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July 30, 2018

Via email: roi@nist.gov

Response of the Center for Individual Freedom on the U.S. National Institutes for Standards and Technology's Request for Information Regarding Federal Technology Transfer Authorities and Processes (Docket Number 180220199-819-01)

On behalf of over 300,000 supporters and activists across the nation, the Center for Individual Freedom (CFIF) hereby responds to the United States National Institutes for Standards and Technology's (NIST's) May 1, 2018 Request for Information (RFI) Regarding Federal Technology Transfer Authorities and Processes, as part of its "effort to refocus Federal technology transfer on sound business principles based on private investment."

America's system governing technology transfer remains a critical aspect of the U.S. research ecosystem, providing innumerable public benefits from products that enter the consumer marketplace as well as the jobs generated through continued research and development of those inventions. We must protect the system that has proven effective and avoid unwise alterations that would jeopardize our world-leading record of success.

The transfer of technology - defined as "the process of transferring scientific findings from one organization to another for purpose of further development and commercialization" - plays a critical role in America's position as the world's leading economy and most innovative nation.¹ In typical circumstances, entities execute technology transfers by protecting their inventions via patents, and subsequently licensing those patented inventions to third parties.

As the NIST has itself acknowledged, "existing federal technology transfer laws have served the Nation well over nearly four decades." The NIST's acknowledgement stands as testament to the success of the Bayh-Dole Act, which became law in 1980 and created the uniform framework for technology transfer of federally sponsored research to the private sector. Among other impacts, Bayh-Dole has allowed universities, small businesses and nonprofit institutions that received federal government support to retain title to patents covering inventions arising from federally funded research, in turn enabling them to license those inventions to private sector partners that could then commercialize them.

Over the four decades since enactment, the Bayh-Dole Act has proven immensely successful in facilitating timely and effective commercialization of federally funded research. Prior to Bayh-Dole, a

¹ AUTM, About Technology Transfer. Available at: <https://www.autm.net/autm-info/about-tech-transfer/about-technology-transfer/>.

minuscule 5% of government-owned patents had been licensed for private sector use.² By 2016, however, over 1,000 startup companies have been formed, and nearly 800 commercial products emerging from university research were introduced into the market.³ Between 1996 and 2015 alone, licensing activity triggered by Bayh-Dole added approximately \$591 billion to U.S. gross domestic product (GDP), and supported an estimated 4.2 million American jobs across all industries.⁴

In addition to acknowledging the success of technology transfer laws, however, the NIST also seeks input regarding "the issues that pose systemic challenges to the effective transfer of technology ... resulting from Federal R&D." Among the identified issues are "Limitations to intellectual property rights, such as ... industry concern about the scope of required government use licenses and whether and under what circumstances the government may exercise march-in rights."

Simply and directly stated, no need to modify the scope of "march-in rights" exists.

The Bayh-Dole Act granted federal funding agencies limited authority - march-in rights - to ensure timely and effective commercialization of federally funded research by requiring owners of patents developed via federal funding to grant additional licenses for use of those technologies. That march-in authority, however, may only be exercised by federal funding agencies under limited circumstances, such as where a current licensee fails to achieve practical application of the subject invention, or fails to reasonably satisfy public health or safety needs.

Expanding those march-in rights beyond the scope intended and established by Bayh-Dole would introduce unnecessary and destructive uncertainty into the innovation sector, and reduce the willingness of private industry enterprises to invest in commercialization of inventions that receive government funding support. As the Congressional Research Service (CRS) reported in 2012, "one of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."

Accordingly, unnecessarily broadening march-in rights would create a chilling effect upon collaboration and innovation, leaving promising inventions to languish on academic shelves.

Additionally, CFIF believes that the license to funding agencies authorized in the Bayh-Dole Act should remain limited to government purpose use. Bayh-Dole grants the federal government "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the Subject Invention throughout the world" in exchange for federal funding.⁵ That ensures that private industry possesses sufficient interest to invest in federally funded inventions, while also providing the funding agency the ability to use for its own purposes an invention that it helped fund. That scope of government license remains appropriate, as illustrated by the Act's demonstrable record of success over four decades since its enactment, and should not be altered.

Despite the Bayh-Dole Act's manifest record of success and fecundity over nearly 40 years, discrete opportunities for improvement exist. As one example, the federal government can help maintain

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

³ AUTM, Statistics Access for Tech Transfer Database. Available at: [http://www.autm.net/resources-surveys/research-reports-databases/stat-database-\(1\)/](http://www.autm.net/resources-surveys/research-reports-databases/stat-database-(1)/) [Last accessed 22 January 2018].

⁴ Lori Pressman, Mark Planting, Robert Yuskavage, Sumiye Okubo, Carol Moylan, and Jennifer Bond, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2015," June 2017, available at: https://www.autm.net/AUTMMain/media/Partner-Events/Documents/Economic_Contribution_University-Nonprofit_Inventions_US_1996-2015_BIO_AUTM.pdf.

⁵ 35 U.S.C. § 202(c)(4).

America's global competitive edge by investing in effective science, technology, engineering and mathematics (STEM) educational programs. The federal government can also work with other stakeholders to build upon existing frameworks for successful university, government and private sector initiatives to enhance research partnerships. Finally, the federal government should more regularly and systematically convene those central stakeholders, including academic research institutions and private industry enterprises, to identify and address potential barriers to effective technology transfer.

Fundamentally, however, the technology transfer regime established in 1980 by the Bayh-Dole Act continues to work effectively, and technology transfer remains a core element of the U.S. research ecosystem. It provides the American public innumerable benefits, including consumer products that enter the marketplace and jobs generated by continuing research and development of subject inventions.

CFIF therefore believes that the most important task to be achieved is protecting a system that works. The Bayh-Dole Act has proven remarkably successful in an era of technological change and an increasingly knowledge-based economy, and we must avoid any disruptions that would jeopardize that record of success. Thank you very much for your attention to this important matter, and please feel free to contact me with any additional questions or concerns.

Sincerely,

Timothy Lee
Senior Vice President for Legal and Public Affairs