



April 5, 2021

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

Re: U.S. Chamber of Commerce Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327); Notice of Proposed Rulemaking regarding Rights to Federally Funded Inventions and Licensing of Government Owned Inventions

The U.S. Chamber of Commerce appreciates the opportunity to submit comments on the National Institute of Standards and Technology's (NIST) Notice of Proposed Rulemaking regarding Rights to Federally Funded Inventions and Licensing of Government Owned Inventions.

The Chamber recognizes the important role innovation plays in our nation's economy and job creation. According to the U.S. Department of Commerce, IP-intensive industries in the innovative and creative sectors are responsible for nearly 40% of our nation's GDP, over 44 million jobs, and over 50% of our trade. The Chamber has long supported a strong domestic IP system that enables our innovative and creative sectors growth and success and appreciates the importance of bringing federally funded inventions to the marketplace as a key driver of our "innovation economy."

Over the past forty years, much of this success has been achieved as a result of the Bayh-Dole Act. The Chamber commends NIST for their efforts to further strengthen the implementation of this landmark legislation which has had such a positive impact on our nation's prosperity and the health and quality of life of our citizens.

The Bayh-Dole Act has been credited for thousands of new products, technologies, and services coming to market. Companies such as Google and products such as high-definition TV's, drones, and FluMist came about through the technology transfer that has occurred since the passage of the Bayh-Dole Act. In addition to helping to bring new products to market, the Bayh-Dole Act has also been an economic catalyst. According to economic reports, in 2019 alone technology transfer generated up to \$865 billion to U.S. GDP, resulted in the creation of 1,040 new startup companies, and, over a 22-year period, up to 5.9 million jobs were created as a result of inventions by universities, hospitals and other public sector research institutions.

Unfortunately, there have been a number of proposals and legislative efforts that would encourage the use of "march-in" provisions in the Bayh-Dole Act in a manner that is inconsistent with the intent of the legislation. The Chamber is especially concerned with efforts to utilize "march-in" to create and implement government controls of prescription drug prices.

According to Sens. Bayh and Dole, in an op-ed they jointly published in the Washington Post, price-based march-in was never intended nor envisioned as an appropriate application of the Act, and as NIST further develops regulatory refinements it must make clear that the march-in provision of the statute will continue to be applied consistent with the original intent of the Act.

The Chamber supports recommendations made by the Association of University Technology Managers (AUTM) on this important issue:

I. BAYH-DOLE MARCH-IN

Clarify that (A) “reasonable terms” as used in the definition of “practical application” in 35 U.S.C. § 203(a)(1) refers to the terms of the license agreement between the contractor/assignee and its licensee and that (B) the end-user price of a successfully commercialized product may not be used as a basis for exercising march-in rights.

These clarifications are needed to ensure the intent of the Bayh-Dole Act, i.e., to turn the federal funding of early-stage research into new products and services, and the resulting improvement in the American standard of living and increased U.S. economic growth, is preserved. As reflected in the public comments that NIST received as part of its ROI Initiative, the Bayh-Dole Act has become an important driver of the U.S. economy while promoting the public welfare.

Nevertheless, concerns remain among universities and their licensees that the march-in provision of the statute will be misused to allow the government to set end-user prices on successfully commercialized products. While such an action is not supported by the statute, it is important to provide reassurance to stakeholders (e.g., universities, licensees and prospective licensees, investors) and federal agencies implementing the law, as even the slightest perceived potential for misuse will have severe detrimental effects on our ability to continue to successfully translate federally funded inventions to the marketplace to improve the standard of living and contribute to the growth of the U.S. economy. Therefore, AUTM supports clarifying the march-in provision of the statute (35 U.S.C. § 203) with the proposed new regulation, 37 C.F.R. § 401.6(e).

However, AUTM recommends two (2) modifications to the proposed language as follows:

*The current proposed language states that “March-in rights shall not be exercised **exclusively** based on the business decisions **of the contractor** regarding the pricing of commercial goods and services arising from practical application of the invention” (emphasis added). Because so much confusion has been generated from misconstruing the words of the statute, AUTM recommends removing (i) the word “exclusively” and (ii) the phrase “of the contractor” so there is absolute clarity that end-user pricing may not be used as a factor in determining whether to exercise march-in rights.*

The Chamber is also concerned that if the Bayh-Dole Act march-in provision is used to control drug prices, it may also lead to proposals to control prices of other products developed through federal government research. Such policies would potentially impact not only the pharmaceutical sector, but also life sciences, environmental sciences, computer sciences, engineering, automotive, and an almost endless array of inventions that could significantly benefit those, and

other, industry sectors. Clearly, this could have a chilling impact on American innovation, the exact opposite of the Bayh-Dole Act's intended purpose.

The Chamber appreciates NIST's work in support of our nation's innovation ecosystem so it may continue to benefit from the technology transfer that has been so significantly enabled by the Bayh-Dole Act. Not only has the Act been an enormous success for America, it has also led to innovations that benefit the entire world.

We stand ready to work with NIST to ensure that any revised regulations only enhance and expand on the last 40 years of success in American innovation resulting from the Bayh-Dole Act.

Sincerely,

A handwritten signature in black ink that reads "Patrick J. Kilbride". The signature is written in a cursive, flowing style with a large initial 'P' and 'K'.

Patrick Kilbride