

February 6, 2024

The Honorable Gina Raimondo
Secretary
U.S. Department of Commerce
Washington, DC 20320

Ms. Laurie E. Locascio
Director, NIST
National Institute for Standards
and Technology
Gaithersburg, MD 20899

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No. NIST-2023-0008.

Dear Secretary Raimondo and Director Locascio:

The undersigned organizations and individuals submit the following comments in response to the request for information regarding proposed interagency guidance for the exercise of march-in rights (“proposed guidance”), which would establish a “march-in” process to override property rights to patents that runs counter to the plain language of the Bayh-Dole Act. If implemented, the proposed guidance would endanger American economic competitiveness, inhibit innovation, impede public private partnerships, and harm U.S. technological leadership in cutting-edge sectors.

We strongly urge the proposed guidance be withdrawn. Our primary concerns are as follows:

- I. The proposed guidance constitutes a confiscation of property rights that would chill private research and development funding;
- II. The actions contemplated by the proposed guidance are unlawful and directly contradict both the plain text and the spirit of the Bayh-Dole Act;
- III. If implemented, the proposed guidance would radically alter and undermine America’s innovation ecosystem, thwarting American technological leadership and the ability of Americans to access the next generation of innovative technologies; and
- IV. Separate from the clear, unambiguous illegality of the proposed guidance, the entire process that led to its issuance lacked transparency, public input, and engagement.

These concerns are outlined in more detail below.

- I. The proposed guidance constitutes a confiscation of property rights that would chill private research and development funding.

The Bayh-Dole Act incentivizes the private sector to build upon government funded basic research to advance relevant scientific discoveries through its own investment in applied research. If the applied research allows for an invention to be commercialized, the Bayh-Dole Act protects the private sector investment and consumers' ability to access new products.

For example, one product that was the subject of a denied march-in petition in 2023, itself reflects the remarkable success of the Bayh-Dole Act. In this case, the university patentee (the researcher(s) that was the recipient of relevant federal funding), received less than \$500,000 in taxpayer funding to support early-stage research that directly contributed to an initial discovery. The patentee's downstream private sector licensees later contributed \$2.2 billion in applied science to develop the product, and perform pre-clinical studies and clinical trials, in order to deliver a safe and effective product to patients. As a result of this collaborative public-private partnership, which proportionally cost taxpayers less than 0.023 percent of the product's overall development cost, hundreds of thousands of patients received a life-saving treatment that otherwise would not exist.

Taking the proposed guidance to its logical extreme, the federal government could hypothetically seize the intellectual property found in cell phones since the miniaturization of electronics was spurred by research undertaken by the government during the Apollo moon program. As will be discussed in greater detail, the Bayh-Dole Act deliberately extended the protection of intellectual property rights, which originate in the Constitution, to these commercialization efforts for the benefit of American consumers. Accordingly, an exercise of march-in constitutes an uncompensated taking of property which is also prohibited by the Constitution.

- II. As the text, legislative history, and opinions of outside experts clearly indicate, NIST's proposed framework is plainly unlawful because nothing in the Bayh-Dole Act gives federal agencies the authority to exercise "march-in" to regulate or fix market prices of commercial products.

Under the Bayh-Dole Act, Congress intended that inventions with some Federal support be developed and commercialized on an equal footing with other inventions. This part of the law also took steps to address concerns that private sector firms might fail to take reasonable steps to **commercialize** a partially taxpayer-funded innovation.¹ Accordingly, Congress included a **very limited** march-in provision, which allows the government to force the patent owner to grant additional licenses if, for example, good faith efforts are not being made to bring the product to market.²

¹ See *Issue Brief: March-In Rights Under the Bayh-Dole Act*, Bayh-Dole Coalition, February 2023.

² *Id.*

Unfortunately, in recent years, some advocates that seek to weaken intellectual property rights have advanced a false theory that march-in rights can be used as a form of market intervention and price control.³ The proponents of this theory wrongly claim that the government has the legal authority to “march-in” and override exclusive patent licenses at any time, for any reason, if it decides a product is too expensive. The government could then simply grant additional licenses to the patent to companies that promise to sell the product at a reduced cost.

This theory is without basis and contrary to Bayh-Dole. The late Senators Birch Bayh and Bob Dole—the lead sponsors and negotiators of the Act—both confirmed march-in rights were never intended to be a mechanism to control prices. Senators Bayh and Dole noted that nothing in the text or legislative history supports such an assertion.⁴ Senators Thom Tillis and Marsha Blackburn – two Members of Congress heavily engaged on issues of intellectual property law and technology transfer – have also affirmed that using march-in rights to set strict price controls “contradicts the purpose and the function of the Bayh-Dole Act.”⁵

Each Administration since the law’s enactment, including the Biden Administration as recently as last year, have recognized that the law is clear, confirming that price has no role to play in determining whether to exercise march-in rights. We believe the draft guidelines are inappropriate and illegal.

- III. If implemented, the proposed guidance would radically alter America’s innovation ecosystem, leading to fewer new products and technologies and seriously damaging America’s global leadership, national security, and economic competitiveness.

We are deeply concerned that, if implemented, the guidance could seriously undermine American innovation. The Bayh-Dole Act has been, since its passage, a foundational element in America’s success in research and development.⁶ The Bayh-Dole

³ Ltr. from Senator Warren et. al. to Secretary Xavier Becerra, February 18, 2022.

⁴ Bayh-Dole Coalition *Issue Brief*, supra note 19.

⁵ Ltr. from Senators Thom Tillis and Marsha Blackburn to Secretary Xavier Becerra, February 24, 2022 (“Stripping intellectual property rights for private actors simply because they are commercializing their applied research on terms opponents dislike contradicts the very purpose and function of the Bayh-Dole Act. March-in rights were never intended to function as price controls nor does the statute allow it. The authors of the statute – Senators Bayh and Dole – have said as much. Every Republican and Democratic Administration dating back to President Clinton has agreed. The statute clearly doesn’t sanction marching in to control prices of successfully commercialized products.”).

⁶ See *Quaadman*, supra note 3 (“Bayh-Dole established a fair, appropriate, and pragmatic system for the federal government to transfer proprietary rights in research. It has been critical to the success of

Act enables public-private collaborations and allows expanded access to new, life-changing innovations that help make the U.S. the global innovation leader.⁷

By any measure, the Bayh-Dole Act has been extraordinarily successful. According to some estimates, since its passage, the Bayh-Dole Act has contributed \$1.9 trillion to the U.S. economy, supported 6.5 million jobs, and helped lead to more than 15,000 start-up companies.⁸ In addition, the Bayh-Dole Act has enabled thousands of commercial products stemming from university research to be introduced to the public.⁹ As *The Economist* put it, the Bayh-Dole Act “unlocked all the inventions and discoveries that had been made in laboratories throughout the United States....”¹⁰

Perplexingly, the proposed guidance would cast a pallor of uncertainty over public-private collaborations. Federally supported inventions would once again be encumbered with legal risk and unpredictability, making it more difficult for universities and private sector inventors to attract the partners and capital needed to develop nascent inventions.

- IV. The entire process that led to the issuance of the proposed guidance lacked transparency and public engagement, and no action taken to date has indicated a willingness to share pertinent facts and details about how the decision to issue it was made.

We are concerned that at no point since the announcement of the interagency working group has the public been permitted to engage. Neither the members of the working group nor their meetings have ever been made public. There is no insight into the working group’s communications with outside parties. The absence of public engagement denies stakeholders the opportunity to provide input and voice concerns.

the United States in bridging the “valley of death” and ensuring that scientific knowledge translates into usable products, services, and technologies that both serve end-users and advance national strategic priorities.”).

⁷ Tom Wilbur, *IP Explained: Four things to know about the Bayh-Dole Act*, September 13, 2019 (“Adopted by Congress in 1980, the bipartisan Bayh-Dole Act allows institutions and grant recipients, such as universities, to hold the title to patents on inventions stemming from government-funded research and to license the rights to those inventions to private sector partners who further develop them for commercialization. These private sector partners, including biopharmaceutical companies, assume the full risk of developing and commercializing the technologies that may eventually prove to be viable products. This can generate royalties for the research institution, paid by the commercial developer, once a product is brought to market.”); see also Stephen Ezell, *The Bayh-Dole Act’s Vital Importance to the U.S. Life-sciences Innovation System*, ITIF, March 2019, available at <https://www2.itif.org/2019-bayh-dole-exec-summary.pdf>

⁸ Home - The Bayh-Dole Coalition (bayhdolecoalition.org).

⁹ See <https://autm.net/surveys-and-tools/databases/statt>.

¹⁰ *Innovation's golden goose*, *The Economist*, December 14, 2002 (Describing how the Bayh-Dole Act was perhaps the most inspired piece of legislation enacted in the last half century.).

The Hon. Gina Raimondo
Director Locascio
February 6, 2024
Page 5

That is why the U.S. Chamber of Commerce has submitted Freedom of Information Act (FOIA) requests to your agencies. These requests seek an immediate disclosure of the information above and aim to determine whether the law has been manipulated due to political interference.

A policy as consequential as this one, reversing nearly four-and-a-half decades of consistent legislative interpretation with respect to a widely acclaimed act of Congress, requires transparency and openness to ensure that all stakeholders have the opportunity to contribute.

V. Conclusion

For all these reasons, the undersigned organizations request you immediately withdraw the proposed guidance. Rather, we urge the Administration to reaffirm a commitment to American innovation.

Sincerely,

U.S. Chamber of Commerce
The Maryland Chamber of Commerce
The Business Council of New York State, Inc.
Small Business & Entrepreneurship Council
The Healthcare Leadership Council
Licensing Executives Society (USA & Canada), Inc.
Joshua Kresh (in his personal capacity), Interim Executive Director, Center for Intellectual Property x Innovation Policy (C-IP2)
Judge Paul R. Michel (Ret.)
James Edwards, Executive Director, Conservatives for Property Rights and Patent Policy Advisor, Eagle Forum Education & Legal Defense Fund
Judge Susan Braden (Ret.), Jurist-In-Residence, Center for Intellectual Property and Innovation Policy, Scalia Law School
Adam Mossoff, Professor of Law, Antonin Scalia Law School, George Mason University