



April 20, 2022

The Honorable Elizabeth Warren
United States Senate
309 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Warren,

High prescription drug prices in the United States are a major problem today for both patients and the sustainability of our healthcare system.¹ Importantly, these prices do not typically reflect material factors like supply shortages, manufacturing difficulties, or labor costs. Instead, drug prices are high primarily because brand-name drug companies use government-granted exclusivities, such as patents, to prevent competition and charge high prices.

Existing law gives the executive branch several tools to intervene when patients and public health are harmed by excessive drug prices. These tools can help the Administration break patent barriers, foster competition where currently there is none, and drive down prices. Critically, using them requires no additional congressional action.

This letter describes three of these tools: the “government patent use power” codified at 28 U.S.C. § 1498, and the Bayh-Dole Act’s “royalty-free license” and “march-in rights.” These tools are integral, longstanding, and legitimate parts of our patent system. Together, their directed use can help the government obtain fair prices for prescription drugs.

Section 1498

One important tool at the federal government’s disposal is the “government patent use power” codified at 28 U.S.C. § 1498. Enacted in 1910, this law formalizes the government’s ability to use any “invention described in and covered by a patent of the United States” without a license, provided that the use is “by or for the United States” and the patent holder is afforded “reasonable and entire compensation.”² Section 1498 permits both direct patent use by the government itself as well as third-party use on behalf of the government.³ Today, federal agencies rely on this authority to procure important patented technologies from manufacturers other than the patent holders, who may charge very high prices. For example, the Department of Defense (DOD) has exercised its § 1498 authority when purchasing defense technologies, such as bullets and night-vision goggles.⁴ This continued reliance underscores the provision’s indisputable legality.

¹ For a more extensive discussion, see *Hearing on the Hospital Insurance Trust Fund and the Future of Medicare Financing Before the Subcomm. on Fiscal Resp. & Econ. Growth of the S. Comm. on Fin.*, 117th Cong. (2022) (statement of Amy Kapczynski, Professor of Law, Yale Law School).

² Act of June 25, 1910, Pub. L. No. 61-305, 36 Stat. 851 (1910) (codified as amended at 28 U.S.C. § 1498 (2018)).

³ JOSEPH ADAMCZYK, ADRIENNE LEWIS & SHIVANI MORRISON, § 1498: A GUIDE TO GOVERNMENT PATENT USE (2021), <http://dx.doi.org/10.2139/ssrn.3882823>.

⁴ *Id.*

As recently as the 1960s and 1970s, federal agencies used the government patent use power to procure low-cost versions of patented medicines.⁵ Though agencies have not used the power to purchase generic medicines since then, it remains an important legal option. In 2001, the George W. Bush Administration threatened to rely on the government patent use power to induce Bayer to lower prices and increase production of ciprofloxacin (Cipro), a then-patented drug used to combat anthrax.⁶

Today, the federal government could and should use this power to curb excessively high drug prices paid by the government. Implementation of § 1498 is straightforward.⁷ In general, the government need not take any special legal or administrative action to use § 1498, nor must it even declare that it expects to take steps that will lead to use of § 1498. Instead, it can simply buy patented drugs from a low-cost manufacturer, or it can manufacture drugs itself. The government can also authorize a third party (e.g., a contract drug manufacturer) to use a patent in the government's place.

When the U.S. government uses a patent, the holder of the patent can sue the government under § 1498 for “reasonable and entire compensation.” Courts have generally found the “reasonable and entire compensation” to require a “reasonable royalty” rather than other, more costly remedies, such as lost profits.⁸ Courts generally set royalties that result in substantial government savings (as measured against the monopoly price),⁹ while still guaranteeing the patent holder a reasonable return on investment.¹⁰

⁵ Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 303–07 (2016). Notably, following use of § 1498 by the Department of Defense (DOD) to purchase a generic antibiotic, the drug industry “lobbied strenuously against the practice and sought an amendment to limit § 1498 to instances where ‘national security’ required it.” *Id.* at 305. This amendment was rejected.

⁶ Amy Kapczynski & Aaron S. Kesselheim, ‘Government Patent Use’: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFFAIRS 792, 794 (2016).

⁷ See generally ADAMCZYK ET AL., *supra* note 3, at 32–39 (providing a roadmap for government officials to implement § 1498 with respect to pharmaceuticals specifically).

⁸ See Christopher J. Morten & Charles Duan, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 44 & nn.187–88 (2020). In fact, in every modern § 1498 case, “the measure of royalties has not been lost profits but rather a ‘reasonable royalty.’” Brennan et al., *supra* note 5, at 313; see also *Dow Chem. Co. v. United States*, 226 F.3d 1334, 1348 (Fed. Cir. 2000) (quoting *Leesona Corp. v. United States*, 220 Ct. Cl. 234, 599 (Ct. Cl. 1979)).

⁹ For example, one study found that, during one three-year period in the 1960s, DOD relied upon § 1498 to save an estimated \$21 million on 50 drugs. MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974).

¹⁰ This is important given that monopoly prices may not represent the pharmaceutical’s real value. Indeed, numerous studies have called into question whether high drug prices truly reflect high costs of research and development. See, e.g., U.S. DEP’T HEALTH & HUM. SERVS., PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS (2016), <https://tinyurl.com/y2df5563> (“Drug manufacturers often point to high drug development costs as a justification for high drug prices and understanding the R&D costs and time to develop a new drug is important. However, the relationship between R&D costs and drug prices is subject to a number of misconceptions. In reality, the prices charged for drugs are unrelated to their development costs. Drug manufacturers set prices to maximize profits. At the time of marketing, R&D costs have already occurred and do not affect the calculation of a profit-maximizing price.”).

Importantly, the “reasonable and entire compensation” guaranteed by § 1498 is the only remedy the patent holder can seek.¹¹ The patent holder cannot obtain a court-ordered injunction to stop the government’s use of a patent.¹²

Government patent use is an assumption of liability on behalf of the federal government, so it requires the authorization and consent of the government. Myriad federal agencies have exercised the government patent use power,¹³ and courts have generally treated this requirement flexibly, allowing many different officials in the government to express consent.¹⁴ The government can provide “authorization or consent” explicitly (i.e., through contracts), implicitly (i.e., government-made blueprints instructing third parties on how to manufacture a product), and even retroactively.¹⁵

The simplest case for government patent use to address drug prices involves the federal government procuring medicines itself. The federal government does so regularly, for example, when it purchases drugs for the Veterans Administration, Indian Health Service, DOD, CHIP, Tricare, and FEHBP.

However, many drugs purchased in the United States are not obtained by governmental entities, but rather by private or state insurers. The federal patent use power can help lower prices for these third-party purchasers as well. Whenever an acquisition is for the “benefit” of the government in a way that is not “merely incidental,” § 1498 applies.¹⁶ We believe that government patent use can facilitate the purchase of low-cost generics by private entities reimbursed by Medicare and Medicaid if the savings benefit these federal programs, for example by reducing costs or allowing expanded coverage for Medicare beneficiaries.¹⁷ Though this argument is well supported by Federal Circuit precedent construing “benefit” broadly, the government could further strengthen

¹¹ *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343–44 (1928) (“The word ‘entire’ emphasizes the exclusive and comprehensive character of the remedy provided.”).

¹² *Id.* at 343 (noting that “entire” was added to the statutory language precisely to avoid the possibility that courts would impose injunctions or other excessively burdensome remedies).

¹³ For example, the Department of Treasury, United States Army Corporation of Engineers, National Institutes of Health, National Gallery of Art, National Park Service, General Services Administration, and Department of Health and Human Services (HHS), among others, have all exercised § 1498. See Brennan et al., *supra* note 5, at 302–03.

¹⁴ *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976) (“‘[A]uthorization or consent’ on the part of the Government may be given in many ways other than by letter or other direct form of communication’—e.g., by contracting officer instructions, by specifications or drawings which impliedly sanction and necessitate infringement, by post hoc intervention of the Government in pending infringement litigation against individual contractors.”).

¹⁵ ADAMCZYK, *supra* note 3, at 20–21.

¹⁶ *Id.* at 19. In addition, use of § 1498 in the pharmaceutical context will require Food and Drug Administration (FDA) approval or authorization for the generic or biosimilar product, and may require navigating non-patent exclusivities offered by other statutes like the Hatch-Waxman Act. For more on how to navigate such issues, see *id.* at 34; Brennan, *supra* note 5, at 340–45.

¹⁷ For a more detailed discussion of how exactly HHS could invoke § 1498 “to extend generic . . . treatments to Medicare and Medicaid enrollees,” see Brennan, *supra* note 5, at 349–50. See also ADAMCZYK, *supra* note 3, at 20 (describing how HHS might “contract[] with a generic manufacturer of drugs not just to supply its own agencies that distribute such drugs directly but also to supply low-cost drugs to non-governmental private insurers that HHS reimburses under contracts administered through Medicare Part D.”).

its position by issuing formal letters that consent to infringement and assume liability for resulting claims.¹⁸

A few final notes about the legal power of the patent use approach: Unlike march-in rights—discussed below—§ 1498 can be invoked for *any* US patent, no matter who owns it or how it was funded. Section 1498 has been used extensively, over decades; is available to any federal agency; and allows for immediate use of patents, which is especially important during crises. The government patent use formalized by § 1498 is so powerful that the government may not actually need to exercise the tool to reap some of its cost-saving benefits. The mere threat of exercising § 1498 may cause patent holders to offer more competitive prices for their patented products. In the Cipro case, the George W. Bush Administration’s threat to use § 1498 to procure the drug from a generic drug maker at a low price led the patent holder, Bayer, to respond by offering the government a discount of almost 50%.¹⁹

Bayh-Dole Act: Royalty-Free License and March-In Rights

Adopted in 1980, the Bayh-Dole Act was intended to ensure that the public would not be deprived the benefits of inventions that it had effectively sponsored through government-funded research. It is often said that the Bayh-Dole Act was intended to promote public-private cooperation to speed drug development, yet this is only *one* of the purposes described in the statute itself. In addition, the Act is designed to ensure the “public availability of inventions,” to “protect the public against nonuse or unreasonable use of inventions,” and to “minimize the costs of administering policies in this area.”²⁰ It accomplishes these goals by “ensur[ing] that the Government obtains sufficient rights in federally supported inventions.”²¹

Thus, when the government directly funds research that results in a patent,²² the Bayh-Dole Act gives the government two additional tools: a royalty-free license in that patent and a right of the government to “march in” on the patent to ensure that the resulting products are “available to the public on reasonable terms.”²³ Though the two tools have different prerequisites and scopes, they can both be used to produce and distribute drugs²⁴ when existing manufacturers fail to provide them at reasonable prices. Even short of formally invoking its rights, the government can use these tools to bolster its leverage in negotiations with manufacturers. Section 1498 and Bayh-Dole rights can be particularly powerful when used together, for example by lowering royalties that must be

¹⁸ See Brennan, *supra* note 5, at 335-36.

¹⁹ Morten & Duan, *supra* note 8, at 30; see also *id.* at 55 (describing how Roche agreed to permit some generic manufacturing of the drug oseltamivir (Tamiflu) after some members of Congress asked the George W. Bush Administration to explore use of § 1498).

²⁰ 35 U.S.C. § 200 (“Policy and objective”).

²¹ *Id.*

²² To be covered by Bayh-Dole, government funding must be proximately related to the actual drug, not merely precursors or biomarkers. 35 U.S.C. § 201(e) (requiring that the invention be “conceived or first actually reduced to practice in the performance of work under a funding agreement”).

²³ 35 U.S.C. § 201(f) (2018) (defining “practical application”).

²⁴ It is important to note that even where the government has rights to patents in a medicine, other patents may cover different aspects of the same medicine, and Bayh-Dole grants licenses only to those patents that resulted from government investment. Practically, this means that Bayh-Dole rights may be more limited than § 1498 rights in certain contexts.

paid in instances when a government has contributed to some, but not all, of the patents covering a drug.

1. Irrevocable Government Licenses

In the Bayh-Dole Act, § 202 grants the government irrevocable, non-transferrable, royalty-free licenses to covered patents. These licenses permit the government to manufacture drugs for its own use or license production on the government’s behalf.²⁵ Importantly, the licenses are fully “paid up,” which means the government can invoke them without incurring any cost beyond its initial investment,²⁶ and without proving the existence of any special or emergency circumstances.²⁷

Unlike the government’s march-in rights under § 203 (discussed below), the only requirement under § 202 is that the patent be used by, for, or on behalf of the government.²⁸ Although the government has not yet invoked its rights under § 202, the plain text and statutory purpose of the Act make a strong case that it encompasses production of drugs for use by government programs, such as Medicare and Medicaid.²⁹ This comports with the broad meaning that the Supreme Court has historically assigned to the phrase “for or on behalf of the United States” in other contexts, which has not required any formal contractual arrangements.³⁰ Thus, as long as production is being used to satisfy government purposes and objectives, the Act should not require purchases be made directly by the government itself.

2. March-In Rights

Bayh-Dole Act § 203 creates a “march in” right, which allows the government to authorize generic drug companies to produce the invention for sale in the private market.³¹ Unlike the government licenses provided by § 202, march-in licenses require payment of royalties to the patent holder. In addition, to issue a march-in license, an agency that funded the research must determine that proper grounds exist. For example, march-in licenses can be authorized if a patent holder has not taken

²⁵ 35 U.S.C. § 202(c)(4).

²⁶ *Id.*; see also 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).

²⁷ Indeed, a manufacturer should be able to bypass, immediately, any patent barriers to FDA approval of a drug otherwise authorized by the FDA by certifying that the drug maker “is seeking approval solely for sale of the product to the US government or government programs” and that the “patents are not infringed because the government owns an irrevocable license to practice the patents.” See Alfred B. Engelberg, Jerry Avorn & Aaron S. Kesselheim, *A New Way to Contain Unaffordable Medication Costs — Exercising the Government’s Existing Rights*, NEW ENGLAND J. MED. (Feb. 9, 2022), <https://www.nejm.org/doi/full/10.1056/NEJMp2117102>.

²⁸ 35 U.S.C. § 202.

²⁹ *Id.*; see also Debate on University and Small Business Patent Procedures Act, 96th Cong., 126 Cong. Rec. 1796 (1980) (statement of Sen. Birch Bayh arguing that § 202 authorizes government use for the public good); Engelberg et al., *supra* note 27 (explaining why the Hatch-Waxman Act does not prevent the government from invoking its licenses in this way). Although the government has never used its licenses in this way, it is likely that the latent threat of use has had significant effects on prices and manufacturer behavior. See Alfred B Engelberg & Aaron S Kesselheim, *Use the Bayh-Dole Act to Lower Drug Prices for Government Healthcare Programs*, 22 NATURE 576 (2016).

³⁰ See, e.g., *Dixon v. United States*, 465 U.S. 482, 490 (1984) (discussing adoption of the phrase in federal bribery statutes).

³¹ 35 U.S.C. § 203.

“effective steps” to “achieve practical application” of a drug,³² or if “action is necessary to alleviate health or safety needs which are not reasonably satisfied” by the patent holder.³³

Any agency “under whose funding agreement the subject invention was made” may initiate march-in proceedings pursuant to regulations set by the National Institute of Standards and Technology (NIST).³⁴ Although third-parties may petition the agency to request that it exercise march-in rights, the agency may also do so of its own accord upon receipt of information that “might warrant the exercise of march-in rights.”³⁵ Each agency retains discretion to design its own proceedings, which are to be “as informal as practicable” while still “consistent with principles of fundamental fairness.”³⁶ This standard is much less burdensome on the agency than formal adjudication under the Administrative Procedure Act, and does not require that proceedings be “on the record.”

Based on the plain text of the statute, excessive pricing alone should provide sufficient grounds for exercising march-in rights. Section 203(a)(1) permits march-in licenses if the patent holder has not effectively achieved “practical application” of the drug, which § 201(f) defines as, *inter alia*, making the drug “available to the public on reasonable terms.”³⁷ Years after the Bayh-Dole Act’s enactment, former Senators Birch Bayh and Bob Dole (who were then working for Washington firms that lobbied for pharmaceutical manufacturers)³⁸ argued that Congress did not intend “reasonable terms” to cover excessive pricing.³⁹ But the text of the statute contradicts this interpretation. The statute’s plain text matters more than a single newspaper op-ed expressing subjective intent of individual lawmakers,⁴⁰ particularly when that intent is expressed years *after* the law has already been passed.⁴¹ Moreover, there were numerous, *contemporaneous* examples

³² *Id.* § 203(a)(1).

³³ *Id.* § 203(a)(2). Note that if a manufacturer is not achieving practical application of a drug, that is independently sufficient for an agency to invoke march-in rights, even if it has not made a determination that action is needed to address “health and safety needs.” Thus, urgent gaps in health and safety needs are best understood as an additional justification for exercising march-in rights on top of the core justification of combatting excessive pricing.

³⁴ *Id.* at § 203(a)(1); 37 C.F.R. § 401.6.

³⁵ 37 C.F.R. § 401.6; *see also* JOEL GOTKIN, THE UNITED STATES BAYH-DOLE ACT AND ITS EFFECT ON UNIVERSITY TECHNOLOGY TRANSFER 41 (2012).

³⁶ *Id.*

³⁷ *See* John H. Rabitschek & Norman J. Latker, *Reasonable Pricing - A New Twist for March-in Rights Under the Bayh-Dole Act*, 22 SANTA CLARA HIGH TECH. L.J. 149 (2005).

³⁸ *See* James Love, Comments of James Love of Knowledge Ecology International (KEI) on the Proposal to Eliminate Unreasonable Prices as a Standalone Basis for March-in Rights (Mar. 18, 2021), https://downloads.regulations.gov/NIST-2021-0001-0023/attachment_1.pdf.

³⁹ *See* Birch Bayh & Bob 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/?itid=lk_inline_manual_40 [<https://perma.cc/835G-JYSU>]; *see also* Rabitschek & Latker, *supra* note 26.

⁴⁰ *See* John F. Manning, *Textualism and Legislative Intent*, 91 VA. L. REV. 419, 431 (2005).

⁴¹ *See* *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011) (“Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation.”); *D.C. v. Heller*, 554 U.S. 570, 605 (2008) (“[S]tatements of those who drafted or voted for the law that are made after its enactment . . . could have had no effect on the congressional vote.”) *See* *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1143 (2018) (“If the text is clear, it needs no repetition in the legislative history; and if the text is ambiguous, silence in the legislative history cannot lend any clarity.”). The fact that the former senators were both deeply involved in lobbying efforts for the pharmaceutical industry by that time illustrates *why* statements such as theirs are generally given little weight.

from debates around the passage of the Act that clearly link the Act’s march-in provisions with the need to control prices and promote accessibility to the public.⁴²

Price is a crucially important element of the terms of a transaction, and providing goods or services only at excessive prices *is* offering only unreasonable terms.⁴³ This interpretation is supported by federal court cases interpreting other statutes discussing the meaning of “reasonable terms.”⁴⁴ Reviewing the reasonableness of prices is well within the competence of both courts and agencies, as illustrated by other aspects of patent law,⁴⁵ contract law,⁴⁶ utilities regulation,⁴⁷ and more. Finally, other industry representatives have argued that the government’s failure to *exercise* march-in rights means that those rights do not exist.⁴⁸ Yet, as the Supreme Court has long held, “[t]he fact that powers long have been unexercised well may call for close scrutiny as to whether they exist; but if granted, they are not lost by being allowed to lie dormant.”⁴⁹

There are strong indications that the White House agrees that this approach is legal. Although the Biden Administration has not publicly commented on the meaning of “reasonable terms,” it halted a proposed NIST rule seeking to exclude unfair pricing from the scope of the Act.⁵⁰ In 2016, the Department of Health and Human Services similarly declined to exclude excessive pricing from the scope of the Act’s march-in rights, instead simply quoting the statutory language and observing that “the statutory criteria are sufficiently clear and additional guidance is not needed.”⁵¹

Conclusion

⁴² 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 Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 659-667 (2001) (describing statements by members of Congress, quoting from committee reports, describing exchanges during public hearings, and noting industry opposition to march-in rights on the basis that they would permit price controls).

⁴³ *Id.* at 651.

⁴⁴ *Id.* at 650-51 (collecting cases).

⁴⁵ See 35 U.S.C. § 284 (2018) (providing for the granting of “reasonable royalties”); see also 28 U.S.C. § 1498 (2018).

⁴⁶ See U.C.C. § 2-305(1)(a) (2000); see also Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 95-97 (1989).

⁴⁷ See, e.g., *Verizon Commc’ns, Inc. v. F.C.C.*, 535 U.S. 467, 481 (2002) (discussing the long history of regulating utility prices to produce “fair” and “reasonable” returns).

⁴⁸ Adam Mossoff, *Comment Submitted to NIST on Bayh-Dole Regulations*, HUDSON INST. (Apr. 6, 2021), <https://www.hudson.org/research/16810-comment-submitted-to-nist-on-bayh-dole-regulations> [<https://perma.cc/PR3E-HQ3Z>].

⁴⁹ *United States v. Morton Salt Co.*, 338 U.S. 632, 647 (1950); see also *Nat’l Petroleum Refiners Ass’n v. F.T.C.*, 482 F.2d 672, 694 (D.C. Cir. 1973) (holding that the FTC’s long held belief that it lacked rulemaking did not divest the agency of that power).

⁵⁰ See Exec. Order No. 14036, 86 Fed. Reg. 36987 (July 9, 2021) (Executive Order on Promoting Competition in the American Economy). The proposed rule dated from the waning days of the Trump Administration, and provoked over 80,000 adverse comments in opposition. See Peter Arno, Robert Sachs & Kathryn Ardizzone, *Will the Biden Administration Use ‘March-In’ to Protect Prostate Cancer Patients from Excessive Drug Prices?* STAT NEWS (Jan. 3, 2022), <https://www.statnews.com/2022/01/03/march-in-rights-protect-prostate-cancer-patients-from-excessive-drug-prices/> [<https://perma.cc/KZ97-5D5R>].

⁵¹ Letter from Sylvia M. Burwell, Secretary of Health and Human Services, to The Honorable Lloyd Doggett, U.S. House of Representatives (Mar. 2, 2016), <http://freepdfhosting.com/be7532cfc0.pdf>.

Section 1498 and the Bayh-Dole Act provide three powerful tools that the executive branch can use to lower drug prices by breaking patent barriers and accelerating competition. In our view, § 1498 is a powerful general-purpose tool to target excessive pricing, while the Bayh-Dole Act is particularly helpful for patents that received government research support. We believe that the two can and should be used together as part of a cohesive strategy when drugs of high public health importance are sold to US patients at excessive prices.

These tools are available, legal, and will be effective. We hope that the current Administration will devote attention to using these tools to address the ongoing crisis in drug prices.

Sincerely,

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