February 2, 2024

Via Electronic Submission

Laurie E. Locascio

National Institute of Standards and Technology

100 Bureau Drive

Gaithersburg, MD 20899

Comments to the National Institutes of Standards and Technology

Re: RFI Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights

(Doc #230831-0207)

Dear Director Locascio,

I appreciate the opportunity to respond to the Request for Information regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights, dated December 8, 2023.[[1]](#footnote-1) I write this in my capacity as Senior Research Fellow at the Mercatus Center, a non-profit non-partisan research organization based at George Mason University.[[2]](#footnote-2) The views set forth herein are attributable solely to me, and do not necessarily represent the views of the Mercatus Center. Previously, I served as the General Counsel of the Federal Trade Commission.[[3]](#footnote-3)

I write to express my opposition to the proposed guidance for interpreting the Bayh-Dole Act's march-in provision. The proposed framework will harm market competition, threaten technology development in a host of critical industries, and weaken the United States' ability to compete strategically on the international stage.

The Bayh-Dole Act was passed on a bipartisan basis in 1980 to respond to the rampant waste of federally-funded R&D dollars in national labs and large research universities.[[4]](#footnote-4) Congress correctly noted that taxpayer-funded research ended up sitting on the proverbial shelf because licensing was centralized in an opaque federal bureaucracy. Prior to the law's passage, less than five percent of federally-funded inventions were ever licensed.[[5]](#footnote-5)

Bayh-Dole's innovation was simple but revolutionary. The law decentralized licensing decisions to university technology transfer offices, which had every incentive to find private sector partners willing to commercialize their research discoveries.[[6]](#footnote-6) This unleashed a flood of commercial activity that created millions of high-paying jobs, thousands of new startups, and more than $1 trillion in economic output.[[7]](#footnote-7) Across critical sectors including the life sciences, agriculture, telecommunications, semiconductors, and more, Bayh-Dole inventions underpin transformative technologies that save lives, benefit consumers, and ensure the United States' continued technological leadership.[[8]](#footnote-8)

Unfortunately, the proposed framework threatens to dismantle this progress by twisting the triggering provisions for march-in under Bayh-Dole Act to include price – contrary to congressional intent and without an express grant of that authority.[[9]](#footnote-9)

As the White House notes, this is the first time the federal government has asserted a right to forcibly relicense a Bayh-Dole patent solely on the basis of price.[[10]](#footnote-10) Price is not mentioned once in the legislation, and as the authors of the law noted, march-in was never intended to be a tool to lower the price of a Bayh-Dole invention.[[11]](#footnote-11) [[12]](#footnote-12) Over the past four decades, administrations from both parties have consistently rejected repeated requests to twist Bayh-Dole into a price control mechanism.[[13]](#footnote-13)

The negative repercussions of such a move cannot be overstated.

The new framework undermines the patent system, which underpins innovation in a wide variety of high-tech industries. As the USPTO reports, IP-intensive industries account for 41 percent of U.S. GDP and directly employ a third of the American workforce.[[14]](#footnote-14)

Empirical research consistently demonstrates that patents do not confer monopoly power to inventors, but rather encourage competitors to "design around" a patent -- that is, to draw on its basic insight in a way that does not infringe on it.[[15]](#footnote-15) [[16]](#footnote-16) This phenomenon spurs further innovation, resulting in superior consumer welfare gains.[[17]](#footnote-17) Weakening patent protections will slow market competition, keeping prices artificially high and depriving patients and consumers of crucial new products and improvements.

Driving the proposed reinterpretation of Bayh-Dole is the desire for lower drug prices.[[18]](#footnote-18) Setting aside several additional cogent critiques of this position (including that most drugs on the market today are protected by several patents, many of which do not fall under Bayh-Dole[[19]](#footnote-19)), note that the proposed framework applies to all technologies, not just to pharmaceuticals. Bayh-Dole inventions power U.S. leadership in sectors including agriculture, telecommunications, and semiconductors.[[20]](#footnote-20) If federal officials deemed the price of any product derived from federally funded research too high, the government could march in on it.

Not only would the proposed framework reduce market competition in precisely the industries the United States is relying on to maintain strategic dominance. It would also undermine several bipartisan initiatives to leverage government investment and public-private partnerships to promote national security and secure domestic supply chains for critical technologies.

Take, for example, the $52 billion CHIPS and Science Act, which emphasizes "nanotechnology, clean energy, quantum computing, and artificial intelligence."[[21]](#footnote-21) The proposed framework could impose price controls on any start-up or firm that leverages federally-funded research in these sectors. This will inevitably chill private investment in these technologies.

With the United States in a generational competition with China, we cannot afford to weaken our most innovative technologists. A study from last year discovered that Chinese research institutions lead the world in 37 out of 44 critical technology sectors.[[22]](#footnote-22) Damaging the U.S. tech transfer ecosystem, which currently drives a "virtuous cycle" of investment and reinvestment into our top institutions, would be catastrophic for our national security and technological leadership.

In sum, the proposed Framework would twist Bayh-Dole and weaken the U.S. intellectual property system. It is misguided and will harm market competition, consumer access to new technologies, and our strategic global interests in technology leadership. I strongly urge NIST to withdraw this proposed Framework and uphold the Bayh-Dole Act as written. Thank you for the opportunity to comment on this critical issue.

Sincerely,

Alden F. Abbott, J.D.

Senior Research Fellow

Mercatus Center at George Mason University

1. https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the#:~:text=The%20objectives%20for%20the%20Draft,determining%20whether%20to%20march%2Din. [↑](#footnote-ref-1)
2. https://www.mercatus.org/scholars/alden-abbott [↑](#footnote-ref-2)
3. https://www.mercatus.org/scholars/alden-abbott [↑](#footnote-ref-3)
4. https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today [↑](#footnote-ref-4)
5. <https://www.gao.gov/assets/rced-98-126.pdf> pg 3 [↑](#footnote-ref-5)
6. https://www.law.cornell.edu/uscode/text/35/200 [↑](#footnote-ref-6)
7. https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-fillable-for-uploading.pdf [↑](#footnote-ref-7)
8. https://bayhdolecoalition.org/about/#hall [↑](#footnote-ref-8)
9. https://www.politico.com/news/2023/12/06/biden-admin-authority-seize-certain-drug-patents-00130452 [↑](#footnote-ref-9)
10. 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/#:~:text=specifies%20for%20the%20first%20time%20that%20price%20can%20be%20a%20factor%20in%20determining%20that%20a%20drug%20or%20other [↑](#footnote-ref-10)
11. https://www.law.cornell.edu/uscode/text/35/203 [↑](#footnote-ref-11)
12. https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ [↑](#footnote-ref-12)
13. https://bayhdolecoalition.org/digital-library/ [↑](#footnote-ref-13)
14. https://www.uspto.gov/about-us/news-updates/latest-uspto-report-finds-industries-intensively-use-intellectual-property-0 [↑](#footnote-ref-14)
15. [https://ipwatchdog.com/2021/09/01/thomas-edison-consumer-welfare-benefits-patent-enforcement/id=137233/](https://ipwatchdog.com/2021/09/01/thomas-edison-consumer-welfare-benefits-patent-enforcement/id%3D137233/) [↑](#footnote-ref-15)
16. https://academic.oup.com/jcle/article-abstract/17/4/1007/6346445?redirectedFrom=fulltext&login=false [↑](#footnote-ref-16)
17. https://truthonthemarket.com/2021/09/07/more-evidence-that-the-patent-system-promotes-dynamic-competition-and-consumer-welfare/ [↑](#footnote-ref-17)
18. 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/ [↑](#footnote-ref-18)
19. https://onpointanalytics.com/pharma/patent-proliferation/ [↑](#footnote-ref-19)
20. https://bayhdolecoalition.org/about/#hall [↑](#footnote-ref-20)
21. https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chains-and-counter-china/ [↑](#footnote-ref-21)
22. https://www.aspi.org.au/report/critical-technology-tracker [↑](#footnote-ref-22)