FORMULATING PUBLIC PHARMA

Shweta Kumar†

In 2022, prices for both brand-name and generic drugs in the United States were nearly three times as high as prices in comparably industrialized nations, with the cost of insulin products in particular being nearly ten times as high. As a result, three out of ten American adults cannot afford to take their medication as prescribed. Furthermore, in 2024, the United States experienced its worst drug shortage in over a decade, with more than 300 drugs in short supply. Generic drugs are particularly vulnerable to shortage, as manufacturers have poor economic incentives to produce drugs with slim profit margins. While the Biden administration has signaled its interest in addressing drug pricing, the federal government has not responded to this crisis effectively with its efforts to regulate the private pharmaceutical industry. For instance, the National Institutes of Health (NIH) refuses to exercise march-in rights for federally funded inventions under the Bayh-Dole Act. More recent efforts to negotiate drug prices under the Inflation Reduction Act (IRA) are limited in scope and have been subjected to a number of constitutional challenges by the pharmaceutical industry. Meanwhile, several states, including Illinois, Maryland, New York, and Minnesota, have tried to address this crisis with laws prohibiting generic drug price gouging. Several of these laws have been struck down as unconstitutional, while others are still being litigated. States need another way to ensure that their citizens have access to medicine, and public pharma paves an unexpected path forward.

Public pharma is the development, manufacture, and distribution of drugs and biologic products by the public sector, rather than by private entities. This Article posits that public pharma is one solution to mitigate the troubles previously outlined: drug shortages and drug prices. Through

† Assistant Professor of Law, University of Kentucky J. David Rosenberg College of Law. I am very grateful to Christopher Morten, John F. Duffy, Joshua Sarnoff, Sapna Kumar, George Horvath, Anya Prince, Larry Solum, Amanda Levendowski, Omolara Bewaji Joseney, Sarah Dorman, Regina Wang, Ashlynn Kendzior, and Sophia Tan for their incredible expertise and insights on this paper. Thank you to the scholars and organizers at the Wiet Life Science Law Scholars Workshop, ASMLE Health Law Professors Conference, Intellectual Property Scholars Conference, and Mid-Atlantic Clinicians Writing Workshop who provided valuable suggestions and helped me workshop this paper.

state-owned pharma, states can take control of unrestrained drug pricing, as well as protect against drug shortages by investing in domestic production. Some state entities are already manufacturing or planning to manufacture generic drugs and vaccines, including California's CalRx and Massachusetts's MassBiologics. However, state liability for patent infringement will be a major legal challenge to state-owned pharmaceutical institutions. To overcome these challenges, this Article considers lessons learned from sovereign immunity doctrine and proposes tools for states to provide reasonable compensation to patent owners. States succeeding in experimenting with public pharma can ultimately serve as an important stepping stone for the establishment of a federal public pharmaceutical sector to ensure uniform access to medicine across the nation.

INTRODUCTION

In the early 20th century, the United States had a serious problem with diphtheria, a highly contagious bacterial infection caused by the bacterium *Corynebacterium diphtheriae* (*C. diphtheriae*).[1] Once in the human body, the bacterium secretes a potent toxin that causes significant damage to

[1] *Diphtheria: Corynebacterium Diphtheriae: Overview*, HISTORY OF VACCINES https://historyofvaccines.org/history/diphtheria/overview [https://perma.cc/B4XX-363Z] (last updated Apr. 9, 2022).

bodily tissues.[2] Patients infected with diphtheria suffered from fevers, skin lesions, respiratory tract infections, and complications such as damage to the heart muscle, airway obstruction, and respiratory failure.[3] In 1921, the United States reported 206,000 cases, resulting in 15,520 deaths, with a fatality rate of 20% for children under the age of five.[4] Michigan, in particular, was experiencing a devastating epidemic of diphtheria, with some sources reporting up to 10,000 hospitalizations per year and a death rate of 1,200 per year, the highest in the world.[5]

Fortunately, in the 1890s, two researchers based in Berlin, Shibasaburo Kitasato and Emil von Behring, discovered an early form of a diphtheria vaccine by injecting guinea pigs with heat-treated diphtheria toxin, causing the animals to produce diphtheria antitoxin, a blood product that neutralizes the toxins produced by *C. diphtheriae*.[6] This procedure immunized the guinea pigs against subsequent diphtheria infections.[7] Kitasato and von Behring also discovered that they could cure diphtheria in an animal by injecting it with the serum of an immunized animal.[8] This eventually led to the development of diphtheria antitoxin and serum therapy for humans, and, in recognition of these discoveries, Von Behring was eventually awarded the Nobel Prize in medicine for his work.[9]

---

2 *Id.*

3 *Id.*; *see also* John R. Murphy, *Corynebacterium Diphtheriae*, *in* MEDICAL MICROBIOLOGY 413, 413 (Samuel Baron, ed., 4th ed. 1996).

4 *Diphtheria: Corynebacterium Diphtheriae: Overview*, *supra* note 1.

5 *See, e.g.*, Jan Peter Verhave, *Paul de Kruif: A Michigan Leader in Public Health*, 39 MICHIGAN HISTORICAL REV. 41, 62 (2013); Norm Hess, *Celebrating Community Health*, MICH. DEP'T HEALTH & HUM. SERVS., https://www.michigan.gov/mdhhs/inside-mdhhs/sesquicentennial/celebrating-community-health [https://perma.cc/U3EH-JJJZ]; PAM GRAHAM, *Privatization of the Biologic Products Program*, *in* NOTES ON THE BUDGET AND ECONOMY, SENATE FISCAL AGENCY (1996), https://www.senate.michigan.gov/SFA/Publications/Notes/1996Notes/NotesNovDec96pg.pdf [https://perma.cc/MAB2-HVGP]; *but cf.*, *Number of Deaths Due to Certain Communicable Diseases, Michigan Residents, 1900–2023*, MICH. DEP'T HEALTH & HUM. SERVS., https://www.mdch.state.mi.us/osr/deaths/comdxtrend.asp [https://perma.cc/Z9FK-V6YR] (reporting 954 deaths from diphtheria in 1921).

6 *Diphtheria: Corynebacterium Diphtheriae: Timeline*, HISTORY OF VACCINES (Apr. 9, 2022), https://historyofvaccines.org/history/diphtheria/timeline [https://perma.cc/86HW-8KRG].

7 *Id.*

8 *Id.*

9 *Id.*; *see also* Noam Leviatan, *Is the Nobel Prize Noble?: A Legacy of Innovation and Dispute*, WEIZMANN INST. OF SCI. (Dec. 19, 2021), https://davidson.weizmann.ac.il/en/online/sciencepanorama/nobel-prize-noble [https://perma.cc/DP4U-K7A6] (noting that Kitasato was nominated for the Prize, but it was

But twenty years after Kitasato and Von Behring's discovery, people in Michigan were still dying at alarming rates, due to the inaccessibility of the antitoxin. Michigan-based bacteriologist Dr. Clifford Young persuaded then-Governor Alexander Groesbeck to address the public health crisis on his hands, demonstrating to Michigan's politicians that they "were swindling Michigan's taxpayers so long as there were not the laboratories to keep Michigan's people from unnecessar[ily] dying."[10] Governor Groesbeck then asked the Michigan Legislature to enact legislation that would allow the State to "produce, purchase, and distribute drug products to treat or prevent diphtheria, and to manufacture the products if and when the purchase price exceeded the cost of production."[11] By 1925, the rising cost of antitoxin spurred the Michigan Department of Public Health to begin producing its own diphtheria antitoxin products.[12] In 1927, the Michigan Legislature repealed the 1921 law and replaced it with one that gave the Department authority to "produce or purchase any biologic product necessary to control the spread of communicable disease and to distribute such products free of charge."[13] What followed was a significant decline in the number of diphtheria deaths,[14] and by 1940, the annual diphtheria death rate in Michigan had fallen to less than 40.[15]

This state-owned biologics manufacturing institution, eventually named the Michigan Biologic Products Institute (hereinafter "Michigan Biologics" or "Biologics Program"), went on to develop and produce products that were critical to preventing communicable and non-communicable diseases, including vaccines for rabies, pertussis, Anthrax, tetanus, and botulinum, and blood products such as human albumin, immune

---

eventually given only to von Behring on the grounds that only one person could be the Nobel laureate—even though in that same year, two people shared the Nobel Peace Prize, and a year later, two Dutch Nobel laureates were chosen in the field of physics—with many suggesting that Kitasato, as a Japanese national, did not receive the Nobel Prize due to racism or nationalism).

10 Verhave, *supra* note 5, at 62–63 (quoting PAUL DE KRUIF, LIFE AMONG THE DOCTORS (1949)).

11 GRAHAM, *supra* note 5.

12 *Id.*

13 *Id.*

14 *Number of Deaths Due to Certain Communicable Diseases, Michigan Residents, 1900–2023*, *supra* note 5 (reporting decline from 954 deaths from diphtheria in Michigan in 1921 to 20 deaths in 1940).

15 *Id.*; *see also* Hess, *supra* note 5 (noting less than 40 deaths from diphtheria in Michigan in 1940).

serum globulin, and anti-hemophilic factor.[16] These products were distributed to Michigan residents for free, and some were sold at cost to other states and distributed to nonstate entities through contracts.[17] In 1939, the state laboratory was producing enough antitoxin for all of Michigan's children "for an annual total outlay of only $35,000, and ha[d] wiped out a diphtheria hospital bill of $300,000 a year."[18]

Michigan Biologics was largely a success story for public health and "public pharma": the development, manufacture, and distribution of drugs and biologic products by the public sector, rather than by private entities.[19] Yet, beginning in 1986, some Michigan officials began questioning the propriety of the state producing biologic products that were now, by and large, the domain of a private sector pharmaceutical industry.[20] This was followed by a budget proposal to eliminate all state support for the Biologics Program.[21] At the same time, a national shortage of the diphtheria-tetanus-pertussis (DPT) vaccine, spurred by two of three private manufacturers of the DPT vaccine halting production in 1984, affected each state except for Michigan and Massachusetts—the only two states that were producing their own vaccines.[22] The shortage, along with continued strong legislative support, kept Michigan Biologics afloat for a few more years.[23]

In the early 1990s, changes in federal vaccine policy led Michigan to reevaluate the possibility of privatizing the Biologics Program.[24] The National Childhood Vaccine Injury Act of 1986 revived the private vaccine industry by imposing an excise tax on childhood vaccine production to fund a national

---

16 GRAHAM, *supra* note 5.

17 *Id.*

18 Verhave, *supra* note 5, at 63 (citing Paul De Kruif, *Toward a Healthy America*, 31 PUB. AFFS. PAMPHLET (1939)).

19 Dana Brown, *Public Pharmaceutical Enterprises are Developers, Manufacturers, and Distributors Owned by the Public, Rather than by Private Shareholders*, NEXT SYSTEM PROJECT (Oct. 2, 2020), https://thenextsystem.org/learn/stories/public-pharmaceuticals [https://perma.cc/9XMT-CDZ6].

20 GRAHAM, *supra* note 5.

21 *Id.*

22 HOUSE LEGISLATIVE ANALYSIS SECTION, SALE OF STATE VACCINE LABORATORY, 1997-HLA-5300-B, at 3 (1999), https://www.legislature.mi.gov/documents/1997-1998/billanalysis/House/pdf/1997-HLA-5300-B.pdf [https://perma.cc/5372-RJWB]. The Massachusetts public pharmaceutical program, MassBiologics, is discussed in Section II.C.

23 GRAHAM, *supra* note 5.

24 *Id.*

vaccine injury compensation pool.[25] The tax was also assessed on vaccines produced by Michigan Biologics, even though the state was immune from liability for vaccine injury.[26] The Act set aside public funds to cushion private manufacturers' liabilities for vaccine injury, while simultaneously increasing the cost for Michigan to manufacture its own vaccines through the imposition of the excise tax.[27] Additional legislation expanded the scope of the federal government's ability to distribute childhood vaccines to states, rendering intrastate production of vaccines less cost effective.[28] Finally, the development of a new and improved version of the pertussis component of the DTP vaccine was generally predicted to make the State's version of the DTP vaccine obsolete in due time.[29]

All of the preceding events culminated in the decision to sell Michigan Biologics to a private company.[30] By 1998, the Michigan Biologics facilities were sold to a relatively new company, Bioport (now Emergent BioSolutions) for $25 million, resulting in the privatization of the resources, facilities, and expertise of Michigan's public pharma enterprise.[31] At the time, Michigan Biologics was the only U.S. producer of the anthrax and rabies vaccines, leaving not only the state, but also the entire nation in a precarious position in the event of another vaccine shortage.[32] Pam Graham, fiscal analyst from the Michigan Senate Fiscal Agency, wrote, "[w]hatever occurs, Michigan will now be in the same position as the other 49 states when it comes to addressing vaccine supply issues."[33] The privatization

---

25 *Id.*; *see also* Pub. L. 99-660, 100 Stat. 3756, Tit. III (1986) (codified at 42 U.S.C. §§ 300aa-1–300aa-34).

26 GRAHAM, *supra* note 5.

27 *Id.*

28 *Id.*; *see also* Federal Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993) (codified at 7 U.S.C. §§ 1421 et seq).

29 GRAHAM, *supra* note 5.

30 *Id.*; *see also* H.B. 6191, 6192, 88th Sess. Reg. Sess. (Mich. 1996).

31 DANA BROWN & TOM LATKOWSKI, PUBLIC PHARMACEUTICALS: STATE POLICY KIT 17 (2022), https://static1.squarespace.com/static/62f41050584b40607baef690/t/63992dceb17a723edcbb9d1e/1670983118927/PUB_Public+Pharmaceuticals+State+Policy+Kit.pdf [https://perma.cc/QZ98-4JN8] (hereinafter "State Policy Toolkit"); *Anthrax Vaccine: Safety and Efficacy Issues: Hearing before the H. Comm. On Gov't Reform*, 106th Cong. 3 (1999) (statement of Kwai-Cheung Chan, Dir., Special Studs. & Evaluations, Nat'l Sec. & Int'l Affs. Div.), https://www.gao.gov/assets/t-nsiad-00-48.pdf [https://perma.cc/9M8L-EPB2] (hereinafter "GAO Anthrax Report").

32 State Policy Toolkit, *supra* note 31, at 17; GAO Anthrax Report, *supra* note 31, at 3.

33 GRAHAM, *supra* note 5.

of Michigan Biologics did in fact put Michigan in the same position as the rest of the country, which is to say entirely reliant on the private pharmaceutical industry for essential drugs. The industrialization of the pharmaceutical industry,[34] legislation promoting private ownership and innovation in pharma,[35] and a prevailing belief in the efficiency of private industry and inefficiency of government-run enterprises halted the development of any kind of public pharmaceutical sector.[36]

However, the failures of an underregulated private pharmaceutical sector are becoming harder to ignore. Drug prices are a public health crisis in the United States—in 2022, prices for both brand-name and generic drugs in the United States were nearly three times as high as prices in thirty-three of thirty-eight Organisation for Economic Co-operation and Development (OECD) countries, with insulin products in particular being nearly ten times as high.[37] As a result, three out of ten American adults cannot afford to take their medication as prescribed, and the consequences of rationing essential drugs can be deadly and devastating.[38] Even worse, generic drugs that are off-patent are highly vulnerable to shortages.[39]

---

34 *See* Shweta Kumar, *Compounding Inequities Through Drug IP and Unfair Competition*, 102 WASH. U. L. REV. 371, 383–385 (2024) (describing the growth and industrialization of the U.S. pharmaceutical sector).

35 *See infra* subpart II.A.1 (discussing how the Bayh-Dole Act incentivizes privatization and commercialization of inventions developed with federal funding); *see also* National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1–300aa-34 (1984).

36 *See, e.g.*, Robert Kuttner, *Neoliberalism: Political Success, Economic Failure*, AM. PROSPECT (June 25, 2019), https://prospect.org/economy/neoliberalism-political-success-economic-failure/ [https://perma.cc/C3ZT-LNEE].

37 *Biden-Harris Administration to Make First Offer for Drug Price Negotiation Program, Launches New Resource Hub to Help People Access Lower-Cost Drugs*, U.S. DEP'T HEALTH & HUM. SERVS. (Feb. 1, 2024), https://www.hhs.gov/about/news/2024/02/01/biden-harris-administration-make-first-offer-drug-price-negotiation-program-launches-new-resource-hub-help-people-access-lower-cost-drugs.html [https://perma.cc/8FBU-4UYB].

38 Grace Sparks, Ashley Kirzinger, Alex Montero, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/L6JS-URC7] ("About three in ten adults report not taking their medicines as prescribed at some point in the past year because of the cost."). Furthermore, in 2021, 1.3 million adult Americans—or 1 in 6 patients—with diabetes reported rationing insulin. Adam Gaffney, David U. Himmelstein & Steffie Woolhandler, *Prevalence and Correlates of Patient Rationing of Insulin in the United States: A National Survey*, 175 ANNALS INTERNAL MED. 1623, 1624 (2022).

39 Kumar, *supra* note 34, at 376 (citing U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: ROOT CAUSES & POTENTIAL SOLUTIONS 6 (2020), https://www.fda.gov/media/131130/download?attachment [https://perma.cc/U37L-RP24] (noting that

In 2024, the United States experienced its worst drug shortage in over a decade, with more than 300 drugs in shortage for over a year.[40] In parallel, several brand-name pharmaceutical companies continue to extend their monopolies over old drugs through tactics made possible by features of the U.S. patent system.[41] As the Supreme Court acknowledged in *Oil States*, the grant of a patent is a matter involving public rights—by issuing patents, the United States Patent and Trademark Office (USPTO) "take[s] from the public rights of immense value, and bestow[s] them upon the patentee."[42] If these exclusionary

---

the root cause of drug shortages in the United States is the lack of profit incentive to ensure a consistent supply of older, off-patent, generic prescription drugs)).

40 *See* Tina Reed, *Six Straight Quarters of Drug Shortages*, AXIOS (July 22, 2024), https://www.axios.com/2024/07/22/six-straight-quarters-of-drug-shortages [https://perma.cc/L2DH-5MX9]; Mary Kekatos, *Drug Shortages Hit Record High, Pharmacists Warn*, ABC NEWS (Apr. 12, 2024), https://abcnews.go.com/Health/drug-shortages-hit-record-high-hundreds-short-supply/story?id=109160863 [https://perma.cc/YCK3-KUPW]; AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, NATIONAL DRUG SHORTAGES: JANUARY 2001–JUNE 2024, at 2 (2024), https://www.ashp.org/-/media/assets/drug-shortages/docs/2024/2024-Drug-Shortages-Survey.pdf [https://perma.cc/KS7R-YQKS].

41 These tactics include evergreening and patent thickets. Evergreening is a strategy employed by pharmaceutical companies to extend patent and regulatory protection for drugs. *See generally* Robin Feldman, *Understanding 'Evergreening': Making Minor Modifications of Existing Medications to Extend Protections*, 41 HEALTH AFFS. 801 (2022). One example of an evergreening tactic is "product hopping," when a brand-name company switches to an "improved" version of a drug that may have minimal therapeutic benefits, but enables the filing of additional patents to prevent generic market entry. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016). Patent thickets are "dense webs of often overlapping patents" that obscure the scope of patent rights, delaying generic and biosimilar market entry. Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American problem*, 9 J. L. & BIOSCIENCES 1, 2 (2022). Ordinarily, patents cannot be granted on inventions that would be obvious to a person having ordinary skill in the art, in light of information publicly known before the effective filing date of a patent ("prior art"). 35 U.S.C. § 103. However, a unique feature of the U.S. patent system facilitates the growth of patent thickets by permitting patent owners to hold patents that are obvious over their own earlier-filed patents, so long as the owner agrees to link the patents together with a "terminal disclaimer" that would cause the patents to expire at the same time. *See* Goode & Chao, *supra*, at 17 (citing 37 CFR § 1.321(c)). A recent proposed rule by the USPTO seeks to address terminal disclaimer abuse by requiring a patentee to agree that a patent with a terminal disclaimer will be enforceable only if the patent has never been tied through one or more terminal disclaimers to a patent in which any claim has been held unpatentable or invalid over prior art. Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (proposed May 10, 2024). In other words, if any claim of a patent is held invalid by a court or the Patent Trial and Appeal Board (PTAB), any other patents tied to it by terminal disclaimer will also be unenforceable.

42 Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 584 U.S. 325, 335 (2018) (quoting United States v. American Bell Tel. Co., 128 U.S. 315, 370 (1988)).

rights are used to significant detriment of public health—as they often are now, with a slew of drugs being either unaffordable or unavailable to the people that need them—at what point should the government intervene to protect the integrity of its franchise?

Scholars and activists are increasingly calling for government intervention as a solution to ongoing access gaps created by drug prices and drug shortages,[43] including intervention through public pharma.[44] However, as discussed below, various arms of the federal government have yet to exercise their powers to address inflated drug prices under 28 U.S.C. § 1498, a statute that permits the federal government to use patented technologies without permission from patent owners via a limited waiver of federal sovereign immunity.[45] Additionally, the National Institutes of Health (NIH) has repeatedly refused to exercise its Bayh-Dole rights to ensure that drugs developed with federal funding are available to the public on reasonable terms.[46] Similarly, recent federal efforts to negotiate drug pricing with pharmaceutical companies under the IRA are limited in scope and have been met with litigation by the pharmaceutical

---

43 Letter from Amy Kapczynski, Professor at Yale L. Sch., et al. to Sen. Elizabeth Warren (Apr. 20, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf [https://perma.cc/9UHQ-ZV7P].

44 *See, e.g.*, Dana Brown & Chris Morten, *Public Pharma Is the Best Solution to the Ongoing Problem of Drug Shortages*, STAT (Aug. 9, 2023), https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/ [https://perma.cc/S2ZR-4H7S]; Letter from Sen. Bernard Sanders to Hon. Robert A. McDonald, Sec'y, U.S. Dep't of Veterans Affs. (May 12, 2015), https://www.sanders.senate.gov/download/051215-letter [https://perma.cc/B28G-8PFN]; Letter from Rep. Ro Khanna (CA-17) et al., to Alex Azar, Sec'y, U.S. Dep't of Health & Hum. Servs. (Feb. 15, 2018), https://khanna.house.gov/sites/khanna.house.gov/files/Final%20Letter%20-%20signed.pdf [https://perma.cc/UZY4-GEFB]; *see generally* Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J. L. & TECH. 1 (2020); Sapna Kumar, *Promoting Public Health Through State Sovereign Immunity*, 4 J. L. & INNOVATION 1 (2021); Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2016).

45 28 U.S.C. § 1498.

46 *See Bayh-Dole Timeline*, KNOWLEDGE ECOLOGY INT'L https://www.keionline.org/bayh-dole/bayh-dole-timeline [https://perma.cc/XN9L-MUX6]. The Bayh-Dole Act provides the government with a royalty-free license in patents filed on certain federally funded inventions, as well as the ability to march-in on patents under certain circumstances to ensure that the resulting products are "available to the public on reasonable terms on drugs developed with federal funding." *See* 35 U.S.C. § 202; *infra* section II.A.i.

industry challenging the constitutionality of the IRA.[47] These shortcomings of the federal government to address drug pricing are discussed in subpart II.A.

However, less attention has been devoted to another powerful sovereign with the ability to protect public health: states.[48] Several states, including Illinois, Maryland, New York, and Minnesota, have tried to address the ongoing drug pricing crisis with state laws prohibiting drug price gouging or requiring price transparency.[49] As discussed in subpart II.B., several of these laws have been struck down as unconstitutional, while others are still being litigated. States need another way to ensure that their citizens have access to medicine, and Part III illustrates how public pharma can pave a path forward.

Legal scholars and health policy experts, including Dana Brown,[50] Tom Latkowski,[51] Robin Feldman,[52] Sapna Kumar,[53] and others,[54] have previously proposed or evaluated public pharma as an option for states. Establishing state-owned public pharma raises plenty of questions and legal issues—for instance, how can states build or rebuild their public sector? What drugs are ideal candidates for states to begin manufacturing? How can states secure funding and buy-in from stakeholders to establish public pharma? To what extent should states establish public-private partnerships to facilitate the development, manufacture, and distribution of drugs? To what extent are private partners, patients, healthcare providers, and

---

47 *Health Care Litigation Tracker: Medicare Drug Price Negotiation*, O'NEILL INST., https://litigationtracker.law.georgetown.edu/issues/medicare-drug-price-negotiation/[https://perma.cc/PK5X-EN4H].

48 *But see* Rebecca Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 391 (2021); Kumar, *supra* note 44.

49 *See 2024 State Legislation to Lower Prescription Drug Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 7, 2025), https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/ [https://perma.cc/7LJN-KAJU].

50 *See generally* State Policy Toolkit, *supra* note 31.

51 *See generally id.*

52 *See* Robin Feldman, *CalRx Biosimilar Insulin: California's Initiative to Enter the Insulin Market*, 183 JAMA INTERNAL MED. 1043, 1043–44(2023), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2807852 [https://perma.cc/84ET-XW4B].

53 Kumar, *supra* note 44.

54 *See generally, e.g.*, KAILA ALSTON, JEANNIE LE, NICOLE KOONCE & ZELLY ROSA, PBM, PROCUREMENT, AND PRODUCTION: PUBLIC PHARMA STRATEGIES FOR STATES TO LOWER INSULIN PRICES (Christopher J. Morten & Allison Hardt, eds., Apr. 2024); Jacob S. Sherkow, Eli Y. Adashi, & I. Glenn Cohen, *Assessing—and Extending—California's Insulin Manufacturing Initiative*, 329 JAMA 533 (2023); Mariana P. Socal, Vishaal Pegany & Mark Ghaly, *When States Step Up: California and the Case for State-Led Insulin Manufacturing,* 175 ANNALS INTERNAL MED. 1756 (2022).

other stakeholders liable for legal risks associated with public pharma? How can states break into drug distribution networks (comprised of pharmacies, pharmacy benefit managers, and wholesalers)? How can states safeguard against corruption and inefficiencies by ensuring that public pharma entities are transparent and publicly accountable? As interest in public pharma is resurging, these are all important questions that scholars have explored or will explore in the future.

After making the case for public pharma, this Article focuses on one piece of the public pharma puzzle: state liability for patent infringement as a barrier to public pharma. Many of the proposals for public pharma have focused on off-patent medicines, including those in shortage. This Article will attend to another important part of the picture that has received less scholarly attention—the ability of states to manufacture drugs that may still be covered by patents. It builds on Professor Sapna Kumar's 2021 essay discussing how states might import or manufacture patented drugs to alleviate drug shortages, particularly during pandemics and other public health emergencies, using sovereign immunity as a defense in federal courts, in Food and Drug Administration (FDA) enforcement proceedings, or at the International Trade Commission.[55] It builds on Professor Kumar's essay by analyzing the singular issue of state liability for patent infringement for manufacturing drugs for any purpose.

Part IV of this Article delves into the sovereign immunity defense through the contours of tribal, federal, and state sovereign immunity to intellectual property (IP) infringement. Case law on tribal immunity in administrative patent proceedings offers important lessons for FDA enforcement against public pharma institutions. Federal waiver of sovereign immunity for patent infringement under Section 1498 offers insights on what constitutes "reasonable compensation" and the limits of contractor immunity to patent infringement. Additionally, as there is no state equivalent to Section 1498 by which states have waived their sovereign immunity to patent infringement claims, states manufacturing patented drugs may assert sovereign immunity as a defense to allegations of patent infringement. Furthermore, Congress may not abrogate state sovereign immunity from patent or copyright infringement suits without evidence of intentional or reckless, widespread, and persisting infringement by states, as well as evidence of inadequate

---

55 Kumar, *supra* note 44.

remedies under state law.[56] Part IV also considers injunctions against state officers as another obstacle to public pharma. It is true that patent owners might pursue injunctions against state officers under the *Ex Parte Young* doctrine,[57] but "a most important application" of the doctrine is where "there is no state forum available to vindicate federal interests."[58]

This Part proposes just such a solution to state takings of intellectual property. States that expect to incur some risk of patent infringement in their public pharma operations might offer reasonable compensation to patent owners through state eminent domain laws or by implementing special state law equivalents to 28 U.S.C. § 1498. This Part also argues that such state patent use laws should not be preempted by federal patent law. Ultimately, states succeeding in experimenting with public pharma will serve as an important stepping stone for the establishment of a federal public pharmaceutical sector to ensure uniform access to medicine across the nation.

I
Paralyzing Regulation of Private Pharma

This Part discusses the U.S. government's interest—and lack thereof—in regulating drug prices. Most recently, on May 12, 2025, the White House published an executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients."[59] In contract law, a "Most Favored

---

56 *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 630 (1999) (finding federal statute abrogating state immunity to patent infringement unconstitutional); Allen v. Cooper, 589 U.S. 248, 251 (2020) (finding federal statute abrogating state immunity to copyright infringement unconstitutional).

57 The *Ex Parte Young* doctrine permits parties to seek injunctions against state officers acting on behalf of States in federal court when the State action is unconstitutional or contrary to federal law. *See* Ex Parte Young, 209 U.S. 123 (1908).

58 Idaho v. Coeur d'Alene Tribe of Idaho, 521 U.S. 261, 270–77 (1997) ("Even if there is a prompt and effective remedy in a state forum, a second instance in which *Young* may serve an important interest is when the case calls for the interpretation of federal law . . . . It is difficult to say States consented to these types of suits in the plan of the Convention. Neither in theory nor in practice has it been shown problematic to have federal claims resolved in state courts where Eleventh Amendment immunity would be applicable in federal court but for an exception based on *Young*. Assuming the availability of a state forum with the authority and procedures adequate for the effective vindication of federal law, due process concerns would not be implicated by having state tribunals resolve federal-question cases.").

59 Exec. Order 14297, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*, 90 Fed. Reg. 20749 (May 12, 2025).

Nation" (MFN) clause, also known as a "most-favored customer clause" or "antidiscrimination clause," holds that a seller must offer the contracting customer the best price offered to all customers.[60] The Order directs the Health and Human Services (HHS) Secretary to "communicate [MFN] price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations" and to consider the importation of drugs from other countries to reduce costs.[61] While such a mandate is aggressive and ambitious, it remains to be seen how the Order shall be enforced. Experts and scholars have expressed reservations about realistic cost reduction while maintaining the safety and efficacy of drugs on the U.S. market.[62]

Recent federal and state efforts to negotiate drug prices with private industry also illustrate the need for state-owned pharma. Part II.A. discusses the shortcomings of federal efforts to address the high cost of drugs, including the IRA of 2022 and the NIH's refusal to exercise march-in rights on a number of drugs developed with federal funding. Meanwhile, a number of states have passed pharmaceutical accountability and transparency laws, variously requiring pharmaceutical companies to justify price hikes or provide detailed information about pricing.[63] However, these laws have not gone unchallenged.

---

60 *See What Is a "Most Favored Nation" Clause in a Contract?*, McNeely Law (Jan. 25, 2024), https://www.mcneelylaw.com/what-is-a-most-favored-nation-clause-in-a-contract/ [https://perma.cc/5XWM-CQKY]. *See also Most Favored Customer*, The Law Dictionary, https://thelawdictionary.org/most-favored-customer/ [https://perma.cc/NF84-E4M5].

61 Exec. Order 14297, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients*, 90 Fed. Reg. 20749 (May 12, 2025).

62 *See, e.g.*, Darius Lakdawalla & Dana Goldman, *'Most-Favored Nation' Drug Pricing Has Three Significant Problems,* USC Leonard D. Schaeffer Inst. Pub. Pol'y & Gov't. Serv. (Apr. 14, 2025), https://schaeffer.usc.edu/research/most-favored-nation-drug-pricing-has-three-significant-problems/ [https://perma.cc/YT8Q-2PS5] (listing three important shortcomings of MFN: (1) it can easily be gamed, such as if pharmaceutical companies artificially raise prices overseas and offer confidential rebates to foreign customers; (2) it may result in firms withdrawing from overseas markets, inflicting untold harm on global health and leaving U.S. customers with the same high prices; and (3) it leaves drug valuation and pricing decisions in the hands of foreign governments, which may undervalue marginal health improvements); Daniel Payne, *White House Unveils Sweeping Plan to Try to Lower U.S. Drug Prices,* STAT (May 12, 2025), https://www.statnews.com/2025/05/12/trump-drug-prices-executive-order-most-favored-nation-prescription-pricing/ [https://perma.cc/96ZV-R8F9] (noting that Scott Gottlieb, former FDA Commissioner, commented that the policy "appears to largely rely on [importation], for now, which will be hard to implement while still guaranteeing the safety and provenance of drugs, and protecting against counterfeits.")

63 *2024 State Legislation to Lower Prescription Drug Costs*, *supra* note 49.

The pharmaceutical industry has filed a number of lawsuits challenging the constitutionality of these state laws, which are examined in Part II.B.

Ultimately, even if the IRA and the existing patchwork of state laws survive the ongoing litigation, these solutions are temporary fixes that require strong governmental oversight and enforcement in order to be effective. As long as drug development and production are privately owned, patients and providers are beholden to corporations, and corporations are beholden to shareholder primacy.[64] This longstanding tradition of corporate governance means that essential drug development and production is often at the mercy of profit maximizing motives, risking patients' lives in the event of drug shortages or price inflation.[65] Part II.C. discusses how investment and development in public pharma can protect access to medicine in the event of drug shortages and drug price inflation.

A. Failure of Federal Efforts

The Bayh-Dole Act of 1980 governs patented inventions developed pursuant to funding agreements with federal agencies.[66] A key provision of the Act permits the funding agency to exercise "march-in rights," which allow the funding agency to grant compulsory licenses on the subject invention to third parties if certain conditions are met.[67] These conditions include circumstances in which "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees" or "to meet requirements for public use specified by Federal regulations and such

---

64 *See* State Policy Toolkit, *supra* note 31, at 3–5; Milton Friedman, *A Friedman Doctrine—The Social Responsibility of Business Is to Increase Its Profits*, N.Y. TIMES (Sept. 13, 1970), https://www.nytimes.com/1970/09/13/archives/a-friedman-doctrine-the-social-responsibility-of-business-is-to.html [https://perma.cc/Z4DY-9LKF] ("In a free-enterprise, private-property system, a corporate executive is an employe [sic] of the owners of the business. He has direct responsibility to his employers. That responsibility is to conduct the business in accordance with their desires, which generally will be to make as much money as possible while conforming to the basic rules of the society. . . .").

65 *See* State Policy Toolkit, *supra* note 31, at 3–5; Kumar, *supra* note 34, at 376 (citing U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: ROOT CAUSES & POTENTIAL SOLUTIONS 6 (2020), https://www.fda.gov/media/131130/download?attachment [https://perma.cc/U37L-RP24] (noting that a 2019 FDA report found that the root cause of drug shortages is the lack of economic incentive to ensure a consistent supply of older, off-patent, generic prescription drugs that have slender or no profit margins)).

66 Bayh-Dole Act, 35 U.S.C. §§ 200–212 (1980).

67 35 U.S.C. § 203.

requirements are not reasonably satisfied by the contractor, assignee, or licensees."[68] Since 1997, activists and public officials have urged the NIH to march in on essential but inaccessible medicines developed with federal funding to alleviate public-health harms and facilitate reasonable public use.[69] The NIH has denied every single one of these petitions.[70]

The most recent example concerns Xtandi (enzalutamide), a drug approved for the treatment of late-stage prostate cancer.[71] Supported by funding from the NIH and the Department of Defense (DOD), researchers at the University of California, Los Angeles (UCLA) began developing Xtandi in 2000.[72] In 2005, UCLA licensed several patents on Xtandi to Medivation, Inc.,[73] which in turn sub-licensed the technology to Japan-based Astellas Pharmaceuticals in 2009.[74] After several clinical trials, many of which were also completed with the aid of federal funding,[75] Astellas obtained FDA approval of Xtandi in 2012.[76] Astellas went on to sell Xtandi in the United States at a cost of $160,000 to $180,000 per year per patient,[77] while selling it in Japan for 16-31% of that price.[78]

---

68 *Id.*

69 *Bayh-Dole Timeline*, *supra* note 46.

70 *Id.*

71 *Id.*; *see also Drug Approval Package: Xtandi (enzalutamide)*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203415_xtandi_toc.cfm [https://perma.cc/6VZ3-Z6KZ].

72 *Xtandi (INN Enzalutamide)*, KNOWLEDGE ECOLOGY INT'L (revised Feb. 14, 2022), https://www.keionline.org/xtandi-timeline [https://perma.cc/EA47-6TXC].

73 *Exclusive License Agreement between the Regents of the University of California and Medivation Inc.*, U.S. SECS. & EXCH. COMM'N (Aug. 15, 2005), https://www.sec.gov/Archives/edgar/data/1011835/000119312505197811/dex1010.htm [https://perma.cc/8FGV-NRLC].

74 *Collaboration Agreement between Medivation Inc. and Astellas Pharma Inc.*, U.S. SECS. & EXCH. COMM'N (Oct. 26, 2009), https://www.sec.gov/Archives/edgar/data/1011835/000119312510057020/dex1015.htm [https://perma.cc/Z93T-XD74].

75 Letter from Knowledge Ecology Int'l & Union for Affordable Cancer Treatment to Nat'l Insts. Health, U.S. Dep't Health & Hum. Servs., & U.S. Dep't Def., at 20–21 (Jan. 14, 2016), https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf [https://perma.cc/D8NM-XNQK] (noting also that federal funding was used for several post-market clinical trials).

76 *Drug Approval Package: Xtandi (enzalutamide)*, *supra* note 71.

77 *US Declines to Force Lower Price on Cancer Drug Xtandi*, REUTERS (Mar. 22, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/us-declines-force-lower-price-cancer-drug-xtandi-2023-03-21/ [https://perma.cc/7HED-LSQX].

78 *Xtandi: 2021-2022 Request to US Department of Health and Human Services to Use the US Government's Rights in Patents*, KNOWLEDGE ECOLOGY INT'L (last updated Mar. 23, 2023), https://www.keionline.org/xtandi2021 [https://

In November 2021, following up on a 2019 petition to the DOD, Robert Sachs, a former attorney who was prescribed Xtandi to treat metastatic prostate cancer, and Clare M. Love petitioned the NIH to march in on Xtandi.[79] After multiple groups requested to join the petition, urging the NIH to take action,[80] the NIH finally responded in 2023 and denied the petition.[81] The agency reasoned that "practical application" is evidenced by the "manufacture, practice, and operation of the invention and the invention's availability to and use by the public,"[82] refusing to consider whether or how the price of Xtandi impacted whether it was "available to the public on reasonable terms."[83] As Astellas had reported that more than 200,000 patients were treated with Xtandi since its approval, the NIH concluded that the patent owner, the University of California, did not fail to bring Xtandi to practical application because the drug was

---

perma.cc/KXP9-FVGB] (citing Hiroyuki Okumura et al., *Cost-Effectiveness Analysis of Enzalutamide for Patients with Chemotherapy-Naïve Metastatic Castration-Resistant Prostate Cancer in Japan*, 51 JAPANESE J. CLINICAL ONCOLOGY 1319, 1323 (2021)).

79 Letter from Clare M. Love & Robert Sachs to Xavier Becerra, Sec'y, U.S. Dep't Health & Hum. Servs. (Nov. 18, 2021), https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf [https://perma.cc/8D6J-LGQU].

80 *Xtandi: 2021-2022 Request to US Department of Health and Human Services to Use the US Government's Rights in Patents*, *supra* note 78.

81 Letter from Lawrence A. Tabak, Acting Director, Nat'l Insts. Health, to Robert Sachs & Clare Love (Mar. 21, 2023), https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-21march2023.pdf [https://perma.cc/E6NZ-SJQE].

82 *Id.* (quoting Letter from Francis S. Collins, Director, Nat'l Insts. Health, to Andrew S. Goldman, Knowledge Ecology Int'l (June 20, 2016), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf [https://perma.cc/HT38-GHQU]).

83 *Id.*; *see* 35 U.S.C. § 201(f) (noting that "practical application" means to manufacture, practice, or operate the invention "under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms"); *see also* Peter Arno & Michael Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 651–53 (2001) ("[T]raditional judicial and agency competence to determine reasonableness of prices is supported by countless cases and a host of statutes, including, for instance, the reasonable price provisions of the Uniform Commercial Code (UCC), the reasonable royalty remedies of patent law, the similar provisions of copyright law, the compulsory licensing provisions of antitrust law, the price control provisions of the Orphan Drug Act, and public utility rate regulation cases.") (footnotes omitted).

"widely available on the market," regardless of its cost on the U.S. market.[84]

Although the Bayh-Dole Act was intended to facilitate public-private partnerships while simultaneously "protect[ing] the public against nonuse or unreasonable use of inventions,"[85] the decision to enforce these safeguards is left entirely to the discretion of the funding agency.[86] Furthermore, a decision to march in can be challenged by the patent owner, which may dissuade an agency from issuing a decision on march-in rights likely to instigate years of litigation.[87] Because the NIH believes that assessing the prices of federally funded inventions falls within the domain of Congress or the Federal Trade Commission (FTC),[88] it considers march-in rights to be an "extraordinary remedy" that it has never exercised.[89] Even though the Bayh-Dole Act empowers agencies to exercise stewardship of intellectual property developed with federal funding, if a funding agency refuses to consider price as a component of unreasonable use, practical utility, or health or safety needs—as the NIH has for every march-in petition it has considered—the public is left with no recourse.

While federal agencies support drug development with considerable funding,[90] Medicare is another source of significant federal expenditure on drugs. For instance, gross spending for

---

84 Letter from Lawrence A. Tabak, Acting NIH Director, Nat'l Insts. Health, to Robert Sachs & Clare Love, *supra* note 81.

85 35 U.S.C. § 200.

86 35 U.S.C. § 203; 37 CFR § 401.6 (2023).

87 *See* Avital Bar-Shalom & Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 MILBANK Q. 637, 667 (2002) (arguing that Bayh-Dole procedures discourage agencies from marching in, because "[i]f an agency decides not to march in, the case is over. If it does decide to march in, the party whose patent is subject to compulsory licensing can contest the decision, which compels the agency to defend its action against a party with a strong financial stake.").

88 Norvir, at 6 (Nat'l Insts. Health July 29, 2004), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf [https://perma.cc/4SS8-6LX2] (noting that the NIH believes "the issue of drug pricing is one that would be more appropriately addressed by Congress," and that "the FTC is the appropriate agency to address the question of whether Abbott [manufacturer of Norvir] has engaged in anti-competitive behavior.").

89 *Id.* at 5.

90 *National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development*, U.S. GOV'T. ACCOUNTABILITY OFF. (Apr. 4, 2023), https://www.gao.gov/products/gao-23-105656 [https://perma.cc/R8YF-AL69] (noting that from fiscal years 2017 through 2021, the NIH, the largest public funder of biomedical research and development, obligated $97 billion for basic research, $28 billion for clinical trials and related activities, and $9 billion for biomedical workforce training).

Medicare Part D (for prescription drug coverage) amounted to $166 billion in 2018—a figure that rose sharply to $216 billion in 2021.[91] Moreover, a small number of drugs constituted a disproportionate share of this spending, with the cost of the top ten selling Part D drugs more than doubling from $22 billion to nearly $48 billion between 2018 and 2021.[92] In an attempt to reign in this spending, in 2022, Congress enacted the IRA, which, among other things, empowers Medicare to negotiate the prices of certain high-cost drugs with manufacturers.[93] Historically, Medicare has been prohibited from negotiating drug prices, instead being forced to accept prices set by pharmaceutical companies with little accountability or oversight.[94] The result of this has been exorbitant costs incurred to the government, and by proxy, the public. The IRA attempts to remediate this by (1) allowing Medicare to negotiate the price of a limited number of high-cost drugs each year that lack generic or biosimilar competition[95] and have been on the market for several years,[96] (2) requiring drug manufacturers to pay rebates if their price increases exceed the inflation rate, and (3) limiting patients' out-of-pocket costs.[97] In August 2023, HHS announced the first ten drugs to be selected for negotiation.[98]

---

91 Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://www.kff.org/medicare/issue-brief/a-small-number-of-drugs-account-for-a-large-share-of-medicare-part-d-spending [https://perma.cc/SC55-3SN5].

92 *Id.*

93 Inflation Reduction Act (IRA) of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022) (codified in scattered sections of 23 U.S.C., 26 U.S.C., 42 U.S.C., & 43 U.S.C.).

94 This prohibition against drug price negotiation is codified in the "noninterference clause," which states that, "in order to promote competition . . . the Secretary [of HHS] (1) may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1860-11(i), Pub. L. 108-173, 117 Stat. 2066, 2098 (codified as amended at 42 U.S.C. § 1395w-111) (modifying the Social Security Act of 1935).

95 IRA, 42 U.S.C. 1320f-1(e)(1).

96 Under the IRA, the price of a drug may only be negotiated if it has been on the market for 9 years (for small molecule drugs) or 13 years (for biologic drugs). IRA, 42 U.S.C. §§ 1320f(b)(3), 1320f-1(e)(1).

97 *See* Arti K. Rai, Rachel Sachs & W. Nicholson Price II, *Cryptic Patent Reform Through the Inflation Reduction Act*, 37 HARV. J. L. & TECH. 57, 65–71 (2023).

98 *HHS Selects the First Drugs for Medicare Drug Price Negotiation*, U.S. DEP'T HEALTH & HUM. SERVS. (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html [https://perma.cc/EEM7-NC3L]. The drugs selected are Eliquis

But, much like other federal legislation intended to reform pharmaceutical accountability and transparency,[99] the IRA was met with significant resistance from the pharmaceutical industry. According to the Georgetown O'Neill Institute's Health Care Litigation Tracker, nineteen cases have been filed which seek to block the government from enforcing the IRA.[100] The plaintiffs in these cases, most of whom are manufacturers of the drugs selected for price negotiation,[101] variously assert that the IRA is unconstitutional as violating the First Amendment (compelled speech), Fifth Amendment (Takings Clause, Due Process Clause), Eighth Amendment (excessive fines), and/or the Vesting Clause (nondelegation doctrine).[102] Of these cases, one has been voluntarily dismissed,[103] and several others are

---

(apixaban, manufactured by Bristol Myers Squibb), Jardiance (empagliflozin, by Boehringer Ingelheim), Xarelto (rivaroxaban, by Janssen), Januvia (sitagliptin phosphate, by Merck), Farxiga (dapagliflozin, by AstraZeneca), Entresto (sacubitril; valsartan, by Novartis), Enbrel (etanercept, by Immunex), Imbruvica (ibrutinib, by Pharmacyclics), Stelara (ustekinumab, by Janssen), and Fiasp; Fiasp FlexTouch; Fiasp PenFill (insulin aspart, by Novo Nordisk); NovoLog; NovoLog FlexPen; NovoLog PenFill (insulin aspart recombinant, by Novo Nordisk). *Id.*

99 *See, e.g.*, *Bayh-Dole Timeline*, *supra* note 46 (citing Warren E. Leary, *U.S. Gives Up Right to Control Drug Prices*, N.Y. TIMES (Apr. 12, 1995), https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html [https://perma.cc/689R-7DBS]) (describing how the NIH abandoned "reasonable pricing" clauses in licenses and Cooperative Research and Development Agreements (CRADAs) between private industry and the federal government due to political pressure from pharmaceutical and biotechnology companies); Brett Norman & Sarah Karlin-Smith, *The One that Got Away: Obamacare and the Drug Industry*, POLITICO (July 13, 2016), https://www.politico.com/story/2016/07/obamacare-prescription-drugs-pharma-225444 [https://perma.cc/484Y-3RPN] (describing how PhRMA lobbying hampered proposed pharmaceutical accountability measures in the Affordable Care Act (ACA), specifically by prohibiting the Patient Centered Outcomes Research Institute (PCORI), a group of independent experts established by the ACA, from considering cost effectiveness in its research comparing various medical treatments); *see also Client Profile: Pharmaceutical Research & Manufacturers of America*, OPEN SECRETS (last updated Oct. 23, 2025), https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2020&id=d000000504 [https://perma.cc/X2NU-MDLR] (noting Senate Office of Public Records data showing that PhRMA spent over $29 million on lobbying in 2025, over $31 million in 2024, over $27 million in 2023, over $29 million in 2022, and over $30 million in 2021).

100 *Health Care Litigation Tracker: Medicare Drug Price Negotiation*, *supra* note 47.

101 *Id.*

102 *See* HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM (Oct. 10, 2024), https://crsreports.congress.gov/product/pdf/R/R47682 [https://perma.cc/AWT6-YJTE].

103 Notice of Voluntary Dismissal, Astellas Pharma US, Inc. v. Dep't of Health & Hum. Servs. (No. 1:23-cv-04578) (N.D. Ill. Sept. 6, 2023).

on appeal.[104] Thus far, courts that have considered these constitutional challenges have almost all dismissed the suits on the grounds that, among other things, participation in Medicare Part D is voluntary, and therefore the government is entitled to place conditions, such as price negotiation, on Medicare participation.[105]

Even if the IRA survives the ongoing litigation, the Act still falls short of fully reforming prescription-drug spending. First, the price negotiation clause is limited in scope inasmuch as it only applies to Medicare beneficiaries, not commercial health plans. Second, the Act only permits Medicare to negotiate the prices of a limited numbers of drugs each year.[106] Third, as Professors Arti Rai, Rachel Sachs, and Nicholson Price have pointed out—because only drugs that lack generic or biosimilar competition may be selected for price negotiation,[107] and much of the manufacturing know-how for biologic drugs is complicated and often protected by trade secrecy[108]—the IRA may incentivize originator biologic manufacturers to share trade secrets with a single biosimilar market entrant to avoid price negotiation while sharing duopoly profits,[109] a form of

---

104 *See Health Care Litigation Tracker: Medicare Drug Price Negotiation*, *supra* note 47.

105 *See, e.g.*, Bristol Myers Squibb Co. v. Becerra, Nos.23-3335 (ZNQ) (JBD), 23-3818 (ZNQ) (JBD), 2024 WL 1855054, at *6–9 (D.N.J. Apr. 24, 2024) (consolidated)(*aff'd*, 155 F.4th 245 (3d Cir. 2025); AstraZeneca Pharmaceuticals LP v. Becerra, 719 F. Supp. 3d 377, 395–97 (D. Del. 2024), *aff'd*, 137 F.4th 116 (3d Cir. 2025).

106 *See* IRA, 42 U.S.C. § 1320f-1(a)(1)–(4) (permitting negotiation of ten drugs in 2026, an additional fifteen in 2027, an additional fifteen in 2028, and an additional twenty in 2029 and each subsequent year).

107 IRA, 42 U.S.C. § 1320f-1(e)(1).

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

109 *See* Rai, Sachs & Nicholson Price II, *supra* note 97, at 81–82; *see also generally* Chintan V. Dave et al., *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANNALS OF INTERNAL MED. 145 (2017), (analyzing price data on generic prescription drugs from 2008 to 2013, finding that price increases over the study period were inversely correlated to the number of generic manufacturers on the market). The Hatch-Waxman Act incentivizes manufacturers to submit Abbreviated New Drug Applications (ANDAs) seeking approval of new generics by providing a 180-day period of exclusivity, during which time the FDA cannot approve any other generic drug for the same reference product. *See* Hatch-Waxman Act § 101, Pub. L. 98-417, 98 Stat. 1585, 1585 (1984) (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iii)–(iv), (j)(5)(D)) (amending the FD&C Act). But the Act does not provide similar incentivizes to the second, or third, or -nth ANDA filer. *Id.*

collusion reminiscent of pay-for-delay agreements.[110] Finally, Rai, Sachs, and Price also observe that the IRA may incentivize product hopping, in which a brand-name pharmaceutical company launches a new, patented product with minor variations or improvements over an existing drug, thus shifting market demand to the new drug with new patent and FDA exclusivities, while also avoiding IRA price negotiation for another nine to thirteen years.[111]

Ultimately, many of the current proposals for the federal government to address drug price inflation are either overly dependent on the political will of federal agencies, such as the Bayh-Dole Act, or slow-moving, modest reforms peppered with too many methods of evasion for the pharmaceutical industry, such as the IRA. Although the IRA represents a step in the right direction, the need to secure a supply of lifesaving medicines is pressing enough that the public cannot wait another decade for real reform.

Fortunately, several states have expressed interest in addressing these drug pricing reform with laws of their own. While federal healthcare or patent reform may be the ideal means of addressing the drug pricing crisis—indeed Professor Rebecca Wolitz has referred to state efforts as a "second-best solution"[112]—states urgently need another way to ensure that their citizens have access to medicine, and state-owned public pharma paves the path forward.

B. Fractured State Efforts

In the wake of federal failures to regulate the pharmaceutical industry, states have passed various reforms to lower prescription drug costs. A number of states have passed pharmaceutical accountability and transparency laws, variously

---

110 "Pay-for-delay" agreements are deals, often made during patent litigation settlement, wherein a brand-name and generic pharmaceutical company agree that the generic will delay market entry for a certain period of time, often in exchange for a sum of money or the brand agreeing not to launch an authorized generic. *See, e.g.*, Fed. Trade Comm'n. v. Actavis, 570 U.S. 136 (2013). Accordingly, the companies can split profits from the brand's market monopoly while consumers continue to pay monopoly prices until delayed generic launch. The Supreme Court has held that such agreements can constitute antitrust violations. *See id.* at 158.

111 *See* Rai, Sachs & Nicholson Price II, *supra* note 97, at 81–89; *see also* FED. TRADE COMM'N., REPORT ON PHARMACEUTICAL PRODUCT HOPPING (Oct. 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p223900reportpharmaceuticalproducthoppingoct2022.pdf [https://perma.cc/96U7-PF5V].

112 Rebecca Wolitz, *supra* note 48, at 391.

requiring pharmaceutical companies to justify price hikes or to provide detailed information about pricing.[113] However, these laws have not gone unchallenged. The Association for Accessible Medicines (AAM), the trade association for generic drug manufacturers, and the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association for brand-name drug manufacturers, have filed a number of lawsuits challenging the constitutionality of these state laws.[114] Unlike the challenges to the IRA, many of these state laws have been struck down as unconstitutional under an expansive view of the "extraterritoriality principle" of the dormant Commerce Clause, which holds that a State may not regulate commerce occurring wholly outside of its borders.[115] Legal challenges to three state laws intended to regulate price increases on generic drugs are examined in turn below.

1. *Maryland*

In 2018, the Fourth Circuit considered a Maryland statute that would prohibit generic drug price gouging.[116] The Act defined "price gouging" as an increase in the wholesale acquisition cost of a prescription drug sold in the state which is "unconscionable," defined as an increase that is "excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health" and results in consumers "having no meaningful choice about whether to purchase the drug at an excessive price" due to "the

---

113 *2024 State Legislation to Lower Prescription Drug Costs*, *supra* note 49.

114 *See, e.g.*, Pharm. Rsch & Mfrs. of Am. v. Stolfi, 724 F. Supp. 3d 1174, 1183, 1202 (D. Or. 2024) (finding that Oregon law mandating drug price transparency was a regulatory taking and unconstitutional government-compelled commercial speech) *rev'd and rem'd* 153 F.4th 795 (9th Cir. 2025); Ass'n for Accessible Meds. v. Ellison, 704 F. Supp. 3d 947, 958(D. Minn. 2023) (holding that Minnesota law requiring drug manufacturers to report certain price hikes for prescription drugs likely violated the dormant Commerce Clause by regulating commerce outside of Minnesota, granting preliminary injunction), *aff'd*,140 F.4th 957 (8th Cir. 2025); Ass'n for Accessible Meds. v. Raoul, 2025 WL 2764558 (N.D. Ill. Sept. 26, 2025) (holding Illinois law prohibiting generic-drug price gouging, defined by unjustified price hikes in wholesale acquisition cost within a specified period of time, likely did not violate the dormant Commerce Clause, denying preliminary injunction); Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666–67, 666 n.1, 670 (4th Cir. 2018) (holding that Maryland statute prohibiting generic drug price gouging was unconstitutional for violating the dormant Commerce Clause).

115 *See, e.g.*, Healy v. Beer Inst., Inc., 491 U.S. 324, 336–37 (1989).

116 *See Frosh*, 887 F.3d at 666–67; *An Act Concerning Public Health–Essential Off-Patent or Generic Drugs–Price Gouging–Prohibition*, Md. H.B. 631, § 2-801 et seq. (2017) (codified at MD. CODE ANN., Health–Gen. § 2-801 et seq.).

importance of the drug to their health" and "[i]nsufficient competition in the market."[117] The Act did not quantify increases in price that would constitute price gouging—although it did require the Maryland Medical Assistance Program to notify the state attorney general of price increases of 50% or more in the preceding two-year period for generic drugs with three or fewer manufacturers.[118]

AAM sought to enjoin enforcement of the Maryland Act on the grounds that it violated the dormant Commerce Clause and was unconstitutionally vague.[119] Reversing the lower court, the Fourth Circuit agreed with AAM that the Act violated the extraterritoriality principle of the dormant Commerce Clause (and thus did not reach the vagueness issue).[120] The Fourth Circuit reasoned that, although the Act applied to drugs available for sale in Maryland, it penalized increases in wholesale acquisition cost, including initial sales of a drug that may occur outside the state—such as a distributor based in New York purchasing a generic drug from a manufacturer based in New Jersey.[121] Thus, by regulating sales that may occur wholly outside of Maryland, the court concluded that the Act violated the dormant Commerce Clause.[122]

2. *Minnesota*

In July 2023, AAM sued the attorney general of Minnesota,[123] seeking to invalidate a new state law prohibiting drug manufacturers from imposing an "excessive price increase, either directly or through a wholesale distributor, pharmacy, or similar intermediary" on the sale of generic drugs "sold, dispensed, or delivered" to consumers in the state.[124] The Act defined excessive price increases by particular percentages of surges in price over a period of time, adjusted for inflation.[125] The Act also

---

117 Md. H.B. 631, § 2-801 (codified at MD. CODE ANN., Health–Gen. § 2-801 (West 2017)).

118 *Id.* at § 2-803(a)(1) (codified at MD. CODE ANN., Health–Gen. § 2-803(a)(1)).

119 *Frosh*, 887 F.3d at 666.

120 *See id.* at 666 & n.1.

121 *Id.* at 670.

122 *Id.* at 671.

123 Complaint, Ass'n for Accessible Meds. v. Ellison, 704 F.Supp.3d 947 (D. Minn. 2023) (No. 23-CV-2024).

124 MINN. STAT. § 62J.842, subdiv. 1 (2024).

125 *Id.* subdiv. 2 (defining excessive increases as, adjusted for inflation, exceeding (1) 15% of wholesale acquisition cost over the previous year; or (2) 40% of wholesale acquisition cost over the previous three years).

required the state health commissioner to notify the state attorney general of excessive price increases for generic drugs[126] and imposed a $500,000 penalty on manufacturers who withdrew their drugs from sale or distribution within Minnesota for the purpose of avoiding the prohibition on excessive price increases.[127] In December 2023, the district court granted AAM's motion for a preliminary injunction, reasoning that the broad language of the Act referring to drugs "dispensed" or "delivered" within the state suggested that the initial "sale" regulated by the Act need not occur within Minnesota.[128] The Court also found significant that the Act penalized manufacturers who would try to avoid liability under the Act by prohibiting their drugs from being sold or distributed in Minnesota, noting that:

> [T]he fact that the Act penalizes manufacturers for choosing not to engage in commerce in Minnesota in order to avoid the Act is fundamentally at odds with dormant Commerce Clause jurisprudence, which often relies on the principle that anyone who wishes to avoid being subject to a state's economic regulation can simply avoid doing business in that state.[129]

Because the Act could regulate such commerce occurring wholly outside the state, the court concluded that it would violate the extraterritoriality principle of the dormant Commerce Clause.[130] The decision was affirmed by the Eighth Circuit.[131]

3. *Illinois*

In January 2024, AAM sued the attorney general of Illinois, challenging a new price-control law that the Association referred to as "draconian."[132] The law, Public Act 103-367 ("Act 367"), which went into effect on January 1, 2024, applies to generic prescription drugs sold in Illinois and manufactured in

---

126 *Id.* § 62J.844, subdiv. 1.

127 *Id.* § 62J.845, subdiv. 3.

128 Ass'n for Accessible Meds. v. Ellison, 704 F. Supp. 3d 947, 953 (D. Minn. 2023), *aff'd*, 140 F.4th 957 (8th Cir. 2025). In response to queries by the Court, this reading of the Act was confirmed by the State. *Id.*

129 *Id.* at 956–57 (citing Nat'l Pork Producers Council v. Ross, 143 S. Ct. 1142, 1154–57 (2023) (plurality opinion)).

130 *Id.* at 956.

131 Ass'n for Accessible Meds. v. Ellison, 140 F.4th 957, 962 (8th Cir. 2024).

132 Complaint for Declaratory and Injunctive Relief, Ass'n for Accessible Meds. v. Raoul, 2025 WL 2764558, at *6 (N.D. Ill. Sept. 26, 2025).

the United States by three or fewer manufacturers.[133] The Act prohibits manufacturers of such drugs from "price gouging," meaning an "unconscionable increase in a prescription drug's price" that would increase wholesale acquisition cost by more than 30% within the preceding year, more than 50% within the preceding 3 years, or more than 75% within the preceding 5 years, and is "otherwise excessive or unduly burdens consumers" unjustified by increases in the cost of production or cost of appropriate expansion of access for public health.[134] Shortly before the Act went into effect, one of its sponsors, Illinois Senator Dave Koehler, commented: "We need to take a stand for our residents and prohibit companies from these manipulative schemes. There should never be a situation when someone has to decide between picking up their medication or groceries for their family."[135]

The complaint alleged that the Act imposes restrictions that place an undue burden on interstate commerce and violate the extraterritoriality principle of the dormant Commerce Clause.[136] AAM further alleged that the Act violates the Due Process Clause of the Fourteenth Amendment by failing to define terms such as "unconscionable" and "otherwise excessive and unduly burden[some]," thus not providing sufficient warning about precisely what pricing behavior constitutes a violation of the Act.[137] In September 2025, the District Court denied AAM's motion for a preliminary injunction, finding that AAM had not made a strong showing of likelihood of success on the merits, at least in part because recent Supreme Court cases, including *National Pork Producers Council v. Ross*, had undercut the continuing viability of extraterritoriality as a standalone doctrine that could strike down state laws without a

---

133 Pharmaceutical and Health Affordability: Restrictions on Manufacturers' Amoral Behavior through Reasonable Oversight Act, Pub. Act 103-367, 2023 Ill. Legis. Serv. (West) (codified at 410 ILL. COMP. STAT. 725/1 et seq.) (effective Jan. 1, 2024).

134 *See id.*

135 Ed Silverman, *Generic Group Sues Illinois Over Price-Gouging Law with 'Draconian Regulations*,' STAT (Jan. 25, 2024) (citing Press Release, Office of Sen. Dave Koehler, *Price Gouging of Generic Medication to End under Koehler's New Law* (Dec. 20, 2023), https://www.senatordavekoehler.com/news/28-press-releases/481-price-gouging-of-generic-medication-to-end-under-koehlers-new-law [https://perma.cc/MCK8-NB6H]), https://www.statnews.com/pharmalot/2024/01/25/medicines-generic-prices-gouging-illnois-constitution-constitutional/ [https://perma.cc/3BQB-BGY8].

136 Complaint for Declaratory and Injunctive Relief, *supra* note 132, at *2, *4, *5 (N.D. Ill. Sept. 26, 2025).

137 *Id.* at 5.

clear protectionist tilt.[138] The case is currently on appeal to the Seventh Circuit.[139]

C. The Limits of State Power

The legal challenges to the state drug price statutes emphasize the extraterritoriality principle of the dormant Commerce Clause as a key hurdle for states seeking to regulate the prices of drugs sold within their borders. Lower courts have increasingly applied an expansive view of the extraterritoriality principle, preventing states from enacting laws that regulate health and safety within their own borders if they have an incidental effect on out-of-state commerce, a trend that Professors Robin Feldman and Gideon Schor describe as invoking a "new *Lochner* era."[140] Feldman and Schor argue that two Supreme Court decisions from the 1980s—*Brown-Forman Distillers Corp. v. New York State Liquor Authority*,[141] and *Healy v. Beer Institute, Inc.*,[142] which involved state "price affirmation statutes" requiring manufacturers to affirm that their prices within the state were no higher than their prices in any other state—misconstrued precedent to craft a new, expansive extraterritoriality principle that mutated the dormant Commerce Clause from a narrow anti-discrimination rule into a broad restriction on state sovereignty.[143]

In 2003, the Supreme Court revisited the extraterritoriality principle in *Pharmaceutical Research and Manufacturers of America v. Walsh*.[144] In *Walsh*, the Court unanimously held that a Maine prescription drug rebate program, under which enrollees could purchase prescription drugs from participating

---

138 Ass'n for Accessible Medicines v. Raoul, No. 24-C-544, 2025 WL 2764558, at *3–*6 (N.D. Ill. Sept. 26, 2025).

139 *See* Association for Accessible Medicines v. Kwame Raoul, 25-2960 (7th Cir. Jan. 22, 2026).

140 *See* Robin Feldman & Gideon Schor, Lochner *Revenant: The Dormant Commerce Clause & Extraterritoriality*, 16 N.Y.U. J.L. & LIBERTY 209, 210 (2022).

141 476 U.S. 573 (1986).

142 491 U.S. 324 (1989).

143 *See* Feldman & Schor, *supra* note 140, at 236–238 (explaining how *Brown-Forman* and *Healy* misconstrued language from *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935) stating that "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." *Baldwin* examined a New York "price-support" law setting a minimum price that in-state milk dealers had to pay to in-state milk producers and prohibiting in-state dealers from buying milk from out-of-state producers at a lower price. The Court found that the statute violated the dormant Commerce Clause.).

144 538 U.S. 644 (2003).

Maine pharmacies at a discount, reimbursed by rebate payments collected from participating drug manufacturers, did not violate the extraterritoriality principle.[145] The *Walsh* court clearly distinguished the price-affirmation statutes in *Brown-Forman* and *Healy*, writing: "[U]nlike price control or price affirmation statutes, 'the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in-state products to out-of-state prices.'"[146] Shortly thereafter, the Ninth and Tenth Circuits affirmed that *Walsh* limited the extraterritoriality principle to price-affirmation statutes,[147] but the Fourth Circuit disagreed in *Frosh*, creating a circuit split.[148]

In 2023, the Supreme Court addressed this circuit split in *National Pork Producers Council v. Ross*, a split decision affirming the Ninth Circuit's dismissal of a challenge to Proposition 12, a California ballot initiative barring sales of pork from pigs confined in conditions that violated state law.[149] The Court unanimously rejected the petitioners' claims that the initiative would violate an "almost *per se*" prohibition against state laws that have the practical effect of controlling commerce outside the state, even if they are nondiscriminatory, noting that "[i]n our interconnected national marketplace, many (maybe most) state laws have the 'practical effect of controlling extraterritorial behavior.'"[150] However, the Justices could not agree on how to evaluate dormant Commerce Clause challenges, and thus did not provide clear guidance on how future courts should weigh extraterritorial effects as a factor in evaluating whether state laws violate the dormant Commerce Clause by burdening interstate commerce. This is evident in the district court opinion holding Minnesota's drug price gouging statute invalid. In its discussion of *Pork Producers*, the district court distinguished

---

145 *Id.* at 669–670.

146 *Id.* at 669 (quoting Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 81–82 (1st Cir. 2001)).

147 *See, e.g.*, Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 951 (9th Cir. 2013); Chinatown Neighborhood Ass'n v. Harris, 794 F.3d 1136, 1146 (9th Cir. 2015); Nat'l Pork Producers Council v. Ross, 6 F.4th 1021, 1028–29 (9th Cir. 2021); Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1175 (10th Cir. 2015).

148 Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 670 (4th Cir. 2018).

149 143 S. Ct. 1142, 1142 (2023).

150 *Id.* (quoting Brief for Petitioners at 22, Nat'l Pork Producers, 143 S. Ct. 1142 (2023) (No. 21-468)).

Proposition 12 as regulating only products that companies choose to sell within California, not upstream sales.[151]

The drug manufacturing supply chain is complex and involves national stakeholders.[152] Furthermore, market forces have driven much of the manufacturing of essential drugs and their ingredients overseas,[153] meaning that drug manufacturing, distribution, and sales are necessarily entangled in interstate commerce. *Pork Producers* leaves open the question of whether a state statute violates the dormant Commerce Clause if it controls any out-of-state transaction that is part of a transaction stream that ultimately enters the state.[154] The Minnesota district court answered this in the affirmative; it will remain to be seen whether Illinois follows suit.[155] Clearly, a number of states consider prescription drug affordability to be a political priority. However, under the extraterritoriality principle—even what remains of it after *Pork Producers*—states would not be able to regulate price hikes for essential medicines that their citizens rely on, making effective drug price reform with state law impossible.

II
Forging Public Pharma

Public pharma is a viable solution to mitigating the troubles previously outlined: namely, drug shortages and drug prices. Scholars and activists have discussed why the establishment of a public pharmaceutical sector is a much-needed disruption to the pharmaceutical industry, particularly in the wake of critical drug shortages and the ongoing COVID crisis.[156] Some of these discussions include calls for the President to invoke national emergency powers to manufacture essential drugs in shortage or to scale vaccine production

---

151 Ass'n for Accessible Meds. v. Ellison, 704 F. Supp. 3d 947, 956–57 (D. Minn. 2023), *aff'd*, 140 F.4th 957 (8th Cir. 2025).

152 U.S. Dep't Health & Hum. Servs., White Paper: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States 4–5 (Fig. 1) (2024), https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf [https://perma.cc/F2AY-FNNE].

153 *Id.* at 3.

154 *See* Feldman & Schor, *supra* note 140, at 282–86.

155 *See Ellison*, 704 F. Supp. 3d at 956–57; Complaint for Declaratory and Injunctive Relief, *supra* note 132, at *6.

156 *See generally, e.g.*, Brown & Morten, *supra* note 44; State Policy Toolkit, *supra* note 31; Kumar, *supra* note 44.

during a pandemic,[157] such as the Defense Production Act (DPA), which empowers the president to directly "allocate materials, services, and facilities" to promote national defense needs.[158] Indeed, in late 2023, President Biden invoked the Act twice "to enable investment in domestic manufacturing of essential medicines . . . deemed by the President as essential to the national defense."[159] While the effectiveness of this measure remains to be seen, it is also unclear whether the Act can be invoked outside the context of a pandemic or severe drug shortages that threaten national security—for instance, to resolve access gaps created by drug prices or shortages that do not plausibly implicate national security. Furthermore, while government patent use under 28 U.S.C. § 1498(a) is certainly not limited to national crises or emergencies, the federal government has not recently invoked § 1498 to obtain patented drugs.[160]

---

157 *See, e.g.*, Zain Rizvi, Jishian Ravinthiran & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, HEALTH AFFS. FOREFRONT (Aug. 6, 2021), https://www.healthaffairs.org/content/forefront/sharing-knowledge-president-joe-biden-can-use-defense-production-act-end-pandemic [https://perma.cc/CXV8-A7UR].

158 50 U.S.C. § 4511. In 2020, Trump invoked the Act through an executive order to address a serious shortage of protective equipment such as masks and ventilators. *See* David Welna, *Trump Invokes a Cold War Relic, The Defense Production Act, for Coronavirus Shortages*, NPR (Mar. 18, 2020), https://www.npr.org/2020/03/18/818069722/trump-invokes-a-cold-war-relic-the-defense-production-act-for-coronavirus-shorta [https://perma.cc/QH23-EMAQ]. In 2021, President Biden invoked the DPA twice—first to increase the production of protective supplies again, and second to supply equipment to Merck facilities needed to manufacture Johnson & Johnson vaccines. *See* Exec. Order No. 14001, 86 Fed. Reg. 7219 (Jan. 21, 2021); Press Release, White House, *Remarks by President Biden on the Administration's COVID-19 Vaccination Efforts* (Mar. 2, 2021), https://bidenwhitehouse.archives.gov/briefing-room/speeches-remarks/2021/03/02/remarks-by-president-biden-on-the-administrations-covid-19-vaccination-efforts/ [https://perma.cc/TZ5N-A32K].

159 *See* Press Release, White House, *Fact Sheet: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors* (Nov. 27, 2023), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/ [https://perma.cc/43WW-WR89]; Presidential Determination No. 2024-03, 89 Fed. Reg. 3 (Dec. 23, 2023).

160 As Professor Amy Kapczynski and others have noted, in the 20th century, the government used § 1498 to purchase generic versions of patented medicines, with agencies such as the Department of Defense and the Veterans Administration deliberately purchasing drug products covered by U.S. patents. *See* Brennan et al., *supra* note 44, at 302–304. The only known example from the 21st century occurred in 2001, when the federal government threatened to invoke § 1498 to secure an adequate supply of anthrax vaccine from Bayer. *See infra* subpart III.B.

Establishing a federal public pharmaceutical sector could be an ideal solution to drug shortages and price inflation. The federal government has at least one pharmaceutical manufacturing facility that develops vaccines and biologics for military use,[161] as well as an arsenal of powerful tools at its disposal to ensure an adequate domestic production of essential medicines.[162] However, as discussed above, fierce opposition from private pharmaceutical companies makes this solution unlikely. Consequently, this Article explores benefits and challenges specifically associated with a state-owned public pharmaceutical sector as a meaningful solution to federal inaction.

A. Public Pharma Precedent

There is growing precedent for state-owned public pharma.[163] Several states have either previously or are currently manufacturing select generic drugs and drug products.[164]

MassBiologics is a public biopharma R&D and manufacturing enterprise and the only nonprofit FDA-licensed manufacturer of vaccines.[165] Since its inception in 1894, MassBiologics has developed and manufactured a number of biologic products, including the smallpox vaccine, typhoid vaccine, scarlet fever antitoxin, Pertussis vaccine, DPT vaccine, human albumin, and special immune globulins for the prevention of specific diseases.[166] Over the past decade, MassBiologics has—either alone or in collaboration with industry partners—developed human monoclonal antibodies targeted to infectious diseases,

---

161 The Walter Reed Pilot Bioproduction Facility is a government-owned pharmaceutical manufacturing facility in Silver Spring, Maryland specializing in developing vaccines and biologics for military-relevant infectious disease threats. *See* Walter Reed Army Inst. of Rsch., *Pilot Bioproduction Facility*, https://web.archive.org/web/20250222145921/https://wrair.health.mil/Collaborate/Pilot-Bioproduction-Facility/ [https://perma.cc/39XG-5TSC].

162 *See, e.g.*, Laura Dolbow, *Public Patent Powers*, 123 MICH. L. REV. 599, 601 (2025).

163 *See* State Policy Toolkit, *supra* note 31, at 15–17; Dana Brown & Chris Morten, *Public Pharma Is the Best Solution to the Ongoing Problem of Drug Shortages*, STAT (Aug. 9, 2023), https://www.statnews.com/2023/08/09/drug-shortages-public-pharma-option/.

164 *See supra*, Part I.

165 State Policy Toolkit, *supra* note 31, at 15–16; *History*, UMASS CHAN MEDICAL SCHOOL: MASSBIOLOGICS, https://www.umassmed.edu/massbiologics/about/history/ [https://perma.cc/P64Y-9XST]. MassBiologics was established by the Massachusetts Board of Health in 1894 to make diphtheria antitoxin, and it is now affiliated with the University of Massachusetts. *Id.*

166 UMASS CHAN MEDICAL SCHOOL, *supra* note 165.

including *C. difficile*, rabies, severe acute respiratory syndrome (SARS), and hepatitis C (HCV) disease.[167]

In 2020, California established CalRx, a state-owned purveyor of generic drugs, including insulin and naloxone.[168] CalRx plans to sell biosimilar insulin for $30 per vial (approximately 10% of current market price) and naloxone nasal spray for $12 per dose (approximately half of current market price).[169] Manufacturing at CalRx is slated to be completed pursuant to contracts with private manufacturers Civica Rx (for insulin)[170] and Amneal Pharmaceuticals (for naloxone).[171] Partnering with private manufacturers, however, does present some risks, such as mission drift, favoring profit-maximizing motives, and failing to invest in a state's own capacity to secure domestic production of drugs.[172] Contracting for drug production with private manufacturers might weaken a state's case for sovereign immunity to patent infringement, if the private manufacture is not entitled to derivative sovereign immunity or the state assumes liability by waiving its immunity by contract.[173] However, partnerships between industry and public pharma can serve as an important step in kickstarting and growing the know-how for drug development and manufacture in the public sector.

---

167 *Research*, UMass Chan Medical School: MassBiologics, https://www.umassmed.edu/massbiologics/research/ [https://perma.cc/HHH5-DWY9].

168 *See* California Affordable Drug Manufacturing Act, SB 852, 2019–20 Reg. Sess. (codified at Cal. Health & Safety § 127690 et seq. (West 2020)); *Making Prescription Drugs More affordable for Californians*, CalRx, https://calrx.ca.gov/#:~:text=California%20will%20disrupt%20the%20drug,just%20for%20a%20privileged%20few [https://perma.cc/UZ2B-C3N9].

169 *See* California Affordable Drug Manufacturing Act, SB 852, 2019–20 Reg. Sess. (codified at Cal. Health & Safety § 127690 et seq. (West 2020)); *Making Prescription Drugs More affordable for Californians*, CalRx, https://calrx.ca.gov/#:~:text=California%20will%20disrupt%20the%20drug,just%20for%20a%20privileged%20few [https://perma.cc/UZ2B-C3N9].

170 *Biosimilar Insulin Agreement with Civica Foundation*, CalRx, https://calrx.ca.gov//uploads/2023/03/Fully-Executed-22-23025-Civica-Foundation-1.pdf [https://perma.cc/T837-H7LC].

171 *Naloxone Access Agreement with Amneal Pharmaceuticals*, CalRx, https://calrx.ca.gov//uploads/2024/04/23-24067-Amneal-Pharmaceuticals-LLC_Redacted.pdf [https://perma.cc/P8ET-FTQY].

172 *See* Audrey Stienon, *Public Pharma's Biggest Barrier*, Am. Prospect (Jan. 5, 2024), https://prospect.org/health/2024-01-05-public-pharmas-biggest-barrier/ [https://perma.cc/FBN8-9AFF]; Amy Kapczynski, Reshma Ramachandran & Christopher Morten, *How Not to Do Industrial Policy*, Boston Rev. (Oct. 2, 2023), https://www.bostonreview.net/articles/how-not-to-do-industrial-policy/ [https://perma.cc/7APT-WHRN].

173 *See infra* subpart II.B.

In 2022, Maine followed California's lead with a pending resolution to address the feasibility of insulin production by the state.[174] Shortly thereafter, Michigan Governor Gretchen Whitmer signed an executive directive to determine how the State could lower the cost of insulin, including by developing its own manufacturing capabilities, revitalizing its position as a leader in public pharmaceutical production.[175] With several states acknowledging the urgency of securing insulin and other essential generic and biosimilar drugs and expressing political will to invest in public drug production, other interested states may soon follow suit.

B. Benefits of State Pharma

While any form of public pharma would be a fundamentally beneficial disruption to the pharmaceutical industry, there are at least three unique benefits to a state-owned public pharma sector. First, state-owned public pharma would address access gaps created by drug prices and establish price transparency. Although several states have attempted to pass drug price gouging laws, these laws face significant constitutional hurdles as lower courts subject them to scrutiny under the extraterritoriality principle of the Dormant Commerce Clause.[176] But under the market-participant exception to the dormant Commerce Clause, states that themselves participate in a market, such as by buying or selling goods and services, are not considered to violate the dormant Commerce Clause. This is true even if their activities favor their own citizens—for instance, if a state manufactured and distributed free or low-cost drugs to only their own citizens.[177] By thus taking matters

---

174 Resolve, To Assess the Feasibility of the Production of Insulin and Insulin Analogs in Maine, S.P. 574–L.D. 1729, 130th Leg., 2d Reg. Sess. (Me. 2022).

175 Mich., Office of the Governor, Executive Directive No. 2022-12, Lowering the Cost of Insulin (Oct. 3, 2022), https://content.govdelivery.com/attachments/MIEOG/2022/10/03/file_attachments/2286607/ED%202022-12%20Lowering%20Costs%20of%20Insulin%20%28221003%29%20%28with%20signature%29.pdf [https://perma.cc/VN6H-724F]; *see also* Press Release, Governor Gretchen Whitmer, *Whitmer Signs Executive Directive Aimed at Lowering Costs, Manufacturing Insulin in Michigan* (Oct. 3, 2022), https://www.michigan.gov/whitmer/news/press-releases/2022/10/03/whitmer-signs-executive-directive-aimed-at-lowering-costs [https://perma.cc/R8A7-VBJW].

176 *See supra* Part I.

177 *See* Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 339–40 (2008); Hughes v. Alexandria Scrap Co., 426 U.S. 794, 808–09 (1976); *see also* McBurney v. Young, 569 U.S. 221, 236–37 (2013) (holding that, where Virginia was the sole manufacturer of public documents in Virginia pursuant to the Virginia Freedom

into their own hands and investing in public drug production, states can avoid at least one major legal obstacle to drug price regulation.

Second, state-owned pharma would secure supply chains and protect against drug shortages.[178] Generic drugs are significantly more likely to go into shortage because the profit margins are slim and bulk ingredients are often sourced from overseas, which renders supply chains vulnerable. Local, domestic production would address this concern while simultaneously boosting state economies and creating jobs, which itself is a social determinant of public health. Recent proposals for states to import generic drugs from Canada under a newly-implemented FDA program[179] do not address the vulnerability of global supply chains and would result in Americans becoming reliant on stable production conditions in foreign nations. While drug importation from Canada could be more stable due to the longstanding geopolitical and trade relationship between the two countries, Canadian officials have previously opposed this importation plan.[180] Canadian Prime Minister Justin Trudeau commented on the program, "Our priority will always be to ensure an adequate and safe supply for Canadians first and foremost."[181] Canada responded to U.S. proposals to import drugs by enacting a provision that would prohibit the export of certain drugs "if that sale could cause, or worsen, a drug shortage in Canada."[182] Relying on drug importation from Canada is, at best, a temporary stop-gap measure, and remains far from a viable long-term solution to address the medicine access gaps caused by drug shortages and drug prices.

A third benefit of investments in state-owned pharma is the acquisition of know-how. Knowledge of drug development

---

of Information Act, the state did not violate the dormant Commerce Clause by limiting access to those documents to its own citizens).

178 Granted that, if the cause of the shortage is a disruption in a single-source bulk ingredient, states may be at a disadvantage relative to other large countries with respect to obtaining the components to produce drugs.

179 *Importation Program under Section 804 of the FD&C Act*, U.S. Food & Drug Admin. (last updated July 7, 2024), https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act [https://perma.cc/6HEP-U2U3].

180 *Trudeau Says He Will 'Take into Account' U.S. Drug Import Plans but Will Put Canadians First*, Reuters (Sept. 25, 2020), https://www.reuters.com/article/idUSKCN26H048/ [https://perma.cc/W9Y8-C6GZ].

181 *Id.*

182 Catharine Tunney, *U.S. Allowing Florida to Import Drugs from Canada, Reviving Fears of Shortages*, CBC News (Jan. 5, 2024), https://www.cbc.ca/news/politics/fda-florida-drug-import-canada-1.7075392 [https://perma.cc/ZZD7-4N6M].

and production have long been concentrated in the private sector, which is not subject to robust transparency measures (such as freedom of information laws).[183] This is especially true for biologic drugs, which are significantly harder to manufacture than small-molecule drugs.[184] Although patents should include sufficient disclosure of how to make and use an invention,[185] a significant amount of industry know-how about the manufacturing process for biologic drugs is actually kept as a trade secret.[186] Further, unlike small-molecule drugs, many complex large molecule drugs products cannot be fully characterized or easily reverse engineered by analyzing the end product.[187] If states invested time and money into developing public drug production through the establishment of manufacturing facilities and staff, this would develop important public knowledge of drug production for posterity. To be sure, if generic and biosimilar firms struggle to develop a viable manufacturing process for biosimilar products and secure FDA approval,[188] one may question how states may undertake such an endeavor. Indeed, obtaining FDA approval for state-manufactured drugs may prove to be a major logistical and financial hurdle for public pharma, and states should explore various workarounds for these barriers. As a starting point, states may opt to begin by manufacturing small-molecule drugs and biologic products that have been well-characterized, such as insulin and certain vaccines. In the long term, collaborating with industry partners and recruiting talented researchers with expertise in drug development, manufacturing, and regulatory approval may eventually enable states to develop and manufacture novel drugs, as demonstrated by the success of MassBiologics.[189]

The path to public pharma is not likely to be frictionless. Parts III and IV discuss two major legal challenges likely to

---

183 *See* State Policy Toolkit, *supra* note 31, at 3–4.

184 Price II & Rai, *supra* note 108, at 1028 (noting the difficulties of manufacturing biologics, in part because slight variations in the manufacturing process can change the quality, safety, or efficacy of the end product).

185 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .").

186 *See* Price II & Rai, *supra* note 108, at 1028–29, 1042–45.

187 *Id.* at 1036–37.

188 *Id.* at 1036. *See generally* Steven Lucio, *The Complexities of Biosimilars and the Regulatory Approval Process*, 24 AM. J. MANAGED CARE S231 (Supp. 2018).

189 UMASS CHAN MEDICAL SCHOOL, *supra* note 167.

crop up for state-owned public pharmaceutical institutions: patents and FDA regulation.

III
Promoting Sovereign Patent Use

Patents offer their holders the exclusive right to make, use, and sell the subject of an invention—such as the chemical composition of a drug, methods of using a drug to treat a particular condition, new formulations or delivery systems for a drug, or methods of manufacturing a drug—for twenty years.[190] The patent system can be characterized as a *quid pro quo*—in exchange for a limited monopoly, patentees must fully disclose the invention so that the public may benefit from and improve the invention upon expiration of the patent. But patentees can hold an immense amount of unchecked market power over essential, inelastic goods, threatening public health at the expense of maximizing profit.

Although patents are a key tool that pharmaceutical companies use to exclude competitors from the market, they are not the only barrier. Data and marketing exclusivities awarded to innovator companies for obtaining approval for new chemical entities, new antibiotics, pediatric drugs, or orphan drugs also prevent the FDA from approving competitor drugs. States should generally seek to obtain FDA approval of the generic or biosimilar drugs they seek to produce. Some drugs may be subject to patent protection, but not FDA exclusivities. Such situations may arise where an innovator company files secondary (follow-on) patents, not on the chemical entity itself, but instead on minor improvements, newly discovered methods of use, or novel delivery systems.

Of course, states may simply choose to avoid manufacturing any drugs subject to patent or FDA exclusivities, as they are doing now. But this may raise serious ethical concerns. For instance, consider pre-exposure prophylaxis (PrEP), a highly effective method of preventing HIV in high-risk populations

190 35 U.S.C. § 271(a) (describing the exclusive rights of patent owners); 35 U.S.C. § 154(a)(2) (defining the term of a patent as 20 years from filing). The actual term of the patent may be shorter due to delay while the Patent Office reviews the patent application or while the FDA reviews and approves the drug application, or longer due to time added by Patent Term Adjustment, 35 U.S.C. § 154(b), which seeks to rectify Patent Office delay, or Patent Term Extension, 35 U.S.C. § 156, which seeks to compensate for FDA delay.

through routine antiviral use.[191] PrEP reduces the risk of contracting HIV from sex by about 99%, and from injection drug use by at least 74%.[192] Yet, HIV remains a persistent problem in the United States, with almost 32,000 new HIV infections in 2022.[193] Since 2001, Gilead Pharmaceuticals has manufactured antiretrovirals for use as PrEP, including Truvada (approved 2012) and Descovy (approved 2016), albeit at a cost of up to around $2,000 per month—a price that activists say contributes to the persistence of new infections each year.[194] Recently, Gilead reported that biannual injections of a new antiviral drug, lenacapavir, completely protected cisgender women from contracting HIV in a large Phase III trial.[195] In the study, none of the women who received lenacapavir contracted HIV. By contrast, about 1.5% of the women who received Truvada, and about 1.8% of women who received Descovy contracted HIV over the course of the trial. States that want to provide low-cost antiretrovirals for their citizens may only manufacture generic versions of Truvada—a less effective HIV prevention measure than lenacapavir—without infringing patents or impinging on FDA exclusivities. Thus, states seeking to address public health crises within their borders must understand their liability for intellectual property infringement in order to make informed decisions about public pharmaceutical production.

In the United States, sovereign immunity establishes that "sovereigns"—such as the federal government, states, and registered Native American tribes—generally cannot be sued in federal or state court without their express consent or waiver of this immunity. This Section does not take a normative position

---

191 *PrEP*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Feb. 18, 2025), https://www.cdc.gov/stophivtogether/hiv-prevention/prep.html [https://perma.cc/9U9X-NGSE].

192 *Id.*

193 *Fast Facts: HIV in the United States*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, (Apr. 22, 2024), https://www.cdc.gov/hiv/data-research/facts-stats/index.html [https://perma.cc/G7RU-E8HY].

194 *See, e.g.*, Kenyon Farrow, *The Downstream Impacts of High Drug Costs for PrEP Have Hindered the Promise of HIV Prevention*, 50 J. L. MED. & ETHICS 47, 48 (2022); Christopher Rowland, *An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But a Pharma Giant Is Making Billions*, WASH. POST (Mar. 26, 2019), https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html [https://perma.cc/S2YE-RSZR].

195 Jason Mast, *Gilead's Twice-Yearly Antiviral Protected Women from HIV Infection in Large Trial*, STAT (June 20, 2024), https://www.statnews.com/2024/06/20/hiv-prep-gilead-lenacapavir-women/.

on the doctrine of sovereign immunity but rather examines the availability of sovereign immunity as a defense wielded by the federal, tribal and state governments in patent law.

A. Tribal Immunity

In 2017, Allergan transferred six patents on its billion-dollar drug, Restasis® (cyclosporine eye drops), to the St. Regis Mohawk tribe, a federally recognized tribe in Franklin County, New York.[196] According to Allergan, the Tribe and its counsel approached Allergan with a "sophisticated opportunity."[197] Under the doctrine of sovereign immunity, the federal government, states, and federally recognized Native American tribes, such as the St. Regis Mohawk Tribe, are generally entitled to sovereign immunity from suit, such as in patent litigation. Coincidentally, a generic competitor had recently challenged the validity of several Restasis patents in *inter partes* review (IPR), a type of post-grant proceeding in which third parties can challenge the validity of recently issued patents at the USPTO Patent Trial and Appeals Board (PTAB).[198] Thus, Allergan and the Tribe theorized that transferring the Restasis patents to the Tribe would shield those six patents from being invalidated at the PTAB. In exchange for sheltering these patents, the Tribe would license the patents back to Allergan for a tidy sum of $13.75 million, plus $15 million in annual royalties from sales of the drug.[199]

In reality, the deal was conceived of and brokered by a wily patent lawyer in Texas named Michael Shore, who recognized that a patent held by a sovereign entity could be immune from being invalidated in a post-grant proceeding and therefore had a greater effective value.[200] Shore approached the St. Regis Mohawk Tribe and Allergan with the proposal, and subsequent discussions quickly led to both parties getting on board.[201]

---

196 Saint Regis Mohawk Tribe, *Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding Restasis® Patents* (Sept. 8, 2017), https://www.srmt-nsn.gov/news/2017/allergan-and-saint-regis-mohawk-tribe-announce-agreements-regarding-restasis-patents [https://perma.cc/DX65-54TF].

197 *Id.*

198 35 U.S.C. §§ 311–319 (statutes laying out procedure for *inter partes* review).

199 Saint Regis Mohawk Tribe, *supra* note 196.

200 Adam Davidson, *Why Is Allergan Partnering with the St. Regis Mohawk Tribe?: Inside the Bizarre World of Patent Law,* New Yorker (Nov. 13, 2017), https://www.newyorker.com/magazine/2017/11/20/why-is-allergan-partnering-with-the-st-regis-mohawk-tribe [https://perma.cc/WX54-LEWF].

201 *Id.*

The scheme resulted in mutual celebration and hope from both sides. Allergan's Restasis patents would be protected in the ongoing IPRs, and the deal would provide the Tribe with much-needed financial resources. Allergan added that they were "impressed with the Tribe's thoughtful and enterprising approach, which will allow them to achieve their goals of self-reliance and help them address the most urgent needs in their community."[202]

The idea was not entirely unfounded—in the very same year, the PTAB had dismissed several IPR proceedings on patents owned by two state universities based on their claims of sovereign immunity (hereinafter "University IPRs").[203] State sovereign immunity is well-established and codified in the Constitution itself.[204] The Eleventh Amendment states in relevant part that "the Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State."[205] In other words, it codifies the common law doctrine of sovereign immunity as applied to states. However, the sovereign immunity of states is broader than the Eleventh Amendment, which "does not define the scope of the States' sovereign immunity," but is "instead only one particular exemplification of that immunity."[206] In the University IPRs, the PTAB noted that the Supreme Court and Federal Circuit had interpreted the Eleventh Amendment to apply broadly to administrative proceedings.[207] The Board noted that its proce-

---

202 Saint Regis Mohawk Tribe, *supra* note 196.

203 Covidien LP v. University of Florida Research Foundation Inc., Nos. IPR2016-01274, IPR2016–01275, & IPR2016–01276, 2017 WL 4015009, at *1 (P.T.A.B. Jan. 25, 2017) (dismissing IPR on patent owned by the University of Florida for a system to integrate medical data from bedside machines, finding that the University was entitled to state sovereign immunity); Neochord, Inc. v. Univ. of Maryland, No. IPR2016-00208, 2017 Pat. App. LEXIS 12969, at *1 (May 23, 2017) (dismissing IPR against patent owned by the University of Maryland for the same reason).

204 *See* Hans v. Louisiana, 134 U.S. 1, 16 (1890) ("The suability of a State, without its consent, was a thing unknown to the law. This has been so often laid down and acknowledged by courts and jurists that it is hardly necessary to be formally asserted.").

205 U.S. CONST. amend. XI.

206 Fed. Mar. Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 752 (2002); *see also* Alden v. Maine, 527 U.S. 706, 728–29, 734 (1999) (holding that sovereign immunity is not derived solely from the Eleventh Amendment, but from "fundamental postulates" and "the Founders' understanding" of the Constitution).

207 *See Covidien LP*, 2017 WL 4015009, at *2–5; NeoChord, 2017 Pat. App. LEXIS 12969. at *6–7 (citing *Federal Maritime Comm'n*, 535 U.S. at 751, 757–59). For instance, in *Federal Maritime Comm'n*, the Supreme Court affirmed a ruling

dures for *inter partes* review bore a strong resemblance to the interference proceedings analyzed in *Vas-Cath*, and concluded that the patent owner universities were entitled to sovereign immunity in their respective IPR proceedings.[208]

Unfortunately for Allergan and the St. Regis Mohawk Tribe, the PTAB and Federal Circuit were not convinced. In 2018, the PTAB declined to grant motions to dismiss numerous IPRs on the Restasis patents (hereinafter "Restasis IPRs"), holding that tribal sovereign immunity cannot be asserted in post-grant review proceedings such as IPRs.[209] The Board noted that its precedent finding that state sovereign immunity applies to IPRs does not necessarily extend to tribal sovereign immunity, as the Supreme Court has held that "the immunity possessed by Indian Tribes is not co-extensive with that of the States."[210] Because an Indian tribe's sovereignty is "subject to the superior and plenary control of Congress,"[211] "general Acts of Congress," such as the provisions of the Patent Act that set forth

---

from the Fourth Circuit finding that the state of South Carolina was entitled to sovereign immunity in an administrative proceeding brought against the South Carolina Port Authority before the Federal Maritime Commission (FMC). 535 U.S. at 751. The Court catalogued numerous similarities between FMC proceedings and civil litigation in federal court, concluding that an FMC proceeding "walks, talks, and squawks very much like a lawsuit" and thus is "truly an adjudication" for the purposes of the Eleventh Amendment analysis. *Id.* at 743, 751, 757–59 (quoting 243 F.3d 165, 174 (4th Cir. 2001)) (noting that FMC adjudications bear a strong resemblance to civil litigation in federal courts). In *Vas-Cath, Inc. v. Curators of University of Missouri,* a case in which the Federal Circuit applied *Federal Maritime Comm'n* to an interference proceeding—a now-defunct type of administrative proceeding used to resolve disputes in patent ownership. Vas-Cath, Inc. v. Curators of Univ. of Mo., 473 F.3d 1376, 1382–83 (Fed. Cir. 2007)). In *Vas-Cath*, the Federal Circuit concluded that interference proceedings could be characterized as a lawsuit for the purposes of Eleventh Amendment immunity analysis, noting numerous similarities between the administrative proceeding and civil litigation. *Id.* at 1382–83. The Federal Circuit nevertheless concluded that the patent owner, the University of Missouri, was not entitled to its claim of sovereign immunity in the interference proceeding, because the state had consented to suit by initiating the interference and participating in the proceeding. *Id.* at 1383.

208 *Covidien LP*, 2017 WL 4015009, at*11–12; *NeoChord*, 2017 Pat. App. LEXIS 12969, at *6–10.

209 *See* Mylan Pharms. Inc. v. Saint Regis Mohawk Tribe, Nos. IPR2016–01127 IPR2016–01128, IPR2016–01129, IPR2016–01130, IPR2016–01131, & IPR2016–01132, 2018 WL 1100950, at *3–7 (P.T.A.B. Feb. 23, 2018) (quoting Kiowa Tribe of Okla. v. Mfg. Techs., Inc., 523 U.S. 751, 756 (1998)), aff'd, 896 F.3d 1322 (Fed. Cir. 2018).

210 *Id.* at *4 (quoting Kiowa Tribe of Okla. v. Mfg. Techs., Inc., 523 U.S. 751, 756 (1998)).

211 *Id.* at *4 (quoting Santa Clara Pueblo v. Martinez, 436 U.S. 49, 58 (1978)). *See also generally* United States v. Kagama, 118 U.S. 375 (1886) (affirming Congress's plenary power over Native American tribes); United States v. Lara, 541 U.S. 193 (2004) (same).

procedures for *inter partes* review, "apply to Indians . . . in the absence of a clear expression to the contrary."[212]

The Board's ruling was upheld by the Court of Appeals for the Federal Circuit later that year.[213] The Federal Circuit noted that tribal sovereign immunity is derived from common law and does not extend to actions brought by the federal government.[214] While there is no blanket rule that tribal immunity does not apply in federal agency proceedings,[215] this immunity generally does not apply where the federal government engages in an investigative action through an agency or pursues an adjudicatory agency action.[216] Thus, the question before the Federal Circuit was whether IPR proceedings are akin to civil litigation or to agency adjudication.

The appellees, generic drug companies seeking to enter the market for dry eye drops, argued that in IPRs, the PTAB is not adjudicating claims between parties but is instead reconsidering a grant of a government franchise, i.e., patents.[217] In assessing this argument, the Federal Circuit contrasted two recent Supreme Court cases describing the nature of IPR proceedings.[218] In *Oil States Energy Services v. Greene's Energy Group,* the Supreme Court held that an IPR is a matter "which arise[s] between the Government and persons subject to its authority,"[219] and IPR is "simply a reconsideration of" the USPTO's original grant of a public franchise, which serves to protect "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope."[220] On the other hand, in *SAS Institute Inc. v. Iancu*, the Court emphasized the "party-directed, adversarial" aspects of IPR which resemble civil litigation—the petitioner "define[s] the contours of

---

212 *Id.* at *4 (first quoting Fed. Power Comm'n v. Tuscarora Indian Nation, 362 U.S. 99, 116, 120 (1960); then citing 35 U.S.C. §§ 101, 261).

213 *See* Saint Regis Mohawk Tribe v. Mylan Pharms. Inc., 896 F.3d 1322, 1325 (Fed. Cir. 2018).

214 *Id.* at 1325.

215 *Id.* at 1326 (citing Fed. Mar. Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 754–56 (2002)).

216 *Saint Regis Mohawk Tribe*, 896 F.3d at 1325–26.

217 *Id.* at 1326.

218 *Id.* at 1327 (first citing SAS Inst. Inc. v. Iancu, 584 U.S. 357, 358–363 (2018); then citing Oil States Energy Servs., Inc. v. Greene's Energy Grp. LLC, 584 U.S. 325, 331 (2018)).

219 *Oil States Energy Servs., Inc.*, 584 U.S. at 334 (quoting Crowell v Benson, 285 U.S. 22, 50, 52 (1932)).

220 *Id.* (quoting Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261, 279–80 (2016)).

the proceeding," while the Director is only given the choice of whether to institute IPR.[221]

Analyzing *Oil States* and *SAS Institute,* the Federal Circuit concluded that IPR proceedings were more akin to agency enforcement actions than civil suits.[222] The Federal Circuit noted that USPTO procedures for IPR differ from the Federal Rules of Civil Procedure in key ways,[223] and the Director of the USPTO has broad discretion on whether or not to institute review, even if the petitioner eventually chooses not to participate in the proceeding—reinforcing the view that IPR is an act by the agency in reconsidering its own grant of a public franchise.[224] In contrast, the Federal Maritime Commission lacked such discretion, and thus its procedures "approximated a civil litigation" "much more closely."[225] Accordingly, the Federal Circuit concluded that "the USPTO is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies 'within their legitimate scope.'"[226] Thus, it followed that Allergan and the St. Regis Mohawk tribe could not assert tribal sovereign immunity to bar the investigation of the federal government, acting through the USPTO and wielding sovereignty superior to that of Native American tribes, into the validity of the Restasis patents.[227] While this holding was limited to tribal

---

221 *SAS Inst. Inc.*, 584 U.S. at 359-65 (2018).

222 *Saint Regis Mohawk Tribe*, 896 F.3d at 1327.

223 *Id.* at 1328–29 (offering examples of procedural distinctions between civil litigation and IPR, including that (1) the Federal Rules of Civil Procedure provide opportunities for a plaintiff to make liberal amendments to its complaint, while in IPR, a petitioner may only make clerical or typographical corrections to its petition; (2) a patent owner in IPR may seek to amend its patent claims during the proceedings, an option not available in civil litigation; (3) IPR lacks preliminary proceedings that exist in civil litigation, such as *Markman* hearings for claim construction; (4) discovery is highly limited in IPR; and (5) IPR "hearings are short, and live testimony is rarely allowed.").

224 *Id.* at 1327–28 (noting that, "although the Director's discretion in how he conducts IPR is significantly constrained, he possesses broad discretion in deciding whether to institute review" and "could deny review for other reasons such as administrative efficiency or based on a party's status as a sovereign"; additionally noting that once IPR has been initiated, "the Board may choose to continue review even if the petitioner [or patent owner] chooses not to participate, and the Director has even been granted the right to participate in appeals at the Board even if the private challengers drop out") (citations omitted).

225 *Id.* at 1329 (citing Fed. Mar. Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 760 (2002)).

226 *Id.* at 1329 (quoting *Cuozzo Speed Techs.,* 579 U.S. at 279–80).

227 *Id.* (citing Miccosukee Tribe of Indians of Fla. v. United States, 698 F.3d 1326, 1331 (11th Cir. 2012) ("Indian tribes may not rely on tribal sovereign immunity to bar a suit by a superior sovereign.")).

immunity in IPR proceedings,[228] in 2019, the Federal Circuit further held that state sovereign immunity does not apply to IPRs either.[229]

While the tale of Allergan's ill-conceived scheme to protect its Restasis patents was hardly sympathetic, tribal sovereign immunity doctrine contains an important lesson for states that seek to manufacture drugs. Scholars have noted an important weakness in FDA's enforcement authority: because FDA has no independent enforcement authority, it must rely on DOJ to bring suit in district court.[230] Thus, one may ask whether states can assert sovereign immunity as a defense to FDA enforcement actions in Article III courts, which the Federal Circuit distinguished from agency adjudication. Although FDA's authority is statutorily restricted by the Food, Drug, and Cosmetics Act (FD&C Act), which is generally limited to products that have moved or will move in interstate commerce,[231] FDA still has broad authority over drugs comprised of even a single component that has moved in interstate commerce.[232] Additionally, FDA has authority to seize

---

228 *Id.* at 1329 ("[W]e leave for another day the question of whether there is any reason to treat state sovereign immunity differently.").

229 *See* Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1330 (Fed. Cir. 2019).

230 *See, e.g.*, C. Joseph Ross Daval, *Litigating Authority for the FDA,* 100 WASH. U. L. REV. 175, 175 (2022); 28 U.S.C. § 516 ("Except as otherwise authorized by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General."); 28 U.S.C. § 519 ("Except as otherwise authorized by law, the Attorney General shall supervise all litigation to which the United States, an agency, or officer thereof is a party . . . ."); 5 U.S.C. § 3106 ("Except as otherwise authorized by law, the head of an Executive department . . . may not employ an attorney or counsel for the conduct of litigation . . . but shall refer the matter to the Department of Justice.").

231 PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, CASES AND MATERIALS: FOOD AND DRUG LAW 271–72 (4th ed. 2014). *See also* FD&C Act § 505, ch. 675, 52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355(a)) (stating that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" without FDA approval).

232 *See, e.g.*, United States v. Cassaro, Inc., 443 F.2d 153, 155 (1st Cir. 1971); Palmer v. United States, 340 F.2d 48, 49 (5th Cir. 1964); United States v. Allbrook Freezing & Cold Storage, 194 F.2d 937, 938–39 (5th Cir. 1952); Baker v. United States, 932 F.2d 813, 814 (9th Cir. 1991); United States v. Regenerative Scis., 878 F. Supp. 2d 248, 259 (D.D.C. 2012), *aff'd*, 741 F.3d 1314 (D.C. Cir. 2014). *But cf.* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 543 (1935) (holding that a product is no longer in interstate commerce after "it had come to a permanent rest within [a] State.").

misbranded or adulterated drugs[233] or falsely labeled biological products[234] without proving any connection to interstate commerce at all. Furthermore, FDA no longer has the burden of demonstrating a nexus to interstate commerce when its enforcement actions are challenged in court.[235] Due to the complexity of the drug supply chain, at least some components of a drug are likely to move in interstate commerce before arriving at a state-owned pharmaceutical manufacturing facility. Therefore, FDA would most likely have authority over drugs produced by state-owned public pharmaceutical institutions, even if those drugs are only distributed to state residents. Thus far, it seems that state-owned pharmaceutical operations have sought FDA licensing and approval for their facilities and products.[236]

While a full examination of how states must navigate FDA regulation in their public pharmaceutical operations is beyond the scope of this article, it is worth listing a number of open questions ripe for further examination. First, a state that seeks FDA approval of a patented generic drug may implicitly waive its sovereign immunity from suit by participating in Paragraph IV litigation.[237] Second, a state that launches a biosimilar may either launch "at risk" or initiate a "patent dance" under the Biologics Price Competition and Innovation Act (BPCIA)—participating in the patent dance would necessarily involve waiver of sovereign immunity, while launching

---

233 FD&C Act § 304(a)(2), ch. 675, 52 Stat. 1040, 1044 (1938) (codified as amended at 21 U.S.C. § 334).

234 Public Health Service Act § 351(b), ch. 373, 58 Stat. 682, 702 (1944) (codified at 42 U.S.C. § 262(b)).

235 Medical Device Amendments of 1976 § 709, Pub. L. 94-295, 90 Stat. 539, 583 (21 U.S.C. § 360j) (amending the FD&C Act).

236 CalRx and Amneal Pharmaceuticals' naloxone, for instance, is FDA-approved. *See* CAL. GOV., *supra* note 169.

237 Under the Hatch-Waxman Act, to seek FDA approval to market a generic drug before patents owned by the brand company expire, a generic applicant must provide a Paragraph IV certification that the patents covering that drug are, in their opinion, invalid, unenforceable, or will not be infringed by the generic product. Hatch-Waxman Act § 101, Pub. L. 98-417, 98 Stat. 1585, 1585 (1984) (codified as amended at 21 U.S.C. § 355). A State may submit a paragraph IV certification saying that, in its opinion, the listed patents are unenforceable against it on the basis of sovereign immunity. However, Paragraph IV certifications are considered artificial acts of infringement that would commence Hatch-Waxman litigation. By filing a Paragraph IV certification, the State has waived its sovereign immunity from suit and consented to the initiation of Hatch-Waxman litigation. *See* Vas-Cath v. Curators of Univ. of Mo., 473 F.3d 1376, 1383 (Fed. Cir. 2007) (holding that university had consented to patent infringement suit by initiating interference proceeding).

at risk may not.[238] Third, marketing and data exclusivities (that may or may not run concurrently with the patent) may prevent the FDA from approving a state's application for a generic or biosimilar drug, even if all of the patents directed to the drug have expired.[239]

As for solutions to navigating FDA authority, states may consider seeking emergency waivers for unapproved essential drugs during critical shortages, as many did in order to import essential medical equipment during the pandemic.[240] Compounded drugs may also be produced by registered pharmacies or outsourcing facilities, which can qualify for exemptions from FDA approval if they meet certain requirements, such as complying with current good manufacturing practices, submitting to FDA inspections, reporting adverse events, and providing FDA with certain information about products compounded.[241] Partnerships with compounding facilities, or creating state-owned compounding facilities may be a viable option to produce drugs in shortage.[242]

B. Federal Immunity

Under 28 U.S.C. § 1498 ("Section 1498"), a patent owner who believes their patent may be infringed by the federal government may file suit against the government in the Court of Federal Claims for recovery of "[r]easonable and entire compensation for such use and manufacture," but cannot obtain

---

238 For an overview of the patent dance, see Cheryl Wang & Kayleigh E. McGlynn, *How Biosimilars are Approved and Litigated: Patent Dance Timeline*, FISH (Aug. 12, 2020), https://www.fr.com/insights/ip-law-essentials/how-biosimilars-approved-litigated-patent-dance-timeline/# [https://perma.cc/M2VA-TC4J]. *See also generally* GOODWIN PROCTOR LLP, *§ 4:2. Patent Dance Overview*, *in* GUIDE TO BIOSIMILARS LITIGATION AND REGULATION IN THE U.S. (2023-2024 ed.).

239 *Frequently Asked Questions on Patents and Exclusivity*, FDA (Feb. 5, 2020), https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity/ [https://perma.cc/K7AS-W6HK].

240 *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN. (last updated June 12, 2025), https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization [https://perma.cc/CGX2-3HSG]; U.S. DEP'T HEALTH & HUM. SERVS., U.S. FOOD & DRUG ADMIN., OFFICE COMMISSIONER, OFFICE CHIEF SCI., OFFICE COUNTERTERRORISM & EMERGING THREATS, EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS (2017), https://www.fda.gov/media/97321/download [https://perma.cc/NHA3-E7Y3].

241 *See Information for Outsourcing Facilities*, U.S. FOOD & DRUG ADMIN. (last updated Mar. 29, 2022), https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities [https://perma.cc/W3F7-NZDG].

242 *See* Kumar, *supra* note 34, at 374–75.

an injunction against the government.[243] In other words, Section 1498 permits the federal government to make and use patented drugs without permission from a patent owner, so long as the government provides "reasonable compensation," which is often royalties of 10% or less of an infringer's sales.[244] Section 1498 constitutes an express, but limited waiver of the federal government's immunity to suit for patent infringement.[245]

In 1910, Congress passed the first iteration of Section 1498.[246] The 1910 Act enabled the government to continue using patented inventions for public benefit under eminent domain, while permitting patent owners to obtain reasonable damages for said use.[247] In 1918, the Act was amended to provide government contractors with immunity from patent infringement litigation.[248] In its current form, Section 1498(a) holds that whenever a patented invention is "used or manufactured by or for the United States without license of the owner thereof . . . the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."[249] The provision also states that infringing acts "by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."[250] While federal

---

243 28 U.S.C. § 1498(a). 28 U.S.C. § 1498(b) consists of similar procedures for bringing suit against the federal government for copyright infringement.

244 Morten & Duan, *supra* note 44, at 45 n.194 (noting that "numerous scholars have suggested that royalties of 10% or less of the infringers' sales are common in § 1498 cases, and that royalties of over 10% are rare").

245 Mary Ellen Coster Williams & Diane E. Ghrist, *Intellectual Property Suits in the United States Court of Federal Claims*, 10 LANDSLIDE 30, 30 (2017), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/september-october/intellectual-property-suits-united-states-court-federal-claims/ [https://perma.cc/6AJU-UNRA].

246 Act of June 25, 1910, Pub. L. No. 61-306, 36 Stat. 851.

247 *See* Crozier v. Fried. Krupp Aktiengesell-Schaft, 224 U.S. 290, 305 (1912); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1283 (Fed. Cir. 1988) ("The patentee takes his patent from the United States subject to the government's eminent domain rights to obtain what it needs from manufacturers and to use the same."), *abrogated on other grounds* by eBay Inc. v. MercExchange, LLC., 547 U.S. 388, 391–94 (2006).

248 Act of July 1, 1918, Pub. L. No. 65-132, 40 Stat. 705 (1918).

249 28 U.S.C. § 1498(a).

250 *Id.*

contractors are immune from suit, they must be provided with notice and opportunity to join as third parties.[251]

To prevail on a Section 1498 claim alleging infringing acts by a contractor, a patentee must prove that contractor was acting (1) "for the Government" and (2) "with the authorization or consent of the Government."[252] To establish that a contractor was acting for the Government, the infringing act must have been performed for benefit to the government which is not merely incidental[253]—for instance, "in furtherance and fulfillment of a stated Government policy."[254] The patentee must also show that the government provided either express or implied authorization or consent to the contractor's infringing activity.[255] For instance, a section of the Federal Acquisition Regulation (FAR), which contains standard clauses which may be included in federal government contracts, contains an express clause providing "authorization and consent" for the use and manufacture of any patented invention.[256] Implied authorization and consent may be shown where "(1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement."[257]

The federal government "routinely relies on" Section 1498 to use patented inventions,[258] from electronic passports[259] to software to help detect fraudulent checks.[260] In the twentieth century, the government also used Section 1498 to purchase generic versions of patented medicines, with agencies such as the Department of Defense and the Veterans Administration

---

251 U.S. CT. FED. CLAIMS RS. 4, 17–20.

252 28 U.S.C. § 1498(a).

253 *See* Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis, 583 F.3d 1371, 1376–79 (Fed. Cir. 2009).

254 IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1362 (Fed. Cir. 2014) (quoting Madey v. Duke Univ., 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006)).

255 TVI Energy Corp. v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986).

256 48 C.F.R. § 52.227-1 (2024). *See also* Sevenson Env't Servs., Inc. v. Shaw Env't, Inc., 477 F.3d 1361, 1367 (Fed. Cir. 2007) (discussing express authorization and consent clause in government contract).

257 Larson v. United States, 26 Cl. Ct. 365, 370 (1992).

258 Brennan et al., *supra* note 44, at 302.

259 *Id.* (citing IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1360 (Fed. Cir. 2014)).

260 *Id.* (citing Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis, 583 F.3d 1371, 1378–79 (Fed. Cir. 2009)).

deliberately purchasing drug products covered by U.S. patents.[261] Professor Amy Kapczynski and coauthors note that the most prominent case occurred in 1958, involving the Department of Defense negotiating to purchase the antibiotic tetracycline hydrochloride at a discount from an Italian supplier instead of from the U.S.-based patent owner, Pfizer.[262]

The only known example of the government using Section 1498 to obtain patented drugs in the twenty-first century involved anthrax. While biological weapons were not used against the United States or its allies during the Gulf War, post-conflict inspections by the United Nations in 1995 and 1996 revealed that Iraq had produced 8,000 liters of anthrax spore suspension, likely for use in biological warfare.[263] Concerned about the impending use of bioweapons in war, in 1997, then Secretary of Defense William Cohen announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield.[264] But obtaining enough doses of the vaccine would prove to be a problem. Since the 1970s, the DOD had been purchasing the anthrax vaccine from Michigan Biologics, the only facility in the country licensed to produce the vaccine.[265] In 1997 and 1998, the FDA identified numerous manufacturing problems at the facility, and BioPort could not secure approval from the FDA for the newly manufactured vaccine until January 31, 2002.[266] Thus, the privatization of Michigan Biologics culminated in a shortage of the anthrax vaccine from 1998-2002.[267]

This became a serious problem in 2001, when over 30,000 individuals in the United States were potentially exposed to anthrax distributed through the U.S. postal service.[268] The threat

---

261 *Id.* at 303–304 (citing *Patent Infringement: Hearing on S. 1047 Before the Subcomm. on Patents, Trademarks, & Copyrights of the S. Comm. on the Judiciary*, 89th Cong. 15 (1965) (Statement of Austin Smith, M.D., President, Pharmaceutical Manufacturers Association)).

262 *Id.* at 304–05 (citing Charles Pfizer & Co., Inc., B-141459, 119 U.S.P.Q. 187 (Comp. Gen.), at *1 (1960)).

263 NATIONAL ACADEMY OF SCIENCES & COMMITTEE TO ASSESS THE SAFETY AND EFFICACY OF THE ANTHRAX VACCINE, THE ANTHRAX VACCINE: IS IT SAFE? DOES IT WORK? (Lois M. Joellenbeck, Lee L. Zwanziger, Jane S. Durch & Brian L. Strom, eds. 2002), https://www.ncbi.nlm.nih.gov/books/NBK220522 [https://perma.cc/2JW3-85KJ] (hereinafter "National Academies Anthrax Vaccine").

264 *Id.*; GAO Anthrax Report, *supra* note 31, at 3.

265 GAO Anthrax Report, *supra* note 31, at 3.

266 National Academies Anthrax Vaccine, *supra* note 263.

267 State Policy Toolkit, *supra* note 31, at 17.

268 National Academies Anthrax Vaccine, *supra* note 263.

of domestic bioterrorism and the sparse availability of anthrax vaccines led the United States to seek to stockpile a patented antibiotic, ciprofloxacin (brand name Cipro), which could be used to treat individuals exposed to anthrax.[269] Bayer, the manufacturer of Cipro, refused to increase its production levels or sell the drug to the U.S. government at a reasonable price.[270] In response, Tommy Thompson, then Secretary of the HHS, threatened to import generic versions of ciproflaxin under Section 1498.[271] With the threat of Section 1498 looming overhead, Bayer eventually agreed to guarantee an adequate supply of ciprofloxacin at a discounted price.[272] While Section 1498 serves as a powerful tool for the federal government to protect public health from private interests, Cipro is the only known recent instance of the federal government invoking Section 1498 to protect access to drugs.[273]

Like federal contractors, state contractors may also be entitled to such derivative sovereign immunity to liabilities arising from work authorized by a state. Courts have applied various multi-factor tests to determine when state contractors are acting as arms of the state or its alter ego,[274] including factors such as the level of autonomy the contractor has in executing the contracted work and whether any judgment rendered against the entity would be paid by the state.[275] Thus,

---

269 Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 794 (2016).

270 *Id.*

271 *Id.*

272 *Id.*

273 *Id.*

274 *See* Kate Sablosky Elengold & Jonathan D. Glater, *The Sovereign Shield*, 73 STAN. L. REV. 969, 988 n.81 (2021) (first citing S.C. Dep't of Disabilities & Special Needs v. Hoover Universal, Inc., 535 F.3d 300, 303 (4th Cir. 2008) (setting out a nonexhaustive list of four factors to be considered in determining whether "a State-created entity is functioning as an arm of the State or its alter ego"); then citing Breakthrough Mgmt. Grp., Inc. v. Chukchansi Gold Casino & Resort, 629 F.3d 1173, 1181 (10th Cir. 2010) (setting out six factors to determine whether a tribal economic entity is entitled to tribal immunity)).

275 The Fourth Circuit's test for determining whether "a State-created entity is functioning as an arm of the State or its alter ego" and is therefore entitled to derivative sovereign immunity is set out in a nonexhaustive list of four factors:

> (1) whether any judgment against the entity as defendant will be paid by the State or whether any recovery by the entity as plaintiff will inure to the benefit of the State; (2) the degree of autonomy exercised by the entity, including such circumstances as who appoints the entity's directors or officers, who funds the entity, and whether the State retains a veto over the entity's actions; (3) whether the entity is involved with state concerns as distinct from non-state concerns, including

states that wish to establish public pharmaceutical manufacturing institutions should weigh the risks of contracting with private entities for manufacturing drugs. Contractors are often wary of contracting with states that are not amenable to suit unless the state waives their sovereign immunity in the contract itself.[276] Interestingly, both CalRx contracts with Civica and Amneal Pharmaceuticals contain indemnification clauses, requiring Civica and Amneal to indemnify, defend, and hold harmless the California Department of Health Care Access and Information and its officers from liabilities, including patent infringement.[277] While some states may be able to negotiate for such indemnification, states that cannot do so must consider whether they exert enough control over their contractors in their respective jurisdictions such that their contractors are entitled to derivative sovereign immunity. Nevertheless, for the reasons articulated in Part II, contracting with private entities is a temporary fix to the issues that public pharma seeks to address. In order to create a robust public pharmaceutical sector, states must invest in state-owned facilities for drug development, manufacturing, and distribution, rather than contracting these essential tasks out to private entities.

C. State Immunity

While the federal government has enacted a limited waiver of its sovereign immunity in 28 U.S.C. § 1498, there are no equivalent statutes by which states have expressly waived their sovereign immunity to patent infringement claims. This Section describes the contours of state sovereign immunity, including its application to claims of patent infringement against states and how Congress might abrogate state sovereign immunity to patent infringement. The following section discusses

---

> local concerns; and (4) how the entity is treated under state law, such as whether the entity's relationship with 'the State [is] sufficiently close to make the entity an arm of the State.'

S.C. Dep't of Disabilities & Special Needs v. Hoover Universal, Inc., 535 F.3d 300, 303 (4th Cir. 2008) (quoting Md. Stdium Auth. v. Ellerbe Becket, Inc., 407 F.3d 255, 262 (4th Cir. 2005)).

276 *See, e.g.*, Sarah Garvey & Alex C. Lakatos, *Managing Sovereign Immunity Risk on a Transaction—What Commercial Parties Need to Know*, MAYER BROWN (July 10, 2024), https://www.mayerbrown.com/en/insights/publications/2024/07/managing-sovereign-immunity-risk-on-a-transaction-what-commercial-parties-need-to-know/[https://perma.cc/2R4Z-ZACE].

277 *See, e.g.*, *Biosimilar Insulin Agreement with Civica Foundation*, *supra* note 170; *Naloxone Access Agreement with Amneal Pharmaceuticals*, *supra* note 171.

why state-owned public pharma institutions must assess the risk of suits against state officers.

In 1793, the Supreme Court held in *Chisholm v. Georgia* that a citizen of one state could sue another state.[278] Two years later, *Chisholm* was overruled in the ratification of the Eleventh Amendment, which states that the "Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State . . . ."[279] A century later, the Court held in *Hans v. Louisiana* (1890) that the Eleventh Amendment precludes suits brought by state citizens against their own state in federal court to enforce federal constitutional provisions, reasoning that "the Constitution was not intended to raise up any proceedings against the States that were anomalous and unheard of when the Constitution was adopted."[280] Another century passed before the Court established in *Alden v. Maine* (1999) that states are entitled to sovereign immunity from suit brought by their citizens in their own state courts.[281] In *Seminole Tribe v. Florida* (1999), the Court further strengthened the doctrine of state sovereign immunity by holding that Congress could not abrogate state sovereign immunity by using its Article I power to regulate interstate commerce to expand the scope of federal courts' jurisdiction

---

278 Chisholm v. Georgia, 2 U.S. 419, 450–52 (1793) (opinion of Blair, J.).

279 U.S. CONST. amend. XI.

280 Hans v. Louisiana, 134 U.S. 1, 18 (1890). *See also id.* at 13 (quoting FEDERALIST NO. 81 (Alexander Hamilton) (Clinton Rossiter ed., 1961) ("It is inherent in the nature of sovereignty not to be amenable to the suit of an individual *without its consent*. This is the general sense, and the general practice of mankind; and the exemption, as one of the attributes of sovereignty, is now enjoyed by the government of every State in the Union. Unless, therefore, there is a surrender of this immunity in the plan of the convention, it will remain with the States . . . . The contracts between a nation and individuals are only binding on the conscience of the sovereign, and have no pretensions to a compulsive force. They confer no right of action, independent of the sovereign will. To what purpose would it be to authorize suits against States for the debts they owe? How could recoveries be enforced? It is evident, it could not be done without waging war against the contracting State; and to ascribe to the federal courts, by mere implication, and in destruction of a pre-existing right of the State governments, a power which would involve such a consequence, would be altogether forced and unwarrantable."); Fed. Mar. Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 755 (2002) (citing *Hans*, 134 U.S. 1, presumption of immunity to hold that FMC adjudications were akin to the type of proceedings from which the Framers believed States were immune).

281 Alden v. Maine, 527 U.S. 706, 728–29 (1999) (holding also that sovereign immunity is not derived solely from the Eleventh Amendment, but from "fundamental postulates" and "the Founders' understanding" of the Constitution).

under Article III.[282] A few years later the Court narrowed that holding in *Central Virginia Community College v. Katz* (2006), holding that states had no immunity from bankruptcy claims in federal court.[283]

Recent Supreme Court precedent holds that Congress may not abrogate state sovereign immunity from patent or copyright infringement suits without evidence of widespread and persisting infringement by states and inadequate remedies under state law. In 1999, the Supreme Court examined whether Congress could abrogate state sovereign immunity to patent infringement in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*. In *Florida Prepaid*, Congress passed an amendment to the Patent Act which, among other things, attempted to abrogate the sovereign immunity of states in patent matters.[284] The Supreme Court held this abrogation to be unconstitutional because it was beyond the scope of Congress's § 5 powers to enforce the Fourteenth Amendment for two reasons. First, the Act was not supported by a legislative record showing "widespread and persisting deprivation of constitutional rights" and "intentional or reckless infringement on the part of States"—although the Court did not provide guidance on what acts on the part of States might rise to this level.[285] And second, Congress did not consider whether adequate state remedies were available to rights-holders.[286] The Court also noted that any abrogation of state immunity should be proportionate to the injury it purports to address.[287]

In 2020, the Court applied *Florida Prepaid* to an analogous copyright statute. In *Allen v. Cooper*, the Court examined

---

282 Seminole Tribe v. Florida, 517 U.S. 44, 64 (1996).

283 Cent. Va. Cmty. Coll. v. Katz, 546 U.S. 356, 362 (2006).

284 Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 631–32 (1999) (citing Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. 102-560, 106 Stat. 4230 (1992) (codified at 35 U.S.C. §§ 271(h), 296(a)).

285 527 U.S. at 645 (quoting City of Boerne v. Flores, 521 U.S. 507, 526 (1997).

286 527 U.S. at 643 ("[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.") (first citing Parratt v. Taylor, 451 U.S. 527, 539–541 (1981); then citing Hudson v. Palmer, 468 U.S. 517, 532–533 (1984)).

287 527 U.S. at 628, 639, 646 (noting that the provisions of the Patent Remedy Act were "so out of proportion to a supposed remedial or preventive object that [they] cannot be understood as responsive to, or designed to prevent, unconstitutional behavior." (quoting City of Boerne, 521 U.S. at 532 (1997))).

an amendment to the Copyright Act that purported to abrogate the sovereign immunity of states in copyright matters.[288] Once again, the Court found that the abrogation of state sovereign immunity was unconstitutional for the same reasons laid out in *Florida Prepaid*—Congress had not provided sufficient evidence in the record of widespread and persisting infringement by states and a lack of state law remedies to address injuries.[289] In both cases, the Court also made it clear that Congress does have the authority to abrogate state sovereign immunity through the Fourteenth Amendment if it found sufficient evidence of widespread and persisting, intentional or at least reckless patent infringement by states for which there were no adequate state remedies available.[290]

After *Allen v. Cooper* was decided, Senators Thom Tillis and Patrick Leahy asked the USPTO to undertake a study of the extent to which patent and trademark owners experience infringement by states and state entities without adequate remedies under state law and the extent to which such infringement may be intentional or reckless.[291] The USPTO report laid out several key findings. First, it found that from 1985 to the present, there were seventy-eight instances of asserted state infringements (of which sixty-eight were actually litigated), including forty-nine patent and twenty-nine trademark suits.[292] However, the USPTO took no position on whether this number was evidence of "widespread and persisting" intellectual property infringement.[293] The report also noted that there was not enough evidence to draw a conclusion about the extent to which states' infringement is intentional or reckless due to a lack of court decisions on intentionality.[294] They found that willful infringement was asserted in thirty-six of the cases that were actually litigated, but that is not necessarily a reliable measure of actual intentional or reckless conduct, because a patent plaintiff has a clear motive to assert willful infringement

---

288 Allen v. Cooper, 589 U.S. 248, 253 (2020) (citing Copyright Remedy Clarification Act of 1990 § 2(a), 17 U.S.C. § 511(a)).

289 *Id.* at 264–65.

290 *See id.* at 249; Fla. Prepaid, 527 U.S. at 645 (1999). *See also City of Boerne*, 521 U.S. at 526–27; *see also generally* Fitzpatrick v. Bitzer, 427 U.S. 445 (1976).

291 U.S. Patent & Trademark Off., Report to Congress: Infringement Disputes Between Patent and Trademark Rights Holders and States and State Entities 9 (Aug. 31, 2021), https://www.uspto.gov/sites/default/files/documents/USPTO-Report-to-Congress-August2021.pdf/ [https://perma.cc/MPG8-5ALX].

292 *Id.* at 6.

293 *Id.* at 4, 8–9.

294 *Id.* at 9–10.

at the complaint stage.[295] And finally, the PTO concluded that there may be significant obstacles to recovery under state law, due to wide variation in state laws governing waiver of sovereign immunity, takings claims in state court, and tort and contract claims.[296]

As of now, until Congress is armed with sufficient evidence of widespread and persisting patent infringement, states continue to be entitled to sovereign immunity in patent litigation. However, this is complicated by the fact that there are various possibilities for interpreting "widespread and persisting." For instance, is this standard based on the number of lawsuits initiated, the number of patents alleged to be infringed, lost profits, the number of states engaged in such infringement, or something else? In the short term, states may be able to avoid "widespread and persisting" infringement by being selective about which drugs are chosen for manufacture. States may choose to be selective based on factors such as which drugs are most critical to manufacture based on shortages, prices, and which drugs are most needed by its residents. In the long term, states should also assess the availability of adequate remedies for patent owners under state law.

Even if states are entitled to claim sovereign immunity from suit for patent infringement, the path is not clear for them to proceed with manufacturing patented drugs. If a state cannot be sued for damages, alternate remedies may be available for patent owners. In *Ex Parte Young,* shareholders of railroad companies sought a federal injunction against a state attorney general who sought to enforce a state rate-setting scheme.[297] The attorney general maintained that shareholders could wait to challenge the law until an enforcement proceeding was brought against the railroads, but the Court found that injunctive relief would be "undoubtedly the most convenient, the most comprehensive and the most orderly way in which the rights of all parties can be properly, fairly and adequately passed upon."[298]

Ex Parte Young established the "legal fiction" of officer immunity doctrine: a state official seeking to enforce an unconstitutional state law is stripped of their authority and therefore

295 *Id.* at 10.

296 *Id.* at 10–14.

297 Ex Parte Young, 209 U.S. 123, 127–128, 143 (1908).

298 *Id.* at 166.

their immunity from suit.[299] The doctrine permits parties to seek injunctions against state officers acting on behalf of States in federal court when the State action is unconstitutional or contrary to federal law. Indeed, the lawsuits against states that sought to pass drug price negotiation statutes all named state attorneys general as defendants.[300]

There are generally two situations in which *Young* has been applied. The first and "most important application" of the doctrine is where "there is no state forum available to vindicate federal interests."[301] Of this application, the Court has said: "Neither in theory nor in practice has it been shown problematic to have federal claims resolved in state courts where Eleventh Amendment immunity would be applicable in federal court but for an exception based on *Young*. . . . Assuming the availability of a state forum with the authority and procedures adequate for the effective vindication of federal law, due process concerns would not be implicated by having state tribunals resolve federal-question cases."[302] For instance, in *Idaho v. Coeur d'Alene Tribe of Idaho*, the Court further held that *Young* relief was precluded because a state forum was available to adjudicate an officer suit alleging an ongoing violation of federal law.[303]

Thus, states that expect to incur some risk of patent infringement in their public pharma operations might opt to offer patent owners reasonable compensation through state eminent domain laws or by implementing special state law equivalents to 28 U.S.C. § 1498. While a patentee could conceivably argue that any compensation under state law is inadequate, it could hardly be said that a standard which the federal government itself uses to determine "reasonable compensation" for patent infringement under § 1498 cannot be adequate under a state remedy. In fact, many state constitutions provide broad constitutional protections for takings.[304] As the Court noted in

---

299 *Id.* at 159–60 ("If the act which the state attorney general seeks to enforce be a violation of the Federal Constitution, the officer, in proceeding under such enactment, comes into conflict with the superior authority of that Constitution, and he is in that case stripped of his official or representative character and is subjected in his person to the consequences of his individual conduct.").

300 *See* cases cited *supra* Section II.B.

301 Idaho v. Coeur d'Alene Tribe of Idaho, 521 U.S. 261, 270–71 (1997).

302 *Id.* at 274–75.

303 *Id.* at 270–71, 274–75.

304 2A NICHOLS ON EMINENT DOMAIN, § 6.01[12][c] (2025) (discussing States passing constitutional amendments so that property "could not be taken or damaged for public use without just compensation. Approximately one-half of the state

Coeur d'Alene Tribe of Idaho, "[a]ssuming the availability of a state forum with the authority and procedures adequate for the effective vindication of federal law, due process concerns would not be implicated by having state tribunals resolve federal-question cases."[305]

The second application of *Ex Parte Young* is for cases that call for the interpretation of federal law. This reasoning is described as the interest in having federal rights vindicated in federal courts, as well as the necessity of avoiding "excessive and oppressive penalties, [the] possibility of [a] multiplicity of suits causing irreparable damage, or [the] lack of proper opportunities for [state] review."[306] Thus, there remains a question as to whether there is a special interest in having a patent right, an exclusivity granted by federal law, vindicated in federal courts. However, the Court has noted that "States have real and vital interests in preferring their own forums in suits brought against them,"

> and "[a] doctrine based on the inherent inadequacy of state forums would run counter to basic principles of federalism. . . . Interpretation of federal law is the proprietary concern of state, as well as federal, courts. It is the right and duty of the States, within their own judiciaries, to interpret and to follow the Constitution and all laws enacted pursuant to it, subject to a litigant's right of review in this Court in a proper case."[307]

There remains a question as to whether these state patent use laws would be preempted by federal patent law. In *Biotechnology Industry Organization v. District of Columbia* (*BIO v. D.C.*), the Federal Circuit held that a D.C. law prohibiting the sale of

---

constitutions contain similar provisions today." (footnote omitted)). *See* also ABA, FIFTY-STATE SURVEY: LAW OF EMINENT DOMAIN (William G. Blake ed., 2012). Consistent with these constitutional obligations, many States have developed a range of procedures to protect both owners and condemning authorities in eminent domain and inverse-condemnation proceedings. That makes sense given the States' historic role in creating, defining, and defending property rights. See Bd. of Regents of State Colls. v. Roth, 408 U.S. 564, 577 (1972); Rogers v. Tenn., 532 U.S. 451, 461 (2001); Murr v. Wisconsin, 582 U.S. 383, 393–94 (2017). *See* also Brief of Minn., Ala., Alaska, Idaho, Indi., La., Miss., Neb., N.J., N.C., N.D., Ohio, Oklahoma, Or., S.C., Utah, and Va. as *Amici Curiae* in Support of Respondent, Devillier v. Texas, 601 U.S. 285 (2023) (No. 22-913), https://www.supremecourt.gov/DocketPDF/22/22-913/293931/20231220171024725_Devillier%20v.%20Texas%20-%20Amici%20Curiae%20Brief.pdf/[https://perma.cc/BV7D-BRBZ].

305 Idaho v. Coeur d'Alene Tribe of Idaho, 521 U.S. 261, 275 (1997).

306 *Id.* at 273–74, (quoting Charles Warren, *Federal and State Court Interference*, 43 HARV. L. REV. 345, 377–378 (1930)).

307 *Id.* at 275.

patented prescription drugs for an "excessive price" stood as an obstacle to the balance of objectives in federal patent law and was therefore impliedly preempted by the Patent Act.[308] This case has been the subject of much criticism and could impede states seeking to regulate drug prices.[309] However, suits against states for patent infringement cannot currently arise under any federal law. As discussed earlier, the Court struck down Congress's attempt to abrogate state sovereign immunity to patent infringement in *Florida Prepaid*.[310] Thus, the current Patent Act does not provide for a claim for relief against states for alleged patent infringement and should not be preempted by a state scheme to compensate patent owners for infringement committed by states. Future research and scholarship should assess whether such laws would pass muster under the precedent created by *BIO v. D.C.* and how to best overcome this precedent.

In *Seminole Tribe*, the Court also found that the application of *Ex Parte Young* was inappropriate where Congress had created an intricate remedial scheme.[311] Another proposal might be that Congress, which clearly remains interested in abrogating state sovereign immunity for intellectual property infringement, might be the one to enact a state law version of § 1498 to provide patent owners with reasonable compensation for patent infringement. Of course, given Congress's inaction to reform pharmaceutical patent abuse, states might prefer to provide remedies under their own laws.

CONCLUSION

With skyrocketing drug prices in the United States, states—which have traditionally had broad powers to protect public health—must consider a variety of options to ensure their citizens have access to essential medicines. The panacea of legal tools to reform drug pricing, including march-in petitions under the Bayh-Dole Act and government patent use under

---

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

309 *See, e.g.*, Wolitz, *supra* note 48, at 429–30; Camilla A. Hrdy, *The Reemergence of State Anti-Patent Law*, 89 U. COLO. L. REV. 133, 140–41 (2018) (arguing that the appropriate patent preemption standard should focus on the IP Clause, rather than congressional intent in enacting the Patent Act); 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.

310 *See supra* Section III.C.

311 *See* Seminole Tribe of Fla. v. Florida, 517 U.S. 44, 74 (1996).

§ 1498, have yet to yield much effect. While the provisions of the Inflation Reduction Act that empower Medicaid to negotiate prices with industry hold promise, the scope of the IRA is limited and leaves plenty of room for industry to collude and avoid negotiation. Gaps in the drug market created by both supply and pricing issues create a prime opportunity for governmental intervention to protect public health. By empowering states to take back the power to create drugs for the public, public pharma can serve as one solution to critical drug shortages and inaccessible drug prices.

Many states, including California, Massachusetts, and Michigan, have created or are considering creating public pharmaceutical manufacturing, purchasing, and distribution networks. However, partnering with private industry—nonprofit or not—is only a temporary fix. To reap the full benefits of public pharma, including curating public knowledge and strengthening domestic supply, states must invest in manufacturing facilities fully owned and operated by state entities. In the near future, these states must consider how public pharma institutions might expose the state entities and officers involved to a variety of liabilities. First, states that anticipate liability for patent infringement should be selective in manufacturing drugs to avoid the appearance of intentional or reckless and "widespread and persisting" patent infringement. Second, if states decide that it is essential to manufacture certain patented drugs, they should consider whether state eminent domain laws provide an avenue for patent owners to recover reasonable compensation. If not, they should consider amending their eminent domain laws to expressly waive their immunity to patent infringement claims, enacting a state law equivalent of 28 U.S.C. § 1498. Such eminent domain laws provide reasonable compensation for Fifth Amendment takings, possibly preempting Takings and Due Process constitutional challenges, as well as challenges seeking injunctions against state-officer action. The challenges that states face in producing drugs constrained by federal patent and FDA law are many, but if nothing else, state investment into public pharmaceutical production might serve as a valuable catalyst for the federal government to take action.[312]

312 *See generally* Kumar, *supra* note 44.