



January 26, 2024

National Institute of Standards and Technology  
100 Bureau Drive  
Gaithersburg, MD 20899

**RE: Docket No. NIST-2023-0008**

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing thousands of Americans, writes in response to the National Institute of Standards and Technology's (NIST) Request for Information Regarding Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights.

NIST's proposal to allow a federal agency to consider an eventual product's price when considering whether to exercise march-in rights will dramatically shift away from what works very well under the Bayh-Dole Act (Bayh-Dole) as written and practiced for more than four decades: secure patent ownership, exclusivity, and rights. The proposed guidance would take a huge step backward, restoring problems that Bayh-Dole fixed. Thus, the proposed framework will cause extensive adverse consequences if this guidance is implemented. ***Failure to proceed with prudence will reduce practical benefits from basic research funded by billions of taxpayer dollars. The proposal to assault related intellectual property (IP) rights will weaken our economy, hurt innovative U.S. startup and early-stage small businesses, and hand adversarial competitors such as China the advantage in technological leadership.***

The single most destructive policy conceivable—subjecting successful commercializers to the tremendous risk that their success will be punished by march-in based on the price the market sets for their products years after beginning commercialization—is exactly what NIST, along with the Departments of Commerce and Health and Human Services, is proposing.

Exclusive IP ownership rights and having control of IP-protected technology incentivize the transfer of technology to willing entities capable of attempting commercialization. The key to this success, as well as to providing confidence to invest

millions of dollars of private risk capital in no-guarantee, protracted product development endeavors is secure, reliable IP rights, which Bayh-Dole achieves.

The 40-plus year experience of Bayh-Dole bears recounting. Bayh-Dole solved the problem of wasted expenditure of taxpayer money. Prior to Bayh-Dole, federally funded research led to many important discoveries. The U.S. government owned 28,000 patents from research it funded. But less than 5 percent of these patents was licensed for attempting commercialization. Therefore, ***taxpayers received little practical benefit from virtually all the research for which their taxes paid.***

Pre-Bayh-Dole, the federal government tightly held the IP resulting from its funded research. Some 26 agencies' rules controlled commercial use of federally owned IP. Grantees were usually not allowed to take title to their discoveries. The government only gave nonexclusive licenses to its patents. Thus, very little new knowledge was ever translated into products.

Thus, this law's success in facilitating commercialization has proceeded directly from assuring grantees and licensees reliable property rights. Bayh-Dole has unleashed thousands of inventions that otherwise would have never moved to commercial application.

For instance, university inventions bring about more than two new products and two new jobs a day.<sup>1</sup> Bayh-Dole made possible the creation of the biotech industry. Its decentralized tech transfer and confidence that march-in has been reserved for exceptional, statutorily designated grounds have contributed \$1 trillion to U.S. GDP from 1996-2020. Its patent licensing is responsible for about \$2 trillion of industry gross output and supports 6.5 million jobs.<sup>2</sup> In the 1970s, most medicines Americans used were developed in Europe; since Bayh-Dole, the United States leads the world in drug discovery, R&D, commercialization, and the development of new innovative medicines.<sup>3</sup>

***The stark contrast between pre-Bayh-Dole's barriers and command-and-control policies and post-Bayh-Dole's democratization of IP ownership must not be missed. The difference is night and day: before, bureaucratic bottlenecks and radically stunted benefits from the millions of taxpayer dollars poured into research over decades; after, grant recipients owning and making decisions over***

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<sup>1</sup> Eagle Forum Education & Legal Defense Fund, summary of remarks by Joseph P. Allen, "Benefiting from Federal Research Funding: Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society," Proceedings of Capitol Hill Briefing, Oct. 18, 2018, p. 5.

<sup>2</sup> AUTM and BIO, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020," June 14, 2022.

<sup>3</sup> Stephen Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System," Information Technology & Innovation Foundation, March 4, 2019.

***their IP, the fruits of their labors.*** Bayh-Dole has spurred widespread invention; efficient, smart technology transfer and commercialization; and the outpouring of new products, startup companies, new jobs, invigorated innovation ecosystems across the country, and even new industries.

The Bayh-Dole Act provides the government with march-in rights (35 U.S.C. § 203) only for certain extremely narrow, extraordinary circumstances. The statutory grounds specified for march-in licensing are when the contractor has failed timely to pursue commercialization of the invention, has not reasonably satisfied public health or safety needs, has failed to ensure the invention is substantially made in the United States, or can't meet or hasn't met specified requirements for public use. ***None of these extremely limited exceptions for march-in relates to product prices. None of them mentions or implies consideration of a product's price. Thus, there is no statutory basis for injecting product price into interpretation or application of this provision of law.*** If exercised, march-in would require the patent owner or exclusive licensee to issue a license to the patented invention and further allow the federal government to issue the license should the patent owner or exclusive licensee fail to do so.

In more than 40 years, march-in has never been used despite a number of petitions requesting it. With administrations of both parties consistently denying march-in petitions based on product price, agencies have heretofore acted appropriately and in accord with the statute. Repeated, consistent decline of requested misuse of march-in helps ensure this law's success. ***Such fidelity to the spirit and letter of the law is vitally important. We strongly urge NIST to withdraw the proposed guidance and comply with the law.***

"Reasonable pricing" policy has been tried, and it failed. It is imperative that the administration recall and learn from the lessons of the National Institutes of Health's (NIH) Cooperative Research and Development Agreement (CRADA) experience of the 1990s. In 1989, NIH began requiring a "reasonable pricing" provision in its CRADAs as a condition for an exclusive license to NIH-developed technologies. That price-control clause injected uncertainty and undermined property rights over eventual products.

The "reasonable pricing" measure caused a significant drop in NIH CRADAs, which fell from 42 in 1989 to an average of 32 the next six years. The dramatic fall-off led NIH to eliminate the pricing provision. CRADAs with NIH thereafter immediately rose to about 90 agreements in 1996 and more than 160 in 1997. NIH confirmed this lesson in 2021.<sup>4</sup>

When the "reasonable pricing" policy was eliminated, NIH Director Harold Varmus said "the pricing clause has driven industry away from potentially beneficial

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<sup>4</sup> NIH, "The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995," Nov. 15, 2021. [https://www.techtransfer.nih.gov/sites/default/files/CRADA\\_Q&A\\_Nov\\_2021\\_FINAL.pdf](https://www.techtransfer.nih.gov/sites/default/files/CRADA_Q&A_Nov_2021_FINAL.pdf)

scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public. . . . Eliminating the clause will promote research that can enhance the health of the American people.” ***By proposing consideration of product price as a factor for exercising march-in rights, NIST proposes to repeat those failures and radically diminish Bayh-Dole’s benefits.***

In closing, ***CPR strongly urges NIST not to implement these “reasonable pricing” provisions, in violation of the Bayh-Dole statute. We insist that NIST withdraw this misguided, dangerous framework.***

Sincerely,

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