Westlaw through 2021 Legis. Sess.).

[271] Letter from Governor Hogan, Md. Off. of the Governor, to Honorable Michael E. Busch, Speaker of the House, Maryland State House (May 26, 2017), https://content.govdelivery.com/attachments/MDGOV/2017/05/26/file_attachments/822635/HB631Letter.pdf; *see also* Press Release, Ass'n for Accessible Meds., AAM Requests Federal Injunction to Block Maryland's Unconstitutional Drug Price Law (July 6, 2017), https://accessiblemeds.org/resources/press-releases/aam-requests-federal-injunction-block-marylands-unconstitutional-drug (arguing that the law "protects high-priced brand name drug companies, while it punishes lower cost generic alternatives").

[272] *Cf. In re* EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., 336 F. Supp. 3d 1256, 1333–1334 (D. Kan. 2018) (rejecting Mylan's arguments that state consumer protection claims alleging marketplace misconduct resulting in higher EpiPen prices were patent preempted). Reconciling this case with *SEPTA* suggests a distinction between regulation of a pricing scheme and unfair conduct impacting price.

[273] Se. Pa. Transp. Auth. v. Gilead Scis., Inc., 102 F. Supp. 3d 688, 694–95 (E.D. Pa. 2015).

[274] *Id.*

[275] *Id.* at 695.

[276] *Id.* at 695–96.

[277] *Id.* at 696.

The court rejected all of plaintiffs' claims and granted Gilead's motion to dismiss. According to the court, "[p]laintiffs' true complaint is that Gilead is making too much money and that it is unfair for Gilead to reap profits based on its high prices for widely needed drugs."[278] The court found Gilead's patent preemption arguments to be "devastating."[279] Relying on *BIO v. D.C.*, Gilead argued "that '[g]iven that it is beyond the authority of a legislature to determine that a pharmaceutical price is "excessive," it is *a fortiori* beyond the authority of a court applying a vague state law of general application to achieve the same result.'"[280] Following this logic, the court concluded:

> To the extent that plaintiffs seek to use state law to challenge Gilead's exercise of its exclusive patent rights to make pricing decisions, plaintiffs' claims are preempted. Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs.[281]

This interpretation of *BIO v. D.C.* is arguably even more expansive than the original. The Federal Circuit explicitly stated that the D.C. Act was problematic in part because, by singling out patented medications, it was "in no way general."[282] Thus, the court implied that a law of general application might be able to avoid patent preemption. *SEPTA* undermines this language. Gilead's interpretation of *BIO v. D.C.*, with which the court appears inclined to agree, deliberately attacks this guidance. In contrast to the Federal Circuit, this court suggests that state laws of any kind, whether general or particular, will be patent preempted when used to address the prices of patented medications; state laws, in the court's view, cannot be used to "lower" prices or "disgorge" profits when a drug is patent protected.

D. *Patent Preemption Revisited*

The Federal Circuit's ruling in *BIO v. D.C.* is provocative. There are prima facie compelling arguments, as the court lays out, to think that state price regulation of patented medications ought to be patent preempted. The patent system is, after all, a federal scheme and Congress ought to have the final say in how exclusive rights are balanced

---

278 *Id.* at 704.

279 *Se. Pa. Transp. Auth.*, 102 F. Supp. 3d at 703.

280 *Id.* at 702 (citation omitted).

281 *Id.* at 703 (footnote omitted).

282 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373 (Fed. Cir. 2007).

against access to inventions in the public domain. The Constitution's Supremacy Clause provides that federal law is "the supreme Law of the Land,"[283] meaning "that when federal and state law conflict, federal law prevails and state law is preempted."[284]

Yet, as argued below, Congress had not and *still* (more than a decade later) has not addressed the problem of excessively-priced patented medications during the patent period. Thus, there is a regulatory vacuum which states can fill. Further, this is a vacuum that states *should* fill. Preemption is costly, both in human and fiscal terms. The existing federal patent scheme, operating without federal correction, imposes tragic choices on individuals and states. These costs and the privileging of private gain untethered to constitutional or statutory purpose are unjustified, both doctrinally and as a matter of public policy. The Federal Circuit's arguments in *BIO v. D.C.* therefore ought to be revisited. This is particularly so given a policy preference for excessive price regulation over alternatives.

1. The Presumption Against Preemption

To determine whether a state statute is preempted, Supreme Court preemption jurisprudence involves "two cornerstones."[285] First, congressional purpose is the "ultimate touchstone."[286] Second, there is a presumption "that the historic police powers of the States [are] not to be superseded . . . [absent] the clear and manifest purpose of Congress."[287]

Beginning with the latter, while much about the presumption against preemption is debated,[288] it remains an ongoing tool in Supreme Court preemption analysis.[289] The Federal Circuit in *BIO v. D.C.*, however, gives it but a glancing look.[290] The court simply notes that D.C.'s "general police power within its borders" is "unquestioned," as is the fact that patent rights "'must be enjoyed in subordination to this

283 U.S. CONST. art. VI, cl. 2.

284 Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461, 1476 (2018).

285 Wyeth v. Levine, 555 U.S. 555, 565 (2009); *see, e.g.*, McCuskey, *supra* note 236 at 108–109.

286 *Wyeth*, 555 U.S. at 565 (citation omitted).

287 *Id.* (citation omitted).

288 *See, e.g.*, *New Evidence on the Presumption against Preemption: An Empirical Study of Congressional Responses to Supreme Court Preemption Decisions*, 120 HARV. L. REV. 1604, 1605 (2007).

289 *See, e.g.*, CTS Corp. v. Waldburger, 573 U.S. 1, 18–19 (2014).

290 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373 (Fed. Cir. 2007); Biotechnology Indus. Org. v. District of Columbia, 505 F.3d 1343, 1351 (Fed. Cir. 2007) (Dyk, J., dissenting) ("I think that the panel failed to give adequate consideration to the presumption against preemption.").

general authority of the State over all property within its limits.'"[291] Presumably, because it found the D.C. Act to conflict with the Hatch-Waxman Act, the court concludes in the next sentence that "general state power must yield to specific congressional enactment."[292] Since D.C.'s law was not general, it stood "exclusively[] within the scope of the patent laws."[293]

In light of a tension between the Supremacy Clause and the underlying principles of federalism within the Constitution, the U.S. Supreme Court has drawn on a presumption against preemption as "a canonical caveat" in cases involving historic state police powers.[294] It establishes, as a rebuttable default, that there is no congressional intent to preempt. When "historic police powers of the States" are involved, courts are to "start with the assumption" that these powers "were not to be superseded by the Federal Act."[295] Those arguing to the court that there *is* preemption have the burden of providing evidence of Congress's "clear and manifest purpose" to do so.[296] This purpose can be shown through express or implied preemption.[297]

Historic state police powers are broad and empower states to regulate diverse kinds of activities.[298] Though the scope of state police powers has ebbed and flowed over the years, health regulations have a long history of being among states' core police powers.[299] Consensus exists among courts and commentators that state regulations for the health, safety, and welfare for their citizens are within the boundaries of states' authority.[300] As observed in *Jacobson v. Massachusetts*, states have the authority to enact "health laws of every description."[301] These laws, however, must be "reasonable."[302]

---

291 Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (quoting *Webber v. Virginia,* 103 U.S. 344, 348 (1880)).

292 *Id.*

293 *Id.* at 1373–74.

294 William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules As Constitutional Lawmaking*, 45 VAND. L. REV. 593, 607 (1992).

295 Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

296 *Rice*, 331 U.S. at 230; *see also* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992).

297 *Cipollone,* 505 U.S. at 516 (citations omitted).

298 McCuskey, *supra* note 236, at 113–14.

299 Santiago Legarre, *The Historical Background of the Police Power*, 9 U. PENN J. CONST. L. 745, 793–94 (2007).

300 McCuskey, *supra* note 236, at 113–14.

301 Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

302 *Id.*; *see also* Wendy Parmet, *Rediscovering* Jacobson *in the Era of COVID-19,* 100 B.U. L. REV. ONLINE 117, 124–26 (2020).

State regulations to protect against price gouging or to otherwise regulate prices in the name of public welfare have long been recognized as legitimate ends of state police powers.[303] Likewise, state payment regulation is familiar.[304] The Supreme Court has held that businesses do not have constitutional rights to "inflict injury upon the public at large, or upon any substantial group of the people."[305] Thus, "in the absence of other constitutional restriction[s], a state is free to adopt whatever economic policy may reasonably be deemed to promote public welfare, and to enforce that policy by legislation adapted to its purpose."[306] The Court explicitly stated that states' ability to regulate any aspect of a business includes product pricing.[307] As with "any other form of regulation," state price regulations are "unconstitutional only if arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature is free to adopt."[308]

Furthermore, the mere fact that a regulated product is patented does not automatically displace appropriate regulation under a state's police powers.[309] State legislation that can be adopted in the absence of a patent, "may equally" be adopted in its presence.[310] The Supreme Court explains:

> Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits.[311]

The Court specified, however, that states cannot interfere with "the incorporeal right"—the exclusive rights granted to patent holders.[312] While states may exercise the police powers to regulate patented products, they cannot regulate the patent rights themselves.

---

303 Nebbia v. People of New York, 291 U.S. 502, 524–25 (1934); *In re* Permian Basin Area Rate Cases, 390 U.S. 747, 768–69 (1968).

304 *See* Feldman et al., *supra* note 45, at 41, 48; Erin C. Fuse Brown, *Resurrecting Health Care Rate Regulation,* 67 HASTINGS L.J. 85, 129 (2015).

305 *Nebbia*, 291 U.S. at 538–39.

306 *Id.* at 537.

307 *Id.*

308 *Id.* at 539; *see also* Pennell v. City of San Jose, 485 U.S. 1, 11 (1988).

309 Patterson v. Kentucky, 97 U.S. 501, 503, 505 (1878).

310 Webber v. Virginia, 103 U.S. 344, 347 (1880).

311 *Id.* at 347–48.

312 *Id*. at 347.

It may seem a close call whether excessive drug pricing laws regulate the product or the underlying right. On the one hand, regulation of patented drug prices implicates the amount of reward a patent holder can receive during its period of exclusivity. More specifically, by restricting what a patent holder can charge, it regulates the incentive offered by exclusivity.

On the other hand, a great many things a state does influences the price a drug manufacturer can charge for its patented product. Why think that price regulation is different? Price regulation is not regulation of the exclusive right conferred by a patent, which is all that a patent provides. Price regulation has nothing to do with the *ability* to exclude others, and as already mentioned, patent rights confer no rights to particular rewards.

This understanding logically coheres with the recognized ability of states to tax patent royalties[313] and to prohibit the sale of patented products within their jurisdictions.[314] In *Patterson v. Kentucky*, for instance, the Supreme Court upheld a statute condemning certain oils as unsafe and imposing a penalty on sales of such oils within the state.[315] There was no way for the patented oil at issue to meet the standards imposed by the statute,[316] yet the Court ruled for the state, asserting that the statute's "enforcement causes no necessary conflict with national authority, and interferes with no right secured by federal legislation, to the patentee or his assigns."[317] Excessive drug price regulation falls far short of prohibiting the sale of products. An exclusive right is only as valuable as background and market conditions permit, and states are within their authority to regulate those conditions. Excessive patented price regulation does not regulate the incorporeal right itself. [318]

For these reasons, state excessive patented drug price regulations ought to be accorded a presumption against preemption. The fundamental purpose of these regulations is to protect the health and welfare of a state's citizens, and regulations of this kind have long been considered within the police powers of states. These are reasonable regulations that states can use to achieve their legitimate goals.

Moreover, as argued below, there is no "clear and manifest purpose" in the federal patent laws to displace state regulation of

313 Fox Film Corp. v. Doyal, 286 U.S. 123, 128 (1932).

314 *Patterson*, 97 U.S. at 503.

315 *Id.* at 502–03.

316 *Id.* at 503.

317 *Id.* at 509.

318 *See* Brief for the Nat'l Legis. Ass'n on Prescription Drug Prices et al., *supra* note 229 (arguing that the D.C. Act regulated patented products).

excessive pricing, or state payment regulation impacting patented products. The presumption is not rebutted. There is no obstacle preemption: excessive price regulation need not be an impediment to federal purposes. The prices of patented drug products are almost completely unregulated federally, and there is no constitutional nor congressional purpose to guarantee patent-holders certain economic rewards.[319] The patent laws do not exist to enrich patent holders. Further, applying Judge Gajarsa's suggested criteria, *excessive* price regulation only incidentally and neither significantly nor directly impedes the purpose of the federal patent scheme. Any intersection of these laws with a purpose to incentivize innovation is incidental, they do not alter the scope of exclusive rights in any way, and by focusing on price *excessiveness* they are compatible with a federal purpose to incentivize.

2. Congressional Purpose

The Federal Circuit found that the D.C. Act was specifically conflict preempted by the Hatch-Waxman Act.[320] In doing so, the court drew on Supreme Court patent preemption precedent[321] that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."[322] That balance refers to the "tension between" free use of "inventive resources" and "an incentive to deploy those resources."[323] "Where it is clear how the

319 See *supra* Part II.

320 Debate exists in the academic literature regarding the appropriate patent preemption standard, with some scholars arguing for focus on the IP Clause rather than congressional intent. Fromer, *supra* note 232, at 265; Camilla A. Hrdy, *The Reemergence of State Anti-Patent Law*, 89 U. COLO. L. REV. 133, 140–41 (2018). Regarding *BIO v. DC*, Hrdy observes that the Federal Circuit is "quite patentee-protective" and that conflict preemption is misguided. According to Hrdy, "[a] state price restriction law that does not significantly affect patentees' incentive to invent and commercialize should not be preempted." *Id.* at 212.

321 The Supreme Court considered patent preemption on several occasions, but this caselaw's underlying fact patterns are not of direct assistance. *See* Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989). State regulation of patented drug prices raises the possibility of diminishing the potential rewards of a federally granted right. By contrast, the Court's patent preemption caselaw "almost exclusively addresses laws granting rights on top of those granted by the patent system, not ones cutting back on federal patent rights." Roger Allan Ford, *The Uneasy Case for Patent Federalism*, 2017 Wis. L. Rev. 551, 561–62 (2017); Hrdy, *The Reemergence of State Anti-Patent Law*, *supra* note 320, at 194–97; *see also* Paul R. Gugliuzza, *Patent Trolls and Preemption*, 101 VA. L. REV. 1579, 1583 (2015).

322 *Bonito Boats,* 489 U.S. at 152.

323 *Id.*

patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess."[324] The Hatch-Waxman Act, in the court's view, purportedly provides how Congress sought to strike this balance for pharmaceuticals.

Yet, the Federal Circuit's reliance on the Hatch-Waxman Act is misplaced.[325] It is far from obvious that the D.C. Act—or any excessive price regulation more generally—*must* undermine the purposes and balance struck in the Hatch-Waxman Act. The same is true of the BPCIA—an analogous law enacted in 2010 that pertains to biologics and biosimilars.[326] Neither law regulates prices—excessive or otherwise—of patented medications.

Congress passed the Hatch-Waxman Act in 1984, and it is generally described as the great compromise between brand and generic drug manufacturers; it aims to balance the availability of lower cost generic drugs upon patent expiration with the incentivization of new drugs.[327] The Hatch-Waxman Act sought to remedy two issues.[328]

First, it sought to maintain incentives for brand name, or originator drug manufacturers.[329] Under the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, the FDA required drug manufacturers "to prove that their drugs were safe and efficacious before the drugs could be sold."[330] Originator drug manufacturers argued that these new requirements "unfairly shortened their effective exclusivity periods by requiring a lengthy process of clinical testing and FDA review."[331] In response, Congress granted patent term extensions to restore some of the time lost to regulatory review.[332] Firms could receive up to an additional five years of patent exclusivity, but patent expiration could not be extended beyond fourteen years post-FDA

---

[324] *Id.*

[325] *See* Sarnoff, *supra* note 45, at 33–34; Lockwood, *supra* note 236, at 177. *See generally* Brief for the Nat'l Legis. Ass'n on Prescription Drug Prices et al., *supra* note 229, at 9.

[326] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001–03, 124 Stat. 804-21 (2010) (codified as amended at 42 U.S.C. § 262 (2012)). Given the Federal Circuit's discussion of the Hatch-Waxman Act, that is the focus of this discussion.

[327] Orrin G. Hatch, *The 30th Anniversary of the Hatch-Waxman Act: Foreword*, 40 WM. MITCHELL L. REV. 1194, 1194–95 (2014).

[328] *See id.; see also* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 301 (2015).

[329] Kesselheim & Darrow, *supra* note 328.

[330] *Id.* at 297.

[331] *Id.* at 306.

[332] *Id.*

approval.[333] In addition to patent term restoration, the Hatch-Waxman Act established several non-patent exclusivities for the FDA to implement. For instance, new chemical entities would receive five years of data exclusivity, during which time generic competitors would be prevented from submitting an application for FDA approval.[334]

Second, and perhaps most importantly, the Hatch-Waxman Act sought to create new pathways to speed up market entry of generics and end the de facto exclusivity extension for originator drugs.[335] The Kefauver-Harris Amendments applied to FDA review of all drug manufacturers, regardless of whether they were originators with patent protection or generics without; all drug manufacturers would need to expend substantial resources on new clinical trials to complete the regulatory process.[336] Yet, generics did not have strong economic incentives to enter the market given a lack of patent-protection, the existence of at least one competitor, and the expense of completing the same regulatory requirements of originators.[337] Further, due to a Federal Circuit ruling, generic manufacturers were barred from even beginning the testing necessary for FDA approval prior to the originator's patent expiration.[338] This meant that patent-holders' period of exclusivity enjoyed a de facto extension.[339] To remedy these problems, the Hatch-Waxman Act created an abbreviated new drug application pathway ("ANDA"), through which generic manufacturers could seek FDA approval.[340] It further permitted generic manufacturers to experiment with patent protected medications in preparation for submitting an ANDA.[341]

While the Hatch-Waxman Act has "indisputably . . . galvanize[d]" an industry of lower cost generic drugs,[342] the benefits of generic entry are conditioned upon patent expiration, invalidation, or non-infringement.[343] Through a 180-day exclusivity period,[344] the Act incentivizes generic applicants to challenge an originator's patents as either invalid or noninfringed. If a patent is invalid, then the patent

333 35 U.S.C. § 156.
334 21 U.S.C.A. § 355(j)(5)(F)(ii).
335 Kesselheim & Darrow, *supra* note 328, at 301; 21 U.S.C.A. § 355(j).
336 Kesselheim & Darrow, *supra* note 328, at 298.
337 *Id.* at 299.
338 *Id.* at 300.
339 *Id.*
340 *Id.* at 302; 21 U.S.C.A. § 355(j).
341 Kesselheim & Darrow, *supra* note 328, at 305; 35 U.S.C. § 271(e)(1).
342 Kesselheim & Darrow, *supra* note 328, at 309.
343 21 U.S.C. § 355(j)(2)(A)(vii).
344 21 U.S.C. § 355(j)(5)(B)(iv).

should not have existed in the first instance. If a patent is non-infringed, then the generic applicant competes beyond the scope of the exclusive right. Thus, the Hatch-Waxman Act can encourage competition during the patent term in addition to facilitating generic competition upon patent expiration. Encouraging competition during the patent period, however, does not address excessive drug pricing and does not regulate patented drug prices.

Thus, the Hatch-Waxman Act does not regulate prices—excessive or otherwise—of patented medications. It facilitates competition and seeks to correct for time lost on patent protection by the regulatory process. There is no indication of congressional purpose to preempt state price regulation through an inference about the law's negative space.[345] It is a stretch to infer that a congressional purpose to facilitate competition in the Hatch-Waman Act reveals congressional intent that prices during the patent term must remain utterly unregulated by states.[346]

The court argues that the D.C. Act conflicts with the Hatch-Waxman Act because of the "central role of enhanced profits in the statutory incentive scheme it has developed."[347] As evidence, the court cites to legislative history, noting the importance of supra-competitive prices for incentivizing innovation.[348] Yet, this history (discussing the patent term extension part of the legislation) merely notes that patents "'enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.'"[349] Neither this cited Committee Report nor a subsequent one offer any more compelling evidence in support of a purpose to preempt state-level excessive price preemption.[350]

Furthermore, the court's position both ignores Congress's less deferential posture towards patents by incentivizing competition during the patent period through a showing of noninfringement and makes a logical flaw. The assumption that supra-competitive pricing is necessarily incompatible with regulation of excessive pricing, or,

345 Brief for the Nat'l Legis. Ass'n on Prescription Drug Prices et al., *supra* note 229, at 10.

346 *See id.* at 9–10; Brief for Defendant-Appellants, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), (No. 2006-1593), 2006 WL 3382103, at *13.

347 *Biotechnology Indus. Org.*, 496 F.3d at 1373.

348 *Id.* (citing H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650).

349 *Id.* (quoting H.R. REP. NO. 98-857, pt. 1, at 17 (1984)).

350 *See* H.R. REP. NO. 98-857, pt. 1 (1984) (Conf. Rep.); *see also* H.R. REP. NO. 98-857, pt. 2 (1984) (Conf. Rep.).

conversely, that excessive price regulation is necessarily an obstacle to supra-competitive pricing, is a mistake. As explained in Part I, a price might be supra-competitive, yet neither excessive nor unfair. Above market pricing, absent additional details, is not in itself sufficient to justify regulation.

Broader consideration of the purposes of federal patent law—beyond the specifics of the Hatch-Waxman Act—also yields the conclusion that state patented price regulation should not necessarily be preempted. Patent law, as previously discussed, serves three primary objectives, of which only one raises a credible potential conflict: the purpose of incentivizing innovation.[351] But again, it is unclear why state-level excessive price regulation *must* inevitably undermine, or be an obstacle to, innovation incentives.

IV. AVOIDING PREEMPTION AND REIMAGINING STATE PARTICIPATION IN FEDERAL PATENT POLICY

The Federal Circuit's ruling should not preempt, on patent law grounds, state level excessive price regulation that reaches patented medications. This is so doctrinally as well as from the perspective of public policy. States should not be blocked from addressing the urgent problems of prescription drug access and affordability given federal abdication of corrective action. This precedent must be avoided or fixed.

Since *BIO v. D.C.* remains good law, important practical questions remain regarding how states might proceed. Given a moral and political preference for price regulation over payment regulation, what characteristics might the next generation of state-level excessive drug price regulations incorporate, and are they workable? Does payment regulation escape patent preemption? What other options might states consider for improving the affordability of excessively priced patented medications? Five options are considered below: (1) congressional amendment; (2) the shield of sovereign immunity; (3) revised general excessive pricing regulations; (4) tax penalties on price increases; and (5) payment regulation.[352]

---

[351] Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979); *see, e.g.*, Burk & Lemley, *supra* note 64, at 1576. *Cf.* Lockwood, *supra* note 236, at 176–77.

[352] States might further consider the possibility of shepherding a new excessive patented drug pricing statute through a different circuit court. Any new pricing regulation that meaningfully reaches the prices of patented medications is very likely to face litigation. The procedural history of *BIO v. D.C.* has the interesting wrinkle that D.C. originally appealed the case to the United States Court of Appeals for the District of Columbia and then filed an unopposed motion to transfer the case to the Federal Circuit. Given its notoriously pro-patent stance, the District's rationale for this transfer is unclear. Moreover, the Federal Circuit *itself* raised the issue of its subject matter

This section further considers some of the larger themes raised by state-level drug pricing reform. States' ability to serve as second-best solutions highlights their potentially underappreciated role in shaping pharmaceutical innovation policy as both collaborators and influencers. They can help recalibrate federal patent innovation policy to align with its intended public-serving purpose. States, unfettered by patent preemption, can correct for an incredibly harmful instance of federal regulatory failure that is neither legally mandated nor consistent with good public policy. Further, as "laboratories of experimentation,"[353] they can influence national conversations about innovation incentives and fair drug pricing.

A. *Congressional Amendment*

Before considering state-level legislative approaches, a first option is the avoidance of price regulation patent preemption through congressional amendment. States could lobby Congress to unequivocally clear the way for states to fill the existing regulatory vacuum; Congress could supersede the Federal Circuit's ruling through legislation expressly asserting that state excessive drug price regulation reaching patented drugs is not preempted.

This proposal initially sounds counterintuitive. The need for state intervention stems from congressional inaction and uncertainty. Congress has not itself resolved the problem of excessively priced patented drugs, yet here it is being suggested that states turn to Congress. Several factors support this strategy. Such legislation gives the appearance of federal action on an issue of immense political importance without Congress directly needing to do anything: it can punt the issue. Without giving up its ultimate authority to legislate, Congress can permit states to intervene in the interim if they want. This solution may be lower stakes than existing congressional proposals for drug pricing reform. The legislation could be fairly straightforward and budget neutral.

Seeking congressional amendment freeing states to address the urgent problems posed by excessively priced patented medications could be an effective tactic. Given the existing political climate, however, it is most likely best conceived as a longer-term strategy for states. Such

jurisdiction over the case sua sponte. *Biotechnology Indus. Org.*, 496 F.3d at 1367. Amendments to 28 U.S.C. § 1295(a) and new U.S. Supreme Court precedent in the intervening years, however, appears to foreclose a way around the Federal Circuit. *See* 28 U.S.C. § 1295(a); *see also* Gunn v. Minton, 133 S. Ct. 1059, 1064–65 (2013).

353 *See* Riley & Lanford, *supra* note 7, at 82.

an amendment is likely to face intense opposition from industry trade associations and their members.

B. *The Shield of Sovereign Immunity*

Rather than lobby Congress, craft excessive price regulations, or institute payment initiatives, states could consider utilizing their sovereign immunity to make excessively priced medications more affordable both for themselves and their constituents.[354] If states can practice a patent without liability, this raises the possibility that they could manufacture otherwise patent-protected medications. Indeed, there has been recent interest in government manufacture of generics in California.[355] Sovereign immunity raises the prospect that this policy solution can apply more broadly to the most fiscally significant medications: those that are patent protected.

U.S. Supreme Court precedent suggests this strategy is doctrinally viable. In 1992, Congress passed a sweeping amendment expressly abrogating state sovereign immunity for claims of patent infringement.[356] The Supreme Court, however, later ruled that states cannot be stripped of their sovereign immunity under the Intellectual Property Clause, and that this particular attempt was an invalid exercise of congressional authority under section 5 of the Fourteenth Amendment.[357] The Supreme Court recently reaffirmed this ruling and its principles in a similar copyright case.[358]

While Congress retains the ability to abrogate sovereign immunity under the Fourteenth Amendment, its powers are remedial.[359] Valid exercise of section 5 authority must be congruent and proportional.[360] Thus, "Congress must identify conduct transgressing the Fourteenth Amendment's substantive provisions, and must tailor its legislative scheme to remedying or preventing such conduct."[361] Importantly for

354 *Cf.* Sapna Kumar, *Promoting Public Health Through State Sovereign Immunity*, U. PA. J.L. & INNOVATION (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846434 (proposing reliance on state sovereign immunity to address patented drug shortages during the COVID-19 pandemic).

355 Sophia Bollag, *New Law Paves Way for California to Make Its Own Insulin, Generic Drugs in Effort to Lower Costs*, SACRAMENTO BEE (Sept. 28, 2020), https://www.sacbee.com/news/politics-government/capitol-alert/article246036870.html.

356 Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 630 (1999).

357 *Id.*

358 Allen v. Cooper, 140 S. Ct. 994, 1007 (2020).

359 *Florida Prepaid*, 527 U.S. at 627–28.

360 *Id.* at 652 (citing City of *Boerne v. Flores,* 521 U.S. 507, 520 (1997)); *Allen*, 140 S. Ct. at 1004.

361 *Florida Prepaid*, 527 U.S. at 627–28.

present purposes, the Court made clear that what is at issue are *due process violations*: state-implemented patent infringement on its own *does not* violate due process. Patent infringement *without* a sufficiently adequate remedy does.

> [U]nder the plain terms of the Clause and the clear import of our precedent, a State's infringement of a patent, though interfering with a patent owner's right to exclude others, does not by itself violate the Constitution. Instead, only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result.[362]

The congressional amendments exposing states to liability for patent infringement in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* neither addressed conduct transgressing the Fourteenth Amendment nor were proportional to the perceived problem. As Justice Kagan recently recounted, these patent amendments had no limitations:

> *Florida Prepaid* held, the Patent Remedy Act swept too far. Recall what the Patent Remedy Act did—and did not. It abrogated sovereign immunity for any and every patent suit . . . it exposed all States to the hilt—on a record that failed to show they had caused any discernible constitutional harm (or, indeed, much harm at all).[363]

The statute did not distinguish between negligent and intentional infringement, nor did it "target States refusing to offer alternative remedies to patent holders."[364]

State-level government manufacturing of patented medications would involve intentional infringement, yet the key issue appears to be ensuring the availability of adequate infringement remedies. It is beyond the scope of this Article to consider the details of an optimal state scheme protected by sovereign immunity,[365] but exploring robust

---

362 *Id.* at 643.

363 *Allen*, 140 S. Ct. at 1005 (citation omitted).

364 *Id.*

365 One thought is perhaps states could explore a "1498 for states"—that is, implementing statutes analogous to 28 U.S.C. § 1498. Section 1498 is a partial waiver of the *federal* government's sovereign immunity. The federal government consents to suit by patent holders in the United States Court of Federal Claims, and a patent holder's only remedy to the government's unlicensed use of patents is "reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498. Section 1498 might be used to combat excessively priced patented medications, and it has been used to purchase cheaper generic versions of patented medications. Brennan et al., *supra* note 50, at 303–304. A state-level statute of this kind, however, raises many additional questions and legal complexities.

use of sovereign immunity to address problems of excessive drug pricing is prima facie promising. It has the benefit of potentially regulating in a manner similar to direct excessive price regulation by controlling the prices of government-manufactured medications. At the very least, it could be of use in negotiations and serve as a "catalyst for change."[366]

Utilizing sovereign immunity for government manufacture also has several disadvantages. First, patent protection is not the only kind of exclusivity of concern. States would also need to grapple with overcoming any applicable non-patent exclusivities. Second, use of sovereign immunity would saddle state governments not just with the task of crafting adequate remedies, but further with any challenges associated with manufacturing medications. These could include challenges pertaining to resources and various kinds of expertise as well as obtaining relevant scientific know-how or information protected by trade secret. Finally, depending upon a policy's specifics, if the judiciary is tasked with making determinations of adequate compensation, this could have the comparative disadvantage of introducing increased instability and a lack of predictability into pharmaceutical markets. In short, strategic use of state sovereign immunity appears a promising option, but any such policies require further development and consideration.

C. *Excessive Patented Drug Price Regulation 2.0*

In reformulating comprehensive excessive patented price regulation, three primary options are initially apparent. First, states could pursue price-gouging laws of general application. Second, states could pursue such laws of limited reach. Third, states could craft laws that demonstrably do not interfere with non-excessive prices—as benchmarked to the goals of federal patent law. A fourth adjacent option regulates via a tax penalty. While new state legislative proposals to penalize unsupported or excessive price increases do essentially regulate excessive prices, this approach is distinct from more traditional price-gouging legislative efforts and is therefore discussed separately in the next section.

In striking down the D.C. Act, the court criticized the law for being "in no way general."[367] Further, Judge Gajarsa, in his subsequent concurrence, wrote that state laws might avoid patent preemption if they only incidentally, insignificantly, and indirectly "imped[ed]"

366 Kumar, *supra* note 354, at 16.

367 Biotechnology Indus. Org. v. District of Columbia, 496 F. 3d 1362, 1373 (Fed. Cir. 2007).

congressional purpose.[368] It is tolerably clear what the Federal Circuit *means* for a law to be general. Excessive patented drug prices should not be singled out. Price-gouging legislation applicable to prescription drugs needs to address all drugs, not just those that are patented. [369] Recent state price-gouging bills that cover patented medications adhere to this guidance; they cover both patented and unpatented or generic medications.[370] Latching onto the court's language, some have argued that framing laws as ones of general application is curative.[371]

States can and should take up this suggestion. Yet, it is unclear why this framing change matters. If a general price-gouging law still reaches patented medications, could it not be invalidated on patent preemption grounds, as applied to patented products? Further, given that patented medications are more likely to be extraordinarily expensive, such laws would target these drugs for examination of excessiveness. If broadening the scope of an excessive price law is all it takes to survive patent preemption, this is an easy fix. This change, however, hardly seems transformative, so much as cosmetic. It is a suggestion to bury the lede. While, of course, one cannot know with certainty, it seems dubious that the court would have cleared the D.C. Act *if only* it were crafted as a general law.

Instead of focusing exclusively on generality, states could pursue excessive pricing regulation of limited ambition. Following the guidance offered by Judge Gajarsa, states could search for a form of price regulation that has an obvious and relatively uncontroverted negligible impact on patent-derived innovation incentives. Excessive price regulation can take different forms—from traditional rate setting to price-gouging laws targeting price increases during emergencies.

Several states have emergency price-gouging laws that explicitly reach prescription medications.[372] The emergency law approach, however, given that these laws are predicated on a severe and unanticipated market disruption, suggests that their application to the

---

368 Biotechnology Indus. Org. v. District of Columbia, 505 F. 3d 1343, 1346 n.1 (Fed. Cir. 2007) (citation omitted).

369 Even so, how general is general enough? Need a law apply even more broadly to cover medical products and services or some category construed more broadly still?

370 *See, e.g.*, *supra* III.B.1 (discussing Minnesota's H.F. 4, which applies to both patented and unpatented medications).

371 Lockwood, *supra* note 236; Alexander Walsdorf, *I Get by with A Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases*, 102 MINN. L. REV. 2497, 2534–35 (2018) (distinguishing a proposed model act from the D.C. Act on the basis of its more general application, among other features).

372 Mello & Wolitz, *supra* note 26, at 898 n.279 ; *see also* H.R. 7040, *supra* note 188.

general problem of excessively priced patented medications would likely be difficult.[373] Perhaps they could reach price spikes involving drug shortages during the current pandemic, but it would likely be a stretch for them to accommodate drug manufacturers' routine price increases, and they are vulnerable to gaming through launch price manipulation.

But emergency price-gouging laws, for the most part, seem to avoid the Federal Circuit's concerns. Perhaps the occasion for litigation simply has not arisen, but emergency price-gouging laws have not been subject to patent preemption challenges. Emergency price-gouging laws are of general application, but what is notable is that these laws apply under a narrow set of circumstances—specified, time-limited emergencies. The United States' mismanagement prolonging the domestic COVID-19 pandemic notwithstanding, these laws assume emergencies that are both rare and relatively short-lived. Consequently, these laws do not impede Congress's purpose of incentivizing innovation through a patent system at all. If it is only in the rare time of an emergency when patented prices are regulated, then the assumption is that the impact of these laws is negligible.

More importantly, however, these laws are distinct from the kind of excessive pricing laws contemplated in this Article: emergency price-gouging laws do not seek to regulate a patent-derived premium at all, but rather a premium procured in excess of that made possible by a patent due to emergency conditions. For these reasons, pursuit of an emergency price-gouging law, while possible, is not a generally compelling strategy for the problem at hand.[374] It is a very limited and likely ineffectual mechanism for addressing fundamental problems with excessive patented drug pricing that occur both through introduction prices and through routine, non-emergency price hikes.[375]

The question, then, is how to imagine what a more ambitious form of excessive price regulation might look like. The Federal Circuit baldly rejected the D.C. Act:

> The underlying determination about the proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make. As the Supreme Court has noted, "[w]here it is clear how the

373 Mello & Wolitz, *supra* note 26, at 953.

374 *See* Mello & Wolitz, *supra* note 26, at 953.

375 *Id.*

> patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess."[376]

As argued above, contrary to the conclusions the court draws about the Hatch-Waxman Act, Congress has not spoken on the matter of excessive patented drug pricing. Moreover, note the subtle shift in framing. The court frames the relevant balance as one between *profits* and access. This shift is misleading. The crucial question is whether state regulation poses an obstacle to Congress's incentive scheme.

Thus, to render the argument more explicit, the court seems to rely on something like the following premise: determinations of excessive pricing have the mandatory prerequisite of determining when pricing is not excessive. Determinations of non-excessive pricing, in turn, must incorporate considerations of sufficient innovation incentives. If states are to reconcile their excessive price regulation with congressional purpose to incentivize innovation, they would need to engage with the underlying question of how much profit during the patent term is sufficient for the innovation to have occurred. The problem is the non-preempted execution of excessive pricing statutes requires preempted determinations. It is conducting the very analysis that demonstrates a state's scheme *lacks* conflict that generates the conflict.

This conclusion embraces, rather than spurns, suboptimal policy and regulatory failure. Neither is legally required nor desirable. Having considered the matters of the presumption against preemption and congressional purpose discussed above, there are strong reasons to think that excessive patented pricing regulations, including the version proposed by the D.C. Act, are not patent preempted. State-level excessive pricing regulation does not regulate the "incorporeal right." It does not alter the exclusive right that actually comprises patent protection. Further, rights in patented products "must be enjoyed subject to the complete and salutary power with which the States have never parted, of so defining and regulating the sale and use of property within their respective limits as to afford protection to the many against the injurious conduct of the few."[377] Given that the Supreme Court has upheld state regulations that effectively *prohibit* the sale of patented products,[378] state regulation of excessive drug prices should be both

---

[376] Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

[377] Patterson v. Kentucky, 97 U.S. 501, 506 (1878).

[378] *Id.* at 501, 508 (noting that there was no way for the patented oil to conform to statutory requirements and further discussing a patented invention for drawing lotteries and Delaware's prohibition of lotteries); *see also id*. at 508:

> It therefore cannot be admitted that the plaintiffs have a right to use an invention for drawing lotteries in this State, merely because they have a

absolutely and comparatively unproblematic. This should be the end of the matter.

To the extent, however, one remains unconvinced by this argument—the nexus between excessive price regulation and congressional purpose to incentivize is thought to be just *too* close—patent preemption is not the conclusion. The conclusion is reconciliation. And reconciliation requires an analysis with which the Federal Circuit appears to think that states should not engage. Yet, if foreclosing this possibility is neither legally required nor good policy, it is deeply troubling.

For state excessive patented price regulations to withstand patent preemption—under a theory of obstacle preemption—they should be able to demonstrate their reconcilability with Congress's goal to provide sufficient incentives through patent rights. States should be able to demonstrate that there is regulatory space for the enactment of excessive patented drug price regulation. This reconciliation appears to require that states, in some form, engage with an underlying determination of how much profit is sufficient to achieve these objectives. They need an argument and methodology for sorting between instances of excessive and non-excessive pricing, as determined by reference to federal patent policy.[379] Without some sense of the amount of reward that provides sufficient incentives, it will be correspondingly difficult to argue that excessive price regulation does not run afoul of federal patent law's mandate.

Take, for instance, the D.C. Act. International reference pricing is a metric of increasing popularity in U.S. domestic discussions of drug pricing.[380] Not only do some claim that it is unfair that Americans pay

> patent for it under the United States. A person might with as much propriety claim a right to commit murder with an instrument, because he held a patent for it as a new and useful invention.

[379] Note that reconciling state statutes that prohibit egregious instances of patented drug price-gouging generates a paradox. Reconciliation of state law with federal law appears to have the practical effect of enlarging a patent holder's rights. Under federal patent law, patent holders are not guaranteed any rewards at all. State law compatibility appears to require pricing consistent with sufficient incentives as a floor. The irony is that if states regulate excessive patented drug pricing, the exclusive rights of patent holders begin to look a bit more affirmative. There is a protected return below, which states may not regulate due to the risk of undermining federal patent policy. *Cf.* Brief for Defendant-Appellants, Biotechnology Indus. Org. v. District of Columbia, *supra* note 346, at 14 (arguing that excessive price regulation operating outside a "zone of protection that Congress reasonably could have meant to give the patent holder" is not preempted).

[380] *See, e.g.*, Press Release, U.S. Dep't of Health & Hum. Servs., HHS Advances Payment Model to Lower Drug Costs for Patients (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html; Elijah E. Cummings Lower Drug Costs Now Act, *supra* note 123.

more for the same drugs relative to our high-income country counterparts,[381] but it has also been suggested that this overpayment is excessive by reference to what companies need to recoup their reasonable costs and make a reasonable profit.[382] In the case of the D.C. Act, patented drug prices 30 percent and above those charged in specified high-income countries were presumed excessive. Yet, if one overlooks the D.C. Act's statutory safeguard of a *rebuttable presumption*, from an incentive perspective, one can understand initial concern about this threshold. Without more information and justification, reference pricing—that is basing one price off the price of another—bears no obvious and explicit relationship to ensuring compatibility with the incentives fundamental to the purposes of federal patent law. A drug might be priced extremely low in the referenced countries, in which case even a 30 percent premium may offer an insufficient incentive to drug manufacturers. The opposite could also be true. To the extent that prices in referenced countries *already* overcompensate patentees, a 30 percent increase above those prices would overcompensate patentees that much more. In short, more information is required to establish definitively that the D.C. Act's presumption of excessive prices would be unlikely to undermine the objectives of federal patent law.

While it is beyond the scope of this Article to advocate for a particular methodology, broadly speaking, in constructing non-obstacle excessive patented pricing legislation, states must grapple with at least two key questions. First, what are the informational and normative requirements for determining that excessive price legislation does not undermine patent incentives?

A determination of sufficient incentives will involve questions about a drug manufacturer's costs as well as a defensible metric for evaluating a reasonable return on investment. Both are fraught topics. As Michelle Mello and I have argued elsewhere, these kinds of calculations involve "bumpy roads."[383] Our evaluation of public utilities rate-of-return regulation revealed that while there are compelling similarities between the idea of public utilities regulation and excessive drug price regulation, these regulatory determinations are complex and

381 *See* Press Release, U.S. Dep't of Health & Hum. Servs., What You Need to Know About President Trump Cutting Down on Foreign Freeloading (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

382 Yu et al., *supra* note 104.

383 Mello & Wolitz, *supra* note 26, at 963.

contentious.[384] They would be perhaps even more so when applied in the context of prescription medications.[385]

Rate-of-return regulation generally suffers from at least three problems: information asymmetries; time and resource intensive processes in establishing formula inputs; and perverse incentives for firms to be inefficient if returns are based on costs.[386] These problems would presumably apply to excessive price regulation of patented prescription medications as well. Much of the necessary information pertaining to drug manufacturers' costs, for instance, is not publicly available, and companies are reticent to share such information. State prescription drug price transparency laws have begun to assemble reported information. Yet, often, important information is withheld as protected because it is non-public.[387] Further complexities absent from electricity regulation also attend to the prescription drug context. For instance, biopharmaceutical companies frequently sell many products, whereas electricity companies sell one, and pharmaceutical markets have entrants and exits that electricity markets do not.[388]

For these reasons, the second, and crucial question, states would need to consider is practical. Are there minimally burdensome ways to demonstrate that an excessive price legislation does not undermine patent incentives? The less this exercise involves a process like traditional rate-setting and resembles a prescription medication specific excessive pricing law with its own standard, the better. It is unclear, however, what this mechanism might look like. These practical challenges could mean that state patented drug price regulation would not be an easy lift if a showing of non-conflict with sufficient patent incentives is required. Thus, while state excessive patented drug price regulation ought to be able to address the problem of excessively priced patented medications, it is not without challenges.

D. *Tax Penalties*

As discussed above, states are now experimenting with a new kind of regulation that specifically targets the widespread problem of price increases. Price increases are "a major driver of prescription drug costs

384 *Id.* at 946–52.

385 *Id*. at 950–52.

386 *Id.* at 941–42.

387 Rebecca Wolitz, *Recent Litigation Developments Regarding Drug Pricing and Access*, SLS L. & BIOSCIENCES BLOG (Jan. 3, 2020), https://law.stanford.edu/2020/01/03/recent-litigation-developments-regarding-drug-pricing-and-access/ (discussing California's drug price transparency law).

388 Mello & Wolitz, *supra* note 26, at 950–51.

. . . [and] [i]ncreases in the price of widely used, existing drugs—not market entry of new drugs—are the primary driver of the rising cost of brand-name drugs . . . ."[389] While specific, dramatic examples of price increases—for instance, the 5000 percent increase of Daraprim—make the news, price increases on drugs are a mundane matter and are taken in the absence of meaningful, if any, justification.[390]

Current state-level unsupported or excessive price increase proposals seek to address this concerning practice through a tax or penalty. Drug manufacturers remain free to set initial prices, but if a manufacturer increases the price of its drug beyond specified criteria, a portion of that excessive increase will be penalized. Would such a tax penalty pose a problem from the perspective of patent preemption? While it will be important for future work to determine the exact limits on a state's power to tax in this context, as an initial matter, U.S. Supreme Court precedent establishes that states may tax both patented products *and* patent royalties.

As already noted, the Supreme Court has repeatedly articulated states' authority to regulate patented products. Given that patent rights grant only a right to exclude, these rights do not conflict with "the power of the states to exercise control over articles manufactured by patentees . . . ."[391] The power of states over patented products has explicitly included the power to tax these physical embodiments of intangible property. "And the right conferred by the patent laws of the United States to inventors . . . does not take the tangible property, in which the invention or discovery may be exhibited or carried into effect, from the operation of the tax and license laws of the State."[392]

Likewise, the Court eventually came around to the view that states may tax patent (and copyright) royalties themselves.[393] In *Fox Film*

---

389 Mello & Riley, *supra* note 108, at 1599–1600.

390 *See* Michelle Mello & Stacie B. Dusetzina, *NASHP's Proposal for Imposing Penalties on Excessive Price Increases for Prescription Drugs* (Aug. 14, 2020), https://www.nashp.org/nashps-proposal-for-imposing-penalties-on-excessive-price-increases-for-prescription-drugs/#toggle-id-1; Michael A. Carrier, *Higher Drug Prices from Anticompetitive Conduct: Three Case Studies*, 39 J. LEGAL MED. 151, 152 (2019); Ed Silverman, *Regeneron CEO Spars with Counterparts, Calling Many Price Hikes 'Ridiculous,'* STAT NEWS (Dec. 2, 2016), https://www.statnews.com/pharmalot/2016/12/02/regeneron-drug-prices-pfizer/.

391 Long v. Rockwood, 277 U.S. 142, 148 (1928), *overruled in part by* Fox Film Corp. v. Doyal, 286 U.S. 123 (1932).

392 Webber v. Virginia, 103 U.S. 344, 347 (1880); *see also* Patterson v. Kentucky, 97 U.S. 501, 501 (1878).

393 *Fox Film Corp.*, 286 U.S. at 126 (overruling Long v. Rockwood); Hrdy, *The Reemergence of State Anti-Patent Law*, *supra* note 320, at 185 (describing the end of the "per se ban on state taxation of patent royalties").

Corp. v. Doyal, the state of Georgia sought to collect taxes on a company's gross receipts of copyright royalties. The company argued that because this intellectual property right was created by the federal government to fulfil a federal government purpose, copyright royalties were to be immune from state taxation. This argument proved unpersuasive. The Court found that Congress did not "provide that the right, or the gains from its exercise, should be free of tax. . . . the mere fact that a property right is created by statute to fulfill a governmental purpose does not make it nontaxable . . . ."[394] Furthermore, the Court explicitly found the same to be true of royalties derived from patents, thereby overruling a prior ruling to the contrary.[395]

For these reasons, again with the caveat that limits on such tax powers require further investigation including beyond their intersection with patent law, state-level unsupported or excessive price increase legislation is highly attractive. From a patent perspective, prima facie, at least some form of such legislation appears to have a strong chance of legal survival. Furthermore, as others have advocated, from a policy perspective, unsupported or excessive price increase legislation could be a "policy win-win": it will either prevent excessive price increases or generate new state revenue.[396] Ensuring reallocation of at least some of that revenue to assist patients with out-of-pocket costs will be an important design feature.[397]

An exclusive focus on excessive price increases is both a feature and a bug. Such proposals leave drug manufacturers free to set initial prices as they wish. Thus, on the one hand, this approach avoids many of the messy and complicated questions surrounding determinations of price excessiveness that could stymie the implementation of more general drug price-gouging laws discussed above. On the other hand, this also means that the important matter of whether and when a drug's underlying price is itself excessive remains unexamined. Such measures might, commendably, stop a wound from getting worse, but do not make that initial wound go away. Moreover, such laws could be vulnerable to

394 *Fox Film Corp.*, 286 U.S. at 127–29.

395 *Id.* at 131 ("[I]n this aspect royalties from copyrights stand in the same position as royalties from the use of patent rights, and what we have said as to the purposes of the government in relation to copyrights applies as well, mutatis mutandis, to patents which are granted under the same constitutional authority to promote the progress of science and useful arts.").

396 Mello & Riley, *supra* note 108, at 1600.

397 *See* H.B. 30 § 5(b)(1), 31st Leg., Reg. Sess. (Haw. 2021), https://www.capitol.hawaii.gov/session2021/bills/HB30_.HTM; NAT'L ACAD. FOR STATE HEALTH POL'Y, *supra* note 191 (stating in FAQ of model legislation that "the revenue from the penalty would be used to offset costs to consumers").

gaming.[398] Anticipating the effects of excessive price increase laws, drug manufacturers introducing new drugs could be incentivized to simply account for money that would otherwise be lost to a tax penalty by raising initial prices accordingly. For these reasons, excessive price increase legislation implemented through a tax penalty is not a comprehensive solution to the problem of excessively priced patented medications. It would "require companion legislation,"[399] which given the existing legal landscape surrounding patent preemption, payment regulation is a plausible candidate.[400]

E. *Payment Regulation*

State-level payment regulation of excessive patented drug prices lacks the doctrinal nuances that attend state-level excessive price regulation; it straightforwardly avoids issues of patent preemption entirely.[401] Not only is payment regulation within traditional state police powers, but neither the Hatch-Waxman Act nor the BPCIA bear on state payment regulation for the purchase or reimbursement of patented products at all. A congressional purpose to incentivize innovation through patent rights is not in conflict with state payment regulation. Payment regulation does not regulate the exclusive rights offered by a patent and does not even regulate the prices that can be charged for patented products. It regulates what consumers and purchasers can pay for medications, including those that are patented.

Unlike general, or comprehensive excessive price regulation, payment ceilings leave drug manufacturers free to charge whatever they would like. Payment regulation does not in any way regulate patent rights nor their potential patent-derived rewards. It is true that payment regulation does regulate innovation incentives. As others observe in the context of Medicare, "[h]ealthcare reimbursements *are* innovation incentives. Indeed, they may be among the largest innovation incentives in the pharmaceutical sector."[402] But the incentives offered by healthcare reimbursements are distinct from those offered by the patent system. Regulation of one does not entail the regulation of the other.

---

398 Mello & Wolitz, *supra* note 26, at 954.

399 Mello & Riley, *supra* note 108, at 1600.

400 *Cf.* Mello & Wolitz, *supra* note 26, at 955–56 (recommending a two-prong approach modeled on consumer lending law in which a statute addresses excessive price increases and a separate mechanism imposing a general prohibition on excessive drug prices that would reach launch prices as well).

401 *See also* Feldman et al., *supra* note 45, at 57 (reaching this conclusion specifically for DABs).

402 Lemley, Ouellette, & Sachs, *supra* note 74, at 107.

Thus, while a general excessive price regulation scheme is preferable to payment regulation, as a pragmatic and workable second-second-best intervention from the perspective of patent preemption, payment regulation is presently the less risky candidate. Payment regulation offers a workaround for states to control costs and facilitate access to more affordable medications. Further, existing payment regulation proposals for DABs have sought to address the setting of payment ceilings through affordability metrics as opposed to drug manufacturers' financial information. In so doing, they avoid some of the problems that could impede a price regulation approach.[403]

Payment regulation, however, has drawbacks. In addition to the moral and political issues discussed earlier, DABs potentially face three pragmatic problems, some of which may be shared by a general price regulation approach. First, there are challenges surrounding the possibility of market exit. Though unlikely to be an issue when there are multiple therapeutic alternatives,[404] it could be a problem particularly when a drug is the only one in its class. The strength of this worry corresponds with the specific state setting payment rates and the size of its market. Drug manufacturers may, for instance, be more reluctant to walk away from the California state payer and purchaser market as opposed to Rhode Island's. The problem of market exit might be abated if multiple states set up DABs and identify the same drug as presenting affordability challenges. Leaving is less attractive if other markets are no more attractive.

Another issue pertinent to market exit is consideration of the Medicaid best price rule. Medicaid is entitled to the lowest price of a drug with certain exclusions.[405] Thus, a concern of drug manufacturers may not be the potential market size of sales forgone in a state, but the ripple effect a lower price in say, Rhode Island, could have throughout the system.

A second potential problem facing payment regulation in the particular form of DABs is its administrability. DABs may be too complex and resource intensive for states, particularly if there are budget shortfalls. On this issue, a general excessive price regulation in the form of a price-gouging statute could be an easier lift—but it depends. Proposals often involve a provided standard for what constitutes an excessive price, and, typically, the state's attorney general

403 Mello & Wolitz, *supra* note 26, at 952.

404 NAT'L ACAD. FOR ST. HEALTH POL'Y, *Maryland Rate-Setting Legislation Question and Answer* (Oct. 17, 2017), https://www.nashp.org/maryland-rate-setting-legislation-question-and-answer/#q8 ("Question 8").

405 42 U.S.C. § 1396r-8(c)(1)(A)(ii)(I)–(C)(i).

is tasked with enforcement.[406] For the reasons discussed above, however, excessive price regulations may or may not be less resource intensive for states. If states need to (and are permitted to) demonstrate that their regulations pose no obstacle to federal law, the practical viability of this depends on whether a suitable shorthand for defining excessive pricing by reference to sufficient pricing can be defended. If, to make such a showing, states ultimately need to engage with complex assessments of sufficient innovation incentives, these assessments may be better suited to a state agency with technical, domain relevant expertise, as opposed to leaving these determinations to the judiciary. If this is the case, setting up such an administrative structure would appear to put the prospect of general state excessive price regulation—in terms of administration and resources—in line with DABs. Further, there may be increased practical challenges to procuring the underlying information necessary to make determinations regarding adequate incentives.[407]

Finally, a third potential problem facing payment regulation is the risk that rates may be set too low, thereby disincentivizing research and development into new therapies. With a focus on affordability, "if DABs err on the side of strict payment limits in the short term, they risk discouraging investment in drug research and development if the limits were widely adopted—an issue of obvious import for consumer welfare."[408] Thus, this concern is not simply a variation on market exit, but one of failed market entrance. From a patent preemption perspective, DABs are completely free in how they set their rates. This raises the prospect that rates could be too favorable towards states in promoting short term affordability goals. While one state in isolation setting such rates may be of limited impact, if aggregated across many states, this could be cause for concern. DABs could ensure there is an adequate floor on their rates, but in their current form, this is not part of their mandate. General excessive price regulation, by contrast, could have the benefit of explicitly regulating those prices that are excessive by reference to the goals of federal patent law.

In contrast to general excessive price regulation, under the existing legal landscape, excessive price increase regulation implemented through a tax retains some comparative practical advantages over DABs. Any problems of market exit may be blunted by the ability of drug manufacturers to still set their own prices. Depending upon the model's

406 *See, e.g.*, MD. CODE ANN., HEALTH-GEN. §§ 2-801, 2-803; *see also* Mello & Wolitz, *supra* note 26, at 877–79 (discussing Maryland's now defunct anti-price-gouging law).

407 *See also* Mello & Wolitz, *supra* note 26.

408 *Id.* at 950.

particulars, the administrability of unsupported price increase laws could be less onerous. Some proposals, for instance, incorporate reliance on determinations made independently and at no cost to states by the Institute for Clinical and Economic Research ("ICER"). ICER evaluates and identifies price increases that are unsupported by clinical evidence, and states could rely on this work to determine which price increases ought to be penalized.[409] Other proposals, such as the one advanced by Massachusetts, could be more labor and resource intensive.[410] Unsupported or excessive price increase proposals also would seem to sidestep any plausible concerns about disincentivizing important new research. Since tax penalties are imposed *merely* on *price increases* benchmarked against the consumer price index or determinations of a lack of supporting clinical evidence, drug manufacturers still have great leeway to price as they wish through launch prices.

As already mentioned, this poses a significant potential disadvantage of excessive price increase legislation. Given its structure, it will not address any excessiveness in the underlying prices upon which price increases are taken. Depending on the proposal's particulars, it further "may or may not" actually prevent price hikes.[411] Unsupported or excessive price increase legislation therefore is likely a tool best paired with other efforts.

For these reasons, to the extent more comprehensive reform is possible, despite its potential challenges, payment regulation—from a patent preemption perspective—emerges as the presently most expedient policy tool of those considered to comprehensively address the problem of excessively priced patented medications. It is less risky than comprehensive excessive price regulation given existing patent precedent. It further appears to be a more facile approach given the unlikeliness of a targeted congressional amendment in the near future and the nascency of exploring future uses of sovereign immunity. It could be enhanced if paired with unsupported or excessive price increase legislation. Finally, payment regulation schemes have the benefit of early-stage state experimentation in implementation already being underway.

409 Under their discussion sub-heading "What Administrative Feasibility Concerns Arise?" Mello & Dusetzina consider state legislative reliance on ICER's evaluations. Mello & Dusetzina, *supra* note 390.

410 *Id.*

411 *Id.* (see discussion heading: "How Effective Would the Massachusetts Model Be?").

F. *Reimagining States as Participants in Federal Patent Policy*

The foregoing analysis demonstrates that states should have the authority to step in and fill the institutional vacuum left by federal law. Federal abdication of patented drug price regulation is suboptimal, but preemption in light of this regulatory vacuum is even worse. States can and should be able to serve as our second-best solution to excessively priced patented medications. For the reasons provided above, patent preemption of excessive drug price regulation is neither legally required nor good policy. State regulation of excessively priced patented medications would improve physical and fiscal health and promote democratic preferences for reform.

State participation in excessive price regulation can further have desirable effects on calibrating and refining federal pharmaceutical innovation policy. Patent law and policy are commonly regarded as dominantly federal.[412] But the prospect of state engagement in patented drug price and payment regulation reveals that states can be foregrounded as active participants in promoting and shaping the contours of patent policy. Through price and payment regulation, states can assume the role of collaborators and influencers.

Unfettered by patent preemption, states can recalibrate federal patent innovation policy to align with its intended public-serving purpose. States can be collaborators in promoting the ends of federal patent law. The goal of states is to protect the health and welfare of their citizens through identifying and correcting for egregious instances of excessive pricing. In so doing, they promote the instrumental purpose of patents to serve the public, as opposed to privileging private gain. State drug price regulation would work towards bringing about the best version of our national innovation system.

As argued above, it is prima facie likely that overcompensation of pharmaceutical patent holders occurs. With lives literally on the line, if states are willing to shoulder the task of determining when egregious overcompensation occurs and when the purpose of patent incentives therefore are not being optimally served, they should not be thwarted. Rather than view state excessive drug price regulation as intrusive incursions on federal prerogative, these efforts should be recast as collaborative.

State regulation further serves as a vehicle for manifesting the overwhelming and ignored bipartisan preference for drug pricing reform. Americans want drug price reform, but the federal government historically has been resiliently unresponsive. While recent

412 *See, e.g.*, Paul R. Gugliuzza, *Patent Law Federalism*, 2014 WIS. L. REV. 11, 12 (2014).

congressional movement has been encouraging, it remains uncertain whether any drug pricing reform provisions will ultimately become law, and if so, what their final form will be. Few would dispute that the best version of a patent system is one that minimizes inefficiencies and treats others fairly. The mandate for a more efficient system is particularly pressing when lives, human health, and the state provision of social and medical services are needlessly curtailed to overcompensate patent holders. Under present circumstances, to the extent that more general, comprehensive state excessive patented drug price regulation is patent preempted, this is a missed opportunity and contrary to bipartisan democratic preferences.[413]

Finally, state experimentation with drug price regulation is a thriving laboratory of democracy for pharmaceutical innovation policy design. State regulation as a means for addressing the affordability of high-cost patented medications presents opportunities for states to influence both innovation policy and associated conversations regarding fair drug pricing. With respect to payment regulation, as already noted, "[h]ealthcare reimbursements *are* innovation incentives."[414] Insurer coverage and payment rates function as "market-based prizes, in which the reward incorporates both a government assessment of social value and market information based on consumer choices."[415] Reimbursement rates can shape the allocation of incentives among different kinds of therapies. Admittedly, these effects may be greatly attenuated in the context of state excessive drug payment reform depending upon the state and how pervasive these reforms are among states. This may mean this insight translates in theory, but not practice. Nevertheless, it is important to mark this possibility.

Perhaps even more important than states' potential influence over the allocation of innovation incentives is their influence on the national conversation of what constitutes fair or unfair patented drug pricing. States need not passively accept the unchecked excessive pricing perpetuated by lax federal regulation. They are, after all, direct participants in the system as purchasers and payers; they have responsibilities as stewards of scarce resources. Through price and payment regulation, states have the opportunity to advocate for their needs and values and to overlay these considerations on federal patent policy. They participate in the push and pull of balancing innovation incentives with public access to novel therapies, and grapple with how to set justified ceilings on drug expenditures. Innovation incentives are

413 *See* Buck, *supra* note 117.

414 Lemley, Ouellette, & Sachs, *supra* note 74, at 107.

415 *Id.* at 106.

important, but they are not the only thing that matters. States as purchasers and payers of patented prescription medications also care about affordability, clinical and social value, and protecting their citizens and health systems from paying far more than necessary for the important medications our nation needs. States have a lot to contribute to these contentious conversations, and all the more so if they may speak from the direct experience gained through experimentation with patented drug pricing reform.

V. CONCLUSION

The purpose of federal patent law is public. Its aim is to bring forth new inventions and only instrumentally to reward patent-holders. It is reasonable to think that overcompensation of drug manufacturers, by reference to the aims of federal patent law, occurs. Against the background of widespread unaffordability of necessary medications, regulation of drug manufacturers' excessive compensation, when it occurs, is both consistent with the purpose of patent law to incentivize innovation and morally compelling on grounds of fairness.

Federal resolution of the problem of excessively priced patented medications is preferred. Despite bipartisan support for reform, however, congressional action has been stalled and continues to be politically uncertain. In the interim, a search for second-best solutions is urgent both for patients and states. Fortunately, in a federal system, states present the possibility of alternative reformers. In contrast to the federal government, states possess the demonstrated political ability to enact a variety of legislation and have been active in experimenting with drug pricing reforms.

States have been stymied in these efforts by misguided existing Federal Circuit precedent. This precedent needs to be corrected or avoided. Comprehensive state excessive drug price regulation need not pose an obstacle to the incentives offered by the federal patent scheme. Further, in light of urgent needs, leaving the regulatory vacuum created by the federal government unaddressed is undesirable as a matter of public policy. To the contrary, states have an important role to play in tackling the problem of excessively priced patented medications and an underappreciated ability to recalibrate federal pharmaceutical innovation policy towards its intended public-serving purpose. Under present conditions, to the extent states are patent preempted from regulation reaching excessively priced patented drugs, this is a significant and unwarranted missed opportunity.