UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

XAVIER BECERRA, In his official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Defendant.

Case No. 3:23-csv-14221-ZNQ-DEA

[PROPOSED] BRIEF OF LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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IDENTITY AND INTERESTS OF PROPOSED *AMICI CURIAE*[1]

Amici are law professors and scholars who focus their scholarship and teaching on intellectual property law, property law, regulatory law, and health law.[2] They write to address the plaintiff, Novartis Pharmaceuticals Corporation (Novartis), contention that the Medicare drug price negotiation program effectuates a taking of personal property in violation of the Fifth Amendment. Amici submit this brief to provide the Court with the historical and legal background necessary to understand two issues: first, the constitutionality of government price negotiations and price regulations; second, the federal government's use of patents. The amici explain how Courts have historically ruled on these questions, as well as the far-reaching consequences that a ruling in Novartis's favor would have on the federal government's ability to provide adequate healthcare to across the United States.

I. INTRODUCTION

Today, about three in ten Americans cannot afford their prescription drugs.[3] High prices also drive-up insurance premiums and public spending, diverting resources from other priorities. The most decisive driver of high drug prices are the monopoly rights that governments grant to drug makers, allowing them to exclude competitors and raise prices.[4] Responding to this deadly

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[1] Amici and their counsel are the sole authors of this brief. No party or counsel for a party authored any piece of this brief or contributed any money intended to fund its preparation or submission.

[2] Four professors in particular have guided the research, drafting, and editing of this brief: Amy Kapczynski, Christopher J. Morten, Aaron S. Kesselheim, & Ameet Sarpatwari.

[3] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, THE KAISER FAMILY FOUNDATION (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

[4] Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for*

dilemma, Congress passed the Inflation Reduction Act (IRA) and, with it, the Medicare drug price negotiation program.

This new program enables the Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (CMS), to negotiate with drug makers over the prices of a small number of drugs that the Medicare program purchases. In so allowing, this law modifies a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—the "non-interference" provision—that prevented the federal government from negotiating the prices of retail medicines it buys via Part D insurance plans that operate its Medicare Part D program. This non-interference provision—a product of extensive pharmaceutical lobbying[5]—has been anomalous since its inception. The federal government negotiates prices and receives discounts on most contracts it enters, including for drugs it purchases for patients covered by the Veterans Health, Section 340B, and Medicaid programs.[6] Yet, it is forbidden from doing the same for Medicare. The IRA's Medicare drug price negotiation program marks an attempt to bring Medicare in line with the other government-sponsored insurance programs, for a limited number of high-revenue drugs, many years after their makers put them on the market.

Novartis now argues that they have a constitutional right to the monopoly prices they have

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Prescription Drugs in the United States, 177 (11) JAMA INTERNAL MED. 1 (2017); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform*, 316 (8) JAMA 858 (2016).

[5] *See* Judie Svihula, *Political Economy, Moral Economy and the Medicare Modernization Act of 2003*, 35 J. SOCIO & SOC. WELFARE 157, 161 (2008); *Drug Industry and HMOs Deployed an Army of Nearly 1,000 Lobbyists to Push Medicare Bill, Report Finds*, PUB. CITIZEN (June 23, 2004), https://www.citizen.org/news/drug-industry-and-hmos-deployed-an-army-of-nearly-1000-lobbyists-to-push-medicare-bill-report-finds.

[6] *See infra* Section II.A.1.

been charging the government. Pharmaceutical companies enjoy some of the highest profit margins in the United States—and will continue to do so even after full implementation of this program.[7] But this reality does not endow them with a Fifth Amendment *right* to a certain price or level of profits when negotiating with the federal government for the purchase of goods—especially when those profits drain the public fisc, directly harm millions of Americans, and flow from government-granted privileges.[8]

The government may negotiate the prices of goods it purchases. The courts have long recognized that the federal government, like any private party, is authorized to negotiate the prices of the goods it purchases without running afoul of the Takings Clause. There is no constitutional entitlement to government purchase of goods at prices a seller unilaterally dictates. Nor is there any rule against the government, or any other purchaser, negotiating in bulk. Suppliers of government purchase orders must accept negotiated terms as a condition of their sales to federal programs. Novartis understands this: they voluntarily participate in the Veterans Health, Section 340B, and Medicaid programs, each of which requires them to negotiate prices and offer price discounts.[9] This rule alone settles the question this case presents. Price negotiations that discipline public

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[7] *See* Sean Dickson & Jeromie Ballreich, *How Much Can Pharma Lose? A Comparison of Returns Between Pharmaceutical and Other Industries*, WESTHEALTH POL'Y CTR. 3 (2019) ("[L]arge pharmaceutical manufacturers could endure significant revenue reductions . . . and still achieve the highest returns of any market sector.").

[8] In *Dayton Area Chamber of Com. v. Becerra*, the Court recently denied the plaintiffs' motion for preliminary injunction, concluding that the plaintiffs failed to show "that no set of circumstances exist where the [Medicare drug price negotiation program] would be constitutionally valid," as is required to "demonstrate a strong likelihood of success on the merits of a constitutional challenge at the preliminary injunction stage." No. 3:23-CV-156, 2023 WL 6378423, at *10 (S.D. Ohio Sept. 29, 2023). There, the plaintiffs alleged the drug price negotiation program violated the Fifth Amendment Due Process Clause. *Id.*

[9] *See infra* Section II.A.1.

spending do not give rise to a constitutional claim.

The government may regulate prices within an industry. Novartis also implies that the Medicare drug pricing negotiation program violates the Takings Clause because they have no realistic option but to participate in it due to the size of the Medicare market and the take-or-leave-it nature of the program. That too is false. The government not only has the right to negotiate in bulk for the program as a whole, but also holds the power to *set* prices in an industry like this one, without interference from the Takings Clause. The Supreme Court has declared the constitutionality of state and federal price regulations to be "settled beyond dispute."[10] Thus, even viewed as a mandatory price regulation—which it is not—the Medicare drug price negotiations do not violate the Takings Clause. Precedent teaches that price regulations are particularly justified and do not implicate the Takings Clause in industries that receive significant government privileges and are highly regulated. Here, drug makers' sales of patented and FDA-approved medicines meet both conditions. First, government-granted privileges, such as patents, data exclusivities, and tax credits, drive the profitability of the pharmaceutical industry. Second, the healthcare and pharmaceutical industry is arguably the most regulated in the country. As a result, Congress's authority to control drug prices extends far beyond that which the IRA achieves: even a mandatory price regulation affecting *all* drugs the industry sells, not just those purchased by Medicare, would be constitutional. Price regulations are a fair and logical trade for the privileges the government has granted drug makers.

Finding a taking here would unravel the principal government healthcare programs. Finally, accepting Novartis's position would have far reaching ramifications for access to healthcare within

[10] *Fed. Commc'ns Comm'n v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987).

the United States. Such a ruling would not only jeopardize the continued operation of the Medicare program, but also undermine the cost containment measures—price negotiations—that enable the Medicaid and Veterans Health programs to function. Indeed, when raised, courts have uniformly rejected Taking Clause challenges to the price negotiations in these programs. This Court should follow suit and decline to overturn decades of settled precedent. Finding that companies and individuals hold constitutional rights to profit from their contracts with government health programs would either invalidate or otherwise transform such programs into compensable takings, miring the courts in a morass of takings lawsuits.

The government may use patents, irrespective of whether patents are personal property subject to the Taking Clause. Congress and the courts have been equally clear that the government may use patents it does not hold to manufacture more affordable versions of patented technologies without running afoul of the Taking Clause. Novartis's states that its medicines are patented, seemingly to shore up its property claim.[11] However, Novartis does not explicitly argue that its patents are personal property subject to the Fifth Amendment's Taking Clause.[12] This is with good reason: the Supreme Court has never so held, and the lower court that has reached the issue held that patents do not qualify as private property subject to the Taking Clause. The Court, however, need not reach this issue as the parties have neither directly raised nor briefed it.

[11] Novartis Memo. of Points and Authorities in Support of Plaintiff's Mot. for Summary Judgment (Novartis S.J. Br.), *Novartis v. Becerra*, Civ. A. No. 23-14221, ECF No. 18 (D.N.J. Nov. 11, 2023) at 13.

[12] *Id.* at 13.

II. ARGUMENT

A. Novartis's core claim—that the federal government should not be allowed to negotiate drug prices—runs contrary to a century of precedent and would jeopardize government healthcare programs, including Medicaid and Medicare.

1. The government can and routinely does negotiate to form contracts for goods and services, including drugs, without implicating the Takings Clause.

Courts have consistently held that "no one has a 'right' to sell to the government that which the government does not wish to buy."[13] The government, "just like any other party participating in an economic market, is free to engage in the efficient procurement and sale of goods and services."[14] To assist in this "efficient procurement," the government holds the authority to (1) "determine those with whom it will deal,"[15] (2) "fix the terms and conditions upon which it will make needed purchases,"[16] and (3) negotiate the prices it will pay for goods and services.[17] Such contracting does not implicate the Takings Clause. The federal government contracts in its

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[13] *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980).

[14] *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016).

[15] *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). *See J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"); *Curtiss-Wright Corp. v. McLucas*, 364 F. Supp. 750, 754 (D.N.J. 1973) ("Courts should not . . . subject purchasing agencies of the Government to the delays necessarily incident to judicial scrutiny at the instance of potential sellers . . . [when a] like restraint applied to purchasing by private business would be widely condemned as an intolerable business handicap.").

[16] *Perkins*, 310 U.S. at 127.

[17] *See Honolulu Rapid Transit Co. v. Dolim*, 459 F.2d 551, 553 (9th Cir. 1972) ("[T]he Supreme Court has left no doubt that the Federal Government enjoys power to conclude commercial bargains;" concluding "transaction had 'passed out of the range of the Fifth Amendment' and was a situation where '[p]arties . . . bargain between themselves as to compensation'" (citing *Albrecht v. United States*, 329 U.S. 599, 603-04 (1947))); *see also* Price Negotiation, 48 C.F.R. § 15.405 (2022) (outlining that the "primary concern" in government contract negotiations should be "the overall price the Government will actually pay").

commercial, not sovereign, capacity.[18] In so doing, the government "removes itself from the ambit of the Fifth Amendment as 'a takings claim cannot be based on the Government's acting in its proprietary capacity.'"[19]

Yet, Novartis seeks a constitutional right to sell its drug at profits levels it dictates—levels that routinely exceed those in all other industries.[20] In its briefing, Novartis claims that the IRA's Medicare drug price negotiation program is a per se taking of their patented drugs.[21] Yet it can point to no reassignment of patent rights or warehouse seizure of ENTRESTO®.

There is no right to a fixed level of profits. The government frequently negotiates prices before entering contracts. In 2022, the government spent $694 billion on contracts.[22] Many of these contracts were fixed-price vehicles that do not guarantee or even encourage profit.[23] The IRA's drug price negotiation program is simply another example of the government negotiating with a private vendor in a commercial capacity to purchase goods.

In fact, the government *already negotiates* drug prices and sets parameters on the prices it will pay for drugs across several federal programs, including the Veterans Health Administration,

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[18] *See Hughes Commc'ns Galaxy, Inc. v. United States*, 271 F.3d 1060, 1070 (Fed. Cir. 2001); *St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1385 (Fed. Cir. 2008).

[19] *Klump v. United States*, 50 Fed. Cl. 268, 272 (2001) (citation omitted), *aff'd*, 30 F. App'x 958 (Fed. Cir. 2002). Contractors seeking to allege a breach of contract also have remedies based on the contract, not based on constitutional rights. *See Hughes Commc'ns*, 271 F.3d at 1070.

[20] *See supra* n.7.

[21] Novartis S.J. Br. at 13.

[22] *See A Snapshot: Government-Wide Contracting*, GOVERNMENT ACCOUNTABILITY OFFICE (May 2023), https://gaoinnovations.gov/Federal_Government_Contracting.

[23] *Id.* (noting that majority of contracts awarded in fiscal year 2022 were fixed price); *United States v. White*, 765 F.2d 1469, 1472 (11th Cir. 1985) ("Under [fixed price] contracts, if the final total costs of the agreed upon services exceed the contracted price, the contractor takes the loss; conversely, he can profit if the costs are lower than the contract price.").

Section 340B, and Medicaid programs. Under each of these programs, the government contracts with a manufacturer to provide drugs.[24] Each program has a baseline statutory discount with options for the federal government or seller (e.g., a hospital) to negotiate further discounts.[25] Drug makers do not have to supply medicines to the government. However, if they opt not to sell to the Veterans Health Administration or the 340B program, the government can limit the drug maker's access to Medicaid (and by extension, Medicare Part B).[26] These programs offer manufacturers the opportunity to negotiate drug prices in exchange for access to various government markets.

Courts have routinely and uniformly held that the structure and requirements of these programs do not effectuate a taking. For example, courts have emphasized that the 340B program is voluntary, even if withdrawal from one program means the drug company will be prohibited from selling its drugs to another government program.[27] "[E]conomic hardship is not equivalent to

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[24] *See* 38 U.S.C. § 8126 (Veterans Health Administration); 42 U.S.C. §§ 256b (Section 340B), 1396r-8 (Medicaid).

[25] *See* 38 U.S.C. § 8126(a)(2) ("[T]he price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price."); 42 U.S.C. § 256b(a)(1), (10) (requiring a price equal to the "average manufacturer price" paid under Medicaid minus the average rebate; noting that additional discounts are permitted); 42 U.S.C. §§ 1396r-8(a) (requiring drug manufacturer to "have in effect a rebate agreement" with HHS); (c)(1) (basic rebate for single source and innovator multiple source drugs must be equal to either 23% of the average manufacturer price, or the difference between the average manufacturer price and the best price, whichever is greater).

[26] *See* 38 U.S.C. § 8126(a)(4) (limiting Medicaid participation for manufacturers who do not meet requirements of Veterans Health Administration drug contract process); 42 U.S.C. §§ 1396r-8(a)(1), (a)(5)(A) (limiting Medicaid and Medicare Part B reimbursement to drug manufacturers that have a "rebate agreement" with HHS and that participate in the 340B program). *See also Eli Lilly & Co. v. United States Dep't of Health & Human Servs.*, No. 21-cv-00081, 2021 WL 5039566, at *2 (S.D. Ind. Oct. 29, 2021) (340B program "requires, as a condition of Plaintiffs' participation in Medicaid and Medicare Part B, that pharmaceutical manufacturers such as Plaintiffs sell their outpatient drugs at a heavily discounted price to "'covered entities'").

[27] *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 209-

legal compulsion for purposes of takings analysis."[28] Indeed, one court described the manufacturers' per se physical takings argument in a 340B case as borderline nonsensical.[29]

The IRA's Medicare drug price negotiation program sets up a structure similar to the existing drug purchase programs under 340B, Medicaid, and the Veterans Health Administration.[30] The takings analysis here should not differ. Accepting Novartis's argument that price negotiations constitute a taking would open the door for nearly all contract negotiations and "[g]overnment contract breaches [to] give rise to compensation under the Fifth Amendment."[31] Such a view would not only undermine settled contract law involving voluntary, bargained-for exchanges, but also upend hundreds of government contracts at an industry's whim.

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10 (D.N.J. 2021), *aff'd in part, rev'd in part sub nom. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023); *Eli Lilly & Co. v. United States Dep't of Health & Human Servs.*, No. 21-cv-00081, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021).

[28] *Eli Lilly & Co.*, 2021 WL 5039566 at *21 (*quoting Garelick v. Sullivan*, 987 F. 2d 913 (2d Cir. 1993)) (quotations omitted).

[29] *See Sanofi-Aventis*, 570 F. Supp. 3d at 208 (D.N.J. 2021) ("Such an argument makes little sense given how the 340B Program works. HHS does not acquire title to Sanofi's drugs. . . obtain them for a third party. . . or compel Novo to surrender them . . . . [T]here is no 'government-authorized invasion.'") (quoting *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2074 (2021)).

[30] *See* P.L. 117-169, § 11101 (enacted in Aug. 2022) (requiring a rebate for single-source drugs and biological products if the price of the product increases faster than inflation).

[31] *See Hughes Commc'ns*, 271 F.3d at 1070.

2. Congress has the authority to directly regulate drug prices, and even a price regulation applied to the whole pharmaceutical industry would be constitutional.

For centuries, the government has implemented—and the Supreme Court has upheld—price regulations for commodities, public utilities, and services. Starting in England, "from time immemorial," it was "customary" "to regulate ferries, common carriers, hackmen, bakers, millers, wharfingers, innkeepers . . . and in so doing to fix a maximum charge to be made for services rendered, accommodations furnished, and articles sold."[32] The colonies continued this practice, with at least eight of the thirteen colonies adopting "expansive" price controls affecting "substantially everything in use at the time."[33] Price controls even extended to patented products. Borrowing from English common law and statutory obligations that a patentee would not use their exclusivity to "be 'mischievous to the State' by raising the prices of commodities,"[34] some colonies granted patents with "working clauses" that stipulated price as a condition.[35]

The Supreme Court first affirmed the constitutionality of price regulations in *Munn v. Illinois*.[36] There, the Court held that price regulations on goods and services "of public consequence" that were "clothed with a public interest"—a categorization encompassing public

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[32] *Munn v. People of State of Illinois*, 94 U.S. 113, 125 (1876).

[33] Breck P. McAllister, *Price Control by Law in the United States: A Survey*, 4 L. & CONTEMP. PROBS. 273, 274, 276 n.11 (1937) (identifying price controls for wages, agricultural products, tobacco, and liquor, and building materials).

[34] An Act Concerning Monopolies, 21 Jac. I, c. 3, § 6 (1623) (Eng.).

[35] Oren Bracha, *The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care*, 38 LOY. L.A. L. REV. 177, 211-16 (2004). Therefore, in Britain and the colonies at the time of the Founding, a patent grant did not convey any private right to profits or immunity from price regulation.

[36] *Munn*, 94 U.S. at 135 (upholding rate controls on railroads and grain warehouses).

utilities and transportation—did not offend the constitution.[37] The Court's decision in *Nebbia v. New York* extended the scope of regulable businesses.[38] *Nebbia* clarified that Congress may regulate the price of commodities sold by private businesses, such as milk, if the "conditions or practices of an industry . . . produce[d] waste harmful to the public [or] threaten[ed] . . . to cut off the supply of a commodity needed by the public."[39]

To ensure equitable access to public utilities post-*Munn*, the federal government and nearly every state established public-service commissions that set utility rates.[40] And Congress concurrently passed antitrust legislation—including the Sherman Antitrust Act—to restrain unchecked monopoly prices.[41] Finally, to limit profiteering and price gouging during the wartime and economic crises of the mid-twentieth century, the government imposed systemic price freezes and price maximums on nearly all commodities, services, rents, and wages.[42] Even these broad

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[37] *Id.* at 126.

[38] *Nebbia v. People of New York*, 291 U.S. 502, 516 (1934).

[39] *Id.*

[40] *See* William Boyd, *Just Price, Public Utility, and the Long History of Economic Regulation in America*, 35 YALE J. REG. 721, 755 (2018). At the federal level, Congress authorized the Interstate Commerce Commission in 1887 to regulate railroad (and later trucking) rates, *see* McAllister, supra note 33, at 280; the Federal Power Commission in 1920—with subsequent grant of authority in the Federal Power Act of 1935 and the Natural Gas Act of 1938—to regulate rates for electricity and gas, *see* Nelson Lee Smith, *Rate Regulation by the Federal Power Commission*, 36 AM. ECON. REV. 405, 406-08 (1946); the Federal Farm Board in 1929 to regulate agricultural prices, *see* Nathan R.R. Watson, *Federal Farm Subsidies: A History of Governmental Control, Recent Attempts at a Free Market Approach, the Current Backlash, and Suggestions for Future Action*, 9 DRAKE J. AGRIC. L. 281, 286-88 (2004); the Federal Communications Commission in 1934 to regulate telephone and telegraph rates, *see* Carl I. Wheat, *The Regulation of Interstate Telephone Rates*, 52 HARV. L. REV. 846, 848-49 (1938); and the Civil Aeronautics Authority in 1938 to regulate air fares, *see* William C. Wooldridge, *The Civil Aeronautics Board as Promoter*, 54 VA. L. REV. 741, 741-43, 747-51 (1968).

[41] *See generally* Boyd, *supra* note 40, at 723 & n.2.

[42] During World War II, for example, the temporary Office of Price Administration set

mandates survived constitutional challenges at the Court.[43]

This price-setting authority is so well-settled that the Supreme Court has upheld price regulations affecting a broad range of industries and services, including essential[44] and recreational commodities,[45] public utilities,[46] rent,[47] and labor.[48] Such regulations are deemed to be

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maximum prices on nearly ninety percent of commodities and imposed rent control over "practically the entire country." *See* Note, *Price and Sovereignty*, 135 HARV. L. REV. 755, 758 (2021); Bernard F. Grainey, *Price Control and the Emergency Price Control Act*, 19 NOTRE DAME L. REV. 31, 32-33 (1943). Episodic price freezes affecting most commodities, services, rents, and wages would be implemented through the 1970s, as authorized by the 1950 Defense Production Act and the 1970 Economic Stabilization Act. *See* John N. Drobak, *Constitutional Limits on Price and Rent Control: The Lessons of Utility Regulation*, 64 WASH. U. L. REV. 107, 117 (1986); Richard H. Field, *Economic Stabilization Under the Defense Production Act of 1950*, 64 HARV. L. REV. 1, 4-8 (1950).

[43] The Supreme Court rejected constitutional challenges to the expansive rent and commodity price controls during World War II in *Bowles v. Willingham*, 321 U.S. 503 (1944) and *Yakus v. United States*, 321 U.S. 414, 420 (1944), respectively. Constitutional challenges to similarly broad-reaching price regulations in the 1950s and 1970s were rejected by lower courts and did not reach the Supreme Court. Drobak, 64 WASH. U. L. REV. at 117 & n.45; *see, e.g.*, *United States v. Excel Packing Co.*, 210 F.2d 596 (10th Cir. 1954), *cert. denied*, 343 U.S. 817 (1954) (rejecting challenges to the constitutionality of the 1950 Defense Production Act).

[44] *See, e.g.*, *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381 (1940) (upholding maximum prices for interstate sale of coal); *German Alliance Insurance Co. v. Lewis*, 233 U.S. 389, 405-12 (1914) (rejecting plaintiff's contention that price controls of fire insurance rates were a "taking of private property"); *Yakus*, 321 U.S. 414 (upholding price controls on meat).

[45] *See, e.g.*, *Townsend v. Yeomans*, 301 U.S. 441 (1937) (upholding maximum prices on the sales of leaf tobacco); *Seagram & Sons v. Hostetter*, 384 U.S. 35 (1966) (upholding price regulations affecting the sale of liquor).

[46] *See, e.g.*, *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 582 (1942) ("The price of gas distributed through pipelines for public consumption has been too long and consistently recognized as a proper subject of regulation."); *Simpson v. Shepard (U.S. Reps. Title: Minnesota Rate Cases)*, 230 U.S. 352, 433 (1913) (holding, in a case involving railroad rates, that "[t]he rate-making power is a legislative power"); *Spring Valley Waterworks v. Schottler*, 110 U.S. 347, 354 (1884) (holding that "it is within the power of the government to regulate the prices at which water shall be sold").

[47] *See Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (holding that rent control did not "involve[] a 'taking' of property").

[48] *See West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937) (upholding minimum-wage legislation).

constitutional even if they have the potential to limit a seller's profits[49] or to reduce the value of the regulated good.[50] Indeed, by 1987, the Supreme Court declared the constitutionality of state and federal price regulation to be "settled beyond dispute."[51] Lower courts have adopted this posture, including in cases involving regulations of hospital and insurance rates.[52]

i. Price regulation in the pharmaceutical industry is particularly justified—and does not implicate the Takings Clause—because the industry is supported by many government privileges, subject to significant monopoly pricing problems, and highly regulated.

Price regulations achieve the "broad societal interest" of "protecting consumers from excessive prices."[53] Price regulation is particularly justified and does not implicate the Takings Clause in industries that (1) benefit from significant government privileges and (2) are highly regulated. Price regulations in such industries are not only logical, but often essential to protect the public from price gouging. Here, the sales of medicines within the pharmaceutical industry to the government meet both conditions. Myriad government-granted privileges—in the form of monopoly power, tax credits, and research funding—have made the pharmaceutical industry one of

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[49] *See, e.g.*, *Hegeman Farms Corp. v. Baldwin*, 293 U.S. 163, 170 (1934) (holding that regulation of milk prices that "deprive [a seller] of a profit . . . is not enough to . . . [allow] revision by the courts").

[50] *See, e.g.*, *Andrus v. Allard*, 444 U.S. 51, 66 (1979) ("When we review regulation, a reduction in the value of property is not necessarily equated with a taking.").

[51] *Fla. Power Corp.*, 480 U.S. 245, 253.

[52] *See, e.g.*, *United Wire Metal and Machine Health and Welfare Fund, v. Morristown Memorial Hosp.*, 995 F. 2d 1179 (3d Cir. 1993) (holding that a New Jersey law setting hospital rates was constitutional and not a taking); *Whitney v. Heckler*, 780 F.2d 963 (11th Cir. 1986) (rejecting a takings challenge to a freeze on physician rates for Medicare).

[53] *Exxon Corp. v. Eagerton*, 462 U.S. 176, 190-91 (1983) (internal citation and quotations omitted).

the most profitable in the world.[54] The pharmaceutical industry is also highly regulated. And caselaw affirms Congress's authority and special latitude to impose conditions on industries that benefit from such government privileges and regulations. As such, Congress could lawfully implement a price regulation affecting *all* drugs on the market, not just those sold to Medicare. Here, the Medicare drug price negotiation program, even if viewed as a mandatory price regulation, survives any takings challenge.[55]

Where the federal government grants an individual or industry a special privilege, it is entitled to impose conditions thereon. *And such conditions do not give rise to takings claims*. The Supreme Court affirmed this principle almost a century ago in *Leonard v. Earle*.[56] In 1929, *Leonard* affirmed that a Maryland law requiring oyster packers to give the state ten percent of their collected oyster shells—a valuable commodity—did not constitute a takings.[57] Even where the oysters had been "taken and reduced to possession by an individual," the Court held that the packer's "ownership may be regulated and restrained by appropriate legislation enacted for considerations of state or the benefit of the community."[58] Indeed, before the Supreme Court, the oyster packers did "not deny the power of the state to declare their business a *privilege* and to demand therefor

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[54] *See Dickson & Ballreich, supra* n.7.

[55] Price negotiation and regulation of medicines is the norm among peer nations. *See, e.g.*, Leah Z. Rand & Aaron S. Kesselheim, *Getting the Price Right: Lessons for Medicare Price Negotiation from Peer Countries*, PHARMACOECONOMICS, Sept. 11, 2022 (finding that the governments in "[h]igh-income peer countries . . . negotiate [drug] prices with manufacturers" using various approaches, including "maximum price setting.").

[56] 279 U.S. 392 (1929).

[57] *Leonard v. Earle*, 279 U.S. 392, 394, 396, 398 (1929); *Leonard v. Earle*, 141 A. 714, 715-16 (1928), *aff'd*, 279 U.S. 392 (1929). *See Horne v. Dep't of Agric.*, 576 U.S. 350, 366-67 (2015) (describing both decisions).

[58] *Leonard*, 141 A. at 716.

reasonable payment of money."[59] The government gave the packers a valuable benefit: the privilege to collect and sell the public goods. In exchange, the packers had to compensate "the State, as owner of the oysters" with ten percent of their shells.[60]

The Supreme Court's decision in *Horne v. Department of Agriculture*—Novartis's principal authority—did not disturb *Leonard*. Instead, *Horne* affirmed *Leonard's* logic.[61] As *Horne* explained, "[t]he oysters, unlike raisins, were 'feræ naturæ' that belonged to the State under state law, and "[n]o individual ha[d] any property rights in them other than such as the state may permit him to acquire."[62] The same can be said of patented medications: no individual holds right to a patent "other than such as the state may permit him to acquire."[63] And without patents, brand manufacturers like Novartis would lose the power to reap the benefit—high profits—they contend has been taken by the Medicare drug price negotiations.

Over fifty years later, in *Ruckelshaus v. Monsanto*, the Supreme Court reiterated the government's authority to set conditions on the benefits of market access it bestows on regulated companies.[64] There, the Court considered, *inter alia*, (1) whether the appellee, Monsanto, had "a property interest" "protected by the Fifth Amendment's Taking Clause in the health, safety, and environmental data" it submitted to the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and (2) if so, whether the EPA's

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[59] *Leonard*, 279 U.S. at 396 (emphasis added).

[60] *Horne*, 576 U.S. at 367 (*quoting Leonard*, 141 A., at 717) (internal quotations omitted).

[61] *Horne*, 576 U.S. at 366-67.

[62] *Id.* at 367.

[63] *Id.*; *see* U.S. Const. Art. I § 8, Cl. 8 (Congress hold the power—but the not the obligation—to grant patents).

[64] *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

competitive use or disclosure of that data constituted a taking.[65] Under FIFRA, companies are required to submit certain data to the EPA as part of their applications for registration to sell insecticides and other dangerous chemicals.[66] Pursuant to the 1978 FIFRA amendments, the EPA could then use that data when considering other companies' applications or disclose the data to the public under certain circumstances.[67]

As to the first question, the Supreme Court noted that the state conceded that the data was "cognizable as a trade-secret property right under Missouri law," and concluded that trade secrets could be protectable property interests under the Takings Clause.[68] As to the second, the Court concluded that Monsanto's "voluntary submission of data . . . in exchange for the economic advantages of a registration can hardly be called a taking."[69] Monsanto could not "successfully"

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[65] *Id.* at 1000.

[66] *Id.* at 991-92. In relevant part, Congress amended FIFRA twice—in 1972 and in 1978. *Id.* at 991-92, 94. Between 1972 and 1978, an applicant could protect its trade secrets by designating them as such in its application. *Id.* at 1010. As to data submitted during that period, the Court concluded that "the Federal Government explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use." *Id.* at 1011. In 1978, Congress amended FIFRA to permit the EPA to disclose the data submitted to it under certain circumstances. *Id.* at 1006.

[67] *Id.* at 992-93.

[68] *Id.* at 1003-04.

[69] *Id.* at 1006-07 (concluding Monsanto was "aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest"). The 1978 FIFRA amendments included "data-consideration and data-disclosure provisions" that put Monsanto on notice that its data might be disclosed. *Id.* at 1006. As for the data Monsanto submitted between the 1972 and 1978 amendments, the Court concluded that the EPA's consideration or disclosure of that data "will constitute a taking . . . the data constituted trade secrets under Missouri law; Monsanto had designated the data as trade secrets at the time of its submission; the use or disclosure conflicts with the explicit assurance of confidentiality or exclusive use contained in the statute during that period; and the operation of the arbitration provision does not adequately compensate for the loss in market value of the data that Monsanto suffers because of EPA's use or disclosure of the trade secrets." *Id.* at 1013-14.

challenge the federal government's ability "to regulate the marketing and use of pesticides . . . for such restrictions are the burdens we all must bear in exchange for 'the advantage of living and doing business in a civilized community.'"[70] As articulated by the Court in *Horne*, Monsanto and other similarly situated insecticide manufacturers "were not subjected to a taking because they received a 'valuable Government benefit' in exchange—a license to sell dangerous chemicals."[71] Not only were the companies seeking licenses to sell insecticides required to share certain information with the government, but the government was also entitled to give that information to the public. Thus, the government is free to impose conditions on the benefits it gives; doing so is not a taking.

The pharmaceutical regulatory system is on all fours with the regulation of insecticides in *Monsanto*. Just as the EPA regulates the issuance of a "license to sell dangerous chemicals,"[72] the FDA regulates the sale of pharmaceuticals, requiring manufacturers to apply, submit safety and efficacy clinical trial data, and receive FDA approval before marketing their (potentially dangerous) drugs.[73] By granting a pharmaceutical company's new drug application, the FDA grants a "valuable Government benefit"[74]—permission to sell the drug. In exchange, the federal government is free to impose conditions and regulations without violating the Taking Clause.

The government also grants drug makers significant benefits that enable their high prices and profits throughout drug development, manufacturing, and sales. First, the government

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[70] *Id.* at 1007 (*quoting Andrus v. Allard*, 444 U.S. 51, 67 (1979).

[71] *Horne*, 576 U.S. 350, 365-66.

[72] *Horne*, 576 U.S. at 365-66.

[73] *Cf. Horne*, 576 U.S. at 366 (distinguishing *Monsato*: "Raisins are not dangerous pesticides; they are a healthy snack. A case about conditioning the sale of hazardous substances on disclosure of health, safety, and environmental information related to those hazards is hardly on point.")

[74] *Monsanto*, 467 U.S. at 1007.

subsidizes new drug development through tax credits and the direct funding of disease and drug research via the National Institute of Health, among other mechanisms.[75] Next, the FDA's licensing requirements—demanding submission of clinical trial data—create barriers to entry, limiting the number of competitors that can enter the market.

Concurrent patent and regulatory exclusivities then permit the approved drug makers to exclude others from the market, setting prices far above those they could obtain in the face of generic competition and far above the average and marginal cost of manufacturing their medications.[76] In addition to the twenty-year term of patent exclusivity a manufacturer usually obtains on its drug's active ingredient, pharmaceutical companies frequently obtain a range of "secondary" patents, such as on the dosage strength of the drug,[77] methods of using the drug,[78] mode of administering the drug,[79] and manufacturing processes.[80] These secondary patents further

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[75] *See* David Austin & Tamara Hayford, *Research & Development in the Pharmaceutical Industry* 18-20, CONG. BUDGET OFF. (2021); Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA HEALTH F. 1, 1 (2023) (finding that between 2010 and 2019, NIH provided funding that contributed to almost every drug approved during that period).

[76] According to the FDA, where only one generic is allowed onto the market, that generic will price its competitor product 39% lower than the brand, on average; with six or more generic drugs on the market, the discount off the brand-drug price increases to 95%. Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. FOOD & DRUG ADMIN. 2-3 (Dec. 2019).

[77] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 142-143 (E.D.N.Y. 2018).

[78] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5-6 (1st Cir. 2020).

[79] *In re Loestrin 24 Fe Antitrust Litigation*, Op. and Order on Def's Mot. to Dismiss, No. 13-2472, ECF No. 299, (R.I. 2017); *In re Loestrin 24 Fe Antitrust Litigation*, Op. and Order on Summ. J. and Order re Mot. to Exclude Expert Ops., No. 13-2472, ECF No. 1380 (R.I. 2019).

[80] *See, e.g.*, *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 823 (N.D. Ill. 2020).

extend the pharmaceutical company's monopoly.[81] The availability of these secondary patents also enables drug makers to engage in a range of (often anticompetitive) behaviors that further delay generic drug competition such as pay-for-delay, product hopping, and market allocation.[82]

On top of patent protections, Congress has created several regulatory exclusivities for new drugs—a benefit unique to the pharmaceutical industry.[83] Like patents, these regulatory exclusivities enable brand drug makers to delay generic competition and continue supra-competitive pricing.

In addition to these exclusivities, statutory purchasing obligations for Medicare and other federal prescription drug programs guarantee drug makers a robust market. The statutes establishing Medicaid, Medicare, Section 340B, and the Veterans Administration drug program

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[81] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 6–8 (Aug. 2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-OverpatentedOverpriced-Report.pdf (finding the top 12 drugs by gross U.S. revenue were associated with an average of 71 patents each); Amy Kapczynski, Chan Park & Bhavan Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 6-7 (2012) (secondary patents extend market exclusivity by several years).

[82] *See, e.g.*, *F.T.C. v. Actavis*, Inc., 570 U.S. 136, 141 (2013) (holding that pay-for-delay settlements can violate antitrust laws); *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 870 (N.D. Cal. Aug. 13, 2021) (denying motion to dismiss claims that "name-brand manufacturer's volume-limited licenses were [not] plausibly anticompetitive market allocations."); *In re Glumetza Antitrust Litig.*, No. C 20-05251 WHA, 2021 WL1817092 at *6 (N.D. Cal. May 6, 2021) (denying defendant's motion for summary judgment because "[a] reasonable trier of fact could further conclude that defendants' restraint of the market delayed generic entry, stifled competition, and caused plaintiffs to pay more for brand and generic Glumetza than they would have otherwise."); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 330-32 (denying defendants' motion for summary judgment finding that there was a triable issue of fact as to the existence of an anticompetitive product hop scheme). *See generally* Robin C. Feldman & Mark A. Lemley, *Atomistic Antitrust*, 63 WM. & MARY L. REV 1869,1907-14 (2022) (describing how a range of patent-related anticompetitive actions work in concert to delay generic-drug entry).

[83] *See* ERIN H. WARD, KEVIN J. HICKEY & KEITH T. RICHARDS, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 12-14, 29 (2021).

require the federal government to purchase or otherwise provide drugs for each program's beneficiaries.[84] Other laws and regulations require government insurance programs to cover certain classes of drugs, including many branded pharmaceuticals.[85]

The protections and benefits the government grants to the pharmaceutical industry permit the former great latitude to regulate the fruits of the latter—i.e., medicines. Drug companies can no more claim a "taking" of their products than could packers over their oysters or insecticide manufacturers over their knowingly disclosed trade secrets. Rightly so. Such price regulation is not only authorized by Congress and the courts, but it also provides essential benefits to the public at large. Indeed, without price regulation in this setting, we face a predictable problem of high—and rising—monopoly prices, unjustified by investment, that put patients and the system at risk.

An apt example is Medicare without the IRA's drug price negotiation program. Medicare makes up the largest portion of the federal government's drug purchase obligation: the program's current regulatory structures require the government to provide coverage for pharmaceuticals, where prescribed, to a market of 65 million people.[86] In 2021, Medicare Part D spending exceeded

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[84] *See* 42 U.S.C. § 1396d(12); 42 U.S.C. § 256b(1) ("The Secretary shall . . ."); 42 U.S.C. § 1395w-3b; 42 U.S.C. § 1395w-101(a)(1) (2018) ("[E]ach part D eligible individual . . . is entitled to obtain qualified prescription drug coverage . . . ."); 38 U.S.C. § 8126(a).

[85] *See, e.g.*, 42 U.S.C. §§ 1395w-102, 104(b)(3) (describing general Part D formulary requirements); 42 C.F.R. § 423.120 (2024); 42 U.S.C. § 1396r-8(d)(1).

CMS requires Part D plans to include at least two drugs in a particular class or formulation on the Part D formulary, where available. These requirements often limit the government's ability to negotiate, especially with manufacturers of single-source brand drugs. *See Chapter 6- Part D Drugs and Formulary Requirements*, *included in* MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL (Jan. 15, 2016).

[86] *See* Gabrielle Clerveau, et al., *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, KAISER FAMILY FOUNDATION (Aug. 14, 2023), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries.

$200 billion.[87] And this figure continues to rise.[88] Despite this spending, as noted above, consumers in this program struggle to pay for drugs.[89] The program currently has no structural price controls and, without the IRA's drug price negotiation program, minimal negotiating power.[90] Medicare Part B does not negotiate at all, paying for drugs at the average sales price set by the drug makers, plus 6%.[91] With no ability to negotiate, the government and seniors—via the Medicare program—are held hostage by the prices (and profits) drug makers unilaterally demand.[92]

The Supreme Court has held that in highly regulated industries, especially where price regulations are present in some domains, the "forseeab[ility]" of price regulations negates certain

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[87] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105270, MEDICARE PART D: CMS SHOULD MONITOR EFFECTS OF REBATES ON PLAN FORMULARIES AND BENEFICIARY SPENDING (September 2023). Medicare Part D is Medicare's prescription drug benefit. Generally, it covers drugs patients purchase through retail or mail order pharmacies.

[88] *See Baseline Projections: Medicare*, CONG. BUDGET OFF. (May 2023) (charting projected growth in Medicare Part D budget between 2023-2033); *see also* David Austin & Tamara Hayford, *Prescription Drugs: Spending, Use, and Prices* 8, CONG. BUDGET OFF. (Jan. 2022) (describing inflation-adjusted growth in Part D spending between 2009 and 2018).

[89] *See* discussion *supra* in Introduction.

[90] *See* 42 U.S.C. § 1395w-101(a)(1).

[91] *See Medicare Part B Drug Average Sales Price*, CMS.GOV (Sept. 6, 2023 4:51 PM), https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price. Medicare Part B is Medicare's medical insurance benefit. In addition to physician visits and hospital services, it often covers drugs that must be administered in an in-patient setting.

[92] *See* 42 U.S.C. § 1395w-111 (2018); U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-111, PRESCRIPTION DRUGS: DEPARTMENT OF VETERANS AFFAIRS PAID ABOUT HALF AS MUCH AS MEDICARE PART D FOR SELECTED DRUGS IN 2017 (Dec. 15 2020) ("Department of Veterans Affairs (VA) paid, on average, 54 percent less per unit for a sample of 399 brand-name and generic prescription drugs in 2017 as did Medicare Part D, even after accounting for applicable rebates and price concessions in the Part D program."); *see also* Aaron S. Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858 (2016) (noting that U.S. drug prices are not based on the price of research and development, but instead on what the market will bear).

constitutional claims.[93] As described above, the pharmaceutical industry is arguably the most regulated industry in the country, and government price negotiations and regulations are part and parcel of federal healthcare programs, including through the Veterans Health Administration, Section 340B, and Medicaid programs.[94]

In sum, even if applied to the entire pharmaceutical industry, which this *Medicare* drug price negotiation program is not, price regulation would be justified. It would not implicate the Takings Clause because it would not "unfairly single[] out the property owner to bear a burden that should be borne by the public as a whole."[95] The beneficiaries of the government's extraordinarily valuable privileges, especially in highly regulated industries, must adhere to the conditions it sets, not wield their privilege to harm the public.

ii. There is no legal mandate to sell medicines, and even if there were, only a minimal "just compensation" requirement would apply.

In certain industries, the government legally *mandates* that a seller serve the market at fixed prices. Historically, courts have exercised some judicial oversight over those rates, but that oversight is the exception, not the rule.[96] In recent years, caselaw requiring just compensation for such

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[93] *See, e.g., Energy Reserves Group, Inc. v. Kansas Power and Light Co.*, 459 U.S. 400, 413, 416, 419 (1983) (concluding that in a "heavily regulated industry," price regulation was "foreseeable as the type of law that would alter contract obligations" and was constitutionally permissible under Contracts Clause). *See also 74 Pinehurst LLC v. New York*, 59 F.4th 557, 567-68 (2d Cir. 2023) (holding that because a "reasonable investor" in the housing market "would have anticipated [that] their rental properties would be subject to regulation"—because of the expansive "regime of rent regulations"—price controls "result[ing] in a loss does not constitute a taking").

[94] *See infra* Section II.A.1.

[95] *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 522-23 (1992).

[96] *See, e.g., Hegeman Farms*, 293 U.S. at 170 ("The appellant would have us say that . . . [a government-regulated price] must be changed whenever a particular dealer can show that . . . its application to himself is to deprive him of a profit. This is not enough to subject administrative

services pertains only to rate-regulated utilities. This is because utility providers are *required*, by law, to serve the market; they cannot pull out.[97] Pharmaceutical companies, on the other hand, *voluntarily* choose to sell their drugs on the market, without any obligation to participate. As a result, they are not entitled to judicial oversight of government price regulations.[98] Unlike in the case of utilities, Congress has not mandated drug makers' market participation. And it need not, particularly because the government has the authority to purchase generic copies of patented

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rulings to revision by the courts."); *Aetna Ins. Co. v. Hyde*, 275 U.S. 440, 447-48 (1928) ("Jurisdiction of this Court to set aside state-made rates as confiscatory will be exercised only in clear cases; and the burden is on one seeking that relief to bring forward and satisfactorily prove the invalidating facts."). *See generally* John N. Drobak, *From Turnpike to Nuclear Power: The Constitutional Limits on Utility Rate Regulation*, 65 B.U. L. REV. 65, 125 (1985) ("The Supreme Court has established a limited role for the judiciary in its constitutional review of [utility] ratemaking, consistent with the judiciary's limited role in reviewing other kinds of economic regulation.").

[97] *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) ("[P]ublic utilities . . . are under a state statutory duty to serve the public."); *Pittsburgh & Lake Erie R.R. Co. v. Ry. Labor Execs' Ass'n*, 491 U.S. 490, 515 (1989) (Stevens, J., concurring) ("Regulated utilities do not have the same freedom to respond to market pressures that unregulated firms have. They may not raise rates or cut services . . . without permission from a regulatory agency . . . [and] they may neither enter nor leave the market without agency approval."); *see also* Jim Rossi, *The Common Law "Duty to Serve" and Protection of Consumers in an Age of Competitive Retail Public Utility Restructuring*, 51 VAND. L. REV. 1233, 1248-50 (1998) (describing long-standing decisions recognizing common-law and statutory "duty to serve" for public utilities and common carriers); Thomas W. Merrill, *Constitutional Limits on Physician Price Controls*, 21 HASTINGS CONST. L.Q. 635, 639 (1994) ("The Supreme Court has made it clear that the Takings Clause imposes significant limits on the power of government to regulate certain prices, most prominently, the rates charged by common carriers and public utilities. On the other hand, other types of price controls . . . have never been thought to raise questions under the Takings Clause.").

[98] *See Yee*, 503 U.S. at 531 ("Because they voluntarily open their property to occupation by others, petitioners cannot assert a per se right to compensation based on their inability to exclude particular individuals"); *Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (upholding World War II rent controls against takings challenge because statute did not require landlords "to offer any accommodations for rent").

medications for provision to the market.[99]

Even if the utility rule applied to pharmaceutical manufacturers, they would only be entitled to a "just and reasonable" compensation.[100] "Just and reasonable" compensation is a minimal standard for rate-setting.[101] Sellers are entitled to a rate that reflects their original capital investments and expenditures and allows them to reasonably attract future capital.[102] The complexity of making these determinations means that courts give the government discretion in setting rates, regardless of the methodology employed,[103] "if the total effect of the rate order cannot be said to be unreasonable."[104] Such compensation certainly does not require that the regulated business earn a profit.[105]

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[99] *See infra* Section II.B.2.

[100] *See Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 602-03 (1944) ("If the total effect of the rate order cannot be said to be unjust and unreasonable, judicial inquiry under the [Natural Gas] Act is at an end.").

[101] *See Duquesne*, 488 U.S. at 310-11; *see also id.* at 315-16 ("'It has repeatedly been stated that no single method need be followed by the Commission in considering the justness and reasonableness of rates.'. . . The designation of a single theory of ratemaking as a constitutional requirement would unnecessarily foreclose alternatives which could benefit both consumers and investors." (quoting *Wisconsin v. FPC*, 373 U.S. 294, 309 (1963)).

[102] *See Hope*, 320 U.S. at 602-03 ("[T]he return to the equity owner should be commensurate with returns on investments . . . . That return, moreover, should be sufficient to assure confidence in the financial integrity of the enterprise, so as to maintain its credit and to attract capital."); *see also Duquesne*, 488 U.S. at 302, 312 (holding that a reduced rate did not constitute a takings and emphasizing that the challenger failed to argue the reduced rate "jeopardize[d] the financial integrity of the companies, either by leaving them insufficient operating capital or by impeding their ability to raise future capital.").

[103] Boyd, *supra* note 40, at 767 (noting that after *Hope*, "in the vast majority of cases, the courts simply deferred to the commissions, no longer twisting themselves into knots trying to make the methods of valuation at the heart of ratemaking comport with received notions of property and its constitutional protections.").

[104] *Duquesne*, 488 U.S. at 310 (quoting *Hope*, 320 U.S. at 602).

[105] *See Permian Basin Area Rate Cases*, 390 U.S. 747, 769 (1968) ("Regulation may, consistent

The Medicare drug price negotiation program is a *price* negotiation, not a rate negotiation. And even if pharmaceutical companies claimed that they were due just compensation, they could not adjudicate that claim now because the government had not yet determined or released the negotiated prices.[106] These arguments are inapposite, as well as premature.

3. A ruling that the Medicare drug price negotiations constitutes a per se taking would upend the Medicare, Medicaid, and Veterans Administration programs.

Federal and state healthcare programs provide a key safety net for more than one in three Americans.[107] But, due to their reach, these programs strain state and federal budgets. In 2021, Medicare alone accounted for 21% of all U.S. healthcare spending and 10% of the federal

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with the Constitution, limit stringently the return recovered on investment."); *Fed. Power Comm'n v. Sierra Pac. Power Co.*, 350 U.S. 348, 355 (1956) (holding that a rate "may not be said to be either 'unjust' or 'unreasonable' simply because it is unprofitable to the public utility").

[106] A challenge after the government releases the prices would only entitle the pharmaceutical companies to a fraction of the profits they presently earn—so not the status quo.

[107] *See Health Insurance Coverage of the Total Population*, KAISER FAMILY FOUNDATION (2021), https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. In 2017, the Veterans Health Administration provided care to 9 million veterans and their families. In 2022, TRICARE, DoD's insurance program, covered approximately 9.5 million service members and their families. As noted above, Medicare provides coverage to 65 million people, and in 2022, Medicaid or CHIP covered almost 90 million Americans. *See* Mike McCaughan, *Veterans Health Administration*, HEALTH AFFAIRS (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/; *Patients by TRICARE plan*, HEALTH.MIL, https://www.health.mil/Military-Health-Topics/MHS-Toolkits/Media-Resources/Media-Center/Patient-Population-Statistics/Patients-by-TRICARE-Plan; Gabrielle Clerveau, et al., *supra* n.86. *MACPAC Releases 2022 Edition of MACStats: Medicaid and CHIP Data Book*, MACPAC (Dec. 15, 2022), https://www.macpac.gov/news/macpac-releases-2022-edition-of-macstats-medicaid-and-chip-data-book.

budget.[108] Medicare's costs are predicted to rise to 18% of the federal budget in 2032.[109] The Medicaid program cost $728 billion, excluding administrative costs, in fiscal year 2021,[110] about 17% of national health expenditures that year.[111]

Price caps and negotiated discounts on healthcare services enable federal and state healthcare programs to offer coverage to millions of Americans. A ruling that these programs' statutory discounts constitute takings would imperil these programs' continued operation. For patients, this would translate into reduced access to healthcare. For courts, it would mean a flood of litigation over the level of payment necessary to compensate takings by voluntary and mandatory programs never-before questioned. Courts would be asked to take on the administrative role of rate-setter, weighing the cost and benefits of each government contract for healthcare services.

But the Medicare, Medicaid, and Veteran Health Administration programs would not be the only areas of healthcare affected. All Americans are entitled to emergency room treatment, irrespective of insurance status, based on the federal Emergency Medical Treatment and Labor Act (EMTALA). This law requires hospitals with emergency departments that receive Medicare funding to accept all patients in critical condition, regardless of their ability to pay.[112] Takings challenges to EMTALA have failed on the grounds that participation in Medicare (and by extension in

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[108] *See* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, KAISER FAMILY FOUNDATION (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing.

[109] *Id.*

[110] *See* Elizabeth Williams et al., *Medicaid Financing: The Basics*, KAISER FAMILY FOUNDATION (Apr. 13, 2023), https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics.

[111] *See NHE Fact Sheet*, CMS.GOV, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

[112] *See* 42 U.S.C. § 1395cc(a)(1)(I)(i); 42 U.S.C. § 1395dd.

EMTALA) is voluntary.[113] A holding that the IRA's Medicare drug price negotiations are coerced could open the door to a similar holding with respect to EMTALA. Every unpaid emergency room visit could be grounds for a takings lawsuit in which a court would have to evaluate the degree of government compensation necessary—an unimaginably complex task given the byzantine world of medical billing and government reimbursement rates.

B. That medicines are patented does not alter the takings analysis: the government may use drug maker's patents without violating the Taking Clause.

1. The Court need not decide whether patents are subject to the Fifth Amendment's Takings Clause.

That the government granted Novartis patents on the medication at issue should not alter the Court's takings analysis. Indeed, as the previous section demonstrates, the government's patent grants actually *support* its ability to regulate prices without implicating the Taking Clause. Nor does Novartis argue that its patents are personal property subject to the Fifth Amendment's Taking Clause. Although Novartis declares that its patents "confer[]" an "'exclusive property in the patented invention which cannot be appropriated or used by the government itself without just compensation,'"[114] Novartis's comment is little more than a passing, conclusory statement.

The Supreme Court and the Federal Circuit have never directly addressed whether patents

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[113] *See, e.g.*, *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F. 2d 1362, 1376 (5th Cir. 1991); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F. 3d 1274, 1279-80 (11th Cir. 2014) (quoting *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("Just as physicians who voluntarily treat Medicare beneficiaries cannot establish the legal compulsion necessary to challenge Medicare reimbursement rates as a taking, so too is the Hospital precluded from challenging the rate at which it is compensated for its voluntary treatment of federal detainees, a regulated industry in which the Hospital as a 'regulated group is not required to participate.'").

[114] Novartis S.J. Br. at 13 (quoting *Horne*, 576 U.S. at 359). Novartis declines to explain that this language from *Horne* is actually *Horne* quoting a 1882 Supreme Court decision as part of an explanation of the history of Takings jurisprudence. *Horne* in no way holds that patents are personal property subject to the Fifth Amendment Takings Clause.

are personal property, and existing Federal Circuit caselaw points in the opposite direction.[115] The most recent Supreme Court analysis of patent rights also suggests that they are *not* property in the relevant sense. In its 2018 *Oil States* decision, a 7-2 majority of the Supreme Court concluded that patents are "public rights," akin to government franchises—not "private rights."[116] In that case, a patent holder filed suit against an alleged infringer in federal district court, and the accused infringer responded by petitioning the Patent Trial and Appeal Board (Board)—an administrative patent review tribunal—for *inter partes* review of the patent.[117] The district court acted first, rejecting some of the defendant's arguments on patent validity.[118] A few months later, the Board reached the opposite conclusion, holding the patent claims to be invalid.[119] The plaintiff, Oil States, appealed that decision to the Federal Circuit, and then Supreme Court, arguing that it was entitled to litigate the patent's validity in an Article III court before a jury.[120]

Historically, Congress has been permitted to "assign adjudication of public rights to entities

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[115] *See Christy, Inc. v. United States*, 971 F.3d 1332, 1335 (Fed. Cir. 2020) ("[T]he cancellation of patent claims . . . did not amount to a compensable taking of . . . property interest."), *cert. denied*, 141 S. Ct. 1393 (2021); *Golden v. United States*, 955 F.3d 981, 987 (Fed. Cir. 2020), (holding that a patent holder cannot raise a takings challenge to patent infringement by the government), *cert. denied*, 141 S. Ct. 908 (2020); *Celgene Corporation v. Peter*, 931 F.3d 1342, 1362-63 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 132 (2020).

[116] *Oil States Energy Servs., LLC v. Greene's Energy Grp.*, LLC, 138 S. Ct. 1365, 1373, 1375 (2018).

[117] *Id.* at 1372. The America Invents Act, which went into effect in 2012, empowered this administrative body to review the validity of granted patents and cancel them when appropriate. *Id.* at 1370-71 (citing 35 U.S.C. § 100 *et seq.*).

[118] *Id.* at 1372.

[119] *Id.*

[120] *Id.*

other than Article III courts[,]" whereas private rights must be adjudicated by Article III courts.[121] Thus, to answer the question raised by Oil States, the Supreme Court first had to determine whether *inter partes* review involved public or private rights.[122] The Court reiterated the "longstanding" principle that a patent is a public franchise: a right the government takes from the public and grants to a private party.[123] As the Court explained, a patent is a "creature of statute"[124] and thus "can confer only the rights that 'the statute prescribes'"[125]—the right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States."[126] Based on this reasoning, the Court held that *inter partes* review—defined as a "reconsideration of the Government's decision to grant a public franchise"—"falls squarely within the public-rights doctrine."[127] As such, it did not need to be resolved in an Article III court.[128]

There is no reason why a right would be "public" for the purposes of Article III but "private" for the purposes of the Fifth Amendment. When faced with this question shortly after the Supreme Court issued its *Oil States* decision, the Court of Federal Claims held that "patents are public franchises, not private property," and because a taking requires private property, "patent

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[121] *Id.* at 1373.

[122] *Id.* at 1373.

[123] *Id.* at 1373-75.

[124] *Id.* at 1374 (quoting *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 40 (1923)).

[125] *Id.* at 1375 (quoting *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 494 (1851)).

[126] *Id.* at 1374 (quoting 35 U.S.C. § 154(a)(1)).

[127] *Id.* at 1373.

[128] *Id.* at 1375.

rights are not cognizable property interests for Takings Clause purposes."[129] In so holding, the court reasoned that because "patent rights derive wholly from federal law, Congress is free to define those rights (and any attendant remedies for an intrusion on those rights) as it sees fit."[130] The Court of Federal Claims highlighted the Court's discussion of the public nature of patent rights and concluded it could not "be dismissed as dicta."[131]

The Court of Federal Claims is the only court to tackle the question of whether patents are personal property subject to the Taking Clause head on. *Oil States* declined to decide whether patents were subject to the Takings Clause.[132] The Federal Circuit has similarly avoided answering this question directly.[133] This case, in which the question has not been properly raised, is hardly the proper vehicle for an unsettled question of this magnitude.

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[129] *Christy, Inc. v. United States*, 141 Fed. Cl. 641, 660 (2019), *aff'd on narrower grounds*, 971 F.3d 1332 (Fed. Cir. 2020).

[130] *Id.* at 658; *see also id* (quoting *Zoltek Corp. v. United States*, 442 F.3d 1345, 1352 (Fed. Cir. 2006)) ("As the Supreme Court has clearly recognized when considering Fifth Amendment taking allegations, property interests are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law. Here, the patent rights are a creature of federal law.").

[131] *Id.* at 659 (rejecting the argument that *Oil States* should be read as acknowledgement that patents are property subject to the Fifth Amendment and concluding that Supreme Court's discussion of patents and Taking Clause "merely defined the scope of the decision").

[132] *Oil States*, 138 S. Ct. at 1379.

[133] *See Christy, Inc. v. United States*, 971 F.3d 1332, 1335-36 (Fed. Cir. 2020) (declining to expressly address the issue on appeal after the lower court concluded that patents are not private property subject to Takings Clause); *Golden*, 955 F.3d 981, 989 n.7("Despite the Claims Court's express finding on the status of patent rights under the Fifth Amendment, we decline to address that question here . . . ."); *Celgene Corp. v. Peter*, 931 F.3d 1342, 1358-59 (Fed. Cir. 2019) (avoiding commenting on the contention that the patentee does not have a "property right" and instead upholding the constitutionality of *inter partes* review on the grounds that a patent's validity has always been subject to challenge).

2. The government's grant of patents has never endowed patent holders with a right to exclude the federal government from making the patented product on terms favorable to the government.

Even if patents were property subject to the Fifth Amendment's Takings Clause, no individual or company has *ever* had the right to enjoin the federal government from making or using a patent. A right that has never existed cannot be "taken."[134] Put another way, there is no property right against the federal government in the "bundle of sticks" that a patentee holds.

A little-known statute—28 U.S.C. § 1498—confirms this point and formally enables the federal government to procure patented inventions in an even more cost-effective fashion than the IRA's Medicare drug price negotiations. Section 1498 allows the government to hire contractors to make "an invention described in and covered by a patent of the United States . . . without [a] license of the [patent] owner."[135] As the statutory language implicitly acknowledges, such patents are granted by the United States, and the grant is limited. In exchange for this use, the government need only pay the patent holder a reasonable royalty—usually less than 10% of the patented price or procurement cost.[136] Thus, rather than negotiate drug prices with Novartis, the government could simply contract with alternative manufacturers to produce the drug at issue, with *less*

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[134] *See Golden*, 955 F.3d at 987. ("[A] cause of action under the Fifth Amendment is unavailable to patent owners alleging infringement by the government.").

[135] 28 U.S.C. § 1498(a) (2018). The text of the statute further states: "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, 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 . . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States 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." *Id.*

[136] *See infra* Section II.B.2.ii.

compensation due to Novartis than what the IRA's Medicare drug price negotiation program offers. Such a decision would not run afoul of the Takings Clause.[137]

i. Section 1498 allows the government to use patented inventions without implicating the Takings Clause.

The existence of § 1498—and the federal government's long-standing use of patents before its passage—shows that no individual or company has *ever* held the right to enjoin the federal government from using patents to make more affordable versions of the products they cover. Until the turn of the twentieth century, the U.S. government's sovereign immunity shielded it from lawsuits brought by patent holders for government use of their patents.[138] In 1894, the Supreme Court clarified that a patentee could not sue the government for patent use as a taking.[139] In *Schillinger v. United States*, the Court explained that Congress had not waived its sovereign immunity as to "claims founded upon torts."[140] Thus, because a patent infringement action "is one sounding

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[137] *See supra* n.134.

[138] *See, e.g.*, Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145, 180-84 (2012) (describing the *de facto* immunity that the government enjoyed until the 1910 version of § 1498 was adopted). The Federal Court of Claims did entertain some patent suits premised on breach of implied contract theories. But such claims had to be plausible, and not merely an attempt to recover for patent infringement. *See, e.g.*, *Pitcher v. United States*, 1 Ct. Cl. 7, 11 (1863) (explaining that patentees may not simply assert an implied contract cause of action where no plausible agent to enter into the contract with existed). If a patent holder could not make a viable implied contract claim, their sole remaining remedy was to petition Congress for compensation. Supporters of the 1910 Act preceding § 1498 argued that this method was ineffective. Many claims would not make it out of the Committee on Claims. *See, e.g.*, 45 CONG. REC. 8758 (1910) (statement of Rep. Graham) ("As a member of the Committee on Claims, I can state that we have had a dozen applications requiring the Government to be honest to a patentee. We have not passed out but a single one of those claims. We have not time to investigate them. This bill simply allows the Court of Claims to pass on the cases.").

[139] *See Golden*, 955 F.3d at 987 (describing *Schillinger v. United States*, 155 U.S. 163 (1894)).

[140] *Schillinger*, 155 U.S. at 168.

in tort[,]" government patent use did not expose the government to takings liability.[141]

In response, Congress *voluntarily* enacted a limited waiver of the U.S. government's sovereign immunity, passing a precursor statute to § 1498. This 1910 law provided patent holders with a claim for "limited relief"[142] for government patent use.[143] The committee notes accompanying the bill clarified that the law not only covered inadvertent use by the government, but also covered the government's *intentional* use of patents when such actions benefitted the public.[144] This 1498 precursor only allowed patent holders to seek "reasonable compensation" for government use of their patents; it foreclosed injunctive relief.[145]

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[141] *Id.* at 169-70.

[142] Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 299 (2016).

[143] Act of June 25, 1910, ch. 423, 36 Stat. 851, 851; *see* Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 14 (2020).

[144] H.R. REP. NO. 61-1288, at 2 (1910) ("[T]he Government ought to have the right to appropriate any invention necessary or convenient for natural defense or for beneficent public use, and that, too, without previous arrangement or negotiation with the owner.").

[145] Act of June 25, 1910, ch. 423, 36 Stat. 851, 851. In 1918, § 1498 went through a set a of revisions in response to a Supreme Court decision and the United States's decision to enter World War I. After the Supreme Court held the government's cloak of sovereign immunity did not protect its contractors, *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28 (1918), then-Acting Secretary of the Navy Franklin D. Roosevelt successfully lobbied Congress to amend the law to clarify that government contractors were also immune from suit. Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 ("That whenever an invention described in and covered by a patent of the United States shall hereafter be used *or manufactured* by *or for* the United States without license of the owner thereof or lawful right to use *or manufacture* the same . . . ." (changes from Act of 1910 italicized)). In 1942, Congress expanded that provision to explicitly cover subcontractors and others acting on behalf of the federal government. Act of Oct. 31, 1942, ch. 634, 56 Stat. 1013, 1014.

The law is now codified as 28 U.S.C. § 1498.[146] In relevant part, it reads: "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, 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."[147] As a panel of the Federal Circuit noted during a subsequent discussion of *Schillinger*, "[h]ad Congress intended to clarify the dimensions of the patent rights as property interests under the Fifth Amendment, *there would have been no need for the new and limited sovereign immunity waiver*" that § 1498 carries forth today.[148]

ii. Through § 1498, the government could control drug prices in an even more extreme fashion: it could procure generic copies rather than buy the plaintiff's brands.

There is no question that § 1498 offers a more extreme—and yet entirely constitutional—remedy to the problem of high prices than the IRA's Medicare drug price negotiations. Amici's past scholarship has documented the government's "routine[]" use of § 1498 to procure everything

[146] Act of June 25, 1948, ch. 646, 62 Stat. 869, 941. In 1949, Congress revised § 1498 to remove changes in phraseology made by the 1948 recodification and to conform the text to the original statute. Act of May 24, 1949, ch. 139, 63 Stat. 89, 102. In 1951, Congress transferred the language added by the Act of October 31, 1942 to § 1498. Act of Oct. 31, 1951, ch. 655, 65 Stat. 710, 727.

[147] 28 U.S.C. § 1498(a) (2018).

[148] *Zoltek Corp. v. United States*, 442 F.3d 1345, 1352 (Fed. Cir. 2006) (emphasis added), *cert. denied*, 551 U.S. 1113 (2007), *opinion vacated on reh'g en banc*, 672 F.3d 1309 (Fed. Cir. 2012). The Federal Circuit later reversed a different part of the *Zoltek* decision *en banc*, obviating the need to determine whether the government's infringement constituted a taking in violation of the Fifth Amendment. Nonetheless, *Golden* affirms this piece of *Zoltek*'s reasoning. *Golden*, 955 F.3d 981, 987-88.

from "electronic passports to genetically mutated mice."[149] And the government relies on this statute "not only when the patent holder is unwilling or unable to negotiate a license with the federal government and infringement is the only way for the government to use the patented technology, *but also when the patent holder is willing and able to negotiate*."[150] For example, in the 1960s, the Department of Defense negotiated purchase of the antibiotic tetracycline from an Italian maker instead of the U.S.-based patent-holder, Pfizer. Even though Pfizer was willing and able to supply the government's purchase order, it nonetheless chose to use Pfizer's patent because the Italian version was 72% cheaper.[151] According to one source, the Department of Defense relied on § 1498 to procure approximately fifty drugs in a three-year period during the 1960s.[152]

The federal government has continued to rely on this statute into the twenty-first century. During the post-9/11 anthrax scare, the Bush Administration, through then-Secretary of Health and Human Services Tommy Thompson, publicly discussed bypassing Bayer's patent to purchase copies of the antibiotic ciprofloxacin.[153] At the time, Bayer held the patents on this drug,

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[149] Brennan et al., *supra* n.142, at 302. As amici document in this Article, "In 2009, the Department of Treasury used § 1498 to shield private banks from liability for using software to help detect fraudulent checks. In another case, the U.S. Army Corp. of Engineers used patented waste removal methods to clean up hazardous waste. Over the past decade, the National Institute of Health, National Gallery of Art, National Park Service, and General Services Administration have also utilized § 1498." *Id.* (citations omitted).

[150] *Id.* (emphasis added) (citations omitted).

[151] Charles Pfizer & Co., Inc., 39 Comp. Gen. 760 (1960); *see* Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right?*, 42 NOTRE DAME L. REV. 5, 11 n.33 (1967).

[152] MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974).

[153] *See* Brennan et al., *supra* n.142, at 303; *see also* Keith Bradsher, *A Nation Challenged: The Cost; Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES (Oct. 25, 2001), https://www.nytimes.com/2001/10/25/business/nation-challenged-cost-bayer-agrees-charge-government-lower-price-for-anthrax.html.

controlled its sale, and refused to lower its prices to supply a purchase order for the government to use in response to a potential biological threat.[154] In response, Secretary Thompson suggested that the government invoke its authority to lawfully use Bayer's patents and import other versions of the medication.[155] The mere specter of this action led Bayer to cut prices in half: Bayer agreed to sell ciprofloxacin for $0.95 or less per pill, half of what the government had been paying ($1.83) and about a fifth of Bayer's list price ($4.67).[156] In contrast to the IRA's Medicare price negotiations, Bayer's price concession—conducted under threat of government patent use—did not result in any lawsuit.

Section 1498's real bite, in comparison to the IRA, springs from its compensation provision. Under § 1498, the government pays the patent holder only a reasonable royalty—in practice rarely exceeding 10% of the price of the generic[157]—as compensation for its infringement.[158] Importantly, the § 1498 case law does not interpret "reasonable and entire

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[154] *See* Morten & Duan, *supra* n.143, at 26-28.

[155] *See id.* at 30.

[156] *Id.*; Bradsher, *supra* n.153.

[157] *See* Joseph Adamczyk, Adrienne Lewis, Shivani Morrison & Christopher Morten, *§ 1498: A Guide to Government Patent Use, A Path to Licensing and Distributing Generic Drugs* 30 (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3882823 ("Courts have consistently found that a royalty of 10% or less represents 'reasonable and entire compensation' fair to both the patent holder and the government."); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 793 (2016) ("Royalties are commonly set at 10 percent of sales or less" in § 1498 cases); Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or Its Contractors*, 18 AIPLA Q.J. 349, 359 (1991) ("Historically, the highest royalty rate that the United States Claims Court has awarded is 10%.").

[158] *See Tektronix, Inc. v. United States*, 552 F.2d 343, 351 (Ct. Cl. 1977), (explaining that, under § 1498, the "goal of 'complete justice' implies that only a reasonable, not an excessive, royalty should be allowed where the United States is the user—even though the patentee, as a monopolist, might be able to exact excessive gains from private users"), *opinion modified on denial of reh'g*, 557 F.2d 265 (Ct. Cl. 1977)

compensation" to mean the entirety of lost profits. Although the precise royalty rate is a case-specific determination, the Court of Federal Claims (where all claims for compensation under § 1498 must be litigated[159]) examines "mixed considerations of logic, common sense, justice, policy and precedent" when setting compensation under § 1498.[160] And the best measure for "reasonable and entire" compensation under § 1498 is the rate the patent holder agreed to in any prior or existing licensing agreements.[161] When the Court of Federal Claims lacks evidence of prior licensing agreements, it will apply the "willing buyer-willing seller" rule to arrive at a royalty rate.[162]

Because "reasonable and entire compensation" does not mean lost profits, Novartis would not be allowed to recover for any government patent use at the prices it currently set.[163] This

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[159] 28 U.S.C. § 1498(a) (2018); *see Golden*, 955 F.3d 981, 986.

[160] *Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 386 (2014) (quoting *Boeing Co. v. United States*, 86 Fed. Cl. 303, 311 (2009)), *aff'd in part*, 835 F.3d 1388 (Fed. Cir. 2016).

[161] *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980) ("Where (a) prior to the time as of which the license taken by the Government is to be valued, the patentee has licensed the infringed patent commercially and (b) the rights of such a commercial licensee are the same or substantially similar to the rights taken by the Government, the court uses, virtually without exception, the reasonable royalty method to value the license taken by the Government."), *cert. denied*, 454 U.S. 819 (1981).

[162] *Tektronix*, 552 F.2d at 349 n.7 ("This willing-buyer/willing-seller technique in determining a reasonable royalty has not been a stranger to the Court of Claims."); *Amerace Esna Corp. v. United States*, 462 F.2d 1377, 1380 (Cl. Ct. 1972) ("In the absence of an existing royalty rate, courts often resort to a 'willing seller-willing buyer' approach to establish what a reasonable royalty should be under the particular facts with which they are faced"); *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1569, 1573 (Fed. Cir. 1996), *vacated on other grounds*, 520 U.S. 1183 (1997).

[163] *Tektronix*, 552 F.2d at 349 (explaining that lost profits will often amount "to excessive compensation, rather than the just compensation payable under the Fifth Amendment"); *Decca*, 640 F.2d at 1172 ("The reasonable royalty method is the preferred method of ascertaining the value of patent rights taken by the Government . . . ."); *see also* DONALD S. CHISUM, 6A CHISUM ON PATENTS § 20.03 (2023) (noting that "[t]here is some doubt whether lost profits is a permissible basis for recovery against the United States" and listing all awards under § 1498 since 1930 to show that there has not been a lost profits award); Brennan et al., *supra* n.142, at 313

interpretation makes sense: because the government is not obligated to purchase from the patent holder, the patent holder has no right to any profits—neither the profits the patent holder lost nor those the contractor gained through the government invocation of § 1498.

Understanding the government's use of § 1498 to procure a wide range of patented technologies provides necessary perspective on the reasonableness of IRA's Medicare drug price negotiations. And to the extent that Novartis suggests the drug price negotiations "coerce" the sale of medications the government would otherwise be unable to procure, § 1498 undermines that position. This statute confirms the government's legal authority to purchase other makers' copies of Novartis's drug should it decline to participate in the negotiations. And the government decision to procure Novartis's drug through the Medicare drug price negotiation program instead of § 1498 shows that the government has chosen the less extreme procurement method, undermining the drug maker's coercion argument.

III. CONCLUSION

For these reasons, amici respectfully request that the Court reject Novartis's takings claims.

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(noting that in "every modern § 1498 case, then, the measure of royalties has not been lost profits but rather a 'reasonable royalty'").

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CERTIFICATE OF SERVICE

I, Donald A. Ecklund, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: January 19, 2024

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