The False Promise of Breaking Patents to Lower Drug Prices

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ABSTRACT

Congressional leaders, policy activists, and scholars contend that patents are a principal cause of rising drug prices. They argue that a solution exists in two federal statutes that allegedly authorize agencies to impose price controls on drug patents: 28 U.S.C. § 1498 and the Bayh-Dole Act. These "price-control theories of § 1498 and the Bayh-Dole Act" maintain that Congress has already endorsed the unprecedented and controversial policy of breaking patents to lower drug prices in private transactions in the healthcare market.

Neither § 1498 nor the Bayh-Dole Act authorize agencies to impose price controls, as confirmed by their plain text and by their interpretation by courts and agencies. Section 1498 is an eminent domain statute that applies only when a patent is used by and for the government, such for the military, the Post Office, or the Veterans Administration. The Bayh-Dole Act promotes commercialization of patented inventions derived from federal funding of upstream research; consistent with this commercialization function, this law specifies four delimited conditions when a federal agency may "march in" and license a patent when a patented product is not sold or available in the marketplace. Applying canons of statutory interpretation, the meaning of these two statutes is clear. Neither specifies that "price" triggers regulatory controls over private market transactions. Congress knows how to enact price-control laws, such as the Emergency Price Control Act of 1942 or when it specifies "reasonable price" as a goal of legislation. The price-control theories of § 1498 and the Bayh-Dole Act profess unprecedented agency powers lacking any authorization in existing statutes. Yet academic scholarship, as well as policy and legal work based on this scholarship, continue to promote the price-control theories of § 1498 and the Bayh-Dole Act. These are policy arguments masquerading as statutory construction.

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I. Introduction

The cost of medical care in the United States has long been debated in healthcare policy.[1] The causes of healthcare prices are complex and multi-varied, if only because the U.S. healthcare system is complex. The modern healthcare system comprises a myriad of legislative, administrative, and regulatory regimes enacted by the federal government and all fifty states, which are intertwined with equally complex commercial institutions built through private rights in property and contract.[2] In policy discussions about drug prices, though, some scholars and policymakers reduce this legal and institutional complexity to a single cause—patents.

The patent system is now at the center of policy debates and academic discussions about drug prices. Scholars blame patents for "rising drug prices."[3] Activists have filed at least ten petitions to federal agencies requesting that they break patents in order to lower drug prices in the healthcare market—petitioning the agencies to authorize through regulatory fiat a generic drug company to make and sell lower-priced drugs protected by patents owned by innovator drug companies.[4] These petitions have all been denied, with the most recent rejection on March 23, 2023 by the National Institutes of Health (NIH) in response to a petition seeking to impose price

[1] *See, e.g.*, *Consumer Group Decries Rise in Drug Prices*, LOS ANGELES TIMES (Mar. 16, 1995) ("Prices of the 20 top-selling prescription drugs are rising faster than inflation, despite drug company promises to slow the increases, a consumer group charged Wednesday."); *Uncertain Progress on Health Costs*, N.Y. TIMES, B20 (July 17, 1984) ("The Reagan Administration is declaring victory over 'the health care inflation monster' because medical costs are rising less feverishly. Any celebration, however, should wait until all the causes of the decline are better understood."); E. RICHARD BROWN, ROCKEFELLER MEDICINE MEN: MEDICINE AND CAPITALISM IN AMERICA 1 (1979) ("The crisis in today's health care system is deeply rooted in the interwoven history of modern medicine and corporate capitalism. The system's most obvious problems are cost, inflation, and inaccessibility of medical care in the United States.").

[2] *See* Douglas A. Hastings, *Foreword: The Changing Face of Law and Medicine in the New Millennium*, 26 AM. J.L. & MED. 135, 135 (2000) ("For over 200 years, our healthcare system has been, in effect, a mixed public and private system, essentially built on a private chassis with a great deal of public funding, regulating and prodding. It also has been a profoundly federalist system, generating fifty-one health regulatory schemes.").

[3] S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. (forthcoming 2022), at 2, https://papers.ssrn.com/abstract=4149718 ("Patients, doctors and insurers have all felt the distress of rising drug prices over the past decade. Underlying much of these cost increases are the exclusive rights granted by patents."); *see also* 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, 277 (2016) ("Drug prices in the United States are among the highest in the world . . . . . [T]hey result from . . . our patent system . . . [and its] grant of a monopoly [that] allows a manufacturer to charge any price . . . ."); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 33 HEALTH AFFAIRS 791, 791 (2015) (claiming that "new medicines . . . are expensive not because they are expensive to manufacture but because they are protected by patents").

[4] *See Return on Investment Initiative for Unleashing American Innovation* 29 (NIST Special Publication 1234, April 2019) (identifying 10 petitions to break patents solely for the purpose of imposing price controls on drug patents).

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controls on a patented drug that treats a prostate cancer.[5][6] A group of activists and academics also lobbied Congress to break patents in order to lower drug prices, arguing that drug prices "are high primarily because brand-name drug companies use government-granted exclusivities, such as patents, to prevent competition and charge high prices."[7]

These agency petitions and lobbying activities over several decades urging the federal government to break patents to lower drug prices assert that two federal statutes authorize this regulatory action. The first is a century-old statute that secures the right of patent owners to sue the federal government when it violates a patent right through its eminent domain power (28 U.S.C. § 1498).[8] Section 1498 requires the government to pay "reasonable and entire compensation" if a patented invention "is used or manufactured by or for the United States."[9] The second is the Bayh-Dole Act of 1980, a statute that declared definitively that inventors had a right to obtain patents if federal funding was used in the discovery or creation of their inventions.[10] To facilitate commercialization of new innovations, the Bayh-Dole Act affirmed that inventors whose research is funded even in part by the federal government may receive patents for their innovations.[11] In

[5] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Director, to Robert Sachs and Clare Love (Mar. 23, 2023), https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf (rejecting petition to impose price controls on Xtandi); *see also Return on Investment Initiative for Unleashing American Innovation*, *supra* note 4, at 29 ("NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority."); John R. Thomas, *March-In Rights Under the Bayh-Dole Act*, CONGRESSIONAL RESEARCH SERVICE 8-9 (Aug. 22, 2016), https://sgp.fas.org/crs/misc/R44597.pdf (As of 2016, "six petitions have been filed requesting that the NIH 'march in' with respect to a particular pharmaceutical. Each petition was denied. A common theme of each of the denials was the agency's views that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights.").

[6] *See* Letter from Clare Love & Robert Sachs to Xavier Becerra, Secretary of the Department of Health and Human Services 2 (Nov. 18, 2021), https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf (proposing "a march-in request" for the drug, Xtandi, on the basis "that the price is demonstrably unreasonable"); Letter from Knowledge Ecology International and Union for Affordable Cancer Treatment to the National Institutes of Health, Department of Health and Human Services & Department of Defense 21 (Jan. 14, 2016), https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf (making "march-in request" that "the federal government grant an open license to any generic drug manufacturer" due to "an excessive price" for Xtandi).

[7] Letter from Amy Kapczynski, Aaron S. Kesselheim, et al. to Senator Elizabeth Warren, at 1 (Apr. 20, 2022), https://tinyurl.com/yt62wt4t.

[8] *See* Decca Ltd. v. United States, 544 F.2d 1070, 1082 (Ct. Cl. 1976) ("It is [the government's] taking of a license, without compensation, that is, under an eminent domain theory, the basis for a suit under § 1498."); Carter-Wallace, Inc. v. United States, 449 F.2d 1374, 1390 (Ct. Cl. 1971) (Nichols, J., concurring) (stating that § 1498 authorizes a claim in court "to recover just compensation for a taking under the power of Eminent Domain"); Irving Air Chute Co. v. United States, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (stating that § 1498 is "an eminent domain statute").

[9] 28 U.S.C. § 1498(a).

[10] *See* University and Small Business Patent Procedures Act of 1980, Pub. L. 96–517, 94 Stat. 3018 (Dec. 12, 1980) (codified in 35 U.S.C. §§ 200-212). This statute is popularly known as the "Bayh-Dole Act," as set forth in its Short Title. *See id.*, 94 Stat. at 3018.

[11] *See* 35 U.S.C. § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor . . . .").

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further promoting commercialization of patented inventions, the Bayh-Dole Act also authorizes federal agencies to "march in" and license a patent without authorization from the patent owner if the patented invention is not commercialized in the marketplace.[12]

Advocates for the price-control theories of § 1498 and the Bayh-Dole Act also make policy arguments, but these arguments are based on a core legal claim: the federal government has the existing statutory authority to lower drug prices by breaking patents on drugs.[13] In sum, the price-control theories of § 1498 and the Bayh-Dole Act maintain that Congress long ago resolved in the affirmative the debate over the highly controversial policy whether the federal government should impose price controls on drug patents. The only remaining policy question, its advocates contend, is whether federal agencies will act on their existing statutory authority.

This article addresses this purported *legal foundation* supporting the argument that breaking patents is the best governmental policy to lower drug prices. Contrary to claims of the price-control theories of § 1498 and the Bayh-Dole Act, these statutes do not authorize the federal government or any federal agencies to break patents solely for the purpose of lowering drug prices. This article derives this conclusion from the text of § 1498 and the Bayh-Dole Act and the consistent judicial and agency interpretations of these statutes. These statutory analyses are essential to the broader policy debates occurring in Congress and in agencies because these statutes define and delimit federal officials' authority to achieve policy goals. As the legal realists reminded us in the early twentieth century, policy arguments "empty without *objective description* of the causes and consequences of legal decisions."[14] They were speaking of court decisions, but this key insight applies equally to the objective description of the meaning of statutes.

In explaining why the price-control theories of § 1498 and the Bayh-Dole Act are a false promise to lower drug prices via price controls on patents, this article proceeds in three parts. First, it details the text and longstanding judicial interpretation of § 1498. Both its text and its interpretation by courts establish that § 1498 does not authorize the federal government to impose price controls on products manufactured and sold by private companies, such as drugs made by pharmaceutical companies and sold to patients in the healthcare market. This was confirmed by a district court's recent decision rejecting Moderna's attempt to use § 1498 as an affirmative defense from a patent infringement lawsuit brought against Moderna for its manufacture and use of its mRNA COVID-19 vaccine in the U.S. healthcare market.[15] Second, the article explicates the march-in provision of the Bayh-Dole Act, which is a more complex statute than § 1498, but the conclusion is the same: It does not authorize unprecedented agency actions to break drug patents

[12] *See* 35 U.S.C. § 203(a)(1)-(4).

[13] *See, e.g.*, Alfred B. Engelberg, Jerry Avorn, & Aaron Kesselheim, *A New Way to Contain Unaffordable Medication Costs – Exercising the Government's Existing Rights*, 386 N. ENGL. J. MED. 1104, 1104 (2022), https://www.nejm.org/doi/full/10.1056/NEJMp2117102 (stating that "existing laws" provide the government with the authority to lower drug prices and identifying § 1498 and the Bayh-Dole Act); Brennan, Kapczynski, et al., *supra* note 3, at 279 (claiming that "a legal remedy that has been hiding in plain sight" in § 1498 to lower drug prices).

[14] Felix S. Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 849 (1935) (emphasis added).

[15] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022).

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to impose price controls on drugs manufactured and sold in the healthcare market. Similar to § 1498, the Bayh-Dole Act does not expressly authorize an agency to impose price controls on products produced and sold by private companies to private consumers in the marketplace, and it has never been used for this purpose. Such a power not only contradicts the commercialization function of the Bayh-Dole Act, it runs afoul of Supreme Court jurisprudence that unprecedented grants of power to an agency, such as imposing price controls on drug patents made and sold by private companies, must be expressly authorized by statute.[16] This construction of the march-in power in the Bayh-Dole Act is further confirmed by agency interpretations of this statutory provision over many decades, including the recent decision by the NIH not to invoke the march-in power on the patents covering Xtandi,[17] that have concluded that this statute does not authorize agencies like the NIH to impose price controls on drug patents.

II. As an Eminent Domain Statute, § 1498 Does Not Authorize Breaking Patents to Impose Price Controls on Private Transactions in the Marketplace

The price-control theory of § 1498 proposes to use this statute as an "important tool" to lower drug prices charged by private companies to private purchasers,[18] but § 1498 is not a price-control statute. It is an eminent domain statute based in nineteenth-century eminent domain cases in which the government directly used patented inventions without authorization of the patent owners. When the federal government did this, nineteenth-century courts responded by protecting patents as constitutional private property under the Takings Clause of the Fifth Amendment.[19] In one key case in 1876, the Supreme Court recognized that "[a]gents of the public have no more right to take such private property [in a patent] than other individuals" who may infringe a patent because the Constitution mandates that "[p]rivate property . . . shall not be taken for public use without just compensation."[20] In the early twentieth century, Congress enacted § 1498 to resolve confusion about the jurisdiction of courts to hear takings claims by patent owners, foreshadowing the enactment of the Bayh-Dole Act in 1980 to eliminate confusion about the patentability of inventions based in research supported by even a modicum of federal monies. The provenance of § 1498 is important, because it establishes that it is an eminent domain statute, as well established by court decisions, and thus its text precludes its use as a legal tool for imposing price controls on drug patents.

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[16] *See* West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587, 2609 (2022) ("[B]oth separation of powers principles and a practical understanding of legislative intent make us 'reluctant to read into ambiguous statutory text' the delegation claimed to be lurking there. . . . The agency instead must point to "clear congressional authorization" for the power it claims.") (citations omitted).

[17] *See supra* notes 5-6, and accompanying text.

[18] *See* Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., *supra* note 7, at 1.

[19] *See* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation."); Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. REV. 689, 701-11 (2007) (discussing case law).

[20] Cammeyer v. Newton, 94 U.S. 225, 234-35 (1876).

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A. Section 1498 is an Eminent Domain Statute

In the patent-takings cases in the nineteenth century, courts rejected numerous defenses by federal officials when called to account for their unauthorized uses of patented inventions. This included their arguments that patents are mere regulatory privileges that can be used by the government without authorization and that government officials are immune from lawsuits given sovereign immunity.[21] In rejecting a federal official's claim to sovereign immunity, one federal court held in 1879 that "[t]his property, like all other private property recognized by law, is exempt from being taken for public use without just compensation, by the supreme law of the land. Const. U. S. art. 5. . . . The property in a patented invention stands the same as other property, in this respect."[22] Unfortunately, the Supreme Court sowed confusion two decades later when the Court blithely stated in an 1894 decision that patent owners lacked a jurisdictional basis to sue the government for its unauthorized uses of their property.[23] Notably, the Court issued this decision without even acknowledging the existence of the earlier precedents in the lower courts and in its own decisions that patent owners had the right to sue the federal government for an unconstitutional taking of their property when officials used their patents without authorization.[24]

In 1910, Congress brought an end to this constitutional confusion by enacting § 1498 to reestablish the previously secure constitutional protection afforded to patents by the Supreme Court under the Takings Clause.[25] The House committee report for the bill that became § 1498 expressly stated that the federal government was using patents without authorization "in flat violation of [the Takings Clause] and the decisions of the Supreme Court."[26] During the congressional debates leading up to the enactment of § 1498, the bill's sponsor, Representative Currier, emphasized that the legislation "does not create any liability; it simply gives a remedy upon an existing liability."[27] (This is the same function of 42 U.S.C. § 1984 and 42 U.S.C. § 1988, which establish jurisdiction for a court to hear a constitutional claim and provide a remedy for a violation of a citizen's constitutional rights.) Throughout the debates in Congress in 1910, legislators repeatedly referenced the earlier Supreme Court decisions that had already secured to

[21] *See* Mossoff, *supra* note 19, at 701-11 (detailing the defenses against the takings or infringement claims).

[22] Campbell v. James, 4 F. Cas. 1168, 1172 (C.C.S.D.N.Y. 1879) (No. 2,361), *rev'd on other grounds*, James v. Campbell, 104 U.S. 356 (1881). Since the Supreme Court held on appeal that the patent is invalid, it did not reach the infringement or sovereign immunity issues as a matter of law. But the *James* Court still thought it important to state in dicta that the "exclusive property in the patented invention . . . cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land." *James*, 104 U.S. at 358.

[23] *See* Schillinger v. United States, 155 U.S. 163 (1894).

[24] Justice Brewer's majority opinion and Justice Harlan's dissenting opinion in *Schillinger* clashed over the legal fiction of an "implied contract" that the Supreme Court had long employed to establish jurisdiction for courts to hear claims for unconstitutional takings of property in both real estate and patents under the enabling legislation that created the Court of Claims in 1855. But the majority opinion does neither acknowledges nor engages with any of the takings cases involving patents. *See* Mossoff, *supra* note 19, at 713 and n.130.

[25] *See* Act of June 26, 1910, ch. 423, 36 Stat. 851, 851-52 (1910) (codified as amended in 28 U.S.C. § 1498).

[26] H.R. REP. NO. 61-1288, at 3 (1910).

[27] Mossoff, *supra* note 19, at 712-13 (quoting 45 CONG. REC. 8755, 8756 (1910)).

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patent owners their constitutional remedy under the Takings Clause.[28] In 1918, in the midst of federal procurement efforts with contractors, Congress amended § 1498 to provide jurisdiction to hear claims by patent owners for compensation when federal contractors infringe their patents.[29]

The text of § 1498 establishes that it is a jurisdiction-conferring statute for claims for compensation arising from exercises of the government's eminent domain power. Section 1498 states that a patent owner can sue the federal government in the Court of Claims (now-styled as the Court of Federal Claims) for "recovery of his reasonable and entire compensation" when a patented invention is "used or manufactured by or for the United States without license of the owner."[30] Judge Philip Nichols thus stated as a truism in a 1971 decision that § 1498 authorizes a court to hear a claim by a patent owner "to recover just compensation for a taking under the power of Eminent Domain."[31] A couple decades earlier, the Court of Claims succinctly stated in 1950 that § 1498 is "an eminent domain statute."[32]

B. Section 1498 Does Not Apply to Market Transactions Between Private Parties

As an eminent domain statute, the text of § 1498 provides that a patent owner may sue the federal government for "reasonable and entire compensation" when its patented "invention . . . is used or manufactured by or for the United States."[33] The nineteenth-century takings cases that underscored the enactment of this statute by Congress confirm that it applies to the classic case of an exercise of eminent domain by the federal government over a patented invention—the government acquires or uses a patented without authorization by the patent owner. Two such prominent nineteenth-century cases, for example, arose from the unauthorized use by the U.S. military of patented tents and patented cartridge (bullet) cases carried by soldiers.[34] The twentieth-century cases brought by patent owners under § 1498 are no different,[35] including a famous twentieth-century case arising from the U.S. military's unauthorized use of a patented battery during World War Two.[36] In sum, the plain text of § 1498 makes clear that it is not a grant of power to the federal government to impose price controls on products sold by private companies

[28] *See* Mossoff, *supra* 19, at 712 (citing H.R. REP. NO. 61-1288, at 1-4 (1910)).

[29] *See* Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 (1918) (codified as amended in 28 U.S.C. § 1498).

[30] 28 U.S.C. § 1498(a).

[31] *Carter-Wallace, Inc.*. 449 F.2d at 1390 (Nichols, J., concurring).

[32] *Irving Air Chute Co.*, 93 F. Supp. at 635.

[33] *Id.*

[34] *See, e.g.*, United States v. Burns, 79 U.S. 246 (1870) (patented tents used during Civil War); McKever v. United States, 14 Ct. Cl. 396 (1878) (patented cartridge boxes).

[35] *See, e.g.*, *Hughes Aircraft Co. v. Messerschmitt-Boelkow-Blohm*, 625 F.2d 580 (5th Cir. 1980); *Hughes Aircraft Co. v. United States*, 534 F.2d 889 (Ct. Cl. 1976); *Croll-Reynolds Co. v. Perini-Leavell-Jones-Vinell*, 399 F.2d 913 (5th Cir. 1968), *cert. denied*, 393 U.S. 1050 (1969).

[36] *See* United States v. Adams, 383 U.S. 39 (1966). This is a famous patent case that is in many patent casebooks. *See, e.g.*, ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 552-59 (7th ed. 2017).

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to private consumers—it confers jurisdiction for a federal court to hear a lawsuit when a patented invention is "used or manufactured by or for the United States without license of the owner."

Despite this clear statutory text that a patented invention must be "used or manufactured" by the United States, a 2016 law journal article argued for a novel price-control theory of § 1498 as a solution to the problem of the "soaring cost" of drugs.[37] The scheme was both clever and simple: Congress enacts a law or a federal agency adopts a regulation that directs a private company to make and sell patented drugs at lower prices for private purchasers in competition with the owner of the drug patent. According to this argument, since the government authorizes the private company to sell the infringing drug at the lower price in the marketplace, the patent owner can only sue the federal government under § 1498 for compensation. It cannot sue the private company directly for patent infringement, because the federal government is the proximate cause of the patent infringement. In this lawsuit, a federal judge would set the "reasonable compensation" due to the owner of the drug patent that will be paid by the federal government. They argued that this "reasonable compensation" determined by a court would reflect a lower amount than the innovator would receive from sales of its patented drug, if only because it is a distinct remedy from the "lost profits" paid by infringing companies in run-of-the-mill patent infringement lawsuits between private companies. Thus, the federal government could impose price controls on drugs sold in the healthcare market with the price set at whatever federal judges think is "reasonable" compensation via a lawsuit against the government under § 1498.[38]

Perhaps recognizing that the government authorizing private parties to manufacture and sell products to private purchasers in the marketplace is not "used or manufactured by or for the United States," the proponents of the price-control theory of § 1498 also argue that federal agencies had done this before under § 1498 in the mid-twentieth century.[39] In an editorial, the *New York Times* repeated this claim that this has all happened before, and thus it can happen again, asserting that it was merely historical accident that the price-control theory of § 1498 "fell out of use."[40]

The problem with this "it's been done before" argument is two-fold. First, the text of § 1498 expressly authorizes lawsuits against the government only when an "invention . . . is used or manufactured by or for the United States."[41] In other words, the statute confers jurisdiction for lawsuits when the federal government exercises its eminent domain power, authorizing patent owners to receive "reasonable and entire compensation" for this unauthorized use—the patent law equivalent of the "just compensation" mandated by the Takings Clause. Even if federal agencies sporadically invoked § 1498 a few limited times during the initial decades of the nascent

[37] *See* Brennan, Kapczynski, et al., *supra* note 3, at 277.

[38] *Id.*; *see also* Joseph Adamczyk, Adrienne Lewis, Shivani Morrison, and Christopher Morton, *§ 1498: A Guide to Government Patent Use, a Path to Licensing and Distributing Generic Drugs* (Jan. 2021), https://dx.doi.org/10.2139/ssrn.3882823 (detailing similar proposal for the use of § 1498 to license generic drug companies to make and sell patented drugs at a lower price than that charged by the drug patent owner).

[39] *See* Brennan, Kapczynski, et al., *supra* note 3, at ___; Adamczyk, Lewis, et al., *supra* note 38, at ___.

[40] *How the Government Can Lower Drug Prices*, N.Y. TIMES (June 20, 2021), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html (repeating and endorsing the price-control theory proposed in the 2016 law journal article).

[41] *Id.*

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administrative state and patent owners did not argue at the time that the agencies lacked authority under § 1498 to do this, these improper agency actions do not justify contradicting the plain statutory text today. As parents often remind their children: Two wrongs do not make a right.

Second, and perhaps more important, the claim by proponents of the price-control theory of § 1498 that the statute has been used in the past for this purpose is false. The federal government has not used § 1498 for the sole purpose of imposing price controls on *private companies* selling products to *private consumers* engaged in transactions in the marketplace. In a co-authored 2018 blog essay, we published the results of our own, independent review of the historical record on the use of this statute as alleged by the proponents of the price-control theory of § 1498.[42] The earlier agency actions that relied on § 1498 represented government procurement contracts, such as acquisition of medicines by the Veterans Health Administration of the U.S. Department of Veterans Affairs. This was not the scheme proposed by the price-control theory of § 1498 in which the federal government authorizes *private companies* to sell patented products or services solely to *private consumers* in the marketplace. In sum: "The historical record is absolutely clear that government agencies and courts have all applied § 1498 only to situations of government procurement and its own direct use. It has never been used to authorize private companies infringing patents for the sole purpose of selling the patented innovation to consumers in the free market."[43]

In a letter to Senator Elizabeth Warren in April 2022, advocates for the price-control theory of § 1498 broadened their argument that § 1498 should also apply to situations in which the use of the patented invention is merely for the general "benefit" of the government.[44] The letter derives this "benefit" language, not from the text of § 1498, but from a 2009 court opinion in *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, in which the court interpreted the phrase "by or for the United States" in § 1498.[45] In this case, the court held that regional Federal Reserve banks acted "for the government" when they used a process for detecting fraudulent Treasury checks that infringed a patent. The court concluded that "the benefits to the government of using the [patent-infringing fraud-detection] technology on Treasury checks are not incidental effects of private interests."[46] *Advanced Software* concluded that the patent owner had to proceed in its lawsuit against the federal government under § 1498, and not in a patent infringement lawsuit against the specific Federal Reserve bank. Given the formal relationship between the federal government and the Federal Reserve System in managing the official currency printed by the U.S.

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[42] *See* Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation* (Nov. 5, 2018), https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/.

[43] Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation* (Nov. 5, 2018), https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/.

[44] *See* Letter from Amy Kapczynski, Aaron S. Kesselheim, et al to Senator Elizabeth Warren, *supra* note 7, at 37.

[45] *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1373-74 (Fed. Cir. 2009). Judge Braden and Joshua Kresh similarly describe *Advanced Software* and *Larson v. United States*, *see* Susan G. Braden & Joshua A. Kresh, *Section 1498(A) is Not a Rx to Reduce Drug Prices*, 77 FOOD & DRUG L.J. 274, 284-85 (2022).

[46] *Id.* at 1379.

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Bureau of Engraving and Printing in the U.S. Department of Treasury, this decision makes sense, both legally and commonsensically.

The Federal Reserve System, however, is not the same legal or commercial entity as a private company that manufactures and sells a drug to other companies or patients in the marketplace. In fact, the *Advanced Software* court distinguished an earlier decision, *Larson v. United States*, whose facts are similar to the proposed scheme to lower drug prices under the price-control theory of § 1498.[47] In *Larson*, a patent owner sued a private medical company for infringing its patent on a medical device (a splint); the splints were paid through government programs such as Medicaid or Medicare, or at least the purchase price was reimbursed.[48] Given that "the government reimbursed the cost [of the infringing splint] through Medicare and other federal programs," the defendant argued that the patent owner's lawsuit must proceed against the government under § 1498.[49] The *Larson* court definitively rejected this argument, stating that "government reimbursement of medical care expenses did not constitute a *use* of a medical patent *for* government purposes," as required by the text of § 1498 in authorizing lawsuits against the federal government.[50] Seventeen years later, the *Advanced Software* court reaffirmed the holding in *Larson*, stating that "[t]he fact that the government has an interest in the [healthcare] program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498."[51]

The interpretation of § 1498 by *Advanced Software* and *Larson* that it applies only to eminent-domain actions by the government in its own unauthorized use of patented technologies was confirmed in a recent decision in *Arbutus Biopharma Corp. v. Moderna*.[52] In this case, Arbutus sued Moderna for infringing Arbutus' patents covering mRNA technology when Moderna produced and sold its famous mRNA vaccine for COVID-19. Moderna filed a motion to dismiss on the basis of § 1498, arguing that the federal government purchased Moderna's mRNA vaccines in response to the COVID-19 pandemic through federal programs like Operation Warp Speed. Thus, Moderna argued that Arbutus was required to sue the federal government under § 1498 for its "entire and reasonable compensation," which precluded it from suing Moderna for patent infringement. In effect, Moderna argued that, since it "contracted with the Government for production and delivery of the vaccine for use in combatting the pandemic," it was immune from a patent lawsuit and Arbutus' real legal dispute was with the federal government, not Moderna.[53]

The *Arbutus* court rejected Moderna's argument because its production and sale of its mRNA vaccines was not "for the Government," as required by § 1498. Moderna's contract with the federal government did not provide that the advance purchases of vaccine doses was for the

[47] *See* Larson v. United States, 26 Cl. Ct. 365 (1992)

[48] *Id.* at 367-68.

[49] *Advanced Software*, 583 F.3d at 1379 (describing the defendant's argument in *Larson*).

[50] *Larson*, 26 Cl. Ct. at 369 (emphases added).

[51] *Id.* (quoting *Larson*, 26 Cl. Ct. at 369).

[52] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022).

[53] *Id.*, at *4.

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benefit of and use by the government; rather, the purchase contract provided only that the government was making these advanced purchases of vaccines as part of a "whole of nation effort" in response to a "national emergency."[54] The *Arbutus* court concluded that Moderna's "development and sale of the vaccines was for the benefit of the vaccine's recipients," not for the benefit of the federal government.[55]At best, the court observed that "the U.S. Government was an *incidental beneficiary* who bore an interest in ensuring the safety of its citizens,"[56] not a *direct beneficiary* as required by § 1498 and the consistent interpretation of this statute by courts.[57] Several months later, the *Arbutus* court reaffirmed its interpretation of § 1498 in response to a surprise Statement of Interest filed by the Biden Administration in support of Moderna's earlier argument that § 1498(a) shielded it from a patent infringement lawsuit by Arbutus.[58]

In its first decision, the *Arbutus* court also recognized that "Moderna's argument . . . could mean that every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense."[59] Given the federal government's widespread funding and regulating of healthcare, Moderna's argument about the broad-based applicability of § 1498 would convert every patent infringement lawsuit arising from patents covering drugs or other healthcare treatments into a suit for compensation against the federal government for the exercise of its eminent domain power. This lack of any limiting principle in Moderna's interpretation of § 1498 is another key insight into the plain meaning of this statute: it does not apply when a drug is made by a private company for use by private citizens in the healthcare market.

In sum, *Larson*, *Advanced Software*, and *Arbutus* establish that general payment from the public fisc to a private party that infringes a patent is not sufficient by itself to qualify as a use of the patented invention "by or for the United States" under § 1498.[60] Given the extensive federal funding of a myriad of private activities far beyond biomedical research, a contrary decision would result in every private lawsuit being converted into a constitutional claim for compensation. It is not the function of § 1498 as an eminent domain statute to wipe out all private patent infringement

[54] *Id.*, at *5-*6 (quoting Moderna's contract with the federal government).

[55] *Id.*, at *7.

[56] *Id.*, at *7 (emphasis added).

[57] Since this was a ruling on a motion to dismiss, the *Arbutus* court was required to "accept as true the allegations of the Complaint," and this was an additional reason why the court ruled against Moderna's attempt to use § 1498 to dismiss the infringement complaint. *Id.*, at 7*. It is conceivable that additional facts might be introduced into evidence in the litigation that would lead the court to revise its analysis of whether the government is a direct beneficiary of the mRNA vaccine purchase contract, as opposed to an incidental beneficiary. Even if the court changed its decision, it would be on the basis of a key distinction between *direct* and *incidental* benefits to the government rooted in the text of § 1498 that it applies only to unauthorized uses of patents "for and by the United States," 28 U.S.C. § 1498, not uses for and by private companies selling to private consumers in the marketplace.

[58] *See* Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2023 WL 2455979 (D. Del. Mar. 10, 2023).

[59] *Id.*

[60] *See Larson v. United States*, 26 Cl. Ct. at 368 & n.3. These judicial rulings are also consistent with agency guidance on government use of licensed rights in patented inventions under the Bayh-Dole Act, as discussed in Part Three below. *See, e.g.*, 32 C.F.R. § 37.860(b) (Bayh-Dole license does not include the right to practice the invention for commercial purposes).

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lawsuits in which federal monies (or regulatory controls) create government interests in the private activities underlying the legal claims of patent infringement.

In conclusion, § 1498 does not apply to private commercial activities in which private companies manufacture and sell products for use by private parties in the marketplace. By its express terms, as confirmed by its interpretation and application by courts, § 1498 is an eminent domain statute that is limited to unauthorized uses of patented inventions by or for the federal government, such as use of patented inventions by the military or by federal agencies, such as the Veterans Administration. Even scholars who support more direct federal government regulation or control of the healthcare market have recognized this legal fact. In fact, one of the monographs relied on by those advocating for the price-control theory of § 1498 acknowledges that § 1498 must be "modified" if it is "to apply to governmental payment for drugs prescribed for beneficiaries of such federal health programs as Medicare and Medicaid."[61]

C. As an Eminent Domain Statute, § 1498 Mandates Full Compensation of the Market Value of a Patent that Vitiates Any Proposed Cost Savings

Even if the price-control theory of § 1498 did not contradict the text and judicial interpretation of this statute as implementing the constitutional limitations imposed on the eminent domain power of the federal government, the use of this statute to impose price controls on drug patents would likely create massive financial liabilities for the federal government. This follows logically from § 1498 as an eminent domain statute in which the government must pay "reasonable and entire compensation"—the patent law version of "just compensation" in the Takings Clause—when a patented invention is "used or manufactured by or for the United States without license of the owner."[62] In eminent domain law, courts have long construed the payment of "just compensation" as tantamount to payment of the *market value* of the property.[63] Similarly in patent law, the basic rule for the statutorily authorized payment of damages is to award *lost profits* to patent owner who is manufacturing and selling the patented invention.[64] Under the scheme proposed by the advocates of the price-control theory of § 1498, these remedies principles would direct courts to award patent owners their lost profits due to the lost sales of their drugs from the unauthorized manufacture and sale of the infringing drug.

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[61] MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974). This monograph is cited in Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., *supra* note 7, at 2 n. 9.

[62] § 1498(a).

[63] *See* United States v. Miller, 317 U.S. 369, 374 (1943) ("In an effort . . . to find some practical standard [for awarding 'just compensation'], the courts early adopted, and have retained, the concept of market value.").

[64] *See* 35 U.S.C. § 284 (providing that "the court shall award the claimant damages adequate to compensate for the infringement"); General Motors Corp. v. Devex Corp., 461 U.S. 648, 654-55 (1983) ("Congress sought to ensure [in § 284] that the patent owner would in fact receive full compensation for 'any damages' he suffered as a result of the infringement."); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) ("[T]he general rule for determining actual damages to a patentee that is itself producing the patented item is to determine the sales and profits lost to the patentee because of the infringement."); Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1326 (Fed. Cir. 1987) ("The general rule for determining the actual damages to a patentee that is itself producing the patented item, is to determine the sales and profits lost to the patentee because of the infringement.").

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The advocates for the price-control theory of § 1498 argue that lost profits for the market value of their property should not be the baseline for compensation, because they believe that courts should not award "monopoly" profits. Instead, they maintain that "reasonable and entire compensation" requires only the payment of a court-determined "reasonable royalty" that would reward drug innovators for their investments in creating the new medical treatment plus some additional compensation, such as reimbursement at marginal cost pricing.[65] This is incorrect for several reasons based in well-established, foundational remedies principles as implemented in patent law, in § 1498, and in Takings Clause jurisprudence.

First, as a matter of remedies doctrine in patent law, when a patent owner has not licensed its patent to others, awarding anything less than the patent owner's lost profits falls short of the statutorily mandated award of "damages adequate to compensate for the infringement."[66] In the foundational case on lost profits and reasonable royalties, *Panduit Corp. v. Stahlin Bros. Fibre Works*, the 6th Circuit held that it is improper for a court to set a reasonable royalty solely as "the equivalent of ordinary royalty negotiations among truly 'willing' patent owners and licensee," especially in the context of a patent owner that does not licensee its patents.[67] This would convert remedies doctrine into a tool for "competitors to impose a 'compulsory license' policy on every patent owner."[68] In such an approach, according to the *Panduit* court, "the infringer would be in a 'heads-I-win, tails-you-lose' position."[69] This contradicts the purpose of the remedies provision in the Patent Act and the general function of remedies law to make the plaintiff whole—to place the plaintiff in its rightful position *but for* the wrong committed by the violation of its rights.[70]

Second, as a matter of the "reasonable and entire compensation" requirement in § 1498, it courts will construe this as an award of lost profits in the scheme of the price-control theory of § 1498. In the last 38 years, the Federal Circuit has decided only four cases interpreting the compensation requirement in § 1498.[71] None of these cases arose from a situation in which an infringing product was sold in the marketplace by a private company competing directly with the patented product sold by the patent owner. (This reinforces the point from the prior section that § 1498 is applicable only to the use or manufacture of a patented invention for or by the federal government, and not for or by private companies.) If the government were to adopt the unprecedented price-control theory of § 1498, which would entail authorizing competing

[65] Brennan, Kapczynski, et al., *supra* note 3, at 307-18.

[66] 35 U.S.C. § 284.

[67] Panduit Corp. v. Stahlin Bros. Fibre Works, 575 F.2d 1152, 1158 (6th Cir. 1978).

[68] *Id.*

[69] *Id.*

[70] *See* Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 507 (1964) ("The question to be asked in determining damages is 'how much had the Patent Holder and Licensee suffered by the infringement. And that question (is) primarily: had the Infringer not infringed, what would Patent Holder-Licensee have made?'") (quoting Livesay Window Co. v. Livesay Industries, Inc., 251 F.2d 469, 471 (5th Cir. 1958)); *Rite-Hite Corp.*, 56 F.3d at 1545 ("To recover lost profits damages, the patentee must show a reasonable probability that, 'but for' the infringement, it would have made the sales that were made by the infringer.").

[71] *See* FastShip LLC v. United States, 892 F.3d 1298, 1310 (Fed. Cir. 2018); Paymaster Techs., Inc. v. United States, 180 F. App'x 942, 944–45 (Fed. Cir. 2006); Gargoyles, Inc. v. United States, 113 F.3d 1572, 1572 (Fed. Cir. 1997); Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998).

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commercial products sold by private companies in the marketplace, then a court would likely apply the same remedies doctrines as those they have applied for all other cases of patent infringement arising from the same commercial competition—applying the default rule of lost profits in construing "reasonable *and entire* compensation."[72] In fact, the Court of Claims has already acknowledged that "awarding lost profits" is a proper method for determining a reasonable royalty rate when a court must "appraise a patent license taken by the Government."[73]

Third, since § 1498 is an eminent domain statute,[74] courts may apply the remedies doctrines they have developed under the Takings Clause to the novel scenario in which the federal government instructs a private company to make and sell a drug without authorization from the patent owner. Takings Clause jurisprudence reflects the same remedies principles discussed above: the Supreme Court has held that a property owner should "be put in as good [a] position pecuniarily as he would have been if his property had not been taken."[75] In sum, property owners are constitutionally entitled to receive the market value of their property when it is taken from them by the government.[76] In the context of a drug patent, its market value is the profits earned by the company in selling the drug in the healthcare market, because a patent owner would not license a competitor without accounting for its lost profits from a new market competitor. Thus, an award of lost profits represents the market value that serves as the legal standard by courts in awarding "just compensation" under the Takings Clause in the Fifth Amendment.[77] As an eminent domain statute, it is reasonable for a court to look to the remedy principles applied under the Takings Clause in determining how to award the "reasonable and entire compensation" under § 1498 in the novel scenario of the federal government directing a private company to infringe a drug patent for its own profit through sales to private consumers in the healthcare market.[78]

In sum, the "reasonable and entire compensation" requirement in § 1498 would likely require compensating a patent owner for its lost profits in the novel legislative or regulatory scheme proposed by advocates of the price-control theory of § 1498. This would be in accord with the remedies principles already adopted by courts in patent law, in their interpretation of § 1498, and in the interpretation of the "just compensation" requirement under the Takings Clause—all of

[72] 35 U.S.C. § 284 (emphasis added).

[73] Decca Ltd. v. United States, 640 F.2d 1156, 1167 (Ct. Cl. 1980) (citing Imperial Mach. & Foundry Corp. v. United States, 69 Ct. Cl. 667 (1930)).

[74] *See supra* notes 8 and 25-32, and accompanying text.

[75] Seaboard Air Line Ry. Co. v. United States, 261 U.S. 299, 304 (1923) (citations omitted); *see also* United States v. 564.54 Acres of Land, 441 U.S. 506, 510 (1979).

[76] *See, e.g.*, United States v. 50 Acres of Land, 469 U.S. 24, 25 n.1 (1984); United States v. 564.54 Acres of Land, More or Less, Situated in Monroe & Pike Counties, Pa., 441 U.S. 506, 511 (1979).

[77] *See supra* note 63, and accompanying text.

[78] *See* Jones v. United States, 529 U.S. 848, 857 (2000); Almendarez-Torres v. United States, 523 U.S. 224, 237–38 (1998).

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which seek to place a property owner in the rightful position it would have been but for the violation of its rights by awarding the owner the market value of its property.[79]

As a result, the price-control theory of § 1498 would not lead to a reduction in total drug costs—unless the federal government chose to massively subsidize the competing sales of drugs by paying the difference to the patent owner the profits it lost due to the unauthorized sales of the drugs. But such massive public subsidies would defeat the very purpose of the price-control theory of § 1498 in lowering drug prices. The legislative or regulatory scheme would become merely another cross-subsidy in which third parties would pay, through taxes or other means, the same costs of development of innovative, life-saving medicines as they had before the adoption of the scheme. In fact, it would be even more costly and inefficient, because now litigation costs would be an added transaction cost that did not exist before the price-control scheme.

D. The Price-Control Theory of § 1498 Creates Uncertainties, Additional Costs, and is Rife with Unintended Consequences

The potential for significant, additional costs in the scheme proposed by the price-control theory of § 1498 is worth highlighting as further evidence of how this policy proposal is not based in the plain meaning of the statute. As observed in the Introduction, the U.S. healthcare system is extremely complex given a myriad of legislative and regulatory regimes in both the federal and state govermments. The scheme to lower drug prices through the price-control theory of § 1498 is seemingly straightforward and surprisingly simple, at least as it is presented in hypothetical scenarios in academic articles, letters to Congress, or in the petitions to the NIH. But real-world legislation necessarily creates transaction costs in the institutional implementation of any new regulatory regime. In this respect, the price-control theory of § 1498 represents the "nirvana fallacy"—the comparison of a real-world institution with all its costs (real-world drug prices) with an idealized institutional arrangement that fails to acknowledge its own inherent transaction costs (the price-control theory of § 1498).[80]

The purpose of this section is to identify some of these legal and institutional complexities that necessarily create uncertainties, additional costs, and unintended consequences. It is not possible in a single section to identify all of the relevant legal and economic issues, but this is not necessary. The purpose is to identify how the price-control theory of § 1498, assuming for the sake of argument it is a legally authorized agency power, is not as simple and easy as it is portrayed by its advocates. Thus, it is sufficient to identify some institutional conflicts and accompanying costs in the panacea-sounding proposal to lower drug prices through the price-control theory of § 1498.

Unintended consequences and unacknowledged costs are well known in the patent system, especially given institutional changes in the patent system over the past several decades. One example is the Patent Trial & Appeal Board (PTAB), the new administrative tribunal to cancel

[79] *See* State Industries, Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989) ("The measure of damages is an amount which will compensate the patent owner for the pecuniary loss sustained because of the infringement.").

[80] *See* Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J. L. & ECON. 1 (1969) (identifying and coining the "nirvana fallacy").

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issued patents that was created in the America Invents Act of 2011.[81] Since the PTAB began operations in 2012, it has precipitated extensive legal and policy debate comprising regulatory disputes at the USPTO,[82] legislative bills proposed in Congress,[83] and six decisions by the Supreme Court in the PTAB's first decade of operation.[84] One would be hard pressed to identify a single administrative tribunal in the modern administrative state that has led to six separate Supreme Court decisions in a ten-year period. Another example is the institutional and legal regime for drug patents created by the Hatch-Waxman Act of 1984.[85] This law, which was enacted to lower drug prices, led to numerous, unforeseen legal disputes requiring resolution by the Supreme Court.[86] It also led to new regulatory actions by other agencies, such as the Federal Trade Commission.[87]

Given its direct function to promote faster generic drug entry into the healthcare market to lower drug prices, the Hatch-Waxman Act especially underscores the institutional and legal complexities that go unacknowledged in the price-control theory of § 1498. Congress enacted the Hatch-Waxman Act to reduce drug prices by creating a regulatory regime that results in faster entry into the healthcare market by generic drug companies competing with a drug innovator.[88] The Hatch-Waxman Act regime is a complex system of patent litigation, regulatory exclusivity, and approval of generic drugs by the Food and Drug Administration (FDA). It is too complex to describe succinctly, but a brief summary will suffice to establish its significance for this section.

Under the Hatch-Waxman Act, a generic company files an abbreviated new drug application (ANDA) with a "paragraph IV certification" at the FDA. An ANDA is filed while the

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[81] *See* Leahy-Smith America Invents Act of 2011, Pub. L. 112-29, 125 Stat. 284 (2011) (codified in 35 U.S.C. § 6) (creating patent trial and review board).

[82] *See, e.g.*, Eileen McDermott, *General Counsels Ask Raimondo to Immediately Repeal* NHK-Fintiv *Framework*, IPWATCHDOG (Feb. 14, 2022), https://www.ipwatchdog.com/2022/02/15/general-counsels-ask-raimondo-immediately-repeal-nhk-fintiv/id=145968/; Britain Eakin, *Tech Giants Urge Fed. Circ. To Abolish 'Unlawful' Fintiv Rule*, LAW360 (Feb. 9, 2022), https://www.law360.com/articles/1463601/tech-giants-urge-fed-circ-to-abolish-unlawful-fintiv-rule; Ryan Davis, *Tech Cos. Back Apple High Court Bid to Ax PTAB's Fintiv Rule*, LAW360 (Aug. 31, 2021), https://www.law360.com/articles/1417615/tech-cos-back-apple-high-court-bid-to-ax-ptab-s-fintiv-rule.

[83] *See, e.g.*, Patent Trial and Appeal Board Reform Act of 2022, S. 4417, 117th Cong. (2022) (creating changes to the procedures at the PTAB); Restoring American Leadership in Innovation Act of 2021, H.R. 5874, 117th Congress (2021) (eliminating the PTAB); STRONGER Patents Act of 2019, S. 2082 & H.R. 3666, 116th Cong. (2019) (adopting numerous procedural and substantive reforms in the PTAB).

[84] *See* United States v. Arthrex, 141 S. Ct. 1970 (2021); Thryv v. Click-To-Call Technologies, 140 S. Ct. 1367 (2020); Return Mail v. USPS, 139 S. Ct. 1853 (2019); Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365 (2018); SAS Institute, Inc. v. Iancu, 138 S. Ct. 1348 (2018); Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016).

[85] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[86] *See, e.g.*, Federal Trade Commission v. Actavis, 570 U.S. 136 (2013); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

[87] *See* Federal Trade Commission v. Actavis, 570 U.S. 136 (2013).

[88] *See* Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018) (describing the enactment of the Hatch-Waxman Act and critiquing the conventional wisdom that this legislation was the result of Congress carefully balancing the interests of patent owners, generics, and the public).

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drug patent is still in force and thus a specific function of the ANDA is to trigger patent infringement litigation between the drug innovator and the generic company. The lawsuit results in the usual patent infringement claims by the drug innovator and the panoply of affirmative defenses asserted by the generic company that the drug patent is invalid.[89] If the patent owner prevails in this litigation—demonstrating infringement by the generic drug company and defending the validity of its patent—the FDA then stays final approval of the ANDA until the patent expires. But the generic company may prepare its manufacturing facilities and ready commercialization of its generic version of the drug.[90] The generic company must also meet the FDA's safety and efficacy standards for generic drug approval. If it meets the FDA's safety and efficacy standards, once the patent expires, the generic company may immediately leap into the market and start selling the drug to patients and it is awarded with a period of "exclusivity" in which it will be the only generic company to compete with the drug innovator. This market exclusivity for the generic drug company is the reward for filing the first ANDA and traversing the costly patent litigation gauntlet. This Hatch-Waxman regime has been in place for four decades.

If an agency implemented the price-control theory of § 1498 in directing a generic drug company to sell a drug covered by a patent, it is unclear how this would function within the existing regulatory and litigation regime for drug innovators and generic companies under the Hatch-Waxman Act. The generic company submits an ANDA for approval to manufacture and sell a drug in competition with the drug innovator at the moment the patent expires, which is done for the purpose of lowering drug prices. The express goal of the Hatch-Waxman Act is the same goal as the price-control theory of § 1498: authorize a generic drug company to make and sell drugs to lower drug prices. If the price-control theory of § 1498 reflected the actual text and function of this statute, then a generic drug company would add an affirmative defense in its Hatch-Waxman litigation that the drug innovator cannot sue the generic company, because it must instead sue the federal government for "reasonable and entire compensation" under § 1498 (just as Moderna tried to argue that this is what Arbutus was required to do).[91]

How this new § 1498 defense would work within the overall Hatch-Waxman regime is unclear, creating significant uncertainty and extensive new litigation to resovle. These additional litigation costs would necessarily add to the costs of drug development and commercialization for drug innovators and to the costs of doing business by generic drug companies. These added costs would result in higher prices for medical care, including drugs.

The failure to account for the well-known Hatch-Waxman regime is just one example of how the price-control theory of § 1498 is no more based on a proper institutional assessment of the reality of drug patents and generic competition today than it is based in the text of § 1498 itself. These institutional and regulatory complexities should be acknowledged and accounted for with proper empirical studies. Without this proper institutional assessment of how the price-control theory of § 1498 would in fact be implemented within the existing institutions and laws governing

[89] 21 U.S.C. § 355(j)(5)(B)(iii).

[90] 35 U.S.C. § 271(e)(4)(A) ("[T]he court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed . . . ."); *see also* 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb).

[91] *See supra* notes 52-59, and accompanying text (describing Moderna's argument and the court's rejection of it).

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drug patents, it has not proven that it will be cost effective compared to the "excessive drug pricing" by patent owners.[92] This is only one example of many institutions and laws implicated by the price-control theory of § 1498, demonstrating the extent to which this is truly a *theory*, not an evidence-based legislative or policy proposal.[93]

The price-control theory of § 1498 is a policy proposal lacking a basis in either the text or function of this eminent domain statute. It contradicts the express text of § 1498, it conflicts with the function of § 1498 in only conferring jurisdiction on the Court of Federal Claims to hear complaints by patent owners for compensation when an invention is used by or for the federal government in an exercise of the eminent domain power. Courts and agencies have consistently interpreted and applied § 1498 according to this plain text. Even if one assumes for the sake of argument that the price-control theory of § 1498 is legally viable, its advocates have not addressed the inherent institutional and legal complexities of their price-control scheme, such as how it would interrelate with the Hatch-Waxman Act and other legislative and regulatory regimes in the modern U.S. healthcare system. In sum, the price-control theory of § 1498 offers a false promise of breaking patents to lower drug prices.

III. The Bayh-Dole Act Does Not Authorize the Federal Government to Control Drug Prices

The search for legal authority authorizing the federal government to break patents to lower drug prices has led to the creation of a second price-control theory—the price-control theory of the Bayh-Dole Act of 1980. Similar to § 1498, the text of the Bayh-Dole Act and its consistent interpretation by federal officials militates against this price-control theory. In fact, the price-control theory of the Bayh-Dole Act was "unrecognized" from 1980 until two professors claimed to have discovered it more than two decades later in a law journal article in 2001.[94] Unlike § 1498, though, the Bayh-Dole Act is a more complicated statutory regime and thus it requires a more detailed exposition of its statutory function, the text that allegedly supports the price-control

[92] Brennan, Kapczynski, et al., *supra* note 3, at 275.

[93] Another statute that may be possibly implicated in the scheme to lower drug prices under the price-control theory of § 1498 is the Federal Acquisition Streamlining Act of 1994 (FARA). *See* Federal Acquisition Streamlining Act of 1994, Pub. L. No. 103-355, 108 Stat. 3243 (1994). This statute established a strong preference for federal acquisition of "commercial items" by the federal government "to the maximum extent practicable." 10 U.S.C. § 3453(a); *see also* 10 U.S.C. § 3454(b) ("The head of an agency shall ensure that procurement officials in that agency, to the maximum extent practicable . . . acquire . . . commercial products . . . to meet the needs of the agency . . . ."). A patented drug that is already available to the public would appear to meet the definition of a "commercial item" under the FARA. *See* 10 U.S.C. § 2376 (A "commercial item" is "any item other than real property, that is of a type customarily used by the general public or by nongovernmental entities for purposes other than governmental purposes, and that – (i) has been sold, leased, or licensed to the general public; or (ii) has been offered for sale, lease, or license to the general public."). If the scheme proposed by the price-control theory of § 1498 was deemed to be a means to avoid direct government purchases of drugs that are readily available as commercial items, then this would conflict with Congress's express policy in the FARA. As with the Hatch-Waxman regime, the price-control theory of § 1498 produces many unanswered legal and institutional questions, sowing extensive uncertainty and creating new, additional costs in litigation or in other legal processes.

[94] *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patients Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001).

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theory, and the repeated agency interpretations of this statute that have consistently rejected the price-control theory.

A. The Function of the Bayh-Dole Act is to Promote Commercialization of Inventions

The Bayh-Dole Act was born of an unintended consequence of the federal government's decision to continue its funding programs for scientific research that it had first adopted during World War Two.[95] In fact, public funding of basic research by the government expanded in both breadth and scope in the post-war era.[96] As noted earlier, the creation of a new government policy can create unintended consequences both in commercial activities in the innovation economy and in the functioning of unrelated statutory or regulatory regimes.[97] The continuation and expansion of public funding of research in the second half of the twentieth century was no different in creating unintended consequences, whether positive or negative.[98]

One unintended consequence was the question of ownership of patented inventions derived from research funded—even if only in small part—by the government. This included funding of basic research in biochemistry and related fields that led to practical innovations, especially life-saving inventions in the modern pharmaceutical sector of the U.S. innovation economy. Beginning in the early to mid-twentieth century, the pharmaceutical sector arose from a business model of substantial investments in research and development to create new drugs that companies were able to commercialize through their property rights in these innovations—patents.[99] What happened

[95] *See* Daniel P. Gross & Bhaven N. Sampat, *America, Jump-Started: World War II R&D and the Takeoff of the U.S. Innovation System* (NBER Working Paper 27375, rev. Sep. 2022), https://www.nber.org/papers/w27375. Of course, the most famous research program was the Manhattan Project, which led to the invention of the first atomic bomb. *See* RICHARD RHODES, THE MAKING OF THE ATOMIC BOMB (1986). Another example is the research and development of radar, a ubiquitous technology today and the basis for consumer inventions like the microwave oven. *See* ROBERT BUDERI, THE INVENTION THAT CHANGED THE WORLD: HOW A SMALL GROUP OF RADAR PIONEERS WON THE SECOND WORLD WAR AND LAUNCHED A TECHNOLOGICAL REVOLUTION (1998).

[96] *See, e.g.*, BRUCE L. R. SMITH, AMERICAN SCIENCE POLICY SINCE WORLD WAR II (1990); Jeffrey K. Stine, *A History of Science Policy in the United States, 1940–1985*, Rep. for Task Force on Science Policy, Committee on Science & Technology, U.S. House of Representatives (1986) [copy on file with author].

[97] *See supra* Part I.D (identifying potential negative consequences of the price-control theory of § 1498 as a result of the "nirvana fallacy").

[98] *See* Gross & Sampat, *supra* note 95 (identifying positive aggregation externalities from federal funding of basic research in WWII).

[99] The modern biopharmaceutical sector and the drug patent were born twins in the nineteen thirties and forties. *See generally* BARRY WERTH, THE BILLION-DOLLAR MOLECULE 111-37 (1994) (discussing the early history of the pharmaceutical industry); THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 7-12 (1983) (same). The development and use of drugs existed prior to the nineteen thirties, but the rigorous research and development methods that are the hallmark of the biopharmaceutical sector did not begin until that time. *See* ALFRED D. CHANDLER, JR., SHAPING THE INDUSTRIAL CENTURY 177-211 (2005) (discussing the birth and evolution of many pharmaceutical companies, such as Merck and SmithKline, from the "therapeutic revolution" in the nineteen forties); JONATHAN LEIBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY (1987) (surveying the pharmaceutical industry from the nineteenth century up through World War One). Werth writes:

> The birth of drug research in the 1930s had introduced a bristling new competitiveness as companies sought to protect their investments. Where patents were once reviled, they were now

(continued…)

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when these drugs and other inventions were produced by research that was now funded several decades later by the federal government through the many post-WWII research programs? The federal government's initial answer to this question was that it owned the inventions no matter how small the contribution from the federal funding program.[100]

Government ownership of patents proved to stifle, rather than to promote distribution of new innovations. The Senate Judiciary Committee Report for the Bayh-Dole Act quoted approvingly an earlier policy report by the Carter Administration that "[e]xperience has shown that the Government . . . is not in a position to take advantage of its ownership of patents to promote enterprise."[101] Congress received evidence about extensive numbers of inventions that were lying fallow due to the government's inability to commercialize the patents it owned or due to costs associated with regulatory restrictions on commercialization created by government ownership of patents.[102] Drugs in particular went undeveloped as medical treatments for patients—not a single new drug had been commercialized from billions distributed by the National Institutes of Health (NIH) for biomedical research.[103]

In response to this problem, Congress enacted the Bayh-Dole Act in 1980.[104] The express function of the Bayh-Dole Act is to make clear that inventors making discoveries or creating inventions produced from research that was funded even in part by the public fisc may receive property rights in the fruits of their labors—patents. The statute expressly states that "[i]t is the policy and objective of the Congress to use the patent system to promote the utilization of

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pursued ruthlessly. Squibb, which had one patent in 1920, had more than 200 by 1940. In 1937 alone, Merck had filed forty-six domestic and foreign patent applications.

WERTH, *supra*, at 122.

[100] *See* S. Rep. No. 480, 96th Cong., 1st Sess., at 21 (1979) (stating that "agencies can retain title to inventions arising from research which only received a small percentage of its funding from the Government").

[101] S. Rep. No. 480, 96th Cong., 1st Sess., at 18 (1979) (quoting Advisory Subcommittee on Patent and Information Policy of the Advisory Committee on Industrial Innovation (Dec. 20, 1978)).

[102] *See* S. Rep. No. 480, 96th Cong., 1st Sess., at 20 (1979) ("A GAO study conducted in 1968 found that [the NIH's] policy of retaining patent rights to inventions arising from its supported research programs resulted in an inability to obtain the cooperation of industry in developing potential new drugs."); S. Rep. No. 480, 96th Cong., 1st Sess., at 28 (1979) ("It is essentially a waste of public money to have good inventions gathering dust on agencies' shelves because of unattractiveness of nonexclusive licenses."); Jay Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2175 (2009) ("Prior to the passage of the Bayh-Dole Act, the government agencies responsible for funding research did not have a uniform policy concerning the fate of the potential intellectual property rights in the fruits of government-funded research."); *see also* Dr. Wolfgang Klietmann, *Ivy League profs taking potshots at patents imperil innovation*, BOSTON HERALD (Dec. 5, 2022), https://www.bostonherald.com/2022/06/27/klietmann-ivy-league-profs-taking-potshots-at-patents-imperil-innovation/ ("Nearly 30,000 government-patented discoveries were sitting idle before Bayh-Dole. This meant that taxpayer money put towards scientific research wasn't actually benefiting taxpayers."); Joseph Allen, *Bayh-Dole Rocks While the Critics Play the Same False Note*, IPWatchdog (June 11, 2019), https://www.ipwatchdog.com/2019/06/11/bayh-dole-rocks-critics-play-false-note/id=110254/ (explaining that in "the pre-Bayh-Dole era . . . . federally funded inventions were micromanaged from Washington . . . . The result: less than 5% of 28,000 inventions were licensed" in the marketplace).

[103] *See* Allen, *supra* note 102 (explaining that in "the pre-Bayh-Dole era . . . . the Comptroller General found that not a single new drug had been developed . . . despite billions of taxpayer dollars invested in the National Institutes of Health (NIH)").

[104] Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200–212).

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inventions arising from federally supported research or development."[105] Accordingly, owners of patented inventions derived from federally funded research have the same basic rights as all other patent owners to commercialize their innovations, barring any limitations accepted by the inventor in the funding contract.[106] This includes obtaining venture capital financing to create startups,[107] licensing or engaging in other commercial transactions to create new innovation markets,[108] or transferring the patents to third parties who can more efficiently commercialize the innovation asset in the marketplace.[109]

The Bayh-Dole Act has been identified as one of the most significant acts of innovation policy adopted by Congress in the modern era,[110] but some scholars have critiqued the law on both empirical and policy grounds. Some academics have argued that it has not been successful given lack of evidence that university researchers are actually incentivized by patents to invent.[111] Others have argued that most universities do not on net benefit from patent licensing insofar as licensing revenue exceeds the operational expenses in running licensing programs, except for highly publicized albeit relatively rare "blockbuster" inventions.[112] Moreover, some academics critique

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[105] 35 U.S.C. § 200.

[106] *See* 35 U.S.C. § 202(c) (specifying additional conditions agencies may adopt in research funding agreement).

[107] *See* Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery,"* 75 J. FINANCE 639 (2020) (identifying a causal link between a startup owning a patent and its increased chances of securing venture capital financing, and further demonstrating a causal link of these patent-based startups with higher rates of success as commercial enterprises in the marketplace).

[108] *See, e.g.*, JONATHAN M. BARNETT, INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL PROPERTY (2020) (detailing the historical and economic evidence of the commercialization function of patents as representing property rights in inventions); B. ZORINA KHAN, INVENTING IDEAS: PATENTS, PRIZES, AND THE KNOWLEDGE ECONOMY (2020) (detailing the historical and economic evidence of the comparative advantage of property rights (patents) over prizes as drivers of economic activity and economic growth); B. ZORINA KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790–1920, at 9-10 (2005) ("[P]atents and . . . intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources. . . . Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.").

[109] *See generally supra* note 108; *see also* Stephen Haber & Seth H. Werfel, *Patent Trolls as Financial Intermediaries? Experimental Evidence*, 149 ECON. LETTERS 64 (2016).

[110] *See Innovation's Golden Goose*, 365 ECONOMIST 3, 3 (2002) (calling the Bayh-Dole Act "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century"); *see also* Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2174 (2009) ("From a patent standpoint, the Bayh-Dole Act was a very significant piece of legislation during the 1980s, because it led to an increase in nonprofit organizations' involvement in the patent system.").

[111] *See, e.g.*, Lisa Larrimore Oullette & Andrew Tutt, *How Do Patent Incentives Affect University Researchers?*, 61 INT'L REV. L. & ECON. (2020), https://doi.org/10.1016/j.irle.2019.105883.

[112] *See, e.g.*, David Orozco, *Assessing the Efficacy of the Bayh-Dole Act Through the Lens of University Technology Transfer Offices (TTOS)*, 21 N.C. J.L. & TECH. 115, 142 (2019) (observing that it is estimated that universities make annual aggregate royalties of $2.7 billion from approximately 8,000 patent licenses but that a "large portion of those royalties, however, are derived from a few sizeable inventions at a handful of academic institutions"); Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2179-81 (2009) (describing university licensing programs and the transaction costs and inefficiencies in these programs).

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university patent licensing as conflicting with norms of open research or undermining incentives by university professors to engage in basic research.[113]

If these critiques are true, they are still too constricted in their accounting of the relevant variables, focusing solely on what occurs *inside* a university, such as on researcher incentives. There is no doubt that university researchers, especially full-time tenured professors, engage in research without the promise of patent protection. But the function of patents is not merely to incentivize invention; as property rights, patents function as all other property rights as a platform for commercialization of new products and services in the marketplace.[114] As stated by Congress, the purpose of the Bayh-Dole is to promote commercialization of new inventions just as all other innovations have been commercialized in the United States—through the longstanding mechanisms of property rights and contracts.[115]

Researchers have demonstrated that the Bayh-Dole Act has achieved its purpose in promoting commercialization in the marketplace by establishing a reliable legal platform on which to license and otherwise commercially deploy new products and services in the marketplace.[116] One recent study found that patent licensing facilitated by the Bayh-Dole Act contributed between $631 billion to $1.9 trillion to industry gross output between 1996-2020.[117] Walter Copan, the former Director of the National Institute for Standards and Technology, has stated that the Bayh-Dole Act has contributed to "more than 4.2 million jobs, and over 11,000 startup companies from the nation's universities."[118] It may be possible that these commercial and economic benefits are

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[113] *See, e.g.*, Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 251 (2006) (noting that a focus on patenting of university research can "be detrimental, leading in some cases to rancor, turf disputes, loss of collegiality, and more," and that "it may lead some academics to shift the focus of their research into areas more likely to generate proprietary, commercializable results"); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government – Sponsored Research*, 82 VA. L. REV. 1663, 1667 (1996) (arguing that the Bayh-Dole's incentives to patent "threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors")

[114] *See supra* notes 107-109, and accompanying text (describing briefly some of the commercial functions of patents as property rights).

[115] 35 U.S.C. § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . ."); *see also* Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271 (2017) ("The commercialization argument takes on even more significance in the university context (where ex ante incentives are less important), and this focus is expressly stated in the text of the Bayh--Dole Act.").

[116] *See* Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose*, 8 TUL. J. TECH. & INTELL. PROP. 151, 155-57 (2006) (surveying evidence of economic success of Bayh-Dole Act in driving economic activity, spurring job growth, and growing the innovation economy).

[117] LORI PRESSMAN, MARK PLANTING, CAROL MOYLAN, & JENNIFER BOND, ECONOMIC CONTRIBUTIONS OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996-2020, at 3 (2022), https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf.

[118] Walter Copan, *Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation*, IPWATCHDOG (Nov. 2, 2020), https://ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/id=126980/.

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outweighed by the costs, but these trade-offs must be fully assessed in evaluating any legal institution, comparing all the benefits and the costs.[119] Thus far, critics of the Bayh-Dole Act have not fully compared and balanced both benefits and costs.[120]

B. The Price-Control Theory of the Bayh-Dole Act: The "March In" Power

Another indicator of the success of the Bayh-Dole Act is the price-control theory itself. Instead of critiquing the statute, advocates for the price-control theory now co-opt it for purposes other than to promote the licensing or other commercial uses of reliable and effective patents. Advocates for the price-control theory of the Bayh-Dole Act now argue that the statute authorizes the federal government (or, more specifically, a federal agency like the NIH) to license patents covered by the statute for the sole purpose of imposing price controls on drug patents. This is known as the "march-in power" or "march-in right," but neither the statutory text nor extra-statutory sources of legislative meaning state that *price controls* are authorized legal action under the prescribed march-in power. Before assessing the price-control theory of the Bayh-Dole Act, it is first necessary to describe the march-in power and the argument that this is an existing legal tool to lower drug prices in the healthcare market through the imposition of price controls.

1. The March-In Power in § 203 of the Bayh-Dole Act

Section 203 in the Patent Act, as enacted in the Bayh-Dole Act, creates the "march in right."[121] The provision authorizes a federal agency like the NIH that has funded research that resulted in a patented invention "to grant a nonexclusive, partially exclusive, or exclusive license" under four specified conditions.[122] Section 203 permits a federal agency to grant licenses "to a responsible applicant" without authorization from the patent owner in four specific, delimited circumstances: (1) if an assignee or licensee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use," (2) "to alleviate health or safety needs which are not reasonably satisfied," (3) "requirements for public use specified by Federal regulations . . . are not reasonably satisfied," or (4) "a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement."[123]

All four conditions in § 203 authorize a federal agency to "march in" and license other companies to make and sell a patented product or service in specific circumstances in which a

[119] *Cf.* Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S Science and Technology Policy*, 24 VT. L. REV. 347 (2000) ("Weighing the costs and benefits of Bayh-Dole is a tremendous task that depends significantly on empirical research of, inter alia, the actual rates of foreign misappropriation of federally-funded research (not simply foreign competition) and a counterfactual measure of deadweight costs from under-utilization.").

[120] *See* Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 311, 376 (2009) ("There is a dearth of hard data on the effect of Bayh-Dole on basic research, and much of what is available is contradictory.").

[121] *See* 35 U.S.C. § 203 (2011).

[122] § 203(a).

[123] § 203(a)(1)-(4).

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patent owner or licensee is not commercializing the patented invention in the marketplace.[124] The first condition, for example, addresses circumstances in which a patent owner or licensee is figuratively sitting on its hands and not achieving the commercialization function that is the purpose of the Bayh-Dole Act. The second condition addresses a situation in which a patent owner or licensee lacks manufacturing capacity to fully respond to demand for health or safety needs. The third condition addresses the situation when regulatory mandates for public use are not met by a patent owner or licensee, such as a licensee being unable to produce enough water filters required for public drinking safety requirements set by the Environmental Protection Agency.[125] The fourth condition identifies the circumstances when a licensee is in breach of its agreement and thus is not commercializing the patented invention.

These are the four prerequisites, provided in the disjunctive, for a federal agency to exercise the march-in power in § 203(a)(1)-(4). Each sub-section in § 203(a) specifies necessary preconditions for the march-in power to be used by a federal agency or other official in the federal government. Notably, there is no mention of "price" in the four authorizing conditions for a federal official to invoke the march-in power to issue licenses without approval without approval from a patent owner.

Moreover, there is no catch-all march-in clause in § 203. This is significant for two reasons. First, Congress knows how to create broadly framed and explicitly expansive authorizations for agency action, if this is its purpose. For example, Congress has expressly created broadly-framed authorizations in other statutes, such as the well-known language in the Federal Communications Act of 1934 authorizing the Federal Communications Commission to grant radio transmission licenses according to whether the "public convenience, interest, or necessity will be served thereby."[126] Second, the canon of statutory construction of *expressio unius est exclusio alterius* establishes that, without a catch-all clause, the march-in power is delimited to only these four express "exemptions" from the longstanding rights of patent owners covered by the Bayh-Dole Act to freely assign or license their property in the marketplace.[127] In sum, Congress chose not to create an open-ended grant of authority in § 203 in listing only four specific march-in conditions

[124] *See* § 203(a)(1)-(4).

[125] Admittedly, § 203(a)(3) is not clear on its face, but this is the meaning attributed to this statutory language. *See* Joseph P. Allen, *Taking the Mystery Out of March-in Rights*, RealClearPolicy (Sep. 16, 2022), https://www.realclearpolicy.com/articles/2022/09/16/taking_the_mystery_out_of_march-in_rights_853859.html. Joseph Allen was a congressional staff member who worked for Senator Birch Bayh in the legislative process that led to the enactment of the Bayh-Dole Act and he was later appointed as the first Director of the new Office of Technology Commercialization in the U.S. Department of Commerce to develop the implementing regulations for the Bayh-Dole Act. More important, since § 203(a)(3) is not invoked as a relevant statutory provision in the price-control theory, whether this particular condition is clear is merely academic for the purpose of this Article.

[126] 47 U.S.C. § 307(a) ("The Commission, if public convenience, interest, or necessity will be served thereby, subject to the limitations of this Act, shall grant to any applicant therefor a station license provided for by this Act.").

[127] *See* Tennessee Valley Authority v. Hill, 437 U.S. 153, 188 (1976) ("In passing the Endangered Species Act of 1973, Congress was also aware of certain instances in which exceptions to the statute's broad sweep would be necessary. Thus, § 10, 16 U.S.C. § 1539 (1976 ed.), creates a number of limited 'hardship exemptions,' . . . . meaning that under the maxim *expressio unius est exclusio alterius*, we must presume that these were the only 'hardship cases' Congress intended to exempt."); *see also* 73 Am. Jur. 2d Statutes § 129 (2002) (describing the statutory canon of interpretation, *expressio unius est exclusio alterius*).

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that strictly specify the narrow scope and application of the march-in power exemption in the Bayh-Dole Act.

2. The Price-Control Theory of § 203

As previously noted, the price-control theory of the Bayh-Dole Act was born of a law journal article published more than twenty years after the Bayh-Dole Act was enacted into law in 1980. In 2001, Professors Peter Arno and Michael Davis published their article, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*.[128] As the title makes clear, they argued that the (previously unrealized) purpose of the march-in power in the Bayh-Dole Act is to impose price controls on the marketplace.

Professors Arno and Davis claim that, in enacting the Bayh-Dole Act, "Congress's concern with march-in rights focused exclusively on maintaining competitive conditions, controlling profits, and doing so through price control."[129] They specifically maintain that the legislative record confirms that Congress intended to the march-in power to be "focused exclusively on . . . price control." This is a surprising claim for a couple reasons.

First, there is a significant dearth of evidence for their claim that price controls was one of the expressly stated purposes of the Bayh-Dole Act. Professors Arno and Davis identify approximately seven references in the legislative record in which a few congresspersons and witnesses raised concerns about "prices," if one excludes their explicit decision to conflate references to the "public interest" in the legislative record as identical to "price control" references.[130] These few, scattered references to "prices" in the legislative record calls to mind the famous statement by Judge Harold Leventhal that the use of legislative history can be "the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends."[131] For example, other scholars have found statements in the legislative history emphasizing the commercialization function of patents as the primary goal of the Bayh-Dole Act—the "first-listed goal in the statute" according to two scholars.[132] In a 2004 statement to the NIH, former Senator Bayh further critiqued the price-control theory of the Bayh-Dole Act given the selective misreading of the legislative record by a march-in petition advancing "the same arguments" by Professors Arno and Davis.[133] In sum, in a lengthy legislative record pages

[128] *See* Arno & Davis, *supra* note 94.

[129] *Id*., at 659.

[130] *See id*., at 656-67 (identifying a total of about seven statements in the entire legislative record to "price" or "pricing" of patented products as something that should be restricted or controlled).

[131] Conroy v. Aniskoff, 113 S. Ct. 1562, 1567 (1993) (Scalia, J., concurring).

[132] *See* Ayres & Oulette, *supra* note 145 (observing that commercialization is the "first-listed goal in the statute" and supporting this point about the function of Bayh-Dole from quotes from the legislative history).

[133] *See Statement of Senator Birch Bayh to the National Institutes of Health* 3-5 (May 25, 2004), https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf.

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underlying the Bayh-Dole Act that is more than 1,000 pages in length,[134] Professors Arno and Davis found a few price-control friends to justify their conclusion that Congress "focused exclusively on . . . price control" in enacting § 203 as part of the Bayh-Dole Act.[135]

Second, as noted above, Professors Arno and Davis conflate "public interest" with "price control," which confirms that they are engaging in the scholarly equivalent of artistic license in reconstructing the legislative history of the Bayh-Dole Act. References to the public interest are not by themselves a confirmation of an "exclusive focus" on "price control." The commercialization of new innovations through patents is in the public interest; the inventions figuratively sitting on shelves unused by the public was the problem spurring the enactment of the Bayh-Dole Act to prompt commercialization of these inventions through patent rights. The Bayh-Dole Act reflects the longstanding policy that reliable and effective patents secured to innovators serve the public interest.[136] In the *Federalist No. 43*, James Madison justified the Patent and Copyright Clause on the basis that the "public good fully coincides in both [patents and copyrights] with the claims of individuals."[137]

Professors Arno and Davis' price-control theory of the Bayh-Dole Act was not based solely in their expansive reading of the legislative record. They did attempt to ground their price-control theory in the statute in a perfunctory section in their article,[138] but most of their article is devoted to critiquing the Bayh-Dole Act and to critiquing agencies and other stakeholders for failing to implement their price-control theory.[139] Nonetheless, their general interpretative approach is the statutory argument restated by advocates for the price-control theory of the Bayh-Dole Act to this day; in fact, perhaps sensing the weakness of their reliance on the legislative record, the statutory argument largely dominates the price-control arguments today.[140]

The statutory interpretation of the Bayh-Dole Act as a price-control statute proceeds in two steps. First, price-control theorists focus on the first march-in condition in § 203(a)(1), which

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[134] *See* Act of December 12, 1980, 94 Stat. 3015, https://1.next.westlaw.com/Document/I71880d30a97e11e0b16e010000000000/View/FullText.html?VR=3.0&RS=cblt1.0&__lrTS=20230211221450846&transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 (listing entire legislative record and identifying lengthy as approximately 1,073 pages).

[135] Arno & Davis, *supra* note 94, at 121.

[136] *See, e.g.*, Douglas Dynamics v. Buyers Products Co., 717 F.3d 1336, 1346 (Fed. Cir. 2013) (recognizing that "the public has a great[ ] interest in acquiring new technologies through the protection provided by the Patent Act"); Blanchard v. Sprague, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1,518) (Story, Circuit Justice) ("Patents for inventions are now treated as a just reward to ingenious men, and as highly beneficial to the public."); Pilot Inc. v. Coolman Outdoor Corp., No. 18-CV-02286 (JAK) (SPX), 2019 WL 2620723, at *5 (C.D. Cal. Apr. 10, 2019) (observing that that "[u]nfair competition through patent infringement is contrary to the interests of the public"); Amazon.com Inc. v. Barnesandnoble.com Inc., 73 F.Supp.2d 1228, 1248-49 (W.D. Wash. 1999), *vacated on other grounds and remanded*, 239 F.3d 1343 (Fed. Cir. 2001) ("The public has a strong interest in the enforcement of intellectual property rights.").

[137] Federalist No. 43 (James Madison), in THE FEDERALIST PAPERS 272 (Clinton Rossiter ed., 1961).

[138] *See* Arno & Davis, *supra* note 94, at 649-53.

[139] *See id*., at 667-91.

[140] *See supra* notes 5-7 (citing sources).

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covers a patent owner or licensee who "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."[141] Second, they look to the statutory definition in § 201(f) of the phrase "practical application," as this term is used in § 203(a)(1); there, "practical application" is defined to "mean manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[142] In this lengthy definition § 201(f), they focus on the phrase, "available to the public on reasonable terms."

The price-control theory is thus based a two-step interpretative process of combining § 203(a)(1) and § 201(f) in the Bayh-Dole Act. The phrase "available to the public on reasonable terms" in the final clause of the definition in § 201(f) is applied to the phrase "practical application" in § 203(a)(1) as a specific condition for authorizing the march-in power.[143] Advocates for the price-control theory argue that high prices prevent drugs from being made "available to the public on reasonable terms," and thus this means that high prices for drugs are not achieving "practical application of the subject invention in the field of use."[144] They conclude that high drug prices

[141] 35 U.S.C. § 203(a)(1). Some advocates for the price-control theory of the Bayh-Dole Act also invoke § 202, which specifies agency powers in imposing conditions in research funding agreements, including that the government may claim a royalty-free license for its own use of patents. *See* § 35 U.S.C. § 202(c)(4); Kapczynski, Kesselheim et al. *supra* note 7, at 5 ("In the Bayh-Dole Act, § 202 grants the government irrevocable, non-transferrable, royalty-free licenses to covered patents. . . . [T]he only requirement under § 202 is that the patent be used by, for, or on behalf of the government."). But whether one looks to § 202 or § 203 is a distinction without a difference. First, § 202 does not specify "price," "reasonable price," or "price controls" as conditions or limitations agencies may impose on inventors in research funding agreements. *See infra* Part III.C. Second, the royalty-free license authorized in § 202(c)(4) is expressly limited to use of a patent "for or on behalf of the United States." This is almost identical to § 1498, the eminent domain statute, which does not authorize agencies to impose price controls on private transactions in the marketplace. *See supra* Part II.B. Courts give similar statutory language similar effects, and thus the eminent domain provision in § 202(c)(4) does not authorize price controls. Third, § 202(c)(8) authorizes agencies to impose conditions in funding research agreements expressly incorporating the march-in conditions in § 203, and thus it incorporates by reference the same phrase "available to the public on reasonable terms" in § 203(a)(1) already invoked by price-control theorists. As explained, this phrase is not an authorization to impose price controls on private transactions in the marketplace. *See infra* Part III.C-F.

[142] 35 U.S.C. § 201(f).

[143] *See, e.g.*, Peter Arno, Robert Sachs & Kathryn Ardizzone, *Will the Biden administration use 'march-in' to protect prostate cancer patients from excessive drug prices?*, STATNEWS (Jan. 3, 2022), https://www.statnews.com/2022/01/03/march-in-rights-protect-prostate-cancer-patients-from-excessive-drug-prices/ (identifying "available to the public on reasonable terms" in § 203(a)(1) as "strong legal underpinnings" for using the march-in power to impose price controls to lower the price of Xtandi); Letter from Eric Sawyer to Xavier Becerra, Secretary of the Department of Health and Human Services (Dec. 13, 2021), at 1, https://www.keionline.org/wp-content/uploads/Eric-Sawyer-HHS-Xtandi-Request-13Dec2021.pdf (proposing march-in power be exercised on Xtandi given "price gouging" by the drug innovator (Astellas) and thus it "is not "making the benefits of the patented inventions 'available to the public on reasonable terms,' which is a requirement of bringing a product to 'practical application,' as defined in 35 USC 201(f)").

[144] *Id.*; *see also* Jeannie Baumann, *New Biomed Unit Under Pressure to Use Untried Drug Patent Grabs*, BLOOMBERG LAW (May 2, 2022), https://www.bloomberglaw.com/bloomberglawnews/pharma-and-life-sciences/XCKMFCBG000000?bna_news_filter=pharma-and-life-sciences#jcite (quoting Emory University law professor Liza Vertinsky that "If no one can afford it, that's not reasonably available"); Steven Seidenberg, *March-*
(continued…)

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triggers an authorizing condition under § 203(a)(1) for a federal agency to march in and grant a license to another drug company to sell the patented drug at a lower price in the U.S. healthcare market. Thus, the price-control theory of the Bayh-Dole Act claims this statute empowers the federal government to impose price controls on drug patents by authorizing it to license these patents to generic drug companies directed by the federal government to charge lower prices.

C. The March-In Section in the Bayh-Dole Act is Not a Price-Control Provision

The price-control theory is based on an unduly narrow, out-of-context interpretation of two phrases within two sections of the Bayh-Dole Act. Although the price-control theory appears to be merely interpreting the text in these two statutory phrases, it does so at the expense of ignoring the plain text of both provisions in which these phrases are contained and ignoring the statute as a whole in which these provisions are contained as well. By myopically focusing on these two phrases, which are taken out of their grammatical and statutory context, the price-control theory violates longstanding canons of statutory construction and additional sources of statutory meaning that militate against this interpretation of § 203. This includes the consistent interpretation of § 203 by agencies over several decades that this section does not authorize price controls, among other extra-textual sources of meaning. This Section details this statutory analysis.

1. Section § 203 Does Not Authorize Price Controls in Its Express Text

The Supreme Court has stated that the "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning."[145] The first place all courts begin is the text of the statute, but the text is not read out of context as individual words. "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole."[146]

In considering the meaning of the text in § 203(a)(1), and the definitional text in § 201(f), one fact stands out: none of these statutory provisions state that "price" or "reasonable price" is a trigger for the federal government to exercise the march-in power. As the United States Supreme Court has explained: "We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a

in Rights: A Lost Opportunity To Lower US Drug Prices, IPWATCH (May 18, 2017), https://www.ip-watch.org/2017/05/18/march-rights-lost-opportunity-lower-us-drug-prices/ ("When inventions are priced exorbitantly – particularly in comparison to prices in other high-income industrialized countries – those inventions are not available to the public on reasonable terms. So march-in rights can, and should, be used to allow third parties to make and sell the invention at lower prices."); Jennifer Penman & Fran Quigley, *Better Late Than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 53 WILLIAMETTE L. REV. 1, 2 (2017) (stating that "the current medicines pricing and access crisis . . . calls for the U.S. agencies to finally fulfill the terms of the [Bayh-Dole] Act").

[145] Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997) (citations omitted); *see also* Caminetti v. United States, 242 U.S. 470, 485 (1917) ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, . . . the sole function of the courts is to enforce it according to its terms.") (citations omitted).

[146] *Robinson*, 519 U.S. at 341 (1997) (citations omitted).

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statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'"[147] This is the "cardinal canon" that all courts apply "in interpreting a statute."[148]

This cardinal canon of statutory interpretation confirms that § 203 does not authorize a federal agency to "march in" to grant a license to a private company directed to charge lower prices to consumers through commercial transactions in the marketplace. If Congress intended to create a price-control power in § 203, it would have specified this as one of the statutory conditions, or at least specified this power in express language in one of the existing statutory conditions.

Congress would have expressly enacted text conferring a price-control power in § 203 if it intended this to be a price-control statute because it has enacted such text many times in past statutes.[149] The Emergency Price Control Act of 1942 is one such example.[150] Similarly, rate-regulation statutes enacted by the states according to their police powers expressly authorize legislators or regulators to set "prices" or determine "rates."[151] Contrary to these price-control or rate-regulation statutes, § 203(a) and § 201(f) are devoid of any archetypical pricing terms, such as "price," "prices charged by an assignee or licensee," "market price," or "reasonable price." According to the "the ordinary meaning of the words used" in § 203 and § 201(f) in the Bayh-Dole Act, the march-in power does not authorize licenses for the purpose of imposing price controls.[152]

Proponents for the price-control theory might still argue that the relevant statutory text is not plain and unambiguous in its meaning, leaving the door open for a federal agency to engage in a reasonable construction of its terms.[153] Accordingly, they would claim that § 203(a)(1) speaks of the lack of "practical application" and "use" of a patented invention as a triggering condition for the exercise of the march-in power by a federal agency, and § 201(f) speaks of the lack of

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[147] Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992) (quoting Rubin v. United States, 449 U.S. 424, 430 (1981)) (internal citations omitted).

[148] *Connecticut Nat'l Bank*, 503 U.S. at 253.

[149] *See, e.g.*, Economic Stabilization Act of 1970, Pub. L. No. 91-379, § 202, 84 Stat. 799, 799-800 ("The President is authorized to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970."); Housing and Rent Act of 1947, Pub. L. No. 129, 61 Stat. 193, 198 (imposing rent controls on existing structures set at levels permitted to be charged under the Economic Price Control Act of 1942).

[150] *See* Pub. L. No. 77-421, 56 Stat. 23 (1942).

[151] *See, e.g.*, Nebbia v. People of New York, 291 U.S. 502, 515 (1934) ("The Legislature of New York established by chapter 158 of the Laws of 1933, a Milk Control Board with power, among other things to 'fix minimum and maximum ... retail prices to be charged by ... stores to consumers for consumption off the premises where sold.'"); Stone v. Farmers' Loan & Trust Co., 116 U.S. 307, 308 (1886) (reviewing "the statute of Mississippi passed March 11, 1884, entitled 'An act to provide for the regulation of freight and passenger rates on railroads in this state, and to create a commission to supervise the same, and for other purposes'").

[152] INS v. Phinpathya, 464 U.S. 183, 189 (1984) (stating that "in all cases involving statutory construction, our starting point must be the language employed by Congress, . . . and we assume that the legislative purpose is expressed by the ordinary meaning of the words used") (quotations and citations omitted).

[153] *See* Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc., 467 U.S. 837, 844 (1984) ("Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.").

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"reasonable terms" in licenses as one example of a failure of this "practical application." Rate-regulation regimes are often adopted for the purpose of ensuring *reasonable* prices or *reasonable* pricing terms.[154] Thus, the absence of "reasonable terms" in patent licenses, as a definitional element in § 201(f) for the march-in condition in § 203(a)(1) of a lack of "practical application" of a patented invention, could conceivably encompass high drug prices.

But this argument does not carry the day for the price-control theory. As noted above, statutory authorizations for imposing price controls or other forms of rate regulation expressly refer to reasonable *prices*, and not merely broadly framed "reasonable terms" of licenses or contracts.[155] In fact, statutes distinguish between "price" and "terms" by listing them separately.[156] This distinction is also consistent with past official usage of "practical application," which referred to the "successful development and terms of the license, not with a product's price."[157] For example, President John F. Kennedy issued a statement on patent policy in 1963 in which he expressly stated that government licensing may be required to achieve "practical application" of an invention to "guard against failure to practice the invention" by a government "contractor."[158] In enacting the Bayh-Dole Act in 1980, Congress could have included language referring to unreasonably high prices as a triggering condition for a march-in provision; this is the standard, undisputed "price" or price-related text that legislatures has long used in price-control or rate-regulation statutes. Congress chose not to include this language in the Bayh-Dole Act.

2. A Power to Impose Price Controls Conflicts with the Bayh-Dole Act as a Whole

It is not an accident that Congress did not include express text specifying high prices or unreasonable prices as a triggering condition for an agency to use its march-in power in § 203. In interpreting a statutory provision, courts inquire into "the specific context in which that language

[154] *See, e.g.*, 47 U.S.C. § 335(b)(3) ("A provider of direct broadcast satellite service shall meet the requirements of this subsection by making channel capacity available to national educational programming suppliers, upon *reasonable prices, terms, and conditions*, as determined by the Commission . . . .") (emphasis added).

[155] *Id.*

[156] *See id.*

[157] Joseph Allen, *New Study Shows Bayh-Dole is Working as Intended—and the Critics Howl*, IPWATCHDOG (March 12, 2019), https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/.

[158] Government Patent Policy, Memorandum of Oct. 10, 1963, Fed. Reg. 10943 (Oct. 12, 1963).

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is used, and the broader context of the statute as a whole."[159] The Supreme Court has bluntly stated: "We do not . . . construe statutory phrases in isolation; we read statutes as a whole."[160]

As Justice Antonin Scalia put the point, "we do not really look for subjective legislative intent. We look for a sort of 'objectified' intent—the intent that a reasonable person would gather from the *text* of the law . . . ."[161] Unlike in some statutes, Congress expressly stated its "objectified intent" in the text of the Bayh-Dole Act: "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development." The march-in power is an *exemption* from the purpose of the Bayh-Dole Act to stimulate universities and other researchers receiving federal research funds to receive patents to license or otherwise commercialize their inventions into the marketplace. In fact, this exemption was included in the Bayh-Dole Act because it advanced its primary commercialization function: if a patented invention is not licensed or made available in the marketplace by its owner or licensees, then an agency is authorized to act to achieve this goal. Thus, § 203(a)(1)-(4) specifies four conditions in which the march-in power is justified, and, as explained above, these conditions identify situations in which inventions are not sold or commercialized in the marketplace.[162]

In construing § 203 within the Bayh-Dole Act as a whole, it becomes apparent that the price-control theory commits the interpretative vice of "wooden textualism." This is the interpretive vice in statutory analysis in which a court or agency focuses solely on the meaning of a word or phrase taken out of its context within the statute as a whole.[163] The price-control theory commits wooden textualism by deriving its statutory argument through a myopic focus on phrases in "isolated provisions" in the Bayh-Dole Act.[164] It invokes "reasonable terms" as a definitional element in § 201(f) without regard to the complete statutory condition set forth in § 203(a)(1) in which the defined phrase "practical application" appears. If "reasonable terms" as a definitional element for "practical application" is considered within the *full context* of the march-in condition

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[159] *Robinson*, 519 U.S. at 340; *see also* Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 290 (2010) ("Courts have a 'duty to construe statutes, not isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 568 (1995)); Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)); Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'") (quoting Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989)); Louisville & N.R. Co. v. Gaines, 3 F. 266, 276 (C.C.M.D. Tenn. 1880) ("Where the language [of a statute] is clear and explicit the court is bound . . . . It must be construed as a whole. The office of a good expositor, says My Lord Coke, 'is to make construction on all its parts together.'").

[160] Samantar v. Yousuf, 560 U.S. 305, 319 (2010) (quoting United States v. Morton, 467 U.S. 822, 828, (1984)).

[161] Antonin Scalia, *Common-Law Courts in a Civil Law System: The Role of the United States Federal Courts in Interpreting the Constitution and Law*, *in* A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 17 (Amy Gutmann, ed., 1997) (emphasis added).

[162] *See supra* notes 121-127, and accompanying text.

[163] *Cf.* Scalia, *supra* note 161, at 23-24 (critiquing out-of-context linguistic construction of statutory terms because a "good textualist is not a literalist").

[164] Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)).

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in § 203(a)(1) and of the Bayh-Dole Act broadly, then the conclusion seems ineluctable that § 203(a)(1) does not authorize a federal agency to impose price controls on drug patents.

The Bay-Dole Act addressed the policy and economic dilemma that innovations were not being commercialized in the marketplace given the government's inability to commercialize the patented inventions it owned as a result of even a modicum of federal funding of upstream research.[165] The Bayh-Dole Act has achieved its goal through a simple declaratory provision: any invention derived from research funded even in part by the federal government may be patented and the owner of this patent has the same rights as all other patent owners to commercialize its property in the marketplace.[166] The Bayh-Dole Act was enacted on the basis of the commercialization function of the U.S. patent system, and these new patent owners, such as universities, have since conveyed their property rights via assignments or licenses in the marketplace.[167]

Given this "broader context of the statute as a whole" of the Bayh-Dole Act,[168] § 203 lists four narrow, delimited circumstances in which federal officials or agencies can "march in" and license other companies when a patented invention is not being deployed in the marketplace pursuant to the commercialization function of this statute. The commercialization function of the Bayh-Dole Act animates all four march-in conditions in § 203, as each sub-section addresses a distinct set of circumstances in which a patented product or service is not available in the marketplace. For example, § 203(a)(4) would authorize a federal agency to march in and license another company if an exclusive licensee is in breach of its license agreement with the patent owner, the patent owner has not licensed another company, and thus the product or service is languishing commercially and not being sold in the marketplace to the benefit of consumers.

The march-in condition set forth in § 203(a)(1) provides that "effective steps" must be taken by a patent owner or licensee "to achieve practical application of the invention in its field of us." This march-in condition must be read in the same "context and with a view to [its] place in the overall statutory scheme" of the Bayh-Dole Act as the other three march-in conditions set forth in § 203.[169] To focus exclusively on a portion of the definition in § 201(f) of "practical application" as ensuring the invention is available on "reasonable terms" without regard to this statutory context

[165] *See supra* notes 99-110, and accompanying text. *See also* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System* 24-27 (ITIF, March 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system?mc_cid=f1a53e317f&mc_eid=5c5d018a35 (detailing inability or lack of licensing of government of inventions developed from federally funded research).

[166] These rights are expressly secured in 35 U.S.C. § 261. *See also* Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 Harv. J. L. & Tech. 321, 343-45 (2009) (discussing legislative history of § 261 and its function in codifying case law reaching back to 1790s securing rights of patent owners to convey their property).

[167] *See supra* notes 108-109, and accompanying text.

[168] *Robinson*, 519 U.S. at 340.

[169] *Davis*, 489 U.S. at 809.

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violates the basic interpretative maxim not to engage in wooden textualism in construing the reasonable meaning of a statutory provision within the context of the statute as a whole.[170]

What is the reasonable meaning of a failure of "practical application" as a trigger for the march-in power in § 203(a)(1), especially as a distinct condition from the other three march-in provisions in § 203(a)(2)-(4)? This is the general provision in the march-in power section specifying a situation in which a patent owner or licensee fails to deploy through regular commercial means a product or process in the marketplace, what those commercial means may be. In the healthcare market, for example, § 203(a)(1) would apply when a drug is not manufactured or sold to patients, as distinguished from a licensee failing to make or sell drugs given its breach of a license agreement under § 203(a)(4) or the patent owner or licensee is unable to manufacture sufficient numbers of drugs to respond to a "health or safety" crisis under § 203(a)(2).[171] In sum, the phrase "reasonable terms" in § 201(f), as comprising part of the definition of "practical application" in § 203(a)(1), is not an open-ended authorization for a federal official or agency to impose price controls—it is part of a statutory regime whose function is to ensure that patented products or services are commercialized in the relevant marketplace.[172]

In construing § 203 within the context of the Bayh-Dole Act as a whole, it is evident why the price-control theory insists that agencies focus only on the isolated phrases "reasonable terms" in § 201(f) and "effective steps to achieve practical application" in § 203(a)(1). If the function of the Bayh-Dole Act is to promote commercialization of new inventions through patent licensing and other commercial activities in the marketplace, then the exemptions would authorize actions that would conflict with this only if the invention is not being commercialized as the statute intended. The exemptions would certainly not promote government actions that would undermine incentives to commercialize, such as an open-ended authorization to impose price controls whenever a federal official may deem a price to be too high or unreasonable.

D. Agency Interpretations of the March-In Power in § 203 Have Consistently Rejected the Price-Control Theory of the Bayh-Dole Act

The plain text of § 203 and its function within the Bayh-Dole Act as a whole explains why federal agencies—spanning bipartisan administrations over several decades—have repeatedly rejected numerous petitions to use the march-in power to impose price controls on drug patents.

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[170] The same rule of construction applies to the use of the phrase "upon terms that reasonable for the circumstances" in the preamble of § 203 that sets forth what a federal agency may do in licensing the patented product or process through its march-in power. In sum, this is not an open-ended reference to or authorization for price controls, but rather it ensures the context-specific commercial conditions for differing innovations are recognized and respected by the agency in its licensing agreements.

[171] This provision could not have been invoked during the COVID-19 pandemic, because there was massive production of the COVID-19 vaccine doses. Approximately 12 billion doses had been manufactured by the end of 2021, almost double the global population. *See* Adam Mossoff & Amesh Adalja, *Patents as a Driver of the Unprecedented Biomedical Response to COVID-19*, 59 INQUIRY: THE JOURNAL OF HEALTH CARE ORGANIZATION, PROVISION, AND FINANCING (2022), https://journals.sagepub.com/doi/10.1177/00469580221124819. It is estimated that approximately 24 billion vaccine doses were produced in 2022. *Id.*

[172] Section 203(a)(3) also authorizes the march-in power when a patent owner or licensee fails to meet the statutory conditions of § 204 (a mandate of manufacturing the product in the U.S.).

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In 2016, the Congressional Research Service identified six petitions submitted to the NIH requesting it to exercise its march-in power solely for the purpose of lowering prices of patented drugs sold in the healthcare market.[173] The NIH denied all six petitions on the grounds that § 203, as confirmed by the NIH's prior interpretation of this statutory, did not permit the march-in power to be used for the purpose of lowering drug prices.[174] By 2019, four more petitions had been filed with the NIH by policy organizations and activists, each requesting again that the NIH invoke the march-in power for the sole purpose of lowering drug prices.[175] As with the prior six petitions reaching back to the 1990s, the NIH rejected these petitions on the statutory ground that "the use of march-in to control drug prices was not within the scope and intent of its authority."[176]

In 1997, for example, the NIH was petitioned to invoke the march-in power for the Isolex 300, a patented medical device used in organ transplant procedures.[177] The NIH rejected the petition for failing to meet the burden of proof that any of the four distinction march-in conditions specified in § 203 had been triggered, authorizing the NIH to march in and license other companies to make and sell this medical device in the healthcare market. The NIH found that the Isolex 300 was being commercialized in the marketplace: the patent owner was actively licensing the patented device, seeking regulatory approval, and meeting research demands.[178] These facts precluded the triggering of the march-in power under the four authorizing conditions in § 203.

The NIH went further and explained why the price-control theory of the Bayh-Dole Act was not justified by the plain text of § 203 and the function of the Bayh-Dole Act in promoting the commercialization of patented inventions. The NIH stated that, even if the petitioner proved that there would be greater accessibility and *lower prices* given additional licenses from the NIH invoking the march-in power, this was by itself insufficient authorization under § 203.[179] The NIH stated emphatically that the march-in power in § 203 did not exist for the purpose of "forced attempts to influence the marketplace."[180] It acknowledged the inherent conflict between the function of the Bayh-Dole Act in promoting and commercializing new innovations and the adoption of the march-in power for the purpose of imposing price controls, observing that "such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies."[181] This was not merely a freestanding policy assessment by the NIH of this petition; it derived this conclusion from the plain meaning of § 203 within the context of the Bayh-Dole Act and its commercialization function.

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[173] *See* John R. Thomas, *March-In Rights Under the Bayh-Dole Act* 8-10 (Congressional Research Service, Aug. 22, 2016).

[174] *Id*.

[175] *See Return on Investment Initiative for Unleashing American Innovation*, *supra* note 4, at 29.

[176] *Id*.

[177] *See, e.g.*, NIH Office of the Director, *Determination in the Case of Petition of CellPro, Inc.* (Aug. 1, 1997), https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf (rejecting petition in part to invoke march-in power given argument that company was too slow in bringing a medical device to market).

[178] *Id.*

[179] *Id.*

[180] *Id.* at 7.

[181] *Id.* at 7.

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Another petition in 2004 again requested that the NIH invoke the march-in power in § 203 to license a patent specifically to lower the price for Norvir, a drug used to treat AIDS. Again, the NIH rejected the petition.[182] The NIH explained that "the extraordinary remedy of march-in is not an appropriate means of controlling prices," and that "[t]he issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[183]

Applying the classic rule, "if at first one does not succeed, try, try again," another petition was submitted to the NIH in 2013 asking it again to invoke the march-in power in § 203 for the purpose of lowering the price of Norvir sold by AbbVie to consumers in the healthcare market. The NIH again rejected the petition, stating that the imposition of price controls on drug patents was not a statutorily authorized march-in power in § 203 of the Bayh-Dole Act.[184] The NIH bluntly concluded: "As stated in previous march-in considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities."[185] The frustration by NIH officials with the serial petitions seeking to impose price controls on drug patents via the march-in provision in the Bayh-Dole Act is palpable.

Lastly, on March 21, 2023, the NIH rejected the latest petition (filed again) for this agency to invoke the march-in power solely to lower the price of Xtandi, a cancer drug covered by patent.[186] In its latest rejection of the price-control theory of the Bayh-Dole Act, the NIH reiterated that the "purpose of the Bayh-Dole Act is to promote commercialization and public availability of government-funded inventions."[187] With this statutory framework and purpose in mind, the NIH expressly "found Xtandi to be widely available to the public on the market" and "[t]herefore, the patent owner, the University of California, does not fail the requirement of bringing Xtandi to practical application."[188] The NIH further pointed out that this decision about Xtandi is consistent with its prior multiple rejections of march-in petitions also seeking to lower drug prices.[189] It also recognized that the administrative processes and delays, especially in light of Xtandi's remaining patent term, led it to conclude that "NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug."[190]

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[182] *See* NIH Office of the Director, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.* (July 29, 2004), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[183] Dr. Elias A. Zerhouni, Nat'l Institute of Health, *Determination in the Case of Norvir I*, at 5-6 (July 2, 2004).

[184] NIH Office of the Director, *In the Case of Norvir Manufactured by AbbVie* (Nov. 1, 2013), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

[185] *Id.*

[186] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Director, to Robert Sachs and Clare Love, *supra* note 5.

[187] *Id.* at 2.

[188] *Id.*

[189] *Id.*

[190] *Id.*

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The NIH's multiple decisions over several decades in interpreting the scope of the march-in power granted to it under § 203 is significant evidence that the price-control theory of the Bayh-Dole Act is without basis in the statute. The eleven or more decisions ranging from the 1990s through 2023 in which the NIH has consistently rejected march-in petitions requesting it impose price controls on drug patents under § 203 constitute "the well-reasoned views of the agenc[y] implementing a statute [that] 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.'"[191] The Supreme Court has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer."[192]

E. The Supreme Court Has Rejected Agencies' Claims to Unprecedented Powers Similar to the Price-Control Theory of the Bayh-Dole Act

The Supreme Court's 2022 decision in *West Virginia v. Environmental Protection Agency* confirms the significance of the NIH's repeated interpretation of § 203 over several decades.[193] As the NIH has repeatedly stated, the march-in power is an "extraordinary" act that is "not an appropriate means of controlling prices" and that proponents of price controls on drug patents must look to "Congress to address legislatively" the power to achieve this goal.[194] The power to impose price controls on drug patents is simply the delimited conditions set forth in § 203 of the Bayh-Dole Act. The price-control theory of the Bayh-Dole Act argues that federal agencies can take the extraordinary and unprecedented administration action in imposing price controls on drug patents solely on the basis of an inference of implied authority from generalized language in two distinct clauses construed in isolation within the entire statute. It would be unprecedented for a federal agency to impose price controls on drugs produced and sold by private companies to consumers and patients in the healthcare market solely on the basis of statutory text stating only that a lack of "reasonable terms" represents a failure of "practical application" of a drug patent.[195]

West Virginia closes the door on this broad-based argument for unprecedented agency power to impose price controls on drug patents absent explicit authorization in § 203.[196] This was not the first time the Supreme Court rejected an argument for discretionary administrative power based in generalized, out-of-context statutory phrases in the governing statute. In *Food & Drug Administration v. Brown & Williamson Tobacco Corporation,*[197] the Court assessed the FDA's broad-based construction of generalized, out-of-context phrases in its governing statute to justify its unprecedented assertion of power to regulate cigarettes. The *Brown & Williamson* Court rejected the FDA's "'expansive construction of the statute,' concluding that 'Congress could not

[191] *See* United States v. Mead Corp., 533 U.S. 218, 227 (2001) (quoting Bragdon v. Abbott, 524 U.S. 624, 642 (1998) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)))

[192] *Chevron*, 467 U.S. at 844.

[193] *See* West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587 (2022).

[194] *See supra* notes 183-185, and accompanying text.

[195] *See supra* note 138-141, and accompanying text (explaining the statutory interpretation set forth by the price-control theory of the Bayh-Dole Act).

[196] *See West Virginia*, 142 S. Ct. at 2609.

[197] Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

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have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'"[198] This conclusion applies with equal force to the price-control theory of the Bayh-Dole Act, which engages in an "expansive construction of the statute" to justify a "sweeping and consequential authority" based entirely in generalized "cryptic" statutory language.[199]

F. The Price-Control Theory was Rejected by the Namesakes of the Bayh-Dole Act

The price-control theory of the Bayh-Doel Act was allegedly "discovered" by two professors more than two decades after the enactment of the Bayh-Dole Act,[200] which reconfirms the applicability of the fundamental principles of statutory interpretation and constitutional law that limit agency powers, as stated in *Brown & Williamson*, *West Virginia*, and in other cases.[201] The eponymous sponsors of the Bayh-Dole Act agree. Senator Birch Bayh and Senator Robert Dole expressly rejected the price-control theory of the Bayh-Dole Act.

Similar to the *New York Times* editorial in 2021 advocating for the price-control theory of § 1498, which was prompted by a 2016 law journal article,[202] Professors Arno and Davis published an op-ed in the *Washington Post* in 2002 restating their argument from their law journal article the year before that the Bayh-Dole Act mandates that patented inventions resulting from "federal funds will be made available to the public at a *reasonable price*."[203] Professors Arno and Davis' op-ed prompted a response from Senators Bayh and Dole, published as a letter to the editor in the *Washington Post* two weeks later:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. . . . The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.[204]

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[198] *See West Virginia* 142 S. Ct. at 2608 (quoting Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000)).

[199] *Brown & Williamson*, 529 U.S. at 159.

[200] *See supra* note 128, and accompanying text.

[201] *See* Alabama Ass'n of Realtors v. Dep't of Health and Human Services, 141 S. Ct. 2485, 2487 (2021) (rejecting the Center for Disease Control's moratorium on rental evictions given the "wafer-thin reed" of support in its organic statute's text and the "unprecedented" nature of the asserted regulatory power).

[202] *See supra* notes 37-40, and accompanying text.

[203] *See* Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, Washington Post (March 27, 2002), https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/ (emphasis added).

[204] Birch Bayh and Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, Wash. Post (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

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In sum, there is no "clear congressional authorization" in § 203 that grants federal agencies power to impose price controls on patented products or services that are commercialized in the marketplace.[205] Beyond the plain text of § 203, the price-control theory of the Bayh-Dole Act contradicts the function of this statute in promoting the commercialization of inventions by patent owners in the marketplace.[206] The NIH has confirmed this lack of express statutory authorization in § 203 to impose price controls in its consistent, repeated rejections of numerous march-in petitions over several decades that have sought use of this power solely to lower drug prices. Although it does not have the same legal status as the canons of statutory interpretation and official interpretation and application of a statute, Senators Bayh and Dole make clear that the price-control theory of the Bayh-Dole Act proposes an unprecedented assertion of agency power to control prices in private market transactions between private parties given only generalized, out-of-context statutory phrases like "practical application" and "reasonable terms."

IV. Conclusion

For at least five decades, a significant policy debate over drug prices has waxed and waned in the U.S. Initially, this was principally a debate only in healthcare policy. In recent decades, the patent system has been drawn into this sometimes heated debate with scholars and activists arguing that drug patents are a primary cause of what they contend are unacceptably high drug prices.[207] They argue that the federal government can break patents and impose price controls on drug patents. They assert that two federal laws—§ 1498 and the Bayh-Dole Act—are an "important tool" authorizing federal agencies to achieve their policy goal of imposing price controls on drug patents.[208]

This is a false promise. The price-control theories of § 1498 and the Bayh-Dole Act represent policy arguments superimposed on two statutes by advocates seeking a quick-and-easy path to justifying an unprecedented regulatory policy—the imposition of price controls on drug patents. Since 1790, Congress has considered proposals for various forms of compulsory licensing of patents, and Congress has consistently rejected these proposals.[209] Perhaps recognizing this significant hurdle in proposing an unprecedented—and expressly rejected—policy proposal for

[205] *See supra* notes 145-157, and accompanying text (describing the text in § 203 and the lack of any express authorization to control or delimit prices).

[206] *See supra* notes 159-172, and accompanying text (applying the canon of statutory interpretation that § 203 must be construed within the entire context of the Bayh-Dole Act).

[207] *See supra* note 3, and accompanying text (detailing this policy argument).

[208] *See supra* note 18, and accompanying text.

[209] *See, e.g.*, BRUCE W. BUGBEE, GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 143-44 (1967) (discussing the rejection of a Senate proposal for a compulsory licensing requirement in the bill that eventually became the Patent Act of 1790); Kali Murray, *Constitutional Patent Law: Principles and Institutions*, 93 NEB. L. REV. 901, 935-37 (2015) (discussing a congressional bill in 1912 requiring compulsory licensing for patent owners not manufacturing a patented invention, which received twenty-seven days of hearings, but was not enacted into law).

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price controls on drug patents, advocates attempt to bootstrap their policy arguments by arguing that Congress has already approved of a price-control policy in two existing federal statutes.

The price-control theories of § 1498 and the Bayh-Dole Act are profoundly mistaken. Neither § 1498 nor the Bayh-Dole Act authorize agencies to impose price controls on drug patents for the purpose of lowering drug prices. This is confirmed by their plain text, their consistent interpretation by courts and agencies, by principles of constitutional law, and by extra-textual sources of statutory meaning. Ultimately, the price control theories of § 1498 and the Bayh-Dole Act engage in interpretative acts of legerdemain that essentially pull a price-control rabbit out of statutory hat to proclaim, "Voila, lower drug prices through price controls on patents!"

This article has not addressed the policy arguments for or against price controls on drug patents, but only because advocates for price controls have chosen to advance as their primary argument a seemingly straightforward claim about statutory authorization—the price-control theories of § 1498 and the Bayh-Dole Act. This requires engaging in rigorous analysis of the meaning of these respective statutes as a necessary first step before engaging with the normative arguments based on the price-control theories of § 1498 and the Bayh-Dole Act. Ultimately, policy advocates should be careful not to replace rigorous normative justifications with statutory claims that are the equivalent of "law office history"—the practice by legal actors of using isolated, out-of-context historical facts in the service of modern policy arguments.[210] The price-control theories of the Bayh-Dole Act and § 1498 are policy arguments masquerading as statutory construction. It is time to lay these legal myths to rest and to have a forthright policy debate.

[210] Larry D. Kramer, *When Lawyers Do History*, 72 GEO. WASH. L. REV. 387, 389-94 (2003) (criticizing bad historiography of lawyers, who produce "law office history" intended only "to generate data and interpretations that are of use in resolving modern legal controversies" (citations omitted)).

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