

WRITTEN TESTIMONY OF

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BEFORE THE

COMMITTEE ON THE JUDICIARY

United States Senate

**“Ensuring Affordable & Accessible Medications: Examining Competition
in the Prescription Drug Market”**

MAY 21, 2024

Chairman Durbin, Ranking Member Graham, and Members of the Committee:

Thank you for this opportunity to speak with you today about the longstanding policy debate over drug prices in which inaccurate claims about the patent laws and other statutes, as well as unreliable data, is impeding the ability of Congress to engage in evidence-based policymaking.¹

For at least half a century, the cost of medical care in the United States has long been debated in healthcare policy.² The causes of healthcare prices are complex and multi-dimensional, 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.³ In policy discussions about drug prices, though, some

¹ I am speaking on own behalf, and my testimony does not reflect the views of my employer or of any institution or organization with which I am affiliated.

² See, e.g., *Consumer Group Decries Rise in Drug Prices*, L.A. TIMES, Mar. 16, 1995, at 1 (“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, July 17, 1984, at B20 (“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 the cost, inflation, and inaccessibility of medical care in the United States.”).

³ 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

activists, scholars and policymakers reduce this legal and institutional complexity to a single cause—patents.⁴

The patent system is now at the center of policy debates and academic discussions about drug prices. Academics and activists blame patents for “rising drug prices.”⁵ Legislators have introduced numerous bills addressing a wide range of legal and policy issues concerning drug patents, such as the number of patents, the quality of patents, and the scope of protection of patents, among others. Federal agencies, such as the Patent and Trademark Office (PTO), the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA), have issued formal requests for information, engaged in studies and investigations, and hosted workshops in considering new regulations or regulatory guidelines for an equally wide range of issues concerning drug patents, such as adopting new requirements for patent applications. Lastly, lawsuits have been filed in courts, and the FTC has engaged in enforcement actions, asserting violations of the antitrust laws.

In written testimony for a single hearing before this committee, it is impossible to address all of these legal and policy activities in all three branches of the federal government. For the sake of brevity, my testimony here is limited to the misinterpretation of two statutes in the policy debates concerning the causes and solutions to allegedly high drug prices: the Bayh-Dole Act and 28 U.S.C. § 1498. For approximately two decades, professors and activists have mistakenly argued that both statutes authorize agencies to “lower drug prices by breaking patent barriers.”⁶ The National Institute of Standards and Technology (NIST), which is charged with implementing the Bayh-Dole Act, is now officially considering this argument. On December 7, 2023, NIST proposed new guidelines that would authorize federal agencies to exercise the “march in” power in § 203 of the Bayh-Dole Act in granting licenses unauthorized by a patent owner for the purpose of lowering prices in the marketplace.⁷ Academics and activists have also long argued that § 1498 is an existing “tool” for the federal government to impose price controls on patented products and services,

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.”)

⁴ See, e.g., Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. 403, 406 (2022) (“Patients, doctors, and insurers have all felt the distress of rising drug prices . . . Underlying much of these cost increases are the exclusive rights granted by patents.”).

⁵ See *id.*; see also I-MAK, *Drug Pricing Crisis* <https://www.i-mak.org/health-equity/#pricing> (accessed June 20, 2021) (stating that a “a root cause of the high cost of medicines is . . . unjust patent monopolies”); 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, 284 (2016) (“Drug prices in the United States are among the highest in the world . . . [T]hey result from . . . [o]ur patent system . . . [and its] grant of a monopoly [that] allows the manufacturer to charge any price[.] . . .”); Amy Kapczynski & Aaron S. Kesselheim, *‘Government Patent Use’: A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFAIRS 791, 791 (2016) (claiming that “new medicines . . . are expensive not because they are expensive to manufacture but because they are protected by patents”).

⁶ See Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., at 8 (Apr. 20, 2022), <https://tinyurl.com/yt62wt4t>. Professor Kapczynski and Professor Kesselheim are the co-authors of this letter, which is based on their previously published academic articles, and thus this letter is identified as the “Kapczynski-Kesselheim Letter.” See also 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).

⁷ See National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 7, 2023).

including drugs.⁸ Their arguments concerning § 1498 have not been implemented yet by any agency, but this price-control theory of § 1498 has been endorsed by Senators and House Members in letters to agencies and administration officials, urging them to take action.⁹

Neither the Bayh-Dole Act nor § 1498 are price-control statutes, and thus they do not authorize federal agencies to impose price controls on patents. This is clear by their plain legal text, as well as by their past interpretation by courts and agencies. The Bayh-Dole Act promotes the commercialization of patented inventions that may result from government funding of research, and § 1498 secures patent-owners in obtaining compensation for unauthorized uses of their property rights by the government. Neither law says anything about drug prices specifically or about reasonable prices generally. If the government used either law to impose price controls on patented drugs, this would conflict with the text and purpose of these statutes. It would also represent an unprecedented and fundamental change in U.S. patent law. From 1790 through the twentieth century, Congress rejected bills that would impose compulsory licensing on patents.¹⁰ The effort to use the Bayh-Dole Act or § 1498 for similar purposes is fundamentally at odds with these statutes and threatens to undermine the U.S. patent system's historic success as a driver of U.S. global leadership in biopharmaceutical innovation.

In this written testimony, I will explain why neither the Bayh-Dole Act nor § 1498 can be used to break patents to impose price controls on prescription drugs. First, it sets forth the proven success of the patent system as a driver of innovation in healthcare, which is the necessary legal and empirical framework to evaluate the argument to “lower drug prices by breaking patent barriers.”¹¹ This argument threatens to undermine the legal system that has saved lives and improved everyone's quality of life. It then describes the Bayh-Dole Act and § 1498, explaining how neither authorizes price controls on patented drugs. The policy argument that these laws are “tools” to impose price controls on prescription drugs contradicts the clear text and purpose of these statutes, violating the principle of evidence-based policymaking that is essential to good governance.

⁸ Kapczynski-Kesselheim Letter, *supra* note 6, at 1; *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> (proposing to use § 1498 to license generic drug companies to make and sell patented drugs at lower price than that charged by a patent owner); Brennan, Kapczynski, et al., *supra* note 5, at 279 (claiming that “a legal remedy that has been hiding in plain sight” in § 1498 to lower drug prices)

⁹ *See, e.g.*, Letter to Secretary Gina Raimondo, Secretary Xavier Becerra, and Under Secretary Laurie E. Locascio from House Member Lloyd Doggett, Senator Elizabeth Warren, Senator Angus S. King, Jr., and 75 other House Members and Senators (Feb. 6, 2024), <https://www.warren.senate.gov/imo/media/doc/Bayh-Dole%20Interagency%20Guidance%20Comment%20Letter%20FINAL%202.6.24.pdf>; Letter to Secretary Xavier Becerra from Senator Bernard Sanders (June 7, 2023), <https://www.sanders.senate.gov/wp-content/uploads/6.7.2023-Letter-from-Chairman-Sanders-to-Secretary-Becerra.pdf>.

¹⁰ *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 *Nebraska Law Review* 901, 935-37 (2015) (discussing 1912 bill that imposed compulsory licensing on patent owners who are not manufacturing a patented invention, which received twenty-seven days of hearings, but was not enacted into law).

¹¹ Kapczynski-Kesselheim Letter, *supra* note 6, at 8.

The Patent System Spurs Innovation in Healthcare

The patent system has been a key driver of the U.S. innovation economy for over 200 years, as economists, historians, and legal scholars have repeatedly demonstrated.¹² The patent system was central to the successes of the Industrial Revolution in the nineteenth century, the pharmaceutical and computer revolutions in the twentieth century, and the biotech and mobile telecommunications revolutions in the twenty-first century.¹³ Patent systems that secure reliable and effective property rights to inventors consistently and strongly correlate with successful innovation economies.¹⁴

Dr. Zorina Khan, an award-winning economist, has demonstrated that reliable and effective property rights in innovation—patents—were a key factor in thriving markets for technology in the United States in the nineteenth century.¹⁵ Other economists have also identified features of these robust nineteenth-century innovation markets—such as an increase in “venture capital” investment in patent owners, the rise of a secondary market in the sale of patents as assets, and the embrace of specialization via licensing business models—as indicators of value-maximizing economic activity made possible by reliable and effective patents.¹⁶ This remains true today: a twenty-first-century startup with a patent *more than doubles* its chances of securing venture capital financing compared to a startup without a patent, and this patent-based startup has statistically-significant increased chances of success in the marketplace as well.¹⁷

These general economic insights and historical facts are especially evident in the biopharmaceutical sector. Historically, the U.S. has been a global leader in first securing innovations in new drugs, diagnostics, and other biotech innovations in healthcare.¹⁸ The U.S. is a global leader in biomedical innovation today. More than one-half of new drugs worldwide are invented in the U.S., improving the quality and duration of human life here and abroad.¹⁹ For this

¹² See, e.g., ROBERT P. MERGES, *AMERICAN PATENT LAW: A BUSINESS AND ECONOMIC HISTORY* (2023); JONATHAN M. BARNETT, *INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL PROPERTY* (2021); DANIEL SPULBER, *THE CASE FOR PATENTS* (2021); B. ZORINA KHAN, *INVENTING IDEAS: PATENTS, PRIZES, AND THE KNOWLEDGE ECONOMY* (2020); Stephen Haber, *Innovation, Not Manna from Heaven* (Hoover Institution, Sep. 15, 2020); B. Zorina Khan, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 *GEO. MASON L. REV.* 825, 837-39 (2014); Naomi R. Lamoreaux, Kenneth L. Sokoloff & Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, 87 *BUS. HIST. REV.* 3 (Spring 2013); RONALD A. CASS & KEITH N. HYLTON, *LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS* (2013).

¹³ See generally MERGES, *supra* note 12; BARNETT, *supra* note 12; KHAN, *supra* note 12.

¹⁴ See, e.g., Stephen Haber, *Patents and the Wealth of Nations*, 23 *GEO. MASON L. REV.* 811 (2016); Jonathan M. Barnett, *Patent Tigers: The New Geography of Global Innovation*, 2 *CRITERION J. INNOVATION* 429 (2017).

¹⁵ See 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.”).

¹⁶ See, e.g., Naomi R. Lamoreaux, Kenneth L. Sokoloff & Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, 87 *BUS. HIST. REV.* 3, 4–5 (2013).

¹⁷ See Joan Farre-Mensa, et al., *What Is a Patent Worth? Evidence from the U.S. Patent “Lottery,”* 75 *J. Finance* 639 (2019), <https://doi.org/10.1111/jofi.12867>.

¹⁸ See Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 *Geo. Mason L. Rev.* 939, 942-44 (2017).

¹⁹ See Ross C. DeVol, Armen Bedroussian & Benjamin Yeo, *The Global Biomedical Industry: Preserving U.S. Leadership* 5 (Sep. 2011), <http://www.ncnano.org/CAMIExecSum.pdf>.

reason, the U.S. patent system was long identified as the “gold standard” in securing reliable and effective property rights in the fruits of innovative labors—patents.²⁰

Studies further demonstrate the fundamental role of patents in the pharmaceutical sector, as compared to other mechanisms for protecting intellectual property investments, such as trade secrets.²¹ The economics of research and development (R&D) in the biopharmaceutical sector explain why reliable and effective patents serve this role. Total R&D expenditures underlying each new drug is estimated to be \$2.6 billion, representing 10-15 years of research, testing, and development before the first patient is prescribed this drug as a treatment.²² The likelihood that these vast investments in time and money will succeed is extremely low: a mere 12% of potential new drugs that reach clinical trials are approved by the Food & Drug Administration.²³

The creation and distribution to patients of new healthcare treatments is made possible by massive investments in R&D and in their commercial development, production, and distribution. Annual private investment in the biopharmaceutical sector is approximately \$129 billion (as of 2018).²⁴ This is almost *triple* the total amount of total public funding of \$43 billion of R&D in healthcare innovations (as of 2018).²⁵ As a result, diagnoses that once were either death sentences or led to a greatly diminished quality of life—cancer, hepatitis, and diabetes—are now treatable and manageable medical conditions within a relatively normal lifespan.

For these reasons, empirical studies demonstrate that weak patent protection lowers investment in R&D in new drugs, delays the introduction of new medicines, and slows economic growth.²⁶ This result is unsurprising: healthcare innovators will not incur very large, risky investments unless they are secured in the fruits of their productive labors. Courts have long recognized that the promise of property rights in inventions serve the same function as property rights promised to a farmer who labors over a year to produce crops.²⁷ The economic and moral principles are the same.

²⁰ Madigan & Mossoff, *supra* note 18, at 940-41.

²¹ See, e.g., Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not)*, NAT’L BUREAU OF ECON. RSCH. (Feb. 2000) (NBER Working Paper No. 7552), <http://www.nber.org/papers/w7552.pdf>.

²² See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016); see also PhRMA, *Research & Development Policy Framework*, <https://www.phrma.org/en/Advocacy/Research-Development>; Henry G. Grabowski, *Patents, Innovation and Access to New Pharms.*, 5 J. INT’L ECON. LAW 849 (2002).

²³ DiMasi, *supra*, note 22, at 25.

²⁴ See U.S. Investments in Medical and Health Research and Development 2013–2018, at 7 (Research America, 2019), https://www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf. This is almost triple the amount of annual public funding of \$43 billion of R&D in healthcare innovations. *Id.* at 8.

²⁵ See *id.*, at 8.

²⁶ See E. R. Berndt & I. M. Cockburn, *The Hidden Cost of Low Prices: Limited Access to New Drugs in India*, 33 HEALTH AFFAIRS 1567 (2014), <https://doi.org/10.1377/hlthaff.2013.1307>; PwC, *Vision 2025: Unlocking India’s Potential for Leadership in Pharmaceutical Innovation*, at 8 (Oct. 2016), <https://www.pwc.in/assets/pdfs/publications/2017/vision-2025-unlocking-indias-potential-for-leadership-in-pharmaceutical-innovation.pdf>.

²⁷ See *Davoll v. Brown*, 7 F. Cas. 197, 199 (C.C.D. Mass. 1845) (“[W]e protect intellectual property, the labors of the mind, productions and interests as much a man’s own, and as much the fruit of his honest industry, as the wheat he cultivates, or the flocks he rears.”); see also *Hovey v. Henry*, 12 F. Cas. 603, 604 (C.C.D. Mass. 1846) (“An inventor holds a property in his invention by as good a title as the farmer holds his farm and flock.”).

The U.S. has been a global leader in securing reliable and effective patent rights to innovators in the biopharmaceutical sector, which has prompted massive investments and successful development of new drugs that have led to longer lifespans and improved quality of life, as well as contributing to growth in the U.S. innovation economy. The principle of evidence-based policymaking establishes this legal and evidentiary framework by which policymaker must evaluate legislative or regulatory proposals to weaken or eliminate patent rights in new drugs. For example, those seeking to break patents to impose price controls on prescription drugs bear the evidentiary burden to prove why weakening this essential legal platform for the global innovation economy will not stifle innovation and ultimately harm patients.

They have not met this burden. Since professors and activists have been unable to meet their evidentiary and policy burden, they instead argue that Congress already made this controversial policy decision in two laws it enacted many decades ago—the Bayh-Dole Act and § 1498. These arguments are legally incorrect, as detailed below.

The Bayh-Dole Act Does Not Authorize Price Controls on Prescription Drugs

Congress enacted the Bayh-Dole Act in 1980 to provide an incentive for private parties to make the significant, risky investments in new product development, in creating manufacturing capabilities, and in setting up supply and distribution chains that bring new innovations to consumers. These are necessary investments in translating original discoveries into useful commercial products.²⁸ Before 1980, the government effectively claimed ownership in inventions resulting from government-funded research, offering nonexclusive licenses to anyone requesting one; this undermined the commercialization of these inventions given the absence of property rights that are the legal platform for contracts and other commercial activities.²⁹ The Bayh-Dole Act corrected this mistaken policy by reaffirming the longstanding rule in the U.S. patent system that innovators can obtain patents for their inventions, even if these inventions arising from some upstream government-funded research in the inventions. As property rights, patents facilitate licensing and other commercial activities in the marketplace.³⁰

Section 203 in the Patent Act, as enacted in the Bayh-Dole Act, creates a limited exception to this core function of the Bayh-Dole Act by creating a “march in right” to further the Bayh-Dole Act’s function in promoting commercialization of new inventions for which there was some federal funding in the upstream research process.³¹ To ensure commercialization of inventions arising from research funded by government agencies, § 203 authorizes a federal agency that has funded research that resulted in a patented invention “to grant a nonexclusive, partially exclusive, or exclusive license” under four specified conditions.³² A federal agency may grant these licenses “to a responsible applicant” without authorization from the patent owner in four delimited

²⁸ See generally BARNETT, *supra* note 12.

²⁹ See, e.g., S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979) (explaining that the government’s policy of owning patents on inventions arising from government-funded research and offering nonexclusive licenses “has proven to be an ineffective policy” and that “the private sector simply needs more protection for the time and effort needed to develop and commercialize new products than is afforded by a nonexclusive license”).

³⁰ See *id.*, at 28 (“It is essentially a waste of public money to have good inventions gathering dust on agencies’ shelves because of unattractiveness of nonexclusive licenses.”).

³¹ See 35 U.S.C. § 203 (2011).

³² § 203(a).

circumstances: (1) if “the contractor or assignee 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 by the contractor, assignee, or licensee,” (3) “requirements for public use specified by Federal regulations . . . are not reasonably satisfied by the contractor, assignee, or licensee,” 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.”³³

For two decades, professors and activists have argued that § 203 authorizes agencies to march in for the purpose of lowering drug prices. NIST’s proposed march-in guidelines implement these arguments in expressly providing that “reasonable price” is a criterion for an agency to issue unauthorized licenses, effectively imposing price controls on patented products or services produced by private companies and sold to private consumers in the marketplace.³⁴

The statutory text of § 203 does not support the unprecedented consideration of “reasonable price” as a basis for authorizing the march-in power. As a preliminary matter, the four march-in conditions, which are set forth in § 203(a) in the disjunctive, constitute the only authorizations in the Bayh-Dole Act for a federal agency to exercise the march-in power. Notably, there is no mention of “reasonable price” or “price” in the four authorizing conditions for a federal agency to invoke the march-in power to issue licenses without approval from a patent owner.

Congress would have expressly enacted text conferring a price-control power in § 203 if it intended a “reasonable price” to trigger use of the march-in power under § 203. Congress has enacted numerous statutes that have authorized officials or agencies to impose price controls on transactions in the marketplace.³⁵ The Emergency Price Control Act of 1942 is one such example.³⁶ Similarly, rate-regulation statutes enacted by the states according to their police powers expressly authorize legislators or regulators to set “prices” or determine “rates.”³⁷ Contrary to these price-control or rate-regulation statutes, § 203 is devoid of any archetypical pricing terms, such as “price,” “prices charged by an assignee or licensee,” “market price,” or “reasonable price.”

³³ § 203(a)(1)-(4).

³⁴ See National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593, 85598 (Dec. 7, 2023) (stating that “march-in is warranted” and thus an agency may issue licenses without authorization by the patent owner if “the price or other terms at which the product is currently offered to the public are not reasonable”).

³⁵ 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).

³⁶ See Pub. L. No. 77-421, 56 Stat. 23 (1942).

³⁷ 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’”).

According to the “the ordinary meaning of the words used” in § 203 in the Bayh-Dole Act, the march-in power does not authorize licenses for the purpose of imposing price controls.³⁸

Moreover, there is no catch-all clause in § 203 authorizing the march-in power for anything not already covered by the four specific march-in conditions. This is significant for at least two reasons. First, Congress knows how to create broadly framed and expansive authorizations for agency action, if this is its purpose. For example, Congress has expressly created broadly-framed authorizations of general administrative powers 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.”³⁹ 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.⁴⁰

In sum, Congress chose not to create an open-ended grant of authority in § 203 by listing only four specific march-in conditions that strictly specify the narrow scope and application of the march-in power exemption in the Bayh-Dole Act. This comports with the primary function of the Bayh-Dole Act in promoting private commercialization of patented innovations in the marketplace. In its preamble provision, the Bayh-Dole Act expressly identifies its general policies and objectives.⁴¹ It does *not* state that a function of this statute is to ensure that patented inventions should be available to consumers at reasonable prices in the marketplace.⁴²

Recognizing this lack of express textual authorization to impose “reasonable price” mandates on patents covered by the Bayh-Dole Act, academics and activists who have argued for over two decades that this price-control power is inherent in the first march-in condition in § 203(a)(1). This condition states that a failure “to achieve practical application” of an invention can be a trigger for any agency to march in and issue licenses without authorization of the patent owner. The advocates for price controls argue that, since “high prices” can prevent the fully “practical application” of invention by preventing some consumers from being able to purchase it, then this provision authorizes an agency’s march-in power to license this patented invention to lower the price in the

³⁸ *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).

³⁹ 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.”).

⁴⁰ *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*).

⁴¹ *See* 35 U.S.C. § 200.

⁴² *Id.* Here, the Bayh-Dole Act lists a series of statutory objectives, including “encourage maximum participation of small business firms in federally supported research and development efforts,” “to promote the commercialization and public availability of inventions made in the United States by United States industry and labor,” and “to promote the utilization of inventions arising from federally supported research or development,” among others, but it does never lists or identifies lower “prices” or “reasonable prices” as a goal. 35 U.S.C. § 200.

marketplace.⁴³ The newly proposed NIST guidelines adopt this theory, stating that if “price or other terms . . . offered to the public are not reasonable,” then this will “unreasonably limit availability of the invention to the public” as a trigger for this march-in power.⁴⁴

This price-control theory of the march-in power is wrong as a matter of law. First, this argument and the proposed NIST guidelines ignore that the march-in power in § 203(a)(1) is limited to only the original federal “contractor or assignee,” and thus it does not apply to the *licensee* that is selling the product or service in the marketplace. Unlike the three other march-in conditions, § 203(a)(1) applies only to when either the original university researcher who obtained a patent (contractor) or the university to whom the researcher transferred his or her patent (assignee) is not *licensing* the invention to firms and other market actors to manufacture and commercially distribute the invention in the marketplace. This limited application of § 203(a)(1) is confirmed by the express inclusion of “licensee” in the three other march-in conditions of § 203(a)(2)-(4) given the function of those march-in conditions in addressing failures by licensees to commercialize a patented invention, such as lacking manufacturing capability to produce the invention or breach of the license itself. In sum, all four march-in conditions in § 203 ultimately serve the Bayh-Dole Act’s core function in promoting commercialization in the marketplace of patented inventions that resulted from research that was supported in some way by federal monies.

Second, the price-control theory of the march-in power violates the rule of statutory interpretation that a statutory provision is always construed in the context of the entire statutory regime in which that specific provision or phrase exists. This is closely related to the first point that the advocates for the price-control theory of the march-in power have invoked the “practical application” language in § 203(a)(1) without recognizing the express limitation of this trigger to actions only by the original inventor or immediate assignee. Here, the price-control theory advocates focus laser-like on the isolated phrase “practical application” in § 203(a)(1) and on a similarly isolated phrase in a lengthy definition of this term in § 201(f) that the invention should be “available to the public on reasonable terms.”⁴⁵ These academics and activists thus derive an entire theory of unprecedented and vast regulatory power to control prices in the marketplace of patented products and services based on only two isolated phrases in two separate sections of the Bayh-Dole Act—“practical application” and “reasonable terms.”

As a matter of statutory interpretation, this out-of-context isolation of brief phrases in statutory provisions commits the classic interpretative error of wooden textualism.⁴⁶ Courts always inquire

⁴³ See, e.g., Kapczynski- Kesselheim Letter, *supra* note 6, at 6-7; Fran Quigley & Jennifer Penman, *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*, 54 WILLAMETTE L. REV. 171 (2017); Peter S. Arno & Michael H Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001).

⁴⁴ National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. at 85598.

⁴⁵ See 35 U.S.C. § 201(f) (defining “practical application” to mean “to 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”).

⁴⁶ See *Sackett v. Environmental Protection Agency*, 143 S. Ct. 1322, 1340 (2023) (“construing statutory language is not merely an exercise in ascertaining ‘the outer limits of a word’s definitional possibilities’”) (quoting

into “the specific context in which that language is used, and the broader context of the statute as a whole.”⁴⁷ The Supreme Court has bluntly stated in far too many cases to cite or quote: “We do not . . . construe statutory phrases in isolation; we read statutes as a whole.”⁴⁸ “Courts have a ‘duty to construe statutes, not isolated provisions.’”⁴⁹ This is especially relevant in assessing a statutory argument that would authorize vast, unprecedented powers by federal agencies to engage in unauthorized licensing of patents that Congress has expressly rejected in other contexts.⁵⁰

Congress stated its express intent in 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.”⁵¹ The march-in power is an *exemption* from the function of the Bayh-Dole Act to stimulate universities and other researchers receiving federal research funds to obtain patents to utilize licenses in commercializing their inventions. In fact, this exemption was included in the Bayh-Dole Act precisely because it advances this primary commercialization function of the statute: 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. Accordingly, § 203(a)(1)-(4) set forth four specific conditions in which the march-in power is justified, and these conditions identify situations in which inventions are not sold or commercialized in the marketplace.

Lastly, the absence of a legal basis in the Bayh-Dole Act for the price control theory of the march-in power in § 203, as adopted in the recently proposed NIST guidelines, is confirmed by Supreme Court precedent that agencies may not arrogate powers to themselves that are not specifically granted in statutes. An unprecedented agency power to impose price controls on all patented products or services produced and sold in the marketplace that were created from upstream research supported by some federal funding requires more than vague or generalized statutory terms like “effective steps to achieve practical application.”⁵² This is especially true given that

FCC v. AT&T, 562 U.S. 397, 407 (2011)); cf. 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 23-24 (Amy Gutmann, ed., 1997) (critiquing out-of-context linguistic construction of statutory terms because a “good textualist is not a literalist”).

⁴⁷ Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997).

⁴⁸ Samantar v. Yousuf, 560 U.S. 305, 319 (2010) (quoting United States v. Morton, 467 U.S. 822, 828, (1984)).

⁴⁹ Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 290 (2010) (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 568 (1995)); see also 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.’”).

⁵⁰ See *supra* note 10, and accompanying text (discussing the rejection by Congress of efforts to adopt in the patent laws or amend the patent laws to authorize compulsory licensing by the U.S. government).

⁵¹ 35 U.S.C. § 200.

⁵² 35 U.S.C. § 203(a)(1).

Congress has consistently and repeatedly *rejected* bills that would impose compulsory licensing on U.S. patent owners, from the First Congress in 1790 up through the twentieth century.⁵³

The Supreme Court has consistently instructed agencies that “Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions— it does not, one might say, hide elephants in mouseholes.”⁵⁴ The Supreme Court has thus rejected other agencies’ claims to regulatory authority under similarly vague and generalized terminology as the statutory phrase “practice application” in § 203(a)(1), the statutory justification of the price-control theory of the march-in power embraced by professors and activists and recently adopted by NIST in its proposed guidelines. In these many other legal cases, the Supreme Court has stated bluntly that “‘Congress could not have intended to delegate’ such a sweeping and consequential authority ‘in so cryptic a fashion.’”⁵⁵ The Supreme Court again stated last year that it repeatedly “requires Congress to enact exceedingly clear language if it wishes to significantly alter . . . the power of the Government over private property.”⁵⁶ The price-control theory, and its adoption by NIST in its proposed guidelines, lacks statutory authorization in § 203 in pursuing the policy goal of imposing price controls on the property rights in patents.

Agency Interpretations of § 203 Confirm It Does Not Authorize a Price-Control Power

The plain text of § 203 and its function within the Bayh-Dole Act as a whole explain 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. 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.⁵⁷ The NIH denied all six petitions on the grounds that § 203, as confirmed by the NIH’s prior interpretation of this statutory provision, did not permit the march-in power to be used for the purpose of lowering drug prices.⁵⁸ 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.⁵⁹ As with the prior six petitions

⁵³ See *supra* note 10, and accompanying text (discussing the rejection by Congress of efforts to adopt in the patent laws or amend the patent laws to authorize compulsory licensing by the U.S. government).

⁵⁴ *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001).

⁵⁵ See *West Virginia v. Environmental Protection Agency*, 142 S. Ct. 2587, 2608 (2022) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)). See also *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 231 (1994) (“It is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to ‘modify’ rate-filing requirements.”).

⁵⁶ *Sackett*, 143 S. Ct. at 1341 (quoting *United States Forest Service v. Cowpasture River Preservation Ass’n*, 140 S. Ct. 1837, 1849-50 (2020)).

⁵⁷ See John R. Thomas, *March-In Rights Under the Bayh-Dole Act* 8-10 (Congressional Research Service, Aug. 22, 2016).

⁵⁸ *Id.*

⁵⁹ See *Return on Investment Initiative for Unleashing American Innovation* 29 (NIST Special Publication 1234, April 2019) (identifying 10 petitions to break patents through the march-in power in § 203 solely for the purpose of imposing price controls on drug patents).

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.”⁶⁰

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.⁶¹ The NIH rejected the petition for failing to meet the burden of proof that any of the four 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.⁶² These facts precluded the triggering of the march-in power under the four authorizing conditions in § 203.

In rejecting this march-in petition, the NIH further explained why lowering prices on a medical device like the Isolex 300—imposing price controls on the healthcare market—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 rationale lacked authorization under § 203.⁶³ The NIH stated bluntly that the march-in power in § 203 did not exist for the purpose of “forced attempts to influence the marketplace.”⁶⁴ It acknowledged the contradiction between the Bayh-Dole Act’s primary function in promoting the commercialization of new innovations in the marketplace and adopting a 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.”⁶⁵ 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.

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.⁶⁶ 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.”⁶⁷ The NIH again rejected another march-in petition seeking to lower the price of Norvir in 2013, again 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.⁶⁸ The NIH bluntly concluded: “As stated in previous march-in

⁶⁰ *Id.*

⁶¹ *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).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *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>.

⁶⁷ Dr. Elias A. Zerhouni, Nat’l Institute of Health, *Determination in the Case of Norvir I*, at 5-6 (July 2, 2004).

⁶⁸ 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>.

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.”⁶⁹ 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 a 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.⁷⁰ 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.”⁷¹ 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.”⁷² 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.⁷³ 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.”⁷⁴

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 Bayh-Dole Act does not authorize an agency to consider “reasonable price” as a criterion for triggering the march-in power. Yet, NIST has now proposed new guidelines that would include “reasonable price” as a criterion for agencies like the NIH to use the march-in power under § 203. 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 agencies implementing a statute [that] ‘constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.’”⁷⁵

The Bayh-Dole Act’s Sponsors Stated Their Law Does Not Authorize Price Controls

The price-control theory of the march-in power was first announced in a law journal article by two professors published more than two decades after the enactment of the Bayh-Dole Act.⁷⁶ In 2001, Professors Peter Arno and Michael Davis claimed to have discovered a previously unrecognized mandate in the Bayh-Dole Act that “Congress’s concern with march-in rights focused exclusively on . . . price control.”⁷⁷ They supported their price-control theory that the exclusive focus of Congress was on price controls in adopting § 203 in the Bayh-Dole by identifying approximately

⁶⁹ *Id.*

⁷⁰ 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).

⁷¹ *Id.* at 2.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ 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)))

⁷⁶ See Arno & Davis, *supra* note 43.

⁷⁷ *Id.*, at 659.

seven references to “prices” in the entire legislative record of the Bayh-Dole Act.⁷⁸ This is a prime example of 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.”⁷⁹ For example, other scholars have found statements in the legislative history of the Bayh-Dole emphasizing the commercialization function of patents as the primary goal of this law—the “first-listed goal in the statute” according to two scholars.⁸⁰

A year after their law journal article was published, Professors Arno and Davis published a *Washington Post* op-ed describing their new price-control theory of the Bayh-Dole Act,⁸¹ and Senator Birch Bayh and Senator Robert Dole responded by rejecting their argument outright. Since Professor Arno and Davis’s price-control theory of the Bayh-Dole Act and its march-in power had never been advanced before—Professors Arno and Davis explicitly recognize in their article’s title that the price-control power was “unrecognized and unenforced”⁸²—this was the first time that Senators Bayh and Dole addressed this issue. They explained in a letter to the editor in the *Washington Post* published two weeks after the op-ed by Arno and Davis:

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.⁸³

This letter to the editor does not have the same legal status under the rules of statutory interpretation as does the text and official interpretation of a statute by courts and agencies, but Senators Bayh and Dole’s analysis of their namesake law is entirely consistent with these rules of statutory interpretation. They come to the same conclusion as these legal rules, as explained in the prior section: the march-in power does not authorize price controls and any such argument that it does is unconnected to the text and function of the law enacted by Congress in 1980. The

⁷⁸ 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). Professors Arno and Davis also conflate all references in the legislative record to “public interest” as necessarily denoting “price control,” but this is an act of linguistic gymnastics that no court would accept in justifying a non-textual interpretation of a statute as authorizing price controls when such authorization is found nowhere in the specific text of the statute.

⁷⁹ *Conroy v. Aniskoff*, 113 S. Ct. 1562, 1567 (1993) (Scalia, J., concurring).

⁸⁰ See Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271, 287 (2017) (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).

⁸¹ 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).

⁸² Arno & Davis, *supra* note 43.

⁸³ 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/>.

arguments by professors and activists for the price-control theory, and the newly proposed march-in guidelines by NIST, are all born of the price-control theory spawned by Professors Arno and Davis in 2001. This price-control theory is an unprecedented assertion of agency power to control prices in private market transactions without a legal basis in the Bayh-Dole Act.

Distorting Bayh-Dole to Impose Price Controls Would Still Not Achieve Any Alleged Benefits

Even if one assumes for the sake of argument that the text and function of the Bayh-Dole Act could permit an agency to break patents to lower drug prices, it will not achieve this benefit alleged by academics and activists. The Bayh-Dole Act applies only to a small subset of patents. It is applicable only to “subject inventions,”⁸⁴ which are defined narrowly in the statute as “any invention of the contractor [i.e., the party receiving government funding] conceived or first actually reduced to practice in the performance of work under a funding agreement.”⁸⁵

Few drug patents satisfy this statutory definition. A 2019 study found that, of the 1,151 patents in the Food and Drug Administration’s (FDA’s) *Approved Drug Products with Therapeutic Equivalence* (the “Orange Book”) covering 197 top-selling drugs, only 30 patents included a disclosure that the patent was covered by the Bayh-Dole Act or was assigned to a government agency.⁸⁶ This is only 10.2% of these 197 approved drugs in the Orange Book,⁸⁷ and a mere 2.6% of the total patents covering FDA-approved drugs. These findings are consistent with an earlier 2011 study of the number of Bayh-Dole patents covering drugs.⁸⁸ The relatively small number of Bayh-Dole patents is unsurprising, since biopharmaceutical companies invest heavily in R&D without relying on any government funding.⁸⁹ If the federal government provides some funding late in the lengthy and multi-stage process of developing a new drug, this often does not trigger the Bayh-Dole Act.⁹⁰ Unless an invention was conceived or first reduced to practice while performing work under the federal funding agreement, the Bayh-Dole Act does not apply to the patent.

In addition, prescription drugs are often covered by more than one patent, just like many products from golf balls to smartphones. Since the march-in provision under the Bayh-Dole Act applies only to specific patents covered by the statute, rather than to all patents that may cover a final commercial product, a federal agency would have no march-in powers to exercise for a

⁸⁴ 35 U.S.C. §§ 202(c)(4), § 203(a).

⁸⁵ *Id.* at § 201(e).

⁸⁶ See Genia Long, *Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs*, 22 J. MED. ECON. 1261, 1262, 1264 (2019). The Bayh-Dole Act requires any patent subject to the law must “include within the specification . . . a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.” 35 U.S.C. § 202(c)(6).

⁸⁷ Long, *supra* note 86, at 1265.

⁸⁸ See Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?* 30 HEALTH AFFAIRS 332 (2011) (finding that 9% of a sample of 379 drugs approved between 1988 and 2005 listed at least one patent in the Orange Book that either had a Bayh-Dole government interest statement or had a government agency as the first-named assignee).

⁸⁹ See *supra* note 24, and accompanying text (reporting average annual private investments of \$129 billion).

⁹⁰ To take just two examples in which the Bayh-Dole Act would not cover a patent despite the use of federal funding at some point in the R&D process for a new drug: first, a federal agency provides a grant to a public university running multi-drug clinical trials on a disease, or, second, a federal agency provides a grant to a private drug innovator who is already in a phase 3 clinical trial.

prescription drug unless *all* of the patents covering that drug qualify as a “subject invention” within the meaning of the Bayh-Dole Act.⁹¹ This is a very narrow slice of the universe of total prescription drugs. In the 2019 study, only *two* of the 197 drugs (1%) in the Orange Book were completely covered by patents that had Bayh-Dole Act disclosures or were assigned to a government entity.

Agency Uses of Patented Inventions under the Bayh-Dole Act is Not a Price-Control Power

Lastly, advocates for breaking patents to lower prices on prescription drugs argue that the federal contract provision in the Bayh-Dole Act provides another statutory basis for achieving this policy goal. But this is equally incorrect. The Bayh-Dole Act grants a federal agency “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”⁹² Even professors and activists acknowledge that this provision has never been invoked by a federal agency to impose price controls on products or services.⁹³ Yet, they still contend that the “plain text and statutory purpose” of this provision permits it to be used for such purposes in the “production of drugs for use by government programs, such as Medicare and Medicaid” in which the government is a third-party payor for drugs manufactured by private companies and prescribed to private citizens.⁹⁴

As with the failure to abide by the text and purpose of the march-in provision in § 203, this secondary argument for the price-control theory of the Bayh-Dole Act represents an unprecedented and unjustified extension of the Bayh-Dole Act. First, the statutory text in the federal contract provision of the Bayh-Dole Act does not refer to or expressly provide for licenses for manufacturing and selling drugs at lower prices when these drugs are paid for by Medicare and Medicaid. These federal assistance programs were in existence at the time the Bayh-Dole Act was enacted, and thus Congress would have acknowledged such a power for federal contracts under these programs if this was a function of this provision in the Bayh-Dole Act. It did not do so, either expressly or impliedly.⁹⁵

Second, the statutory phrase “for or on behalf of the United States” in the federal contract provision is not an open-ended authorization for the government to create unauthorized licenses for private companies to make and sell patented inventions in the healthcare market to consumers. If it did confer this power, then it makes the march-in provision irrelevant, because any general purpose sought by the government, such as imposing price controls on prescription drugs in healthcare market transactions, could be achieved through the federal contract provision in the Bayh-Dole Act. There would be no need for Congress to enact the march-in power provision in § 203 because these specific, limited conditions would necessarily be encompassed within the unlimited grant of power in the federal contract provision. Again, it is a fundamental rule of statutory interpretation

⁹¹ See 35 U.S.C. § 202(c)(4).

⁹² *Id.*

⁹³ See Kapczynski-Kesselheim Letter, *supra* note 6, at 5.

⁹⁴ *Id.*

⁹⁵ The Supreme Court has repeatedly rejected agency claims to new, unprecedented powers based in generalized statutory language like the federal contract provision in the Bayh-Dole Act. The Supreme Court has been clear that “‘Congress could not have intended to delegate’ such a sweeping and consequential authority ‘in so cryptic a fashion.’” *West Virginia v. Environmental Protection Agency*, 142 S. Ct. 2587, 2608 (2022) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)).

that a provision must be construed within the context of the entire statute and that any one provision must not be construed in a way that renders other provisions in the statute to be irrelevant.⁹⁶

For these reasons, federal agencies have interpreted the meaning of the federal contract provision to permit direct use of an invention by the government for “government purposes,” such as use of patented inventions for and by the military, rather than for purely commercial use by private companies and private citizens.⁹⁷ Similarly, the NIH has repeatedly declined petitions to create an unauthorized license under the federal contract provision for drugs.⁹⁸

Section 1498 Does Not Authorize Agencies in the Executive Branch to “Break” Patents

A second law invoked by advocates for breaking patents to impose price controls on prescription does not have a name, and thus it’s known only as § 1498.⁹⁹ As noted, Representative Doggett and Senators Warren and King urged the Biden Administration earlier this year to use § 1498 to impose price controls on drug patents.¹⁰⁰ A year ago, Senator Bernard Sanders wrote to Secretary Xavier Becerra that he can use § 1498 to “break the patent monopoly” and impose price controls on a new drug to treat Alzheimer’s currently under review by the FDA.¹⁰¹ Similarly, professors and activists have argued that § 1498 confers a generalized “patent use power” on agencies that they can invoke to break patents to lower prices on prescription drugs in the healthcare market.¹⁰² Similar to the arguments to use various provisions of the Bayh-Dole Act to impose price controls on drug patents, these claim contradict the text, function, and longstanding interpretation of § 1498. Section 1498 does not grant the government a freestanding power to infringe patents, let alone to “break” them to impose price controls.

⁹⁶ See, e.g., *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)).

⁹⁷ See, e.g., Dep’t of Defense, *Intellectual Property: Navigating Through Commercial Waters*, 2-2-2-3 (Apr. 30, 2001) (“[T]he general approach is that the contractor is permitted to retain title to the invention, and the Government receives a nonexclusive license to use that invention for Government purposes.”); Nat’l Institute of Health, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers’ Interest are Protected*, 5 (July 2001) (“By law, the funding agency retains residual interest in grant- and contract-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes.”); 32 C.F.R. § 37.860(b) (Bayh-Dole license does not include the right to use or practice the invention for commercial purposes).

⁹⁸ See Dr. Francis Collins, Nat’l Institute of Health, *Determination in the Case of Xtandi*, 1 (Jun. 20, 2016) (“[W]e decline to . . . utilize the government’s license in the patents.”), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf; Dr. Francis Collins, Nat’l Institute of Health, *Determination in the Case of Norvir II*, 5 (Nov. 1, 2013) (noting that “the NIH is a research institution not a drug manufacturer”), <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf>.

⁹⁹ See 28 U.S.C. § 1498.

¹⁰⁰ See note 9, and accompanying text.

¹⁰¹ See Letter from Senator Bernard Sanders to Xavier Becerra, Secretary of Commerce (June 7, 2023), <https://www.sanders.senate.gov/wp-content/uploads/6.7.2023-Letter-from-Chairman-Sanders-to-Secretary-Becerra.pdf>.

¹⁰² Kapczynski-Kesselheim Letter, *supra* note 6, at 1-4.

Section 1498 is an eminent domain statute, authorizing a lawsuit to be filed in court for compensation when the government uses a patent without authorization.¹⁰³ It provides that “[w]henever ... a patent ... is used or manufactured by or for the United States without license of the owner,” the patent owner may file a lawsuit “against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation.”¹⁰⁴ Congress first enacted this law in 1910 following some confusion in the courts at the turn of the twentieth century concerning the continuing protection afforded by nineteenth-century federal courts to patents as private property rights under the Takings Clause of the Fifth Amendment.¹⁰⁵ The Takings Clause states that “nor shall private property be taken for public use, without just compensation.”¹⁰⁶ This explains the statutory requirement in § 1498 that manufacture or use of a patent must be “by or for the United States,” which triggers the jurisdiction of a court to receive a lawsuit by a patent owner seeking “reasonable and entire compensation” for the governmental use of a patent.

The similar language in the federal contract provision of the Bayh-Dole Act that an agency has a license to a patent covered by this statute when the invention is used “for or on behalf of the United States” is evidence of the same meaning this language has in § 1498: both statutes apply when patented inventions are directly used by the federal government or made for the federal government pursuant to a government contract (in which case the contractor is immunized by the government). The classic scenarios in which § 1498 applies are the production and use of patented inventions for the U.S. military, the U.S. Postal Service, and, in the modern era, U.S. agencies like the Veterans Health Administration of the U.S. Department of Veterans Affairs.¹⁰⁷ For this reason, courts have consistently and unequivocally interpreted § 1498 as an eminent domain statute that is applicable only to the manufacture or use of a patented invention by or for the federal government.¹⁰⁸

Still, professors, activists, and policymakers advocating for the price-control theory of § 1498 maintain that § 1498 can authorize any use of a patented invention by any private person or company from which the federal government may receive some type of generalized “benefit.”¹⁰⁹ Thus, they argue, § 1498 can be used to impose price controls via an agency authorizing a generic drug company to make and sell a patented drug. This would “benefit” the government by reducing

¹⁰³ Such laws are required for all citizens seeking protection of their constitutional rights. For example, § 1498 serves the same function as 42 U.S.C. § 1984 and 42 U.S.C. § 1988, which authorize courts to receive complaints for claims that the federal or state governments violated someone’s constitutional rights under the due process or equal protection provisions of the Fourteenth Amendment.

¹⁰⁴ 28 U.S.C. § 1498(a).

¹⁰⁵ See Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, 97 ST. JOHN’S L. REV. (forthcoming 2023), <https://papers.ssrn.com/abstract=4348499>; 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).

¹⁰⁶ U.S. CONST. amend. V.

¹⁰⁷ This is true reaching back to nineteenth-century court decisions applying the Takings Clause to unauthorized governmental uses of patents, and which Congress was explicitly codifying in enacting § 1498. See Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, *supra* note 105, at 7-10 (describing cases).

¹⁰⁸ See, e.g., *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.”); *Irving Air Chute Co. v. United States*, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (stating that § 1498 is “an eminent domain statute”).

¹⁰⁹ See Kapczynski-Kesselheim Letter, *supra* note 6, at 3.

costs for federal programs like Medicare, whose beneficiaries are prescribed drugs produced by private companies and prescribed by private physicians.¹¹⁰

This is an unconstrained reading of § 1498 that contradicts its plain text. As already noted, Congress knows how to enact price-control statutes, such as the Emergency Price Control Act of 1942,¹¹¹ and § 1498 does not authorize price controls in private transactions in the marketplace. Nor does it provide that lawsuits must proceed against the government whenever the government broadly “benefits” from a product or service that it paid for through some agency program or law. Section 1498 states only that the government must pay “reasonable and entire compensation” when a patent is used “by or for the United States.” This is statutory text that has deep roots in eminent domain law in which the government has used property rights like patents without authorization.¹¹² As an eminent domain statute, the plain text of § 1498 makes clear that it *protects* patent owners when their property rights are taken by or for the government. It is not an *authorization* to the government to use patents or to license others to use patents whenever the federal governments may “benefit” from this use in some way or other.

This is why courts have repeatedly rejected this argument advanced by professors, activists, and some policymakers when defendants have made this same argument in patent infringement cases.¹¹³ In *Larson v. United States*,¹¹⁴ for example, a patent owner sued a medical device company for patent infringement and the defendant argued that, since “the government reimbursed the cost [of the infringing medical device] through Medicare and other federal programs,” the patent owner must proceed against the government in the Court of Federal Claims under § 1498.¹¹⁵ The *Larson* court flatly 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 when a patent is used by or for the federal government.¹¹⁶ Almost two decades later, another federal court affirmed the decision 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.”¹¹⁷

These court decisions were reaffirmed last year in *Arbutus Biopharma Corp. v. Moderna*. In this case, Arbutus sued Moderna for patent infringement in its production and sale of its COVID-19 vaccine and Moderna filed a motion to dismiss, arguing that Arbutus could only sue the government under § 1498 given the federal government’s advance purchase contracts for COVID-19 vaccine doses produced by Moderna. The court rejected Moderna’s argument and permitted the

¹¹⁰ *Id.*

¹¹¹ See *supra* notes 35-37, and accompanying text (describing this and other price control statutes).

¹¹² See, e.g., *James v. Campbell*, 104 U.S. 356, 358 (1881) (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.”). In 1952, Congress codified in the patent statutes that patents are property rights. See 35 U.S.C. § 261 (“patents shall have the attributes of personal property”).

¹¹³ See Hon. Judge Susan G. Braden & Joshua A. Kresh, *Section 1498(A) Is Not a Rx to Reduce Drug Prices*, 77 FOOD & DRUG L.J. 274, 282-86 (2022) (reviewing cases).

¹¹⁴ *Larson v. United States*, 26 Cl. Ct. 365 (1992).

¹¹⁵ *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1379 (Fed. Cir. 2009) (describing the defendant’s argument in *Larson*).

¹¹⁶ *Larson*, 26 Cl. Ct. at 369.

¹¹⁷ *Advanced Software Design Corp.*, 583 F.3d at 1379 (quoting *Larson*, 26 Cl. Ct. at 369).

lawsuit to proceed against, holding that the government purchase contracts of vaccine doses manufactured by Moderna were for use by and for private citizens and not just government employees like military personnel or civil servants.¹¹⁸ The court concluded that Moderna’s “development and sale of the vaccines was for the benefit of the vaccine’s recipients,” who were private citizens, and it was not solely for the benefit of the federal government or its employees.¹¹⁹

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 by multiple 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. Contrary to the argument advanced by professors and activists in a letter to Congress in 2022, and repeated in the more recent letters by senators to administration officials, § 1498 does not apply to circumstances in which the federal government “facilitate[s] the purchase of low-cost generics by private entities,” even if the private entities are “reimbursed by Medicare and Medicaid.”¹²⁰ In fact, one of the sources of scholarship cited by the professors and activists in their 2022 letter acknowledges forthrightly that § 1498 would need to be “modified” in order “to apply to governmental payment for drugs prescribed for beneficiaries of such federal health programs as Medicare and Medicaid.”¹²¹

Distorting § 1498 to Impose Price Controls Would Still Not Achieve Any Alleged Benefits

If one assumes for the sake of argument that the government could invoke § 1498 to authorize the manufacture and sale of generic versions of patented drugs, this would not achieve the policy goal of lowering healthcare prices. Given the plain text of § 1498, patent owners must receive “reasonable and entire compensation” for the unauthorized use of their patents,¹²² which is the market value of the patent and any resulting license rate. This would impose an enormous cost on the U.S. Treasury, vitiating any benefits to the federal government from lower costs for healthcare services.

Section 1498 requires payment of “reasonable and entire compensation” to a patent owner, which is consistent with the requirement in Takings Clause cases and remedies law generally that a plaintiff be made whole, as if the violation of one’s rights did not occur.¹²³ In the past 39 years, the U.S. Court of Appeals for the Federal Circuit has decided four § 1498 cases—a rate of about

¹¹⁸ *Arbutus Biopharma Corp. v. Moderna*, CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022), *affirmed*, 2023 WL 2455979 (D. Del. Mar. 10, 2023).

¹¹⁹ *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7.

¹²⁰ Kapczynski-Kesselheim Letter, *supra* note 6, at 3.

¹²¹ MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974). This monograph is cited in the Kapczynski-Kesselheim Letter, *supra* note 6, at 2 n. 9.

¹²² 28 U.S.C. § 1498(a).

¹²³ *See, e.g., Seaboard Air Line Ry. Co. v. United States*, 261 U.S. 299, 304 (1923) (Under the Takings Clause, the property owner is entitled to “be put in as good [a] position pecuniarily as he would have been if his property had not been taken.”) (citations omitted); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) (In awarding damages, a court “simply asks, once infringement of a valid patent is found, what compensable injuries result from that infringement, i.e., how may the patentee be made whole.”).

one per decade.¹²⁴ Consistent with the text and function of § 1498 as an eminent domain statute, none of these cases arose from an agency directing a private company to make a product that competed in the marketplace with another product sold by another private company. Thus, these cases are not precedent for determining what counts as “reasonable and entire compensation” in the proposed price-control scheme in which the government authorizes a generic drug company to make and sell a prescription drug at a lower price than the drug innovator and the patent owner is required to sue the government under § 1498.

If the government undertakes this unprecedented use of § 1498 in which the government authorizes a generic competitor in the marketplace to make and sell a drug at lower prices than the drug innovator, courts will likely apply the legal rules for patent infringement cases in which they award, according to the patent statute, “damages adequate to compensation for the infringement.”¹²⁵ Courts have construed this statutory language to award a patent owner’s *lost profits* when the patent owner is forced to compete against an infringing, commercial competitor.¹²⁶ In at least one earlier § 1498 case, the Court of Claims observed that lost profits may be available when a patent owner is unwilling to license a patent, which would include a drug innovator under the price-control scheme for § 1498.¹²⁷

Thus, even under the price-control scheme of § 1498, the federal government would be required to pay the lost profits to the drug innovator as “reasonable and entire compensation” for the governmental authorized infringement by the generic drug company. This eliminates any alleged savings to the public fisc and thus eliminates any alleged “benefit” to the government. In fact, it vastly *expands* the federal government’s financial liabilities in paying for medical care, as the federal government would now be paying for extensive numbers of drugs produced and sold in the private healthcare market. The government would incur additional costs through paying lost profits as compensation to drug innovators in innumerable § 1498 claims that were not occurring before.

The Price-Control Scheme of § 1498 Creates Legal Uncertainties and Additional Costs

The potential for significant, additional costs in the price-control theory of § 1498 also arises from other existing regulatory regimes in patent law that go unacknowledged by its proponents. Among several, the most apparent source of uncertainty and additional costs is the Hatch-Waxman Act.¹²⁸

¹²⁴ 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); *Hughes Aircraft Co. v. United States*, 140 F.3d 1470 (Fed. Cir. 1998); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1572 (Fed. Cir. 1997).

¹²⁵ See 35 U.S.C. § 284 (providing that “court shall award the claimant damages adequate to compensate for the infringement”).

¹²⁶ See, e.g., *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.”).

¹²⁷ See *Decca Ltd.*, 640 F.2d at 1167.

¹²⁸ See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 84-417, 98th Cong. (Sep. 24, 1984). This law is commonly known as the Hatch-Waxman Act.

Enacted in 1984, the Hatch-Waxman Act created a regulatory system in the FDA and a litigation regime in the courts to promote faster generic drug entry in the healthcare market while maintaining incentives for innovation.¹²⁹ Although the 2002 letter from professors and activists references the Hatch-Waxman Act in its footnotes,¹³⁰ they fail to address how the proposed price-control theory of § 1498 would necessarily and inescapably become intertwined with the Hatch-Waxman regime, raising costs and legal uncertainties. For the sake of brevity, this section will only briefly summarize this serious threat of extensive legal and policy questions and disputes.

Under the Hatch-Waxman Act, a generic drug company seeking to market a generic version of a drug files a special application with the FDA requesting approval to market its drug, and the final approval date depends on the existing patent term of the drug patent, legal protections by other statutes, or both. The generic drug company can enter the market before patent expiration by challenging the validity of the patent or alleging noninfringement. There are legal requirements for notice to the innovator drug company, which typically leads to a patent infringement lawsuit in court.¹³¹ If the generic drug applicant is successful in court, it may enter the healthcare market prior to the expiration of the patent term. If not, it cannot market its drug until the patent expires. The proponents of the price-control theory of § 1498 do not acknowledge how the proposed regulatory directives for a generic drug company to make and sell a patented drug would be affected by the existing Hatch-Waxman regime for generic drug companies. This legal uncertainty will lead to additional litigation and add significantly to the costs of doing business for generic drug companies and drug innovators alike. It will also significantly increase the administrative costs in the U.S. Court of Federal Claims.¹³² Without a proper institutional and legal assessment of how the price-control theory of § 1498 would be implemented within existing institutions and laws governing drug patents, any attempt to do so by an agency would violate the fundamental requirement of good government that it engage only in evidence-based policymaking.

Conclusion

The price-control theories of the Bayh-Dole Act and § 1498 represent policy arguments superimposed on two statutes by professors and activists seeking a quick-and-easy path to lower drug prices. The theories rationalize unprecedented regulatory powers for imposing price controls on prescription drugs in the healthcare market without a statutory basis in either the Bayh-Dole Act or § 1498. In perhaps sensing their failure in fulfilling their burden of evidence-based policymaking in their argument to break patents as the primary solution to lower drug prices in a complex healthcare market, advocates bootstrap the necessary policy and economic arguments by asserting that Congress has already adopted a price-control policy over patents in these two federal statutes. These price-control schemes under both the Bayh-Dole Act and § 1498 contradict the text, function, and past interpretation of both of these statutes by courts and agencies. Neither the Bayh-Dole Act nor § 1498 is an existing “tool” for breaking patents to lower drug prices.

¹²⁹ For a complete description of the Hatch-Waxman Act and its complex regulatory and litigation regime, see Thomas, *supra* note 57; see also Christopher M. Holman, *Government Involvement in Pharmaceutical Development Can Come Back to Haunt a Drug Company*, 40 BIOTECHNOLOGY L. REP. 4 (2021). For an in-depth review of the history, enactment, and political economy of the Hatch-Waxman Act, see Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018).

¹³⁰ See Kapczynski-Kesselheim Letter, *supra* note 6, at 3 n.16 & 5 n.29.

¹³¹ See 21 U.S.C. § 355(j)(5)(B)(iii).

¹³² See Braden & Kresh, *supra* note 113, at 293.