



February 1, 2024

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Research!America Comment Letter on NIST Request for Information (RFI) Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023); (Docket NIST–2023–0008)

Dear Dr. Locascio:

I am writing on behalf of Research!America to strongly urge the National Institute of Standards and Technology (NIST) to revise the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (“Draft Framework”) by removing product pricing as a basis for applying the 35 USC 203(a)(1) and (a)(2) “march-in” criteria under the Bayh-Dole Act of 1980 (Public Law 96–517, 35 USC 200 *et seq*) and its implementing regulations (37 CFR 401 and 404).

Introducing pricing as a basis for march-in contravenes the letter and intent of the Patent and Trademark Law Amendments Act (Pub. L. 96-517), also known as the Bayh-Dole Act. Further, doing so would create substantial new uncertainties and risks, discouraging the public-private collaborations that are the end-goal of the Bayh-Dole Act itself. These Bayh-Dole-enabled collaborations are demonstrably crucial to life science and other scientific and technological innovation. Since 1980, American universities alone have generated over \$1.3 trillion dollars in economic growth, 4.2 million jobs, and 11,000 start-ups that can be directly attributed to the Bayh-Dole Act’s enactment and the execution of its provisions in a manner consistent with legislative intent¹.

¹ G. Athanasia, “The Legacy of Bayh-Dole’s Success on U.S. Global Competitiveness Today”, Center for Strategic and International Studies (CSIS), January 12, 2023.

I. Inclusion of Product Pricing as a Basis for March-In is Inconsistent with Historic Bipartisan Implementation of Bayh-Dole March-In Rights.

More than 40 years of successful implementation, rulemakings, and agency adjudications have enabled an extraordinary history of successful federal technology transfer that NIST itself assessed “in the U.S. from 1996 to 2015 demonstrate[d] over \$1 trillion in economic growth and millions of new jobs” - a history under which, notably, no Federal agency has ever exercised march-in rights.²

We are concerned that the Draft Framework abandons these decades of sound and enormously beneficial policy precedents to adopt a policy stance that is inherently inconsistent with the statutory objective laid out in the Bayh-Dole Act, which is expressly “to promote--

- the utilization of inventions arising from federally supported research or development;”
- collaboration between commercial concerns and nonprofit organizations, including universities;” and
- the commercialization and public availability of inventions made in the United States.”³

While the Bayh-Dole Act affords the Government “sufficient rights... to protect the public against *nonuse* or unreasonable *use* of inventions,” the law does not authorize such rights in relation to, nor do any provisions of that law refer to, prices.⁴

The Draft Framework, and the Executive Order and final regulations preceding it, constitute a reversal of NIST’s own intended policy in its recent 2021 proposed rule: that “[m]arch-in rights shall not be exercised exclusively based on... the pricing of commercial goods and services arising from the practical application of the invention.”⁵ In 2023, Executive Order 14036⁶ and the agency’s subsequent final regulations⁷ reversed this intended policy. This reversal, which is now imbedded in the Draft Framework, undercuts the important certainty and predictability that the policies of previous bipartisan Administrations had built and that the 2021 proposed rule would have enshrined.

² NIST, Green Paper: [Return on Investment Initiative for Unleashing American Innovation](#) (NIST Special Publication 1234, April 2019).

³ 35 USC 200, “Policy and Objective”.

⁴ Id.

⁵ 86 Fed Reg 35, 41 (January 4, 2021).

⁶ E.O. 14036, [Promoting Competition in the American Economy](#), July 9, 2021.

⁷ 88 Fed Reg 17730 (March 24, 2023).



II. Lack of Factual Basis for Abandoning Prior Implementation of Bayh-Dole March-In Rights.

Research!America is also concerned that NIST has not shared the logic underlying the decision to begin using pricing as a basis for march-in. We could find no evidence or new data in NIST's 2023 final rule or the Draft Framework to justify the change.

The final rule does provide information on the process that led to the framework – it refers to “comments received, NIST’s examination of them, and the Executive Order [14036]”⁸ – but it is unclear how that process engendered new federal policy that contravenes the letter and legislative intent of the Bayh-Dole law and decades of federal precedent. In the final rule, NIST committed to “engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of march-in provisions.” However, other than a 2023 interdepartmental announcement that the Draft Framework would be developed, to our knowledge, neither NIST nor the Department of Health and Human Services (HHS) has made any evidence or data available to the public to support the Draft Framework’s novel inclusion of pricing as a march-in criterion.⁹

III. Reliance on Product Pricing as a Basis for March-In is Inconsistent with the Intent and Language of the Bayh-Dole Act.

As previously noted, introducing product pricing as a basis for march-in is inconsistent with the legislative intent and the language of the Bayh-Dole Act. In 2002, retired Senators Bayh and Dole confirmed in the *Washington Post* that:

“[The] Bayh-Dole [Act] 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.”¹⁰

The Senate committee report accompanying the Bayh-Dole Act does not describe or specify “reasonable pricing” or “price” in relation to march-in rights.¹¹ Additionally, because the Bayh-Dole march-in provision at 35 USC 203 was “taken directly from

⁸ 88 Fed Reg 17730, 17732.

⁹ HHS press release, “[HHS and DOC Announce Plan to Review March-In Authority](#)”, March 21, 2023.

¹⁰ B. Bayh, R. Dole, “Our Law Helps Patients Get New Drugs Sooner,” *Washington Post*, April 11, 2002.

¹¹ Senate Report No. 96-480, University and Small Business Patent Procedures Act, 96th Congress, 1st Sess. (1980).

existing Executive Branch [march-in] policies”,¹² which only applied to “reasonable terms” for licensure (not product pricing) to “guard against failure to practice the invention”¹³, the law’s authors also find support in the Administration’s contemporaneous testimony such as the Department of Energy’s 1979 testimony to the House:

“The primary benefit to... ‘march-in’ rights is... limited to those cases, and only those cases, where an invention is commercially important to two or more parties who cannot settle their differences.”¹⁴

and a response a former Assistant Secretary of Commerce gave at the same hearing indicating that march-in rights were intended to be exercised “should something go wrong” and if there is “any remote possibility of abuse” should licensure not lead to application and commercialization.¹⁵

Moreover, even the House report on the bill the chamber passed (but which was replaced in the Senate by the bill, ultimately signed into law, authored by Senators Bayh and Dole) also emphasized that its march-in provision was:

“...intended to continue existing practice and the [House Judiciary] Committee intends that agencies continue to use the march-in provisions in a restrained and judicious manner as in the past.”¹⁶

We recognize that some individuals dismiss the clarifying statements by the late Senators Bayh and Dole as their “subjective intent...expressed years after the law has already been passed.”¹⁷ These individuals claim, “there were numerous,

¹² S.M. O’Connor, The Real Issue Behind *Stanford v. Roche*: Faulty Conceptions of University Assignment Policies Stemming from the 1947 Biddle Report. 19 Mich. Telecomm. & Tech. L. Rev. 378 (2013), at 406; see also Congressional Research Service, March-In Rights Under the Bayh-Dole Act, R44597 (August 22, 2016) at 5.

¹³ Memorandum of October 10, 1963, “Government Patent Policy”, 28 Fed Reg 10943 (October 12, 1963).

¹⁴ Government patent policy: hearings before the Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, U.S. House of Representatives, 96th Congress, 1st Sess., October 16, 17, 1979, at 16 (Testimony of James E. Denny, Assistant General Counsel for Patents, Department of Energy).

¹⁵ The University and Small Business Patent Procedures Act: Hearing on S. 414 before the Senate Committee on the Judiciary, U.S. Senate, 96th Cong. 1st Sess., (1979) at 153-154.

¹⁶ House Report 96-1307, part 1, Amending the Patent and Trademark Laws, 96th Congress, 1st Sess. (1980), reprinted in 1980 U.S.C.C.A.N. 6460, 6474.

¹⁷ Harvard Medical School/BWH PORTAL program and Law Yale Law School GHJP program, [Letter to Senator Warren](#), April 20, 2022.

contemporaneous examples 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.”

However, this point of view appears to rely solely on secondary sources¹⁸ (also cited in consistently unsuccessful march-in petitions to the National Institutes of Health (NIH), see *infra* IV.) that erroneously claim the Bayh-Dole Act’s legislative history links march-in rights with product pricing and that “reasonable terms” under the Act means “reasonable prices”.¹⁹ For example, a key secondary source claims that the 1980 Senate committee report documents that “[m]arch-in rights were designed to prevent ‘windfall profits,’ about which there was much discussion”.²⁰ In fact, the authors misattribute the Senate’s discussion of “section 204 of the bill, the Government pay back provision” to march-in rights under 35 USC 203.²¹

We urge NIST to take cautionary note of such erroneous claims that 35 USC 203 was written to address product pricing. The reason Senators Bayh and Dole spoke publicly in 2002 was, in fact, to directly rebut a *Washington Post* editorial written by the authors of the erroneous secondary sources that “mischaracterized the rights retained by the government under Bayh-Dole”.²² It is notable that Senator Bayh continued to publicly correct these mischaracterizations: during the NIH’s deliberations on, and subsequent denial of, march-in petition regarding Norvir (ritonavir) in 2004, he criticized the petition’s reliance on the aforementioned erroneous scholarship that “flagrantly misrepresent[s] the legislative history supporting Bayh-Dole.”²³

¹⁸ See P. Arno, M. 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).

¹⁹ Id. *contra* J.H. Rabitschek, N.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).

²⁰ Arno, Davis, 5 TUL. L. REV. 631 at 663.

²¹ Senate Report No. 96-480 (1980) at 30. See also Denny testimony, note 15: “In any debate on this issue one always hears charges of windfall profits and concerns expressed regarding a Government giveaway... *Government-supported studies, however, have found no basis in fact for these charges, concerns and beliefs.*” (italics added)

²² P. Bayh, M Davis, “Paying Twice for the Same Drugs,” *Washington Post*, March 27, 2002.

²³ Testimony of Senator Birch Bayh. NIH Public Meeting on Norvir/Ritonavir March-in Request (May 25, 2004) at 5-6.



IV. The Draft Framework Abandons Prior Agency March-In Adjudications Related to Product Pricing That Should Instead Be Relied Upon in Its Revision.

Research!America is concerned that the Draft Framework makes no reference to the extensive regulatory and adjudicatory history that the National Institutes of Health (NIH) – unique among all Federal agencies – has compiled in refusing multiple Bayh-Dole march-in petitions relating to prescription drugs– in 1997, twice in 2004, 2013, 2016 and 2023. Among these omissions, we are concerned that NIST has not acknowledged the above public testimony by Senator Bayh regarding the law he authored. But most importantly, the Draft Framework omits the extensive fact-finding and legal reasoning that NIH has undertaken and relied upon repeatedly to “examine the criteria of 35 U.S.C. §203(1)(a) and (b) and [find] that “march-in is not warranted under either criteri(on).”²⁴

Since the first petition in 1997, NIH has consistently concluded that Bayh-Dole license holders, including leading universities, medical schools and biopharmaceutical sponsors, have “met the statutory and regulatory standard for practical application” through the “manufacture, practice, and operation” of the invention, including clinical development and securing product approval from the Food and Drug Administration (FDA), as well as the inventions’ “availability to and use by the public” by marketing the prescription drugs in question. In promulgating the Draft Framework, NIST has unfortunately offered no reason or evidence why the agency’s long-standing reasoning and interpretation of the law should be reversed.

Notably, in the NIH’s refusal of the 2004 Norvir (ritonavir) petition, NIH Director Zerhouni stated that:

“...because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively.”²⁵

That same year, NIH also denied a march-in petition regarding Xalatan (latanoprost), noting that “the issue of whether drugs should be sold in the United States for the same price as they

²⁴ Harold Varmus, Director, NIH, Determination in the Case of Petition of CellPro (August 1, 1997).

²⁵ Elias Zerhouni, Director, NIH, Determination in the Case of Petition of Norvir (July 29, 2004).



are sold in Canada and Europe... is appropriately left for Congress to address legislatively.”²⁶ We urge NIST to maintain these precedents, which reinforce that Congress has plenary authority – and responsibility – to enact laws to address product pricing and could choose at any time to amend the Bayh-Dole Act to specifically address product pricing in the context of march-in rights.²⁷

Of note, in 1995, “after an extensive review” NIH struck the controversial “reasonable pricing” clause from its Cooperative Research and Development Agreements (CRADAs) as “a restraint on the new product development that [is] an important return on [public] research investment”.²⁸ NIH found “the pricing clause has driven industry away from potentially beneficial scientific collaborations with [Public Health Service] PHS scientists without providing an offsetting benefit to the public”... “at the expense of a more open research environment and more vigorous scientific collaborations.”

Absent the requested revision, we read the Draft Framework as reinstating these and other complex adjudications as a daily matter for NIH and other research and development (R&D) funding agencies. Requiring NIH and other federal R&D funding agencies to assess and regulate product pricing is outside of their respective statutory missions and would divert from those missions. These agencies are charged with advancing science and technology. The mission of NIH is to “seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.” Diverting its scientists and managers from executing this statutory mission to address commercial market considerations (such as assessing the cost-basis of product manufacturing and marketing or analyzing domestic market pricing) that are extraneous to their responsibilities and expertise would be a tragic misstep bearing on the wellbeing of this and future generations. Decades of bipartisan support for NIH’s current role and that of other R&D funding agencies reflects the significance of their respective contributions to the US and the global community. These roles should not be diluted or compromised by conflicts of interest created by new responsibilities for regulating product prices.

In that same context, we urge NIST to consider the new, day-in-day-out administrative responsibilities that would be associated with this policy change and the related new costs

²⁶ Elias Zerhouni, Director, NIH, Determination in the Case of Petition of Xalatan (September 17, 2004).

²⁷ In the context of prescription drug pricing, Congress has legislated extensively to address the issue, from enacting the Medicaid outpatient prescription drug “best price” rebate program in 1990 to enacting the Medicare Drug Price Negotiation Program in 2022.

²⁸ NIH, Press release (April 11, 1995).



federal R&D funding agencies would be required to bear in implementing the Draft Framework as written.

The Bayh-Dole Act addressed a chasm between federally funded research and its translation into societal solutions that had severely limited that societal impact of federally funded science & technology. The Draft Framework, as written, threatens to resurrect this enormous gulf of unmet potential and missed opportunities to the detriment of all Americans dependent upon innovation to improve our health and generate new medicines, foster economic growth, and master technologies vital to our national defense.

Research!America respectfully requests that NIST remove product pricing as a march-in criterion from the Draft Framework in accordance with the letter and intent of the Bayh-Dole law, in order to sustain the extraordinary momentum this landmark law has lent to scientific, technological, medical, public health, and economic progress in the United States and across the globe.

Thank you for considering our views.

Sincerely,

A handwritten signature in black ink that reads "Ellie Dehoney". The signature is fluid and cursive, with the first name "Ellie" being larger and more prominent than the last name "Dehoney".

Ellie Dehoney
Senior Vice President, Policy and Advocacy
Research!America