The Constitutionality of Medicare Drug-Price Negotiation under the Takings Clause

Health Policy Portal

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Abstract: In recent months, pharmaceutical manufacturers have brought legal challenges to a provision of the 2022 Inflation Reduction Act (IRA) empowering the federal government to negotiate the prices Medicare pays for certain prescription medications. One key argument made in these filings is that price negotiation is a "taking" of property and violates the Takings Clause of the US Constitution. Through original case law and health policy analysis, we show that government price negotiation and even price regulation of goods and services, including patented goods, are constitutional under the Takings Clause. Finding that the IRA violates the Takings Clause would radically upend settled constitutional law and jeopardize the US's most important state and federal health care programs.

The Inflation Reduction Act (IRA) of 2022 empowers the Centers for Medicare & Medicaid Services to negotiate the prices Medicare will pay for a small number of top-selling brand-name prescription drugs, a process that is expected to save patients and taxpayers billions of dollars every year. Yet this significant achievement is now threatened by at least 10 different lawsuits brought by the brand-name pharmaceutical industry and associated trade organizations. These cases allege a slew of constitutional violations, including that drug-price negotiation works an unconstitutional "taking" of private property. The taking argument is one of the most consequential claims brought against the IRA's drug-price negotiation program, as it would put a great many government programs at risk, from critical healthcare programs like Medicaid to the Emergency Medical Treatment and Labor Act (EMTALA).

In this review, we evaluate the takings claim made in litigation against the IRA and conclude that it is without merit.[1] It should fail in court and the challenged portions of the IRA should not be struck down on these grounds. We show, based on original analysis of case law, policy precedents, and other sources, first, that price negotiation and price controls by the US government have long been held constitutional under the Constitution's Takings Clause; and second, that the fact that brand-name drugs are commonly covered by patents does not convert price negotiation on those drugs into a taking.

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About This Column

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Background

As part of the Inflation Reduction Act (IRA), Congress for the first time empowered the Department of Health and Human Services (HHS) to negotiate with drug-makers the prices of a small number of drugs that the Medicare program purchases. The IRA requires the HHS Secretary, acting through the Centers for Medicare & Medicaid Services (CMS), to negotiate the prices Medicare pays for a certain set of drugs meeting a number of key criteria, such as that they are responsible for the highest Medicare Parts B and D spending, have been marketable for at least seven years, and lack bona fide generic or biosimilar competitors.[2]

In so doing, the IRA's drug-price negotiation program modifies the Medicare non-interference provision in the Medicare Modernization Act of 2003. That provision, a victory of extensive pharmaceutical lobbying,[3] prevented CMS from negotiating prices for drugs it buys through its Part D program.[4] The Medicare non-interference provision 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 Administration and the Medicaid program for low-income patients. The IRA's Medicare drug-price negotiation program thus begins to bring Medicare in line with these other government-sponsored health insurance programs, if only for a limited number of high-revenue drugs and only many years after marketing.

Drug Manufacturers' Challenges to the Medicare Drug-Price Negotiation Program

Failing to defeat the drug-price negotiation program in Congress, a host of drugmakers have brought suits to challenge the new law. They assert that the law violates a variety of constitutional provisions. A key claim is that the price negotiation program "takes" their property without just compensation in violation of the Takings Clause of the Fifth Amendment.[5]

The Fifth Amendment prevents the government from taking private property unless for public use and requires that the government provide just compensation when it does so. The scope of the Takings Clause has expanded over time: until the twentieth century, the Takings Clause only protected against physical appropriations of property by the government.[6] The Supreme Court extended the reach of the Takings Clause to "regulatory takings" in *Pennsylvania Coal Co. v. Mahon*, holding that "while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking."[7] In assessing whether a regulatory taking has occurred, courts apply three factors: the economic impact of the regulation on the claimant, the extent to which the regulation has interfered with distinct investment-backed expectations, and the character of the governmental action.[8]

The standard for what constitutes a "public use" for which the government may take property is broad.[9] As such, the constitutional question at the heart of most takings claims — as here — is whether a regulation interferes with "property" in the relevant sense. In the classic scenario, where government condemns land for public use, as when building a railroad, the standard is easily satisfied. But more difficult cases arise, particularly where regulations are involved.

If property is "taken," courts must evaluate the compensation to determine if it is "just;" if the government provides "just" compensation to the property owner, then the court will award no further remedy. Of course, judicial monitoring of just compensation may add substantial costs and complexity to government programs, especially because formulations of just compensation are unsettled and context-dependent.[10]

The Takings Clause applies not just to real estate but to personal property — cars, crops, and more. The Takings Clause requires just compensation when regulations effect a government seizure of personal property.[11] This much is settled doctrine.

In their lawsuits, drugmakers advance a novel argument: allowing the government to negotiate the prices of a prescription drug constitutes a taking that deprives a drugmaker of its property.[12] As one drug-maker contends, "a Government-imposed 50% discount on forced transfers of Eliquis is no different than if the Government were to seize 50% of BMS's inventory."[13] Because no drugmaker is forced to surrender its medications to the government, the drugmakers — which are not protesting the sale itself but the government's opportunity to reduce the sale price — appear to be asking courts to confer constitutional protection to their profits.

As the following sections show, and as we have described in amicus briefs

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filed in several courts, the companies' takings arguments are unsound as a matter of law. We also show that they are dangerous; indeed, if accepted by courts, their claims would radically rewrite takings doctrine and jeopardize a range of government healthcare programs.

Government Price Negotiation and Price Regulation in the US

Price negotiation and price regulation are ubiquitous economic tools available to, and regularly used by, the federal government. The voluntariness of prescription drug market participation disqualifies a takings claim. This alone should end this argument against the IRA's Medicare drug-price negotiation program. Companies also argue that the government is coercing their participation in the program because a great deal of profit is at stake. We show that this is irrelevant to the voluntariness of the program. Finally, even if the government were to introduce an *industry-wide* program extending beyond Medicare, this would not "take" property in the relevant sense. In highly regulated industries that receive substantial government privileges — as the pharmaceutical industry clearly does — Congress may set regulatory conditions such as these without running afoul of the takings clause.[14]

Government Price Negotiation Does Not Create a Takings Violation

As a purchaser of goods and services, the government regularly engages in price negotiation without raising any kind of takings issue. In 2022, the government spent $694 billion on contracts.[15] Many of these contracts were fixed-price vehicles that do not guarantee profit.[16] Courts have consistently held that no one is constitutionally entitled to sell to the government.[17] Rather, the government, like any other purchaser, is allowed to select its commercial partners,[18] adjust the terms and conditions of its sales contracts,[19] and negotiate the prices it will pay.[20] The federal government contracts like any other commercial party bargaining for sale, as opposed to when it seizes possession of goods as a sovereign entity.[21] As a result, government contracting does not implicate the Takings Clause,[22] even when price negotiations reduce the profit amount that a contracting party hoped to net.

Prescription drugs are no different. 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, the Medicaid program, and the 340B program (a special program through which safety net hospitals can acquire medications at prices far lower than commercial purchasers'). Under each of these programs, the government contracts with a manufacturer to provide prescription drugs.[23] Each program ensures a baseline statutory discount for drug price, with options for the federal government or seller (e.g., a hospital) to negotiate further discounts.[24] Drugmakers 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 Medicare Part B.[25] In essence, 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 structures and requirements of these programs do not violate the Takings Clause. In facts, courts have expressly distinguished the "economic hardship" that these programs may impose on drugmakers from the kind of compulsion that triggers the Takings Clause.[26] 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] Indeed, one court described as borderline nonsensical the argument that 340B negotiated discounts amounted to the government physically taking a company's prescription drugs.[28]

Drug manufacturers have revived similar claims here. They claim that the IRA's Medicare drug-price negotiation program is a "taking" of their patented drugs but can point to no reassignment of patent rights or physical seizure of their tablets or injections. Instead, their true argument is that curbing Medicare spending interferes with the enormous profits they expect from this program,[29] constituting a "taking" of their property. But courts have consistently, and properly, rejected similar claims.

The breadth of health care price negotiation programs already approved by courts underscores the extent of disruption that a takings holding here would engender. The IRA's Medicare drug-price negotiation program sets up a structure similar to the existing drug purchasing programs under 340B, Medicaid, and the Veterans Health Administration.[30] If a court were to accept drug-makers' argument that price negotiations constitute a taking, the door would open for nearly all government contract negotiations to be challenged as takings under the Fifth Amendment.[31] Such a holding would undermine settled contract law involving voluntary, bargained-for exchanges. This view would also upend a vast array of government contracts, not just limited to health care, whenever a company was displeased with a contracted-for rate. The government's leverage to secure favorable rates for its myriad social service programs would in turn diminish.

Even as to health care alone, a loss would be devastating. A determination that price negotiation effects a taking would jeopardize altogether the viability of federal and state health care programs. Government health care programs provide a key safety net for more than one in three Americans.[32] Due to their reach, these programs often strain state and federal budgets. In 2021, Medicare alone accounted for 21% of all US healthcare spending and 10% of the federal budget.[33] Medicare's costs are predicted to rise to 18% of the federal budget by 2032.[34] Excluding administrative costs, the Medicaid program cost $728 billion in fiscal year 2021,[35] or about 17% of national health

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expenditures that year.[36] Without negotiated discounts, the combination of exclusive rights and coverage mandates afforded by these programs would confer almost limitless pricing power to drug manufacturers.

Government price negotiation for these health care services enables federal and state health care 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 health care, especially for our country's elderly and low-income populations. For courts, it would mean a flood of litigation over the level of payment necessary to compensate takings by longstanding programs.

The Medicare, Medicaid, and Veteran Health Administration programs would not be the only areas of healthcare affected. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) entitles all Americans to emergency room treatment irrespective of insurance status. This law requires hospitals with emergency departments that receive Medicare funding to accept all patients in critical condition, regardless of their ability to pay.[37] Takings challenges to EMTALA by hospitals have failed on the grounds that participation in Medicare (and by extension in EMTALA) is voluntary.[38] A holding that the IRA's Medicare drug-price negotiations effect a taking could reopen 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 necessary extent of government compensation — no small feat considering the byzantine systems of medical billing and government reimbursement rates.

Price Regulations Are Common, and Generally Not Constitutionally Suspect

Companies do not directly argue that price regulations themselves "take" property, perhaps because they are aware that, historically, price regulation was widespread and violated no constitutional rights. Still, they argue they are somehow "coerced" to accept the government's prices. This argument is belied by the fact that price regulations have only very rarely been understood to interfere with "property" at all.

History shows us that price controls were commonplace in the early US. At least eight of the thirteen colonies adopted "expansive" price controls affecting "substantially everything in use at the time."[39] Price controls extended even 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,"[40] some colonies granted patents with "working clauses" that stipulated price as a condition.[41]

Courts have consistently rejected claims that price controls violate constitutional rights. Early cases were litigated under the Due Process Clause. During this era, the Supreme Court constructed the so-called *Lochner* doctrine, a controversial constitutional doctrine prioritizing and protecting the right to contractual freedom. Under this doctrine, the Court struck down many economic regulations, including labor laws, eventually generating the constitutional crisis that led Franklin Roosevelt to threaten to pack the court. The *Lochner* doctrine was abandoned in the late 1930s, paving the way for the modern rule that Congress is free to enact social and economic legislation without judicial interference.[42] But even while the *laissez faire Lochner* doctrine stood, courts repeatedly upheld price regulations against challengers who claimed they interfered with the right to contractual freedom.

In the "pioneer"[43] case of *Munn v. Illinois*,[44] the Supreme Court held that property "used in a manner to make it of public consequence" was "clothed with a public interest."[45] The purveyors of such goods and services — a categorization encompassing public utilities and transportation — had to "submit to be controlled by the public for the common good" through price regulation.[46] Post-*Munn*, the federal government and nearly every state established public service commissions that set utility rates.[47] Congress also passed antitrust legislation, including the Sherman Antitrust Act, to restrain unchecked monopoly prices.[48]

Later, in *Nebbia v. New York*, the Court extended the scope of regulable businesses,[49] pronouncing it "clear that there is no closed class or category of businesses affected with a public interest."[50] *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."[51] After the Court stood down and abandoned its effort to overturn economic regulations in areas it determined were not "clothed in the public interest," it affirmed a general presumption that price regulation was constitutional.[52] Such regulation continued to play a prominent role in American history. For example, 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;[53] these broad mandates all survived constitutional challenges.[54]

Congress's price-setting authority was so well-established that the Supreme Court upheld price regulations affecting a broad range of industries and services, including essential[55] and recreational commodities,[56] public utilities,[57] rent,[58] and labor;[59] prices that have the potential to limit[60] or deny a seller's profits,[61] or reduce the value of the regulated good;[62] price regulations that have differential effects on members of a regulated class;[63] retroactive price regulations to recover excessive profits;[64] and the prevention of economic waste as a permissible justification for price regulation.[65] In 1987, the Supreme Court declared the constitutionality of state and federal price regulation to be "settled beyond dispute."[66]

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The one area where the Supreme Court has found price regulation subject to some constitutional oversight is in industries for which market participation is *legally mandated* — namely, public utilities.[67] To compensate for public utilities' compulsory service at fixed rates, courts have exercised some judicial oversight over those rates. But even the modicum of oversight applied in the utility context is the exception, not the rule.[68] The reason it applies at all is that utilities have a legal mandate to supply their services. In their suits, the pharmaceutical companies have not argued that they should be treated like public utilities, perhaps because courts have done relatively little to regulate rates even for utilities and have not deemed such companies entitled to any particular level of profit.[69]

For industries that are highly regulated and sell potentially dangerous products, such as prescription drugs, Congress has great freedom to set conditions on market entry without implicating the Takings Clause.[70] Courts have seen such regulations as not implicating property rights but rather establishing the conditions for market entry. Even a regulation covering the entire pharmaceutical market, in other words, would merely establish a legitimate condition for market entry which companies voluntarily accept in exchange for enormous privileges. A price regulation convering the entire industry would complement existing federal regulations, including the Food and Drug Administration's review of safety and efficacy and the patent and other exclusive rights that allow drugmakers to establish high prices, that benefit the pharmaceutical industry enormously — and that generate the possibility of price gouging which the IRA seeks to combat.

Of course, the IRA does not affect the whole industry. It merely enables the government to negotiate as one purchaser for one portion of the market: Medicare. As such, courts need not traverse this broader issue. They can hold simply that the drug manufacturers at hand voluntarily choose to sell their drugs to Medicare, and as such cannot argue that their medicines are "taken" without their consent.

That Medicines Are Patented Does Not Alter the Takings Analysis

Some of the pharmaceutical industry's court challenges to the IRA's drug-price negotiation program have suggested that the fact that many brand-name drugs are protected by government-granted patents should somehow alter the takings analysis. For example, in its lawsuit, BMS declares that "patented medicines are protected by the Takings Clause."[71]

The fact that drugs are patent-protected does not strengthen the pharmaceutical industry's takings claims. The IRA works no interference with constitutionally protected patent rights. No Supreme Court case has ever held that patents are private property protected by the Takings Clause. Even if a court were to conclude this, it would not help companies here, because courts see property as a bundle of rights, not all of which have to be granted together. Since Congress has never given companies the specific right to prevent the federal government from interfering with their patents, this "right" cannot now be taken away.

Patents Are Not Private Property Eligible for the Protection of the Takings Clause

The Supreme Court and the Federal Circuit have never directly addressed the question of whether patented drugs are personal property eligible for protection under the Takings Clause. The most recent Supreme Court analysis of the fundamental nature of patent rights suggests strongly — but does not hold outright — that patents are not private property in the relevant sense. In its 2018 *Oil States* decision, a 7-2 majority of the Supreme Court concluded that patents are not private rights, but are public rights, akin to government franchises: a right the government takes from the public and grants to a private party.[72] As the Court explained, a patent is a "creature of statute"[73] and thus "can confer only the rights that 'the statute prescribes'"[74] — the right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States."[75] The Court observed that, as creatures of statute, patents are not personal property *per se*; instead, "[t]he Patent Act provides that, '*[s]ubject to the provisions of this title*, patents shall have the *attributes* of personal property.'"[76]

All this language and reasoning in *Oil States* strongly suggests that patents are not private property for purposes of the Takings Clause. There is no reason for patent rights to be considered public for the purposes of Article III, but private for the Fifth Amendment. In a recent article, intellectual property law professor Robin Feldman summarizes *Oil States* as follows: "the Court made absolutely clear its view that there is a strict, categorical difference between land/chattels as 'core' private property rights and patents as public rights."[77] Feldman also argues more broadly, based on history, the text and structure of the Fifth Amendment, and many decades of case law, that patents simply should not be protected by the Takings Clause.[78]

Although the *Oil States* majority cautioned that it was not formally deciding that "patents are not property for purposes of the Due Process Clause or the Takings Clause,"[79] a lower court responded by taking *Oil States* to its logical conclusion. In 2019, shortly after *Oil States*, the Court of Federal Claims held in *Christy, Inc.* that "patents are public franchises, not private property," and therefore that "patent rights are not cognizable property interests for Takings Clause purposes."[80] In so holding, the court echoed *Oil States* and 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."[81] Highlighting the Court's discussion of the public nature of patent rights, the Court of Federal Claims concluded that the Court's reasoning in *Oil States* could not "be dismissed as dicta."[82]

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The Court of Federal Claims is so far the only court to directly tackle the question of whether patents are personal property subject to the Taking Clause. As noted above, *Oil States* declined to hold that patents are not protected by the Takings Clause.[83] Although language from a nineteenth-century Supreme Court decision may appear to describe patents as constitutional property,[84] scholars note both that this language is dicta (or non-binding commentary) and that it refers not to patents but to the distinct English property law construct of "letters-patents."[85] The Federal Circuit has similarly avoided answering this question directly, including in its review of the *Christy* decision (a decision it affirmed on narrower grounds).[86] As a result, no court has ever held that patents are private property protected by the Takings Clause.

No Right To Exclude the Federal Government from Patented Products

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, procuring, or using a product covered by a patent — even without the patent holder's consent.[87] Put another way, there is no property right to exclude the federal government in the "bundle of sticks" that a patent confers.

Until the twentieth century, the US government's sovereign immunity completely shielded it from lawsuits brought by patent holders for government use of their patents.[88] In 1894, in *Schillinger v. United States,* the Supreme Court confirmed as much, holding that a patent holder could not bring a takings claim against the government in the event of government patent use.[89] The Court explained that Congress had not waived the government's sovereign immunity as to "claims founded upon torts."[90] Because a patent infringement action "is one sounding in tort[,]" *Schillinger* held that government patent use did not expose the government to liability.[91]

In response, Congress enacted a limited waiver of the US government's sovereign immunity. This law provided patent holders with a claim for "limited relief"[92] for government patent use.[93] 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 benefited the public.[94] This provision only allowed patent holders to seek "reasonable and entire compensation" for government use of their patents; it foreclosed injunctive relief.[95]

The law is now codified as 28 U.S.C. § 1498.[96] 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."[97]

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 effects today.[98] Put more directly, if the Constitution ensured that patent holders were entitled to compensation when the government uses their patents, Congress would not have had to so provide.

Today, § 1498 offers a more extreme — and yet entirely constitutional — remedy to the problem of high prices than the IRA's Medicare drug-price negotiation program. Some of the authors' past scholarship has documented the government's "routine[]" use of § 1498 to procure everything from "electronic passports to genetically mutated mice."[99] The government relies on § 1498 "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*."[100] For example, in the 1960s, the Department of Defense negotiated purchase of the antibiotic tetracy-

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cline from an Italian maker instead of the US-based patent-holder, Pfizer, even though Pfizer was able to supply the government's purchase order, because the Italian version was 72% cheaper.[101] According to one source, the Department of Defense relied on § 1498 to procure approximately fifty drugs in a three-year period during the 1960s.[102]

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-HHS Secretary Tommy Thompson, publicly discussed bypassing Bayer's patent to amass a stockpile of the antibiotic ciprofloxacin (Cipro).[103] At the time, Bayer held the patents on this drug, controlled its sale in the US, and refused to lower its prices to supply a purchase order for the government to use in response to a potential biological threat.[104] In response, Secretary Thompson suggested that the government could invoke § 1498 to lawfully use Bayer's patents and import cheaper versions of the medication.[105] The mere specter of this action led Bayer to slash its prices: 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).[106] In contrast to the IRA's Medicare price negotiations, Bayer's price concession — made 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 typically pays the patent holder only a reasonable royalty — in practice rarely exceeding 10% of the price of the generic[107] — as compensation for its infringement.[108] Importantly, the § 1498 case law does not interpret "reasonable and entire compensation" to mean the entirety of the patent holder's 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)[109] examines "mixed considerations of logic, common sense, justice, policy and precedent" when setting compensation under § 1498.[110] 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.[111] When the Court of Federal Claims lacks evidence of prior licensing agreements, it typically applies the "willing buyer-willing seller" rule to arrive at a royalty rate.[112]

Because "reasonable and entire compensation" does not mean lost profits, pharmaceutical companies would not, under § 1498, be guaranteed profits on sales to or for the federal government.[113] This 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.

Finally, government patent use doctrine undermines pharmaceutical companies' suggestion that the drug price negotiations coerce the sale of medications the government would otherwise be unable to procure.[114] The government has legal authority to purchase other drugmakers' copies of pharmaceutical companies' drugs should the patent-holding companies decline to participate in the price negotiations. The government has chosen a more generous approach, negotiating prices with patent-holding companies instead. This too shows that companies' constitutional arguments are without merit.

Conclusion

Last year, Congress took an important step to address the US drug-price crisis by bringing Medicare in line with other government healthcare programs that negotiate drug prices with their manufacturers. In response, drug-makers advanced the radical argument that these negotiations are a constitutional taking of their profits, likening the government's mere ability to negotiate prices to a forcible seizure of their private property. But as this article has illustrated, decades of Supreme Court precedent upholding government price negotiations and regulations — an analysis unchanged by the fact that patents cover the negotiated drugs — demonstrate the incorrectness of the drug-makers' claims. In fact, the government is constitutionally empowered to procure patented drugs at below-market cost even *without* the manufacturer's consent, a tool that would likely reduce pharmaceutical companies' profits more than mere price negotiation.

The drug-makers' takings challenge may well end up before the Supreme Court, and their argument has implications for far more than the IRA's price-negotiation program. Robust government healthcare programs depend on negotiated discounts to offer essential services for our most vulnerable populations, including the low-income, those with disabilities, veterans, and the elderly. A successful takings challenge to the IRA's price negotiation provisions would threaten these and other government programs involving price negotiations. Courts should reject the takings arguments as they have always done, and affirm the constitutionality of price negotiation.

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4. 42 U.S.C. § 1395w-111(i).
5. *See, e.g.*, Memorandum of Law in Support of Motion for Summary Judgment at 16, *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JB (D.N.J. Aug. 16, 2023).

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6. R. Meltz, *Takings Decisions of the U.S. Supreme Court*, Cong. Rsch. Serv. 1 (2015); *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (describing history of Takings Clause).
7. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922).
8. *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).
9. *See Kelo v. City of New London*, 545 U.S. 469, 479-80 (2005) (describing longstanding interpretation of "public use" to mean "public purpose," which is itself broadly defined in deference to legislative judgments).
10. C. Serkin, "The Meaning of Value: Assessing Just Compensation for Regulatory Takings," *Northwestern University Law Review* 99 (2005).
11. *Horne v. Dep't of Agric.*, 576 U.S. 350, 357-61 (2015).
12. Memorandum of Law in Support of Motion for Summary Judgment at 18, *Janssen v. Becerra*, No. 3:23-cv-3818 (D.N.J. Aug. 16, 2023).
13. Memorandum of Law in Support of Motion for Summary Judgment at 12, *Bristol Myers Squibb v. Becerra*, No. 23-3335 (D.N.J. Aug. 16, 2023).
14. Brief of Law Scholars as Amici Curiae at 13-17, *Janssen v. Becerra*, No. 3:23-cv-3818 (D.N.J. Oct. 23, 2023).
15. *A Snapshot: Government-Wide Contracting*, Government Accountability Office (May 2023), *available at* <https://gaoinnovations.gov/Federal_Government_Contracting> (last visited Dec. 20, 2023).
16. *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.").
17. *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980).
18. *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016); *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940); *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.").
19. *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940).
20. *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))); 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").
21. *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).
22. *Klump v. United States*, 50 Fed. Cl. 268, 272 (2001), *aff'd*, 30 F. App'x 958 (Fed. Cir. 2002). Contractors seeking to allege a breach of contract have separate remedies based on the contract. *See Hughes Commc'ns*, 271 F.3d at 1070.
23. 38 U.S.C. § 8126 (Veterans Health Administration); 42 U.S.C. §§ 256b (Section 340B), 1396r-8 (Medicaid).
24. 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).
25. 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); *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"').
26. *Eli Lilly & Co.*, 2021 WL 5039566, at *2.
27. *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 209-10 (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.,* 2021 WL 5039566, at *21.
28. *See Sanofi-Aventis*, 570 F. Supp. 3d at 208 ("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.'").
29. S. Dickson and J. Ballreich, "How Much Can Pharma Lose? A Comparison of Returns Between Pharmaceutical and Other Industries," *WestHealth Policy Center* 3 (2019).
30. P.L. 117-169 § 11101 (2022) (requiring a rebate for single-source drugs and biological products if the price of the product increases faster than inflation).
31. *Hughes Commc'ns*, 271 F.3d at 1070.
32. *Health Insurance Coverage of the Total Population*, Kaiser Family Foundation (2021), *available at* <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Dec. 20, 2023). 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. Mike McCaughan, "Veterans Health Administration," *Health Affairs*, Aug. 10, 2017, *available at* <https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/> (last visited Dec. 20, 2023); "Patients by TRICARE Plan," *Health.mil*, *available at* <https://www.health.mil/Military-Health-Topics/MHS-Toolkits/Media-Resources/Media-Center/Patient-Population-Statistics/Patients-by-TRICARE-Plan> (last visited Dec. 20, 2023); G. Clerveau, et al., "A Snapshot of Sources of Coverage Among Medicare Beneficiaries," Kaiser Family Foundation, Aug. 14, 2023, *available at* <https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries> (last visited Dec. 20, 2023).
33. J. Cubanski and T. Neuman, "What to Know About Medicare Spending and Financing," Kaiser Family Foundation, Jan. 19, 2023, *available at* <https://www.kff.org/medicare/issue-brief/

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what-to-know-about-medicare-spending-and-financing> (last visited Dec. 20, 2023).
34. *Id.*
35. E. Williams et al., "Medicaid Financing: The Basics," Kaiser Family Foundation, Apr. 13, 2023, *available at* <https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics> (last visited Dec. 20, 2023).
36. *NHE Fact Sheet*, CMS.gov, *available at* <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet> (last visited Dec. 20, 2023).
37. 42 U.S.C. § 1395cc(a)(1)(I)(i); 42 U.S.C. § 1395dd.
38. *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) ("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.'").
39. B. P. McAllister, "Price Control by Law in the United States: A Survey," *Law & Contemporary Problems* 4 (1937) (identifying price controls for wages, agricultural products, tobacco, and liquor, and building materials).
40. An Act Concerning Monopolies, 21 Jac. I, c. 3, § 6 (1623) (Eng.).
41. O. Bracha, "The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care," *Loyola of Los Angeles Law Review* 38 (2004).
42. *See West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937).
43. *Bowles v. Willingham*, 321 U.S. 503, 518 (1944).
44. 94 U.S. 113 (1876).
45. *Id.* at 126.
46. *Id.*
47. *See* W. Boyd, "Just Price, Public Utility, and the Long History of Economic Regulation in America," *Yale Journal on Regulation* 35 (2018). At the federal level, Congress authorized the Interstate Commerce Commission in 1887 to regulate railroad (and later trucking) rates, *see* McAllister, *supra* note 39; 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* N. L. Smith, "Rate Regulation by the Federal Power Commission," *American Economic Review* 36 (1946); the Federal Farm Board in 1929 to regulate agricultural prices, *see* N.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," *Drake Journal of Agricultural Law* 9 (2004); the Federal Communications Commission in 1934 to regulate telephone and telegraph rates, *see* C. I. Wheat, "The Regulation of Interstate Telephone Rates," *Harvard Law Review* 52 (1938); and the Civil Aeronautics Authority in 1938 to regulate air fares, *see* W. C. Wooldridge, "The Civil Aeronautics Board as Promoter," *Virginia Law Review* 54 (1968).
48 .*See generally* Boyd, *supra* 47; *supra* note 2.
49. *Nebbia v. People of New York*, 291 U.S. 502, 516 (1934).
50. *Id.*
51. *Id.*
52. *Olsen v. Nebraska*, 313 U.S. 236, 245 (1941). *See also Ribnik*, 277 U.S. at 374 (Stone, J., dissenting) ("To say that there is constitutional power to regulate a business or a particular use of property because of the public interest in the welfare of a class peculiarly affected, and to deny such power to regulate price for the accomplishment of the same end, when that alone appears to be an appropriate and effective remedy, is to make a distinction based on no real economic difference, and for which I can find no warrant in the Constitution itself nor any justification in the opinions of this court.")
53. During World War II, for example, the temporary Office of Price Administration set maximum prices on nearly ninety percent of commodities and imposed rent control over "practically the entire country." *See* Note, "Price and Sovereignty," *Harvard Law Review* 135 (2021); B. F. Grainey, "Price Control and the Emergency Price Control Act," *Notre Dame Law Review* 19 (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* J. N. Drobak, "Constitutional Limits on Price and Rent Control: The Lessons of Utility Regulation," *Washington University Law Review* 64 (1986); R. H. Field, "Economic Stabilization Under the Defense Production Act of 1950," *Harvard Law Review* 64 (1950).
54. 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, *supra* note 53; *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).
55 *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).
56. *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).
57. *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").
58. *See Bowles*, 321 U.S. at 517 (holding that rent control did not "involve[] a 'taking' of property").
59. *See West Coast Hotel Co.*, 300 U.S. 379 (upholding minimum-wage legislation).
60. *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").
61. *See Yakus v. United States*, 321 U.S. 414, 486 n.40 (1944) ("[T]he Fifth Amendment does not insure a profit to any given individual or group not under legal compulsion to render service.").
62. *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.").
63. Permian Basin Area Rate Cases, 390 U.S. 747, 769 (1968).
64. *Lichter v. United States*, 334 U.S. 742, 787 (1948).
65. *Cities Serv. Gas Co. v. Peerless Oil & Gas Co.*, 340 U.S. 179, 185-86 (1950).
66. *FCC* v. *Fla. Power Corp.*, 480 U.S. 245, 253.
67. 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."); *Hegeman Farms Corp. v. Baldwin*, 259 U.S. 188, 190 (1922) ("A public utility…has no

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outlet of escape."); *see also* J. Rossi, "The Common Law "Duty to Serve" and Protection of Consumers in an Age of Competitive Retail Public Utility Restructuring," *Vanderbilt Law Review* 51 (1998) (describing long-standing decisions recognizing common-law and statutory "duty to serve" for public utilities and common carriers).

68. *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 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* J. N. Drobak, "From Turnpike to Nuclear Power: The Constitutional Limits on Utility Rate Regulation," *Boston University Law Review* 65 (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.").
69. *See Market St. Ry. Co. v. R.R. Comm'n of California*, 324 U.S. 548, 566 (1945) ("regulation does not assure that the regulated business make a profit").
70. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (holding that a federal law requiring relinquishment of certain alleged trade-secret information was not a taking because Monsanto received market access in exchange for submitting the information and because its products were hazardous); *Horne*, 576 U.S. at 365-66 (interpreting *Monsanto* as holding that Monsanto and other companies "were not subjected to a taking because they received a 'valuable Government benefit' in exchange — a license to sell dangerous chemicals.").
71. Memorandum of Law in Support of Motion for Summary Judgment at 12, *Bristol Myers Squibb v. Becerra*, No. 23-3335 (D.N.J. Aug. 16, 2023).
72. *Oil States Energy Servs., LLC v. Greene's Energy Grp.*, LLC, 138 S. Ct. 1365, 1373, 1373-75 (2018).
73. *Id.* at 1374 (quoting *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 40 (1923)).
74. *Id.* at 1375 (quoting *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 494 (1851)).
75. *Id.* at 1374 (quoting 35 U.S.C. § 154(a)(1)).
76. *Id.* at 1375 (quoting 35 U.S.C. § 261) (emphasis added).
77. R. Feldman, "Patents as Property for the Takings," *The New York University Journal of Intellectual Property and Entertainment Law* 12 (2023).
78. *Id.*
79. *Oil States*, 138 S. Ct. at 1379.
80. *Christy, Inc. v. United States*, 141 Fed. Cl. 641, 660 (2019), *aff'd on narrower grounds*, 971 F.3d 1332 (Fed. Cir. 2020).
81. *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.").
82. *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").
83. *Oil States*, 138 S. Ct. at 1379.
84. *James v. Campbell*, 104 U.S. 356, 357-58 (1881)),
85. Feldman, *supra* 77; *see also* J. S. Masur and A. K. Mortara, "Patents, Property, and Prospectivity," *Stanford Law Review* 71 (2019)
86. *See Christy*, 971 F.3d 1332, 1335-36 (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 … ."); *Peter*, 931 F.3d 1342, 1358-59. (avoiding commenting on the contention that the patent holder 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).
87. *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.").
88. *See, e.g.*, S. M. O'Connor, "Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy," *John Marshall Review of Intellectual Property Law* 12 (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 patent holders 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, as 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.").
89. *See Golden*, 955 F.3d at 987 (describing *Schillinger v. United States*, 155 U.S. 163 (1894)).
90. *Schillinger*, 155 U.S. at 168.
91. *Id.*
92. H. Brennan, A. Kapczynski, C. H. Monahan, and Z. Rizvi, "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," *Yale Journal of Law & Technology* 18 (2016).
93. Act of June 25, 1910, ch. 423, 36 Stat. 851, 851; *see* C. J. Morten and C. Duan, "Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises," *Yale Journal of Law & Technology* 23 (2020).
94. 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.").
95. Act of June 25, 1910, ch. 423, 36 Stat. 851, 851. In 1918, the predecessor statute to § 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,

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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.

96. 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.
97. 28 U.S.C. § 1498(a) (2018).
98. *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.
99. Brennan et al., *supra* note 92. 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).
100. *Id.* (emphasis added) (citations omitted).
101. 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?" *Notre Dame Law Review* 42 (1967).
102. M. Silverman and P. R. Lee, *Pills, Profits, and Politics* (University of California Press, 1974).
103. *See* Brennan et al., *supra* note 92; *see also* K. Bradsher, "A Nation Challenged: The Cost; Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine," *New York Times*, Oct. 25, 2001, *available at* <https://www.nytimes.com/2001/10/25/business/nation-challenged-cost-bayer-agrees-charge-government-lower-price-for-anthrax.html> (last visited Dec. 20, 2023).
104. *See* Morten & Duan, *supra* note 93.
105. *See id.*
106. *Id.*; Bradsher, *supra* note 103.
107. *See* J. Adamczyk, A. Lewis, S. Morrison, and C. Morten, "§ 1498: A Guide to Government Patent Use, A Path to Licensing and Distributing Generic Drugs," SSRN (2021), *available at* <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."); A. Kapczynski and A. S. Kesselheim, "'Government Patent Use': A Legal Approach to Reducing Drug Spending,"*Health Affairs* 35 (2016) ("Royalties are commonly set at 10 percent of sales or less" in § 1498 cases); R. J. McGrath, "The Unauthorized Use of Patents by the United States Government or Its Contractors," *AIPLA Quarterly Journal* 18 (1991) ("Historically, the highest royalty rate that the United States Claims Court has awarded is 10%.").
108. *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).
109. 28 U.S.C. § 1498(a) (2018); *see Golden*, 955 F.3d 981, 986.
110. *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).
111. *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).
112. *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).
113. *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 awards under § 1498 since 1930 to show that there has not been a lost profits award); Brennan et al., *supra* n.145, at 313 (noting that in "every modern § 1498 case, then, the measure of royalties has not been lost profits but rather a 'reasonable royalty'").
114. Memorandum of Law in Support of Motion for Summary Judgment at 15, *Bristol Myers Squibb v. Becerra*, No. 23-3335 (D.N.J. Aug. 16, 2023); Memorandum of Law in Support of Motion for Summary Judgment at 4, *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JB (D.N.J. Aug. 16, 2023).

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