February 6, 2024

By Federal eRulemaking Portal

Laurie E. Locascio
Director and Undersecretary of Commerce for Standards & Technology
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

RE: Request for Information Regarding Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights (Docket No.: 230831–0207])

Dear Director Locascio,

As scholars, former judges, and former government officials who are experts in patent law, patent licensing, and innovation policy, we respectfully submit this comment in response to the Request for Information (RFI) by the National Institute of Standards and Technology (NIST) on the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights (Guidance Framework).[1] In the RFI, NIST states that it seeks "to ensure that [the Guidance Framework] is clear, and its application will both fulfill the purpose of march-in rights and uphold the policy and objectives of the Bayh-Dole Act."[2] We believe that the Guidance Framework contradicts both the text and purpose of the Bayh-Dole Act, and thus it should be withdrawn by NIST.

For the first time since the enactment of the Bayh-Dole Act in 1980, NIST proposes a Guidance Framework for the four march-in powers in 35 U.S.C. § 203 that provides 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."[3] The RFI expressly states that agencies that provided funding for subject inventions under the Bayh-Dole Act may "include consideration of factors that unreasonably limit availability of the invention to the public [as triggers of the march-in powers under § 203], including *the reasonableness of the price* and other terms at which the product is made available to end-users."[4]

The Guidance Framework's inclusion of "the reasonableness of the price [paid by] end-users" as a new criterion for any agency exercising the march-in powers in § 203 represents unprecedented and unauthorized regulatory authority. It lacks statutory authorization in the Bayh-Dole Act, as confirmed by its text, its purpose, and by other sources of statutory interpretation long relied on by courts and agencies, such as past interpretations of a statute by government officials. In fact,

[1] *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).

[2] 88 Fed. Reg. 85593.

[3] *Id.* at 85598.

[4] *Id.* (emphasis added).

§ 203 of the Bayh-Dole Act never mentions "price" as a criterion for the exercise of the four specified march-in powers, as contrasted with the RFI's reference to "price" twenty-six (26) times.

Congress knows how to enact a price-control statute and to state clearly in a statute's text that federal officials or agencies may consider "reasonable price" or even merely "price" as a condition for authorizing direct or indirect price controls on products produced and sold by private companies to consumers. One example is the Emergency Price Control Act of 1942,[5] among many others. The Bayh-Dole Act does not authorize this administrative power to control directly or indirectly prices, neither generally nor specifically in the four march-in conditions in § 203.

Other organizations and individuals with direct experience and knowledge in research and development in companies and universities, patent licensing under the Bayh-Dole Act, and in other related commercial activities in the U.S. innovation economy have submitted comments on these matters about which they have expertise. As legal experts, our comment explains why the Bayh-Dole Act does not authorize an agency to issue march-in licenses for the purpose of lowering prices on any product or service embodying a patent covered by this statute. First, it describes the evidence of the proven success of the patent system as a driver of innovation and economic growth. This is the necessary legal and policy framework for evaluating any proposed regulatory alterations to patent rights, especially unprecedented proposals like the Guidance Framework that would weaken or eliminate these patent rights. Second, it explains why the Guidance Framework lacks authorization in the Bayh-Dole Act according to its plain text, its statutory function, and its consistent implementation by agencies over several decades by bipartisan administrations. Third, it identifies how Senators Birch Bayh and Robert Dole expressly rejected claims by professors over two decades ago that the Bayh-Dole Act authorized agencies to use the march-in powers to control market prices of products and services. NIST should withdraw the proposed Guidance Framework.

The Success of the Patent System as a Driver of Economic Growth and Innovation

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.[6] 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

[5] *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).

[6] *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).

revolutions in the twenty-first century.[7] Patent systems that secure reliable and effective property rights to inventors consistently and strongly correlate with successful innovation economies.[8]

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.[9] 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.[10] 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.[11]

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.[12] As a result, the U.S. 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.[13] For this reason, the U.S. patent system was identified as the "gold standard" in securing reliable and effective property rights in the fruits of innovative labors—patents.[14]

The real-world results of reliable and effective property rights—whether in real property or in patents—is extensive private investments, development of new products and services, and the creation and growth of new commercial markets. Just as in the high-tech sector and in the mobile revolution,[15] these same economic consequences are manifest in modern healthcare. The annual

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[7] *See generally* MERGES, *supra* note 6; BARNETT, *supra* note 6; KHAN, *supra* note 6.

[8] *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).

[9] *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.").

[10] *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).

[11] *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.

[12] *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).

[13] *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.

[14] Madigan & Mossoff, *supra* note 12, at 940-41.

[15] *See* Letter from Alden Abbott, Kristina M.L. Acri, et al. to Assistant Attorney General Jonathan Kanter, Nov. 30, 2022,

private investment in research and development (R&D) of new pharmaceutical and biotech innovations is approximately $129 billion (as of 2018).[16] This is almost *triple* the total amount of total public funding of $43 billion of R&D in healthcare innovations (as of 2018).[17] Medical 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. This data is relevant in assessing the Guidance Framework because the Biden Administration has argued that it serves the purpose of lowering drug prices,[18] although the Guidance Framework does not state this nor does it limit the proposed "reasonable price" criterion to patented drugs and other inventions resulting from some upstream research funding in the life sciences by the federal government.

The evidence of the historical, economic, and empirical success of the U.S. patent system in driving innovation and economic growth is the baseline by which NIST should consider new regulatory proposals that ultimately weaken or restrict reliable and effective patents on new innovations throughout all sectors of the U.S. innovation economy. This includes the Guidance Framework, which includes an unprecedented power to issue nonexclusive licenses for the purpose of controlling prices on any patented product or service because a funding agency may deem it to be sold at "unreasonable prices." The eight scenarios and examples in the Guidance Framework make clear that consideration of "reasonable price" as a condition for exercising the march-in power applies to every sector of the U.S. innovation economy, from manufacturing of highway signage to the 5G communication technologies implemented in connected cars.[19]

The evidentiary burden is on any official or agency proposing wide-ranging regulatory restrictions, additional costs, and additional legal uncertainties on patent owners. First, they must explain that proposed regulations are legally authorized. Second, they must explain, even if legally authorized,

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https://s3.amazonaws.com/media.hudson.org/Letter+to+AAG+Kanter+re+SEPs+and+Patent+Pools+10.30.22.pdf, at 1-2 (detailing economic evidence); *see also* Alexander Galetovic, Stephen H. Haber & Ross Levine, An Empirical Examination of Patent Holdup, 11 J. COMP. L. & ECON. 549, 564-69 (2015), https://papers.ssrn.com/abstract=2588169 (finding quality-adjusted prices for devices and other products in the patent-intensive telecommunications market to have fallen at a faster rate as compared to other sectors of the innovation economy).

[16] 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 (estimating total private investment in biopharmaceutical R&D in 2018 is estimated to be $129 billion). For each drug approved by the FDA for use by patients, there is on average $2.6 billion in R&D expenditures incurred over 10–15 years. See Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20 (2016).

[17] *See* U.S. Investments in Medical and Health Research and Development 2013–2018, supra note 17, at 8.

[18] *See* FACT SHEET: Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition (Dec. 7, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/ ("Today, the Biden-Harris Administration is announcing new actions to promote competition in health care and support lowering prescription drug costs for American families, including the release of a proposed framework for agencies on the exercise of march-in rights on taxpayer-funded drugs and other inventions, which specifies that price can be a factor in considering whether a drug is accessible to the public.").

[19] *See* 88 Fed. Reg. 85601-85605 (detailing the eight scenarios in which the march-in power may be used by an agency).

that there is reliable and robust data that supports this proposal as evidence-based policymaking. As will now be explained the Guidance Framework fails on both of these necessary conditions for an agency adopting new regulations, especially those that authorize unprecedented powers such as the Guidance Framework's authorization of an agency to impose price controls under a "reasonable price" criterion for issuing nonexclusive licenses under § 203 of the Bayh-Dole Act. § 1498. These arguments are equally incorrect, as detailed below.

A Price-Control Power Contradicts the Text and Statutory Purpose of the Bayh-Dole Act

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.[20] 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.[21] The Bayh-Dole Act corrected this mistaken policy by establishing that innovators can obtain patents for inventions arising from some government-funded research and retain ownership in these patents, which facilitates licensing and other commercial activities in the marketplace.[22]

Section 203 in the Patent Act, as enacted in the Bayh-Dole Act, creates the limited exception to this core function of the Bayh-Dole Act by creating the "march in right."[23] 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.[24] A federal agency may grant these licenses "to a responsible applicant" without authorization from the patent owner in four delimited 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," (3) "requirements for public use specified by Federal regulations . . . are not reasonably satisfied," or (4) "a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement."[25]

The statutory text of § 203 does not support the unprecedented inclusion of "reasonable price" as a criterion for any agency in imposing price controls on patented products or services produced by

[20] *See generally* BARNETT, *supra* note 6.

[21] *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").

[22] *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.").

[23] *See* 35 U.S.C. § 203 (2011).

[24] § 203(a).

[25] § 203(a)(1)-(4).

private companies and sold to private consumers in the marketplace. The four march-in conditions, set forth in § 203(a) in the disjunctive, constitute the only authorizations in this exemption in the Bayh-Dole Act for a federal agency to exercise the march-in power. Notably, there is no mention of "reasonable 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.[26] The Emergency Price Control Act of 1942 is one such example.[27] Similarly, rate-regulation statutes enacted by the states according to their police powers expressly authorize legislators or regulators to set "prices" or determine "rates."[28] 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." According to the "the ordinary meaning of the words used" in § 203 and § 201(f) in the Bayh-Dole Act, the march-in power does not authorize licenses for the purpose of imposing price controls.[29]

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."[30] 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

[26] *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).

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

[28] *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'").

[29] 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).

[30] 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.").

Bayh-Dole Act to freely assign or license their property in the marketplace.[31] In sum, Congress chose not to create an open-ended grant of authority in § 203 in 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, which comports with the general function of the Bayh-Dole Act in promoting private commercialization of patented innovations in the marketplace.

The inclusion of "reasonable price" as a criterion in the Guidance Framework follows the work of activists and academics who have argued for over two decades that 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 means that that prices can prevent this "practical application" with consumers.[32] As is typical of modern legislation, the Bayh-Dole Act has a lengthy definition of "practical application" in which these advocates for this price-control theory of § 203 have focused on a single phrase ("available to the public on reasonable terms").[33] These activists and academics have spun an entire theory of unprecedented and vast regulatory power to control prices in the marketplace of patented products and services based on only two general phrases in two separate sections of the Bayh-Dole Act—"practical application" and "reasonable terms."

This price-control theory of § 203 is wrong as a matter of law and statutory interpretation. First, their argument creates vast administrative powers based on an out-of-context, laser-like focus on phrases that have been isolated from lengthy and complex statutory provisions. This commits the classic interpretative error of wooden textualism.[34] For example, these activists and academics do not acknowledge that "terms" is often a distinct legal concept from "price," as these distinct words

[31] *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*).

[32] *See, e.g.*, Letter from Amy Kapczynski, Aaron S. Kesselheim, et al. to Senator Elizabeth Warren, at 6-7 (Apr. 20, 2022), https://tinyurl.com/yt62wt4t; 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).

[33] *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").

[34] *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 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").

have been used in many legal instruments. In fact, statutes often distinguish between "price" and "terms" by listing these two words separately.[35]

These advocates for the price-control theory of § 203 also do not acknowledge that the partial definition of "practical application" in § 203(a)(1) as "reasonable terms" in § 201(f) in the Bayh-Dole Act follows past usage of "practical application," which was understood to refer to the "successful development and terms of the license, not with a product's price."[36] 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."[37]

Second, in interpreting a specific statutory provision or a specific clause within a statutory provision, the advocates for the price-control theory of § 203 violate fundamental legal rules governing the interpretation and application of statutes. Courts always inquire into "the specific context in which that language is used, and the broader context of the statute as a whole."[38] 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."[39] "Courts have a 'duty to construe statutes, not isolated provisions.'"[40]

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

[36] 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/.

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

[38] Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997).

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

[40] 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

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."[41] 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 advanced 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. Thus, § 203(a)(1)-(4) specifies four 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.[42]

Lastly, the Guidance Framework's lack of legal authorization in the Bayh-Dole Act is confirmed by Supreme Court precedent that agencies may not arrogate powers to themselves that are not specifically granted in statutes. An unprecedented 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." This is especially true given that 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.[43]

The Supreme Court has consistently instructed agencies that "Congress, we have held, 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."[44] The Supreme Court has rejected other agencies' claims to regulatory authority under similarly vague and generalized terminology as the statutory phrase "practice application" in § 203, which has been the justification of the price-control power that the Guidance Framework implements. 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.'"[45] The Supreme Court again stated last year that it repeatedly "requires Congress to enact exceedingly clear language if it wishes to

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[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.'").

[41] 35 U.S.C. § 200.

[42] *See supra* notes 23-31, and accompanying text.

[43] *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).

[44] Whitman v. Am. Trucking Associations, 531 U.S. 457, 468 (2001).

[45] *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.").

significantly alter . . . the power of the Government over private property."[46] The Guidance Framework lacks a clear authorization in § 203 to justify its unprecedented inclusion of "reasonable price" as a criterion for authorizing the march-in power.

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 explains why federal agencies—spanning bipartisan administrations over several decades—have repeatedly rejected numerous petitions to use the march-in power to impose price controls on drug patents. 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.[47] 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.[48] 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.[49] As with the prior six petitions reaching back to the 1990s, the NIH rejected these petitions on the statutory ground that "the use of march-in to control drug prices was not within the scope and intent of its authority."[50]

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.[51] 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.[52] 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

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

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

[48] *Id.*

[49] *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).

[50] *Id.*

[51] *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).

[52] *Id.*

invoking the march-in power, this rationale lacked authorization under § 203.[53] The NIH stated bluntly that the march-in power in § 203 did not exist for the purpose of "forced attempts to influence the marketplace."[54] 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."[55] 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.[56] 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."[57] 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.[58] The NIH bluntly concluded: "As stated in previous march-in considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities."[59] The frustration by NIH officials with the serial petitions seeking to impose price controls on drug patents via the march-in provision in the Bayh-Dole Act is palpable.

Lastly, on March 21, 2023, the NIH rejected the latest petition (filed again) for this agency to invoke the march-in power solely to lower the price of Xtandi, a cancer drug covered by patent.[60] 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."[61] 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."[62] The NIH further pointed out that this decision about Xtandi is consistent

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[53] *Id.*

[54] *Id.* at 7.

[55] *Id.* at 7.

[56] *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.

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

[58] 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.

[59] *Id.*

[60] *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).

[61] *Id.* at 2.

[62] *Id.*

with its prior multiple rejections of march-in petitions also seeking to lower drug prices.[63] 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."[64]

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 NIST to 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.'"[65]

Original Sponsors of the Bayh-Dole Act Stated Their Law Did Not Authorize Price Controls

The Guidance Framework's inclusion of "reasonable price" as a criterion for applying the march-in power under § 203 is a statutory power that was allegedly discovered and argued for by two professors in a law journal article published more than two decades after the enactment of the Bayh-Dole Act.[66] When they later published an op-ed advancing their article's argument, Senator Birch Bayh and Senator Robert Dole responded by expressly rejecting their theory that the Bayh-Dole Act authorized price controls as an essential tool of the march-in power in § 203.

Professors Peter Arno and Michael Davis published an op-ed in the *Washington Post* in 2002 restating their argument from their law journal article the year before that the Bayh-Dole Act mandates that patented inventions resulting from "federal funds will be made available to the public at a *reasonable price*."[67] Professors Arno and Davis' op-ed prompted a response from Senators Bayh and Dole, published as a letter to the editor in the *Washington Post* two weeks later:

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

[63] *Id.*

[64] *Id.*

[65] *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)))

[66] *See* Arno & Davis, *supra* note 32.

[67] *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).

> the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.[68]

Although this letter does not have the same legal status as the canons of statutory interpretation and official interpretation and application of a statute, Senators Bayh and Dole make clear that the inclusion of "reasonable price" as a criterion authorizing the march-in power is unconnected to the text or purpose of their statute. The proposed Guidance Framework, ultimately born of the price-control theory spawned by Professors Arno and Davis, is an unprecedented assertion of agency power to control prices in private market transactions without a legal basis in the Bayh-Dole Act.

Conclusion

The Guidance Framework proposes the addition of "reasonable price" as an unprecedented criterion for exercising the march-in powers specified in § 203 of the Bayh-Dole Act. This is a legally unjustified and unauthorized arrogation of power by NIST. The Bay-Dole Act does not state in its plain text a congressional authorization for federal agencies to consider "reasonable price" as a criterion for imposing price controls on all Bayh-Dole patented products or services that are commercialized in the marketplace. In addition to lack of authorization in the plain text of § 203, the Guidance Framework's inclusion of "reasonable price" as a march-in criterion contradicts the function of Bayh-Dole in promoting the commercialization of inventions by patent owners in the marketplace. The NIH has consistently and repeatedly confirmed this lack of statutory authorization in § 203 to impose price controls across bipartisan administrations over several decades in rejecting all march-in petitions seeking to impose price controls.

NIST states in its RFI, "[t]o date, no agency has exercised its right to march-in," but it fails to acknowledge the numerous, repeated rejections by the NIH of march-in petitions seeking to impose price controls on drug patents. NIST should follow these repeated actions by the NIH, including in its most recent rejection of the Xtandi march-in petition less than a year ago, in applying the clear text and function of the Bayh-Dole Act. Thus, NIST should withdraw the proposed Guidance Framework and permit the Bayh-Dole Act to function according to its intended function in promoting the commercialization of innumerable innovations in the marketplace.

Sincerely,[*]

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

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