UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

Plaintiffs,

v.

UNITED STATES DEPARTMENT of HEALTH and HUMAN SERVICES, *et al.*,

Defendants.

Case No. 3:23-cv-01103-RNC

MOTION FOR LEAVE TO FILE BRIEF OF LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

This case concerns the constitutionality of the Inflation Reduction Act's (IRA) Medicare drug-price negotiation provisions. Proposed amici are law professors and scholars who focus their scholarship and teaching on intellectual property law, property law, regulatory law, and health law. Amici write to address the plaintiff's, Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), contention that the Medicare drug price negotiations effectuate 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 Boehringer's favor would have on the federal government's ability to provide adequate healthcare to Americans.

Amici move for leave to file the attached proposed amicus brief in opposition to Boehringer's motion for summary judgment, ECF No. 28, and in support of the defendant's cross motion for summary judgment and response to Boehringer's motion for summary judgment, ECF No. 48.

II. ARGUMENT

In absence of clear standards, courts follow Rule 29 of the Federal Rules of Appellate Procedure, which provides that an "amicus curiae may file a brief only by leave of court or if the brief states that all parties have consented to its filing." The movants seek leave to file this amicus brief.

"[D]istrict courts have broad inherent authority to permit or deny an appearance as amicus curiae in a case."[1] In *Kistler v. Stanley Black & Decker Inc.*, this Court stated that an "amicus brief should normally be allowed when a party is not represented competently or is not represented at all, when the amicus has an interest in some other case that may be affected by the decision in the present case (though not enough affected to entitle the amicus to intervene and become a party in the present case), or when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide."[2] The movants respectfully submit that these factors support granting leave to file the attached amicus brief.[3]

The movants are scholars and professors with expertise in intellectual property law, property law, health law, and regulatory law. Their work focuses on the theory, history, and doctrine of these—often overlapping—areas of law. Some of their works also focuses on the effect that various laws and judicial decisions have on health outcomes both in the United States and abroad, including patients' access to affordable medications.

As professors of law and academic scholars in the legal, healthcare, and regulatory fields, the movants have a unique perspective on the implications this suit holds for the future of property law, intellectual property law, government regulation of health and safety, and access to healthcare. The movants posit that the IRA's drug pricing negotiation program is a necessary,

---

[1] *Kistler v. Stanley Black & Decker, Inc.*, No. 3:22-CV-966 (SRU), 2023 WL 1827734, at *1 (D. Conn. Jan. 25, 2023) (quoting *Ross v. Mellekas*, 2020 WL 8680019, at *1 (D. Conn. Aug. 5, 2020)) (internal quotations omitted).

[2] *Kistler*, 2023 WL 1827734, at *1 (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)) (internal quotations omitted).

[3] These factors are not dispositive, and the proposed amicus is not required to satisfy all four to succeed. *See id.*

valuable, and lawful step towards reducing the unnecessarily high cost of prescription drugs for Medicare patients. The movants are concerned that Boehringer's incorrect view of takings jurisprudence, if adopted by this Court, would have far-reaching and negative implications for the federal government's ability to implement regulations that protect the health of the U.S. population. The movants respectfully submit that the concepts explored in their proposed amicus brief—including the history of price negotiation and regulation in the United States and the federal government's right to use patents—are vital to a holistic analysis of the issues raised in this action. The movants are also unaware of any other amici that would represent this perspective and champion their unique interests.

The movants' proposed amicus brief is attached to this motion, providing the parties ample time to address the issues raised therein, should they so choose. Summary judgment briefing in this action does not conclude until February 26, 2024.

III. CONCLUSION

For these reasons, proposed amici respectfully request that this Court grant their motion for leave to file the attached amicus curiae brief.

Date: December 22, 2023

Respectfully submitted,

/s/ Hannah W. Brennan
Hannah W. Brennan (admitted *pro hac vice*)
HAGENS BERMAN SOBOL SHAPIRO LLP
Rebekah Glickman-Simon (admitted *pro hac vice*)
Claudia Morera (admitted *pro hac vice*)
One Faneuil Hall, 5th Fl.
Boston, MA 02109
Tel.: (617) 482-3700
Fax: (617) 482-3003
hannahb@hbsslaw.com
rebekahgs@hbsslaw.com
claudiam@hbsslaw.com

Attorneys for Amicus Curiae

CERTIFICATE OF SERVICE

I, Hannah W. Brennan, 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: December 22, 2023

/s/ Hannah W. Brennan
Hannah W. Brennans

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT of HEALTH and HUMAN SERVICES *et al.*,

Defendants.

Case No. 3:23-cv-01103-RNC

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

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's, Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), 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 Boehringer'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 dilemma, Congress passed the Inflation Reduction Act (IRA) and, with it, the Medicare drug price

---

[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 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).

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.

Boehringer now argues that it has a constitutional right to the monopoly prices it has 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

---

[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.

[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.").

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. Boehringer 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 spending do not give rise to a constitutional claim.

Finding a taking here would unravel the principal government healthcare programs. Accepting Boehringer's position would have far reaching ramifications for access to healthcare within 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

[8] In *Dayton Area Chamber of Com. v. Becerra*, the Court 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.

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 Takings Clause. In its complaint, but not in its motion for summary judgment, Boehringer asserted that the drug price negotiation program implicates its property interests in its patented medicine and the Takings Clause protects its right to exclude others from making Jardiance.[10] However, Boehringer did not explicitly argue that its patents are private property subject to the Fifth Amendment's Taking Clause.[11] 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. This Court, however, need not reach this issue as the parties have neither directly raised nor briefed it.

[10] Boehringer Compl., *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Dep't of Health & Hum. Servs. et al*, Civ. A. No. 3:23-cv-01103-RNC, ECF No. 1 (D.C.T. Aug. 18, 2023) at 30, 34-35.

[11] *Id.*

II. ARGUMENT

A. Boehringer'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."[12] 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."[13] To assist in this "efficient procurement," the government holds the authority to (1) "determine those with whom it will deal,"[14] (2) "fix the terms and conditions upon which it will make needed purchases,"[15] and (3) negotiate the prices it will pay for goods and services.[16] Such contracting does not implicate the Takings Clause. The federal government contracts in its commercial, not sovereign, capacity.[17] 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

---

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

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

[14] *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.").

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

[16] *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").

[17] *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).

proprietary capacity.'"[18]

Yet, Boehringer appears to seek a constitutional right to sell their drugs at profits levels they dictate—levels that routinely exceed those in all other industries.[19] In their briefing, Boehringer claims that the IRA's Medicare drug price negotiation program is a per se taking of its drug.[20] Yet Boehringer points to no reassignment of patent rights or warehouse seizure of Jardiance tablets. Rather, Boehringer's chief concern is that its compensation will be capped, so it argues, "well below market-based prices."[21] The true "taking" at issue is a reduction of its profits.

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,

---

[18] *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.

[19] *See supra* n.7.

[20] Memo. of Law in Support of Plaintiff's Mot. for Summary Judgment (Boehringer S.J. Br.), *Boehringer Ingelheim Pharmaceuticals, Inc. v. U.S. Dep't of Health & Hum. Servs. et al*, Civ. A. No. 3:23-cv-01103-RNC, ECF No. 28-1 (D.C.T. Sept. 27, 2023) at 20-14.

[21] Boehringer S.J. Br. at 20.

[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

[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, 209-10 (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.

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 Boehringer's argument that a government price negotiation program constitutes a per se taking of a drug maker's medicine 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.

2. A ruling that the Medicare drug price negotiations constitute 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.[32] But, due to their reach, these programs strain state and federal budgets. In 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.

[32] *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,

Medicare alone accounted for 21% of all U.S. healthcare spending and 10% of the federal budget.[33] Medicare's costs are predicted to rise to 18% of the federal budget in 2032.[34] The Medicaid program cost $728 billion, excluding administrative costs, in fiscal year 2021,[35] about 17% of national health expenditures that year.[36]

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

---

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.**Error! Bookmark not defined.**. *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.

[33] *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.

[34] *Id.*

[35] *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.

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

to accept all patients in critical condition, regardless of their ability to pay.[37] Takings challenges to EMTALA 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 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 Boehringer's patents on Jardiance should not alter the Court's takings analysis. Nor does Boehringer even argue that its patents are personal property subject to the Fifth Amendment's Taking Clause. The Supreme Court and the Federal Circuit have never directly addressed this question, and existing Federal Circuit caselaw points in the opposite direction.[39] 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

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

[38] *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.'").

[39] *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).

Supreme Court concluded that patents are "public rights," akin to government franchises—not "private rights."[40] 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.[41] The district court acted first, rejecting some of the defendant's arguments on patent validity.[42] A few months later, the Board reached the opposite conclusion, holding the patent claims to be invalid.[43] 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.[44]

Historically, Congress has been permitted to "assign adjudication of public rights to entities other than Article III courts[,]" whereas private rights must be adjudicated by Article III courts.[45] 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.[46] 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.[47] As the Court explained, a patent is a "creature of statute"[48] and thus "can confer only the rights that 'the statute prescribes'"[49]—the right "to exclude others

---

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

[41] *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.*).

[42] *Id.* at 1372.

[43] *Id.*

[44] *Id.*

[45] *Id.* at 1373.

[46] *Id.* at 1373.

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

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

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

from making, using, offering for sale, or selling the invention throughout the United States."[50] 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."[51] As such, it did not need to be resolved in an Article III court.[52]

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 rights are not cognizable property interests for Takings Clause purposes."[53] 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."[54] 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."[55]

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

---

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

[51] *Id.* at 1373.

[52] *Id.* at 1375.

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

[54] *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.").

[55] *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").

patents were subject to the Takings Clause.[56] The Federal Circuit has similarly avoided answering this question directly.[57] This case, in which the question has not been properly raised, is hardly the proper vehicle for an unsettled question of this magnitude.[58]

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."[59] 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

---

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

[57] *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 ("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).

[58] To the extent Boehringer seeks to rely on the Supreme Court's pre-*Oil States* decision in *Horne v. Dep't of Agriculture*, such reliance is misplaced. 576 U.S. 350 (2015). *Horne* involved the federal government's physical appropriation of the plaintiff-farmers' raisins. The Supreme Court concluded that raisins, as "the fruit of the growers' labor," were private property, not "'public things subject to the absolute control of the state.'" *Id.* at 356-57. Patents, however, fall within the public rights doctrine like oysters: "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." *Id.* at 366-67. 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." *Id.* at 367; *see* U.S. Const. Art. I § 8, Cl. 8 (Congress hold the power—but the not the obligation—to grant patents). And without patents, brand manufacturers like Boehringer would lose the power to reap the benefit—high profits—it contends will be taken by the Medicare drug price negotiations.

[59] *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.").

make "an invention described in and covered by a patent of the United States . . . without [a] license of the [patent] owner."[60] 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.[61] Thus, rather than negotiate drug prices with Boehringer, the government could simply contract with alternative manufacturers to produce the drugs at issue, with *less* compensation due to Boehringer than what the IRA's Medicare drug price negotiation program offers. Such a decision would not run afoul of the Takings Clause.[62]

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.[63] In 1894, the Supreme

[60] 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.*

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

[62] *See supra* n.59.

[63] *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

Court clarified that a patentee could not sue the government for patent use as a taking.[64] In *Schillinger v. United States*, the Court explained that Congress had not waived its sovereign immunity as to "claims founded upon torts."[65] Thus, because a patent infringement action "is one sounding in tort[,]" government patent use did not expose the government to takings liability.[66]

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"[67] for government patent use.[68] 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.[69] This 1498 precursor only allowed patent holders to seek "reasonable compensation" for government use of their patents; it foreclosed injunctive relief.[70]

---

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.").

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

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

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

[67] 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).

[68] 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).

[69] 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.").

[70] 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*

The law is now codified as 28 U.S.C. § 1498.[71] 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."[72] 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.[73]

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

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

---

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.

[71] 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.

[72] 28 U.S.C. § 1498(a) (2018).

[73] *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."[74] 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*."[75] 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.[76] According to one source, the Department of Defense relied on § 1498 to procure approximately fifty drugs in a three-year period during the 1960s.[77]

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 generic copies of the antibiotic ciprofloxacin.[78] At the time, Bayer held the patents on this drug, controlled its sale, and refused to lower its prices to supply a purchase order for the government to

[74] Brennan et al., *supra* n.67, 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).

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

[76] 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).

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

[78] *See* Brennan et al., *supra* n.67, 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.

use in response to a potential biological threat.[79] In response, Secretary Thompson suggested that the government invoke its authority to lawfully use Bayer's patents and import other versions of the medication.[80] 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).[81] 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[82]—as compensation for its infringement.[83] Importantly, the § 1498 case law does not interpret "reasonable and entire 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[84])

---

[79] *See* Morten & Duan, *supra* n.68, at 26-28.

[80] *See id.* at 30.

[81] *Id.*; Bradsher, *supra* n.78.

[82] *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%.").

[83] *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)

[84] 28 U.S.C. § 1498(a) (2018); *see Golden*, 955 F.3d 981, 986.

examines "mixed considerations of logic, common sense, justice, policy and precedent" when setting compensation under § 1498.[85] 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.[86] 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.[87]

Because "reasonable and entire compensation" does not mean lost profits, Boehringer would not be allowed to recover for any government patent use at the Jardiance price it currently sets.[88] 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.

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 Boehringer suggests that the drug price negotiations "coerce"

---

[85] *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).

[86] *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).

[87] *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).

[88] *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.67, at 313 (noting that in "every modern § 1498 case, then, the measure of royalties has not been lost profits but rather a 'reasonable royalty'").

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 Boehringer's Jardiance should it decline to participate in the negotiations. And the government decision to procure Boehringer's medicine through the Medicare drug price negotiation program instead of § 1498 shows that the government has chosen the less extreme procurement method, undermining Boehringer's coercion argument.

III. CONCLUSION

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

IV. SIGNATORIES[89]

Aziza Ahmed
Professor of Law
Boston University School of Law

Brook K. Baker
Professor of Law
Northeastern University School of Law

Yochai Benkler
Jack N. and Lillian R. Berkman Professor for Entrepreneurial Legal Studies
Faculty Co-Director, Berkman Klein Center for Internet and Society
Harvard Law School

Scott Burris
Professor of Law and Public Health
Director, Center for Public Health Law Research
Temple University Beasley School of Law

Troyen Brennan
Adjunct Professor of Health Policy and Management
Harvard T. H. Chan School of Public Health

[89] Institutional affiliations are provided for informational purposes only.

Michael A. Carrier
Board of Governors Professor
Co-Director, Rutgers Institute for Information Policy and Law
Rutgers Law School

Bernard Chao
Professor of Law
University of Denver Sturm College of Law

Jorge L. Contreras
James T. Jenson Endowed Professor for Transactional Law
Director, Program on Intellectual Property and Technology Law
Adjunct Professor of Human Genetics
University of Utah College of Law

Nathan Cortez
Co-Director of the Tsai Center for Law, Science and Innovation
Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino Studies
Southern Methodist University Dedman School of Law

Stacey L. Dogan
Professor & Law Alumni Scholar
Boston University School of Law

Charles Duan
Assistant Professor of Law
American University Washington College of Law

Samuel F. Ernst
Associate Dean for Academic Affairs
Professor of Law
Golden Gate University School of Law

Robert I. Field
Professor of Law
Drexel University Kline School of Law
Professor of Health Management and Policy
Drexel University Dornsife School of Public Health

Sean Flynn
Professorial Lecturer of Intellectual Property and Human Rights
Director, Program on Information Justice and Intellectual Property
American University Washington College of Law

Lawrence O. Gostin
Founding O'Neill Chair in Global Health Law
Faculty Director, O'Neill Institute
Director, WHO Collaborating Center on Global Health Law
Georgetown Law

Peter Henderson
Incoming Assistant Professor
School of Public and International Affairs
Department of Computer Science
Princeton University

Laura Hermer
Professor of Law
Mitchell Hamline School of Law

Allison K. Hoffman
Deputy Dean, Professor of Law
University of Pennsylvania Penn Carey Law School

Nicole Huberfeld
Edward R. Utley Professor of Health Law & Professor of Law
Co-Director, Boston University Program on Reproductive Justice
Assistant Director, Center for Health Law, Ethics & Human Rights
Boston University School of Public Health
Boston University School of Law

Peter D. Jacobson
Professor Emeritus of Health Law and Policy
University of Michigan School of Public Health

Timothy S. Jost
Emeritus Professor of Law
Washington and Lee University School of Law

Amy Kapczynski
Professor of Law
Faculty Director of the Global Health Justice Partnership
Yale Law School

Aaron S. Kesselheim
Professor of Medicine
Harvard Medical School
Director of the Program on Regulation, Therapeutics, and Law
Division of Pharmacoepidemiology and Pharmacoeconomics
Brigham and Women's Hospital

Renee M. Landers
Professor of Law
Faculty Director, Health and Biomedical Law Concentration and Master of Science in Law, Life Science Program
Suffolk University Law School

Stacey M. Lantagne
Professor of Law
Western New England University School of Law

Mark A. Lemley
William H. Neukom Professor
Director, Stanford Program in Law, Science, and Technology
Stanford Law School
Senior Fellow, Stanford Institute for Economic Policy Research
Affiliated Professor, Stanford Symbolic Systems Program

Christopher J. Morten
Associate Clinical Professor of Law
Columbia Law School

Jordan Paradise
Georgia Reithal Professor of Law
Co-Director, Beazley Institute for Health Law and Policy
Loyola University Chicago School of Law

Wendy E. Parmet
Matthews University Distinguished Professor of Law and
Professor of Public Policy and Urban Affairs
Northeastern University

Srividhya Ragavan
Professor of Intellectual Property and International Trade Law
Director of International Programs
Texas A&M University School of Law

Arti Rai
Elvin R. Latty Professor
Faculty Direction, Center for Innovation Policy
Duke Law School

Christopher Robertson
Associate Dean for Strategic Initiatives
Professor of Health and Disability Law
Boston University School of Law
Professor of Health Law, Policy & Management
Boston University School of Public Health

Marc A. Rodwin
Professor of Health Law and Policy
Suffolk University Law School

Sara Rosenbaum
Professor of Emerita, Health Law and Policy
Milken Institute School of Public Health
George Washington University

Ana Santos Rutschman
Professor of Law
Charles Widger School of Law
Villanova University

Ameet Sarpatwari
Assistant Professor of Medicine,
Harvard Medical School
Assistant Director of the Program on Regulation, Therapeutics, and Law
Division of Pharmacoepidemiology and Pharmacoeconomics
Brigham and Women's Hospital

Cason Schmit
Assistant Professor
Director, Program in Health Law and Policy
Department of Health Policy & Management, School of Public Health
Texas A&M University

Jason M. Schultz
Professor of Clinical Law
Director of NYU's Technology and Policy Clinic
Co-Director of the Engelberg Center on Innovation Law & Policy
New York University School of Law

Jessica Silbey
Professor of Law and Yanakakis Faculty Research Scholar
Boston University School of Law
Affiliate Fellow, Information Society Project (ISP), Yale Law School
Affiliate Faculty, Center for Innovation in Social Sciences (CISS), Boston University

Michael S. Sinha
Assistant Professor of Health Law and Intellectual Property Law
Center for Health Law Studies
Saint Louis University School of Law

Talha Syed
Lecturer on Intellectual Property, Torts and Antitrust Law
University of California Berkeley Law

S. Sean Tu
Arthur S. Dayton Professor of Intellectual Property and Food and Drug Law
West Virginia University College of Law

Michael R. Ulrich
Assistant Professor
Center for Health, Law, Ethics & Human Rights
Boston University School of Public Health
Boston University School of Law
Distinguished Visiting Scholar
Solomon Center for Health Law & Policy
Yale Law School

Liza Vertinsky
Professor of Law
University of Maryland Francis King Carey School of Law

Sidney Watson
Professor of Law and Scholar in Residence
Center for Health Law Studies
Saint Louis University School of Law

Rebecca Wolitz
Assistant Professor of Law
The Ohio State University Moritz College of Law

Peter K. Yu
Regents Professor of Law and Communication
Director, Center for Law and Intellectual Property
Texas A&M University

Esther van Zimmeren
Professor of Intellectual Property Law & Governance
University of Antwerp

Date: December 22, 2023

Respectfully submitted,

/s/ Hannah W. Brennan
Hannah W. Brennan (admitted *pro hac vice*)
HAGENS BERMAN SOBOL SHAPIRO LLP
Rebekah Glickman-Simon (admitted *pro hac vice*)
Claudia Morera (admitted *pro hac vice*)
One Faneuil Hall, 5th Fl.
Boston, MA 02109
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
hannahb@hbsslaw.com
rebekahgs@hbsslaw.com
claudiam@hbsslaw.com

Attorneys for Amici Curiae

CERTIFICATE OF SERVICE

I, Hannah W. Brennan, 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: December 22, 2023

/s/ Hannah W. Brennan
Hannah W. Brennan

CERTIFICATE OF COMPLIANCE

I, Hannah W. Brennan, certify that amici's brief complies with the type and volume requirements set forth by this District Court pursuant to Local Rule 7(a)(5) and Federal Rules of Appellate Procedure 29. It contains 7,743 words in 12-point font with 10-point font footnotes. A copy of this brief has been sent to the Court.

Dated: December 22, 2023

/s/ Hannah W. Brennan
Hannah W. Brennan

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

Plaintiffs,

v.

UNITED STATES DEPARTMENT of HEALTH and HUMAN SERVICES, *et al.*,

Defendants.

Case No. 3:23-cv-01103-RNC

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

Having considered the Law Scholars' motion for leave to file a brief as *amici curiae* in support of Defendant's cross-motion for summary judgment and in opposition to Plaintiff's motion for summary judgment; and all parties, by and through their counsel, having received due notice of the motion and having the opportunity to be heard; and for good cause shown,

IT IS on this _____ day of _____, 202_, **ORDERED**:

1. The Law Scholars' motion for leave to file a brief as *amici curiae* is hereby granted;
2. The Law Scholars' proposed amicus brief is hereby deemed filed and will be considered by the Court.

_____
Hon. Robert N. Chatigny, Senior U.S.D.J