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Congress of the United States Washington, DC 20515

May 29, 2024

The Honorable Laurie Locascio Director of NIST and the Undersecretary of Commerce for Standards and Technology U.S. Department of Commerce

Dear Dr. Locascio:

We write to express profound concern with the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights ("Draft Framework") given the risk it poses to U.S. competitiveness and America's global leadership in technological innovation. The proposal would enable the use of march-in as a misguided tactic to control the prices of a broad range of products derived from government funded research, and it would defeat the purpose of the authorizing statute, which was to promote the transfer of technology from the lab to the market.

Aside from the Draft Framework's radical departure from agency precedent under both Republican and Democratic presidents, upending the marketplace for federally supported inventions will send the U.S. back to a time when private enterprise refused to license government-funded research for practical application, leaving valuable research undeveloped, while nonetheless divulging it for other countries and foreign enterprise to develop. In response, Congress enacted the Patent and Trademark Law Amendments Act of 1980, or the Bayh-Dole Act as it is commonly referred to today, with the goal to promote U.S. competitiveness by encouraging the domestic development and commercialization of products derived from government funded research. Now the agency seeks to reinterpret provisions of the law in the Draft Framework undermining the central goal of the Bayh-Dole Act of keeping government-funded inventions from languishing. This radical departure from longstanding precedent would put our nation's leadership in technological innovation at risk.

The Bayh-Dole Act is widely recognized for its role in bolstering American innovation.¹ Previously, Congress sought to ramp up federal funding for scientific research to facilitate space exploration and promote national security during the Cold War. But at the time, the commercial benefit of the discoveries funded by the American government had no real practical benefits for the American taxpayer. The government retained ownership of the underlying intellectual property rights and all too often failed to license those rights for commercial development. Prior to the 1980 Bayh-Dole Act, the government licensed *only* 5% of its patents to the private sector.²

While the benefits of billions of dollars in taxpayer-funded discoveries went unused domestically, intense competition to U.S. leadership in technology innovation emerged elsewhere. Congress responded by passing Bayh-Dole, a system that permits universities, non-profits, and businesses to own patents forged from research supported by the U.S. government. The Bayh-Dole Act enabled these entities to license and commercialize their inventions, and in turn incentivized further private investment into federally supported research to transform those discoveries into useful products to benefit the greater public good.

The Bayh-Dole Act has been an unmitigated success. As a result of the innovation engine it created, from 1996 to 2020, the Bayh-Dole system in academic research generated \$1.9 trillion in U.S. gross industrial output, contributed \$1 trillion to the nation's gross domestic product, supported 6.5 million jobs, helped to form 17,000 startups, and created nearly half-a-billion individual inventions.³ In fact, U.S. university patents exploded after Bayh-Dole, increasing from 390 patents in 1980 to 3,088 in 2009, to 6,680 in 2015.⁴ The growth in public and private sector collaboration that followed also allowed many universities and other institutions to set up or expand robust systems of technology transfer to facilitate the commercialization of products from federally funded research, which, in turn, produces revenue for our universities that funds further research.

The Bayh-Dole Act's reliable allocation of ownership of intellectual property rights plays a critical role in attracting private investment. It becomes untenably risky to invest in the development of basic research if the government could later arbitrarily rescind the underlying license agreement, thereby eliminating the prospect of a return on investment. Because the Bayh-Dole Act further requires universities and other non-profits to reinvest Bayh-Dole patent

4 https://itif.org/publications/2023/08/18/maximizing-nih-levers-to-catalyze-technology-transfer/
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¹ The Economist, Technology Quarterly, December 2002. Available at: https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose

² Government Accountability Office (GAO), Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions (July 27, 2009), available at http://www.gao.gov/products/GAO-09-742

³ https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf

revenues back into scientific research and education,⁵ the Draft Framework would disrupt the virtuous cycle of recapturing funds to support additional scientific research and discovery in the U.S.

The system Bayh-Dole created, now emulated by countries around the world, is a system that has served our nation and economy well.⁶ Yet, when our nation's global leadership is under significant threat, the Draft Framework would contravene decades of America's efforts to promote public-private collaboration, and foster the development of new, innovative products. In line with our domestic policy, the World Intellectual Property Organization (WIPO) has extolled the importance of replicating the Bayh-Dole system by helping member states establish technology and innovation support centers to promote the commercialization of state-sponsored research.⁷ The Draft Framework would retreat from years of publicly supported research to bolster global competitiveness at a time when our country needs it the most.

As we face unprecedented challenges from foreign adversaries and competitors, many of whom have emulated the Bayh-Dole regime, we cannot afford to reverse course and abandon Bayh-Dole as proposed by the Draft Framework. The Draft Framework will make the U.S. less competitive, less attractive to investment, and less conducive to promoting scientific progress. As Undersecretary and the Director of NIST, you have the power to prevent that by withdrawing the Draft Framework, and we urge you to do so. Instead, we encourage you to look for opportunities to further leverage the Bayh-Dole model of public-private partnerships to promote more research and investment in the United States.

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⁵ 35 U.S.C. § 202(c)(7)(C).

⁶ National Innovation Policies: What Countries Do Best And How They Can Improve 5, GLOBAL TRADE & INNOVATION POLICY ALLIANCE (June 2019), available at https://www2.itif.org/2019-national-innovation-policies.pdf

^TWorld Intellectual Property Organization, "Technology and Innovation Support Centers,"

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