



February 5, 2024

VIA: Regulations.gov: NIST-2023-0008

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

ATT: APLU's Response to the *National Institute of Standards and Technology Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*

Dear Under Secretary Locascio,

On behalf of the Association of Public and Land-grant Universities (APLU), thank you for the opportunity to provide input on the draft interagency framework shared in the *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.

APLU is a membership organization that fosters a community of university leaders collectively working to advance the mission of public research universities. The association's U.S membership consists of more than 230 public research universities, land-grant institutions, state university systems, and affiliated organizations spanning across all 50 states, the District of Columbia, and six U.S. territories.

The association and its members collectively focus on increasing access, equity, completion, and workforce readiness; promoting pathbreaking scientific research; and bolstering economic and community engagement. Annually, its U.S. member campuses enroll 4.5 million undergraduates and 1.3 million graduate students, award 1.3 million degrees, employ 1.2 million faculty and staff, and conduct \$48.5 billion in university-based research.

Technology transfer and commercialization are important aspects of public research universities' mission to provide access to high-quality education and foster research and innovation across the country. Public research universities provide the opportunity for faculty and students to create and join the most innovative start-ups in the world. Before Bayh-Dole, many universities and companies avoided collaborating on patented work due to difficulty with

agency petition processes to retain access to a publicly funded patent¹. As a result, fewer than 250 patents were issued to U.S. universities annually. Many discoveries were confined to university laboratories because pre-Bayh-Dole intellectual-property laws did not provide the incentives necessary to justify the business risk of developing these discoveries and making them available to the public. As a direct result of Bayh-Dole, U.S. universities were issued 7,739 patents, spinning off 998 start-ups in 2022 alone.²

In 2017, APLU released a report, *Technology Transfer Evolution: Driving Economic Prosperity*³, delineating expectations of technology transfer offices on campus and how to foster an entrepreneurial culture. Drawing on a deep base of research, the report identified university-based startups as key partners connecting the university with the local economy and innovation ecosystem and the challenges to these partnerships. Using this report and subsequent activities, universities and the entrepreneurship community have been working together to lower barriers and ease the translation of knowledge from the basic research performed at public universities to implementation for public benefit. However, matching research to marketplace needs takes time and dedicated resources, and negotiations around intellectual property agreements are complex. Adding regulations to the technology transfer process, such as the currently proposed framework, that increases complexity will result in fewer new products and innovations in the marketplace.

APLU appreciates the opportunity to provide public comments to ensure that NIST's draft framework will "both fulfill the purpose of march-in rights and uphold the objectives of the Bayh-Dole Act." The Bayh-Dole Act is a pivotal element of the nation's innovation ecosystem, encouraging the use of federally funded research in the private sector. APLU agrees that the benefits of commercialized research should be accessible across the country. Unfortunately, the proposed framework will have negative unintended consequences across the entire R&D ecosystem and is unlikely to significantly impact the cost of prescription medications.

APLU has joined with other higher education associations including AAU, AAMC, ACE, COGR, and AUTM in expressing broad community concerns about this proposal. In this response, APLU conveys specific concerns about the limited efficacy and high degree of unintended consequences of the proposed NIST framework as listed below:

The proposed march-in rights will decrease the innovative partnerships between universities and private enterprise. The consideration of price within march-in petitions will decrease industry's willingness to partner with universities, especially small businesses. The current framework enables small businesses and start-ups to commercialize university research. Yet this process naturally includes an early phase of higher priced first-generation technologies – that are often still unprofitable on a unit basis – to serve as prototypes for the eventual cheaper and more accessible versions of the product. If the patent holder is working to "achieve practical application" and no emergency situations exist, the patent holding company can focus on the work at hand. However, under the new framework, large corporations could submit march-in petitions under the auspices of price. The larger corporation's resources would be used as evidence that they could commercialize the product faster and cheaper. *The result would be a chilling effect on start-up and small business collaboration with universities on basic and*

¹ <https://doi.org/10.1016/j.respol.2006.04.009>

² <https://autm.net/surveys-and-tools/tech-transfer-infographic>

³ <https://www.aplu.org/wp-content/uploads/technology-transfer-evolution-driving-economic-prosperity.pdf>

applied research, such as through the SBIR/STTR programs. At a time when small businesses are on the rise⁴, NIST should consider how the draft framework may reverse or stifle the hard-won progress of the Administration’s small business programs.

Given the potential growth of this type of predatory behavior across all fields, universities and their collaborators will be required to spend more time and resources on risk assessments rather than speeding technology transfer. This comes at a time when universities are looking to increase collaboration with industry and to build the research and development talent pipeline of the future. APLU’s *Driving U.S. Competitiveness Through Improved University-Industry Partnerships* Report⁵ highlights that “industry R&D spending has soared over the past few decades; however, only about one percent of total industry R&D is spent on formal research collaborations with universities, and only 6 percent of university research funding comes from industry.” This gulf between two vital elements of the nation’s research ecosystem would grow wider if companies perceived federally funded basic and applied research performed at universities to be high risk due to the new framework and loss of Bayh-Dole precedent.

The proposed march-in rights framework will affect an insignificant portion of drugs derived from federal support and is unlikely to have the desired impact on drug pricing. APLU and its members are sensitive to the need to address access and affordability of expensive medicines. APLU’s membership includes many universities and colleges hosting medical campuses and conducting clinical research.

As stated in the Administration’s press release on December 7th, the draft interagency guidance framework enables agencies to use march-in when taxpayer-funded drugs are not reasonably affordable⁶. Unfortunately, the draft framework would have minimal effect on the drug pricing ecosystem due to the sparsity of Bayh-Dole covered drug patents. A 2019 study⁷ found that patents for the top selling drugs covered by the Bayh-Dole Act constituted only 2.6% of the total best-selling FDA-approved drugs from 2013-2017. The number of cases with complete Bayh-Dole coverage is 1%, only 2 of the 197 drugs in the Food and Drug Administration’s (FDA’s) Approved Drug Products with Therapeutic Equivalence. While this draft framework will not have an appreciable effect on drug prices, it will have a strong effect on many elements of American innovation and competitiveness.

The proposed march-in could enable petitions to be used by international competitors.

While the Administration’s publicly stated goals are specifically targeted at drug prices, the current interagency framework is written to be technology agnostic. Therefore, the proposed framework could also enable march-in petitions based on price across all R&D agencies. In addition, as the framework does not establish criterion for petitioners, it is possible for international competitors to file a petition. The petitions could be filed on the basis of price and

⁴ <https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/11/statement-from-president-joe-biden-on-record-setting-small-business-applications-2/>

⁵ <https://www.aplu.org/our-work/3-deepening-community-economic-engagement/meeting-workforce-needs/driving-us-competitiveness/>

⁶ <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/>

⁷ Genia Long, Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs, 22 J. MED. ECON. 1261, 1262, 1264 (2019)

target subjects important for our national defense and research eminence such as advanced manufacturing, artificial intelligence, hypersonics, and semiconductors⁸. Small innovative business and universities could be forced to spend time and resources defending march-in petitions from both domestic and foreign competitors.

The proposed march in framework does not uphold the policy and objectives of the Bayh-Dole Act. Senators Birch Bayh (D-IN) and Bob Dole (R-KS) publicly stated that the legislation was never intended to address pricing⁹. Specifically, “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.” The purpose of Bayh-Dole and march-in rights are to increase the number of federal patents being commercialized by industry. Pricing concerns, while in certain cases legitimate, are expressly outside the scope of march-in and can be addressed through other means, such as congressional action or executive order¹⁰.

Since its inception, agencies have maintained the original interpretation of Bayh-Dole that avoids price control. NIH rejected petitions in 2016, and more recently with Xtandi¹¹, explicitly stating that, “NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug.”

The need to address drug prices in the U.S. is a pressing issue that affects millions of citizens. Unfortunately, the proposed framework will not effectively address this problem while creating substantial negative side-effects to the vital university-industry partnerships that power the nation’s innovation engine. We urge NIST and the Department of Commerce to reject the proposed framework and remove the pricing consideration from future iterations.

Sincerely,



Mark Becker, Ph.D.

President

Association of Public and Land-grant Universities

⁸ <https://www.whitehouse.gov/ostp/news-updates/2022/02/07/technologies-for-american-innovation-and-national-security/>

⁹ <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>

¹⁰ <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/>

¹¹ <https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf>