

September 28, 2023

The Honorable Bernie Sanders
Chairman
Committee on the Health,
Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Dr. Bill Cassidy
Ranking Member
Committee on the Health,
Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Jason Smith
Chairman
Committee on Ways and Means
United States House of Representatives
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Sanders, Ranking Member Cassidy, Chairman Smith, and Ranking Member Neal:

As former judges, former government officials, and scholars who are experts in patent law, healthcare policy, or both, we write to express our concerns about lobbying efforts for the government to impose price controls on patented drugs. Some activists and academics have written to Congress and to agency officials arguing that existing laws are “tools” for the government to impose price controls on patented drugs to lower drug prices.¹ Their arguments mischaracterize these statutes by inaccurately claiming that Congress has endorsed the imposition of price controls on patented drugs. It has not.

Drug pricing presents a multi-dimensional policy issue because the U.S. healthcare system comprises a complex, intermingled system of federal and state laws and regulations, as well as a myriad of equally complex and intermingled set of public and private institutions. Yet, activists and others inaccurately reduce the causes of drug prices to a single issue: patents. They argue that the federal government can “lower drug prices by breaking patent barriers,”² and they claim that two statutes can be used to achieve this policy goal: the Bayh-Dole Act and 28 U.S.C. § 1498.

Neither the Bayh-Dole Act nor § 1498 are price-control statutes, and thus they do not authorize the federal government to impose price controls on patents. This is clear by their plain legal text, as well as by their consistent 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. If the government used either law to impose price controls on patented drugs, this would conflict with the clear 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

¹ See Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., at 1 (Apr. 20, 2022), <https://tinyurl.com/yt62wt4t>. Professor Kapczynski and Professor Kesselheim are the co-authors of this letter, which is based on their articles, and thus this letter is identified as the “Kapczynski-Kesselheim Letter.”

² *Id.* at 8.

impose compulsory licensing on patents.³ The calls to use the Bayh-Dole Act or § 1498 for similar purposes fundamentally are at odds with these statutes and threaten to undermine the U.S. patent system’s historic success as a driver of U.S. global leadership in biopharmaceutical innovation.

This letter explains why neither the Bayh-Dole Act nor § 1498 can be used to break patents to impose price controls on drugs. First, it sets forth the proven success of the patent system as a driver of innovation in healthcare, which is the framework to evaluate the argument to “lower drug prices by breaking patent barriers.”⁴ 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 seeking to impose price controls on drugs contradicts the clear text and purpose of these statutes.

The Patent System Spurs Innovation in Healthcare

The United States is a global leader in biomedical innovation. 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.⁵ The patent system is a key driver of this success. Economists, historians, and legal scholars have demonstrated that patents have been a pillar of the U.S. innovation economy for over 200 years.⁶

Studies also demonstrate the fundamental role of patents in the pharmaceutical sector, as compared to other mechanisms for protecting intellectual property investments, such as trade secrets.⁷ The economics of research and development (R&D) in the biopharmaceutical sector explain why reliable and effective patents serve this role. Annual private investment in the biopharmaceutical sector is approximately \$129 billion.⁸ Total R&D expenditures underlying each new drug is

³ 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).

⁴ Kapczynski-Kesselheim Letter, *supra* note 1, at 8.

⁵ See Yali Friedman, *Where Are Drugs Invented, and Why Does It Matter?*, 16 *ACS MEDICINAL CHEMISTRY LETTERS* 589, 590 (May 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5467189/#> (“North America (largely the United States) accounts for more than half of drug patent inventorship . . .”).

⁶ See, e.g., 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), <https://www.hoover.org/research/innovation-notmanna-heaven>; 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*, *BUS. HIST. REV.* (Spring 2013); RONALD A. CASS & KEITH N. HYLTON, *LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS* (2013).

⁷ 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>.

⁸ 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.

estimated to be \$2.6 billion and takes between 10-15 years of research, testing, and development before the first patient is prescribed this drug as a therapeutic treatment.⁹ 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.¹⁰

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.¹¹ 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.¹² The economic and moral principles are the same.

The U.S. has been a global leader in securing reliable and effective patent rights to innovators in the biopharmaceutical sector,¹³ which has prompted massive investments and successful development of new drugs that have contributed to economic growth, longer lifespans, and improved quality of life. This is the legal and evidentiary framework by which to evaluate proposals to weaken or eliminate patent rights in new drugs. Thus, 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 academics 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 years ago—the Bayh-Dole Act and § 1498. These arguments are equally incorrect, as detailed below.

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

In a sign-on letter sent to Congress last year, Professors Kapczynski and Kesselheim argued that the Bayh-Dole Act is a “tool” to break patents and impose price controls on prescription drugs.¹⁴ Their argument conflicts with both the function and text of the Bayh-Dole Act. Congress knows

⁹ 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).

¹⁰ DiMasi, *supra*, note 9, at 25.

¹¹ 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>.

¹² 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.”).

¹³ 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) (summarizing how the U.S. patent system facilitated the biotech revolution, which began and continues primarily in the U.S.).

¹⁴ Kapczynski-Kesselheim Letter, *supra* note 1, at 4-7.

how to enact price-control laws, such as the Emergency Price Control Act of 1942,¹⁵ or archetypical rate-regulation laws that authorize the setting of “prices” or “rates.”¹⁶ This is not what the Bayh-Dole Act does. Given its function in promoting private commercialization of patented innovations, the Bayh-Dole Act does not authorize price controls on patents.

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.¹⁷ Before 1980, the government claimed ownership in inventions resulting from government-funded research; this undermined the commercialization of these inventions given the absence of property rights that are the legal platform for contracts and other commercial activities.¹⁸ The Bayh-Dole Act corrected this mistaken policy by establishing that innovators can obtain patents for inventions arising from government-funded research and retain ownership in these patents, which facilitates licensing and other commercial activities in the marketplace.¹⁹

To ensure commercialization of inventions arising from research funded by government agencies, the Bayh-Dole Act also authorizes a “march in” power in a limited set of circumstances.²⁰ If a patent owner or licensee is not commercializing a patented invention in the market, the federal agency that provided the research funds may “march in” and grant a license to a third party to commercialize the patent without authorization from the patent owner. The Kapczynski-Kesselheim letter argues that this “march in” power is congressional authorization for imposing price controls by breaking patents on drugs.

The statutory text does not support this argument for imposing an unprecedented policy of price controls on patented drugs produced by private companies and sold to private patients in the

¹⁵ See Pub. L. No. 77-421, 56 Stat. 23 (1942); see also 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).

¹⁶ 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’”).

¹⁷ See generally JONATHAN M. BARNETT, *INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL PROPERTY* (2021).

¹⁸ 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”).

¹⁹ 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.”).

²⁰ See 35 U.S.C. § 203(a).

healthcare market. First, the Bayh-Dole Act expressly identifies several general policies and objectives. It does *not* state that patented innovations should be available at reasonable prices.²¹

Second, the specific march-in provision in the Bayh-Dole Act does *not* state that “prices” or “reasonable prices” are a condition triggering the march-in power. This provision specifies four conditions for when an agency is authorized to invoke the march-in power.²² All four represent different situations by which a product or service is unavailable in the marketplace. For example, a licensee is in breach of its license and thus is not producing or selling the invention.²³ Another march-in condition can be triggered when a patent owner or licensee is unable to meet regulatory mandates for public use of an invention due to lack of manufacturing capacity,²⁴ such as a licensee’s inability to manufacture enough water filters to meet safety requirements set by the Environmental Protection Agency. In sum, the march-in provision is explicitly limited to only situations in which patented products or services are not commercialized or available at all in the marketplace.

Activists and academics, such as those in the Kapczynski-Kesselheim letter, focus on the first condition in the march-in provision that specifies the failure “to achieve practical application” of an invention as a trigger for the march-in power, arguing that prices can prevent this “practical application” with consumers.²⁵ As is typical of modern legislation, the Bayh-Dole Act has a lengthy definition of “practical application” in which advocates for price controls focus on a single phrase (“available to the public on reasonable terms”).²⁶ In addition to wrongly taking phrases and words out of context from their statutory context, this argument ignores that “terms” is a distinct legal concept from “price,” as these words are used in the law. In fact, statutes distinguish between “price” and “terms” by listing them separately.²⁷ Moreover, the statutory definition of “practical

²¹ 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.

²² See 35 U.S.C. § 203(a)(1)-(4). The specific conditions in § 203(a) are: (1) “because 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 their licensees,” (3) “to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees,” or (4) “because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.”

²³ See *id.* at § 203(a)(4).

²⁴ See *id.* at § 203(a)(3).

²⁵ Kapczynski-Kesselheim Letter, *supra* note 1, at 6-7.

²⁶ 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”).

²⁷ 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

application” as “reasonable terms” in the Bayh-Dole Act followed official usage of “practical application,” which was understood to refer to the “successful development and terms of the license, not with a product’s price.”²⁸ For example, President John F. Kennedy issued a statement on patent policy in 1963 in which he proposed mandating licensing of government-owned inventions in order to achieve “practical application” of an invention and to “guard against failure to practice the invention.”²⁹

Following the legal rule for interpreting provisions in their statutory context, the march-in provision must be consistent with the commercialization function of the Bayh-Dole Act. Courts and agencies are required to construe a specific statutory section within the overall statutory regime of which it is a part.³⁰ Again, the Bayh-Dole Act does not list controlling prices or the setting of prices as a statutory objective,³¹ a point directly confirmed by Senators Birch Bayh and Bob Dole. When the clever price-control theory of the Bayh-Dole Act was first pronounced by two academics more than twenty years after this law was enacted,³² Senators Bayh and Dole responded that their law “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. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.”³³

added); 42 U.S.C. § 2375 (“The *charges and terms* for the transfer of any utility may be established by advertising and competitive bid, or by negotiated sale or other transfer at such *prices, terms, and conditions* as the Commission shall determine to be fair and equitable.”) (emphases added); 10 U.S.C. § 3372(a)(1) (“A contracting officer of the Department of Defense may not enter into an undefinitized contractual action unless the contractual action provides for agreement upon contractual *terms, specifications, and price . . .*”) (emphasis added); 43 U.S.C. § 375c (“The Secretary is authorized to sell such land to resident farm owners or resident entrymen, on the project upon which such land is located, at *prices* not less than that fixed by independent appraisal approved by the Secretary, and upon *such terms* and at private sale or at public auction as he may prescribe . . .”) (emphases added); 2 U.S.C. § 4103 (“[I]n any contract which is entered into by any person and either the Administrator of General Services or a contracting officer of any executive agency and under which such person agrees to sell or lease to the Federal Government (or any one or more entities thereof) any unit of property, supplies, or services at a *specified price or under specified terms and conditions (or both)*, such person may sell or lease to the Congress the same type of such property, supplies, or services at a *unit price or under terms and conditions (or both)* . . .”) (emphases added).

²⁸ 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/>.

²⁹ Government Patent Policy, Memorandum of Oct. 10, 1963, Fed. Reg. 10943 (Oct. 12, 1963).

³⁰ See, e.g., *Graham County 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)); *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)).

³¹ See *supra* note 21, and accompanying text.

³² 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).

³³ Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST (April 11, 2002), <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>.

Lastly, on the basis of the statutory text and function of the Bayh-Dole Act, the National Institutes of Health (NIH) has repeatedly and consistently rejected petitions over several decades asking NIH to invoke its march-in power solely to lower prices of drugs that are available in the healthcare market. Since the 1990s, NIH has received and rejected at least 10 march-in petitions seeking to impose price controls on drugs.³⁴ The NIH most recently rejected a petition on March 23, 2023, requesting that it use its march-in power to lower prices of Xtandi, a patented drug that treats prostate cancer.³⁵ A recent report by the National Institute for Standards and Technology succinctly summarized the legal basis for these numerous denials: “NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority.”³⁶

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,”³⁷ 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.”³⁸

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.³⁹ This is only 10.2% of these 197 approved drugs in the Orange Book,⁴⁰ and a mere 2.6% of the total patents covering FDA-approved drugs. These findings are consistent with an earlier

³⁴ 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)

³⁵ 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).

³⁶ *Return on Investment Initiative for Unleashing American Innovation*, *supra* note 34, at 29; see also 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.”).

³⁷ 35 U.S.C. §§ 202(c)(4), § 203(a).

³⁸ *Id.* at § 201(e).

³⁹ 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).

⁴⁰ Long, *supra* note 39, at 1265.

2011 study of the number of Bayh-Dole patents covering drugs.⁴¹ The relatively small number of Bayh-Dole patents is unsurprising, since biopharmaceutical companies invest heavily in R&D without relying on any government funding.⁴² 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.⁴³ 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 prescription drug unless *all* of the patents covering that drug qualify as a “subject invention” within the meaning of the Bayh-Dole Act.⁴⁴ 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.

Lastly, advocates for breaking patents to lower prices on prescription drugs argue that the federal contract provision in the Bayh-Dole Act provides another avenue for achieving this goal. 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.”⁴⁵ Even the Kapczynski-Kesselheim letter acknowledges that this provision has never been invoked by a federal agency to impose price controls on products or services, but it still contends that its “plain text and statutory purpose” 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.⁴⁶

As with the failure to abide by the text and purpose of the march-in provision, this argument 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

⁴¹ 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).

⁴² See *supra* note 8, and accompanying text (reporting average annual private investments of \$129 billion).

⁴³ 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.

⁴⁴ See 35 U.S.C. § 202(c)(4).

⁴⁵ *Id.*

⁴⁶ Kapczynski-Kesselheim Letter, *supra* note 1, at 5.

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.⁴⁷

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 third parties to commercialize patented inventions in the healthcare market. If it did confer this power on agencies, then this would make 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. But it is a fundamental rule of statutory interpretation 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.⁴⁸

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.⁴⁹ Similarly, the NIH has repeatedly declined petitions to create an unauthorized license under the federal contract provision for drugs.⁵⁰

Section 1498 Does Not Authorize 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 § 1498.⁵¹ Recently, Senator Bernard Sanders wrote to Secretary Xavier Becerra that he can use § 1498 to “break the patent monopoly” and

⁴⁷ 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)).

⁴⁸ 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)).

⁴⁹ 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).

⁵⁰ 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>.

⁵¹ See 28 U.S.C. § 1498.

impose price controls on a new drug to treat Alzheimer’s currently under review by the FDA.⁵² Similarly, the Kapczynski-Kesselheim letter last year 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.⁵³ Similar to the arguments to use the Bayh-Dole Act, these claims contradict the text, function, and longstanding interpretation of § 1498. Section 1498 does not grant the government any power to infringe patents, let alone to “break” them to impose price controls.

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.⁵⁴ It provides that “[w]henver ... 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.”⁵⁵ Congress first enacted this law in 1910 following some confusion in the courts at the turn of the twentieth century concerning the ongoing protection of patents as property rights under the Takings Clause of the Fifth Amendment.⁵⁶ The Takings Clause states that “nor shall private property be taken for public use, without just compensation.”⁵⁷ 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 to receive “reasonable and entire compensation.”

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 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.⁵⁸ For this reason, courts have

⁵² 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>.

⁵³ Kapczynski-Kesselheim Letter, *supra* note 1, at 1-4.

⁵⁴ 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.

⁵⁵ 28 U.S.C. § 1498(a).

⁵⁶ 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).

⁵⁷ U.S. CONST. amend. V.

⁵⁸ 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 56, at 7-10 (describing cases).

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.⁵⁹

Still, advocates for the price-control theory of § 1498 maintain that the government can use § 1498 for any use of a patented invention by any person or company that may “benefit” the government.⁶⁰ Thus, they argue, § 1498 can be used to impose price controls via an agency authorizing a generic drug company for the “benefit” of the government to make and sell a patented drug. This would benefit the government by reducing costs for federal programs like Medicare, whose beneficiaries are prescribed drugs produced by private companies and prescribed by private physicians.⁶¹

This is an unconstrained reading of § 1498 that contradicts its plain text. Congress knows how to enact price-control statutes, such as the Emergency Price Control Act of 1942,⁶² 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.⁶³ As an eminent domain statute, the plain text of § 1498 thus *protects* patent owners when their property rights are taken by or for the government without authorization.

This is why courts have repeatedly rejected the same argument by the Kapczynski-Kesselheim letter and by defendants in patent infringement cases.⁶⁴ In *Larson v. United States*,⁶⁵ 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 § 1498.⁶⁶ 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

⁵⁹ 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”).

⁶⁰ See Kapczynski-Kesselheim Letter, *supra* note 1, at 3.

⁶¹ *Id.*

⁶² See *supra* notes 15-16, and accompanying text (describing this and other price control statutes).

⁶³ 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”).

⁶⁴ 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).

⁶⁵ *Larson v. United States*, 26 Cl. Ct. 365 (1992).

⁶⁶ *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*).

the federal government when a patent is used by or for the federal government.⁶⁷ 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.”⁶⁸

These court decisions were recently reaffirmed earlier this year in *Arbutus Biopharma Corp. v. Moderna*, in which another federal court held that the advance purchase contracts for COVID-19 vaccine doses that were manufactured by Moderna for use by and for private citizens did not trigger the jurisdictional mandate in § 1498 that a patent-owner’s lawsuit must proceed only against the federal government in the Court of Federal Claims.⁶⁹ 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.⁷⁰

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 in the Kapczynski-Kesselheim letter, and in the more recent Senator Sanders letter, § 1498 does not apply to situations in which the government “facilitate[s] the purchase of low-cost generics by private entities,” even if the private entities are “reimbursed by Medicare and Medicaid.”⁷¹ As one of the sources cited in the Kapczynski-Kesselheim letter explains, § 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.”⁷²

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

Even if the government could invoke § 1498 to authorize the manufacture and sale of generic versions of patented drugs, doing so would impose an enormous cost on the U.S. Treasury. This vitiates any alleged 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.⁷³ In the past 38 years, the

⁶⁷ *Larson*, 26 Cl. Ct. at 369.

⁶⁸ *Advanced Software Design Corp.*, 583 F.3d at 1379 (quoting *Larson*, 26 Cl. Ct. at 369).

⁶⁹ *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).

⁷⁰ *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7.

⁷¹ Kapczynski-Kesselheim Letter, *supra* note 1, at 3.

⁷² MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974).

⁷³ 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

U.S. Court of Appeals for the Federal Circuit has decided four § 1498 cases—a rate of about one per decade.⁷⁴ Consistent with the text and function of § 1498 as an eminent domain statute, none of these cases arose from a governmental authorization to a private company to make a competing product in the marketplace. 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 apply the legal rules for patent infringement cases in which they award, according to the patent statute, “damages adequate to compensation for the infringement.”⁷⁵ 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.⁷⁶ In an 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 § 1498.⁷⁷

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, because it vastly *expands* the federal government’s financial liabilities in paying for medical care. The government would necessarily be incurring additional costs through paying lost profits as compensation to drug innovators in innumerable and ongoing § 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 scheme of § 1498 arises from other existing regulatory regimes in patent law that go unacknowledged by its proponents. Among

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.”).

⁷⁴ 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).

⁷⁵ See 35 U.S.C. § 284 (providing that “court shall award the claimant damages adequate to compensate for the infringement”).

⁷⁶ 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.”).

⁷⁷ See *Decca Ltd.*, 640 F.2d at 1167.

several, the most apparent source of uncertainty and additional costs is the Hatch-Waxman Act.⁷⁸ 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.⁷⁹ Although the Kapczynski-Kesselheim letter references the Hatch-Waxman Act in footnotes,⁸⁰ it fails to address at all how its proposed price-control scheme under § 1498 would necessarily impact this regulatory regime and inescapably become intertwined with it, raising costs and legal uncertainties.

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.⁸¹ 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 scheme of § 1498 do not acknowledge how their 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.⁸² Without a proper institutional and legal assessment of how the price-control scheme of § 1498 would in fact be implemented within the existing institutions and laws governing drug patents, its advocates have not proven that it will be cost effective compared to the allegedly high prices paid today for patented drugs.

Conclusion

The price-control theories of the Bayh-Dole Act and § 1498 represent policy arguments superimposed on two statutes by academics and activists seeking a quick-and-easy path to an unprecedented regulatory policy for imposing price controls on prescription drugs in the healthcare market. Failing the burden of evidence-based policymaking in making the proper case for breaking patents as the sole solution to lower drug prices in a complex healthcare market, they instead bootstrap the necessary policy and economic arguments by arguing that Congress has already approved of a price-control policy in two existing federal statutes. Their proposed price-control

⁷⁸ 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.

⁷⁹ For a complete description of the Hatch-Waxman Act and its complex regulatory and litigation regime, see Thomas, *supra* note 36; 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).

⁸⁰ See Kapczynski-Kesselheim Letter, *supra* note 1, at 3 n.16 & 5 n.29.

⁸¹ See 21 U.S.C. § 355(j)(5)(B)(iii).

⁸² See Braden & Kresh, *supra* note 64, at 293.

schemes under both the Bayh-Dole Act and § 1498 contradict their text, their function, and the consistent and repeated interpretation of these statutes by courts and agencies. Neither statute is a “tool” for lowering drug prices by breaking patents.

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