March 24, 2021

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EAGLE FORUM EDUCATION & LEGAL DEFENSE FUND

Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive MS 2201
Gaithersburg, MD 20899

RE: Notice of Proposed Rulemaking "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," Docket No. 201207-0327

To Whom It May Concern:

Eagle Forum Education and Legal Defense Fund ("Eagle Forum ELDF" or "EFELDF"), a nonprofit organization founded by Phyllis Schlafly[1] in 1981, is pleased to provide comments on "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," Docket No. 201207-0327.

Eagle Forum ELDF appreciates the opportunity to engage in this effort. As the National Institute of Standards and Technology (NIST) knows, we have provided input through NIST's Request for Information (RFI) in 2018,[2] commented on the draft Green Paper of the Return on Investment Initiative for Unleashing American Innovation,[3] and now respond to the proposed revisions to regulations that implement the Bayh-Dole Act.

At the outset, we commend NIST for a constructive, thoughtful, collaborative process and positive recommendations for regulatory and legislative amendment. The proposed changes generally adhere to the Bayh-Dole framework. Thanks to the vision of NIST Director Walter Copan and the leadership of Dr. Courtney Silverthorn, the tree they planted and watered and pruned has borne good fruit.

We begin by opposing the recommendation connecting price with march-in rights, then briefly discuss three recommendations we support. We conclude our comments with a discussion of the larger context in which the Bayh-Dole Act, federal technology transfer, and the commercialization of inventions stemming from federally funded basic research play roles. We believe this broader context should always be kept in mind when crafting laws and rules impinging upon American innovation.

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[1] Phyllis Schlafly was an outspoken advocate of the rights of inventors, emphasizing the importance of these traditional rights to our national prosperity and security. She wrote often about this subject. A compilation of her writings on this topic is *Phyllis Schlafly Speaks: Patents & Invention*. Skellig America, 2018 (Ed Martin, Editor).

[2] Request for Information Regarding Federal Technology Transfer Authorities and Processes, May 1, 2018, Docket No. 180220199-819-01. EFELDF comments dated July 26, 2018.

[3] National Institute of Standards and Technology Special Publication 1234 (December 2018). EFELDF comments dated January 9, 2019.

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March-In Rights
We take issue with one specific proposal that would be counterproductive and is unfounded: the proposal relating to Bayh-Dole's march-in provision. This is the bad apple on an otherwise fruitful tree.

In our comments on the NIST Green Paper draft, we discussed the Bayh-Dole Act's march-in rights. That discussion bears repeating here:

> Regulatory clarification under Bayh-Dole of the statute's march-in rights is badly needed, given the uncertainties injected by creative activists seeking to force change in the application of this emergency-only measure for extra-statutory purpose. Defining when march-in is *appropriate, pursuant to statute*, and clarifying the meaning of "reasonable terms" and "practical application" so as *to definitively exclude price of goods and services* — that is, to codify the original intent of the law's authors, as stated by Sens. Birch Bayh and Bob Dole[4] — would *safeguard the ability of commercializers to rely on the IP exclusivity* that is critical to achieving commercial success and ensuring that private investors will continue to assume the risk involved in bringing an invention to market. *March-in must never be twisted into a means of enacting price controls*[5] (emphasis added).

Proposed Section 401.6 relates to the government's statutory march-in rights. The proposal says that a march-in decision should not be based "exclusively" on a resulting product's "pricing." However, the statute (35 U.S.C. § 203) omits price of goods and services as an element for consideration of whether to exercise march-in. The law provides four narrow grounds for the exercise of march-in rights. Not one of them includes price as a consideration. Therefore, no statutory basis for injecting product price into march-in exists.

We can only conclude that the absence of "price" or "pricing" in the underlying statute itself leaves no room for introducing just such a new, substantive term in regulation. To do so as proposed would exceed the metes and bounds of the statute and, thus, is not permissible. The term "pricing" must be stricken from the proposed revision, or otherwise be clearly excluded from consideration, if the rule is to accord with the statute.

When a novel theory urging the government to march-in based on product price was floated, Sens. Bayh and Dole confirmed they omitted price on purpose, writing: "The

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[4] Letter to the Editor from Sens. Bayh and Dole, *Washington Post*, "Our Law Helps Patients Get New Drugs Sooner" (April 11, 2002).
[5] At pp. 3-4, EFELDF January 9, 2019, comment letter on NIST Green Paper Discussion Draft.

law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional ....”[6]

In addition, including the term “exclusively” in connection with “pricing” in the rule does not reduce the weight of “pricing” as an element considered for whether or not to invoke march-in. Because consideration of “pricing” is not allowed by the statute, considering “pricing” nonexclusively is statutorily prohibited. March-in may not legitimately be based on “pricing,” whether based “exclusively” or otherwise on pricing. Further, this addition would open wide the doors to belligerent actors bent on turning march-in into price controls. The “exclusively” element merely would require them to dress up their petitions with other bases. The extra-statutory damage would be done by exceeding the limits of the statute in the first place by injecting “pricing.” Its qualifier cannot save the proverbial patient’s life after that point.

Despite numerous efforts to goad the government to abuse Bayh-Dole’s march-in provision, officials of both Democratic and Republican administrations have uniformly refused to base march-in on price. March-in has never been invoked. Bipartisan prudence, rejecting this power’s use, including on the basis of a product’s price, over 40 years’ time is strong evidence of the illegitimacy of the underlying assertion. They have found no basis in the law; that should be good enough for corresponding regulation.

Therefore, we urge NIST to remove the references for considering “pricing” from the proposed regulatory provision. As proposed, the provision would be inconsistent with the statute with this word. The effect could be highly disruptive and damaging to technology transfer and commercialization of the inventions and discoveries arising from federal research funding.

The proposal in its current form could be the equivalent of the National Institutes of Health’s (NIH) CRADA catastrophe. In 1989, first NIH required a “reasonable pricing” provision in its Cooperative Research and Development Agreement (CRADA) contracts in order to obtain an exclusive license to NIH-funded technologies. The pricing measure caused tech transfer from the agency to fall precipitously until NIH removed the pricing requirement six years later.

Bayh-Dole has yielded tremendous practical benefits. But injecting “pricing” considerations into march-in regulations would place these benefits of practical usage for taxpayers and society at great risk.

Notable Positive Proposals

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[6] Bayh and Dole, *Washington Post* letter, op.cit.

Among NIST's other proposals, we comment on three of the proposals, which we support and suggest expansions on.

First, Section 401.13 recommends confidential treatment of business information contained in contractors' submissions. Agencies would be expected not to disclose confidential, proprietary information, whether in Freedom of Information Act (FOIA) or other requested public disclosures by third parties that have no need to know this sensitive information. This revision would assure contractors that their business information remains secure. This directly affects the success or failure of efforts to develop products and services, along the path of commercialization of the invention derived from federal research funds. EFELDF supports this proposal. Further, augmenting this proposal to provide blanket confidentiality protection of all "subject invention" information would further safeguard contractors' sensitive business information that should not be disclosed. Such expansion should be considered.

Also, Section 401.14(a)(2) would clarify limits of the government's right to use a "subject invention." The proposed language would make clear that the government does not have rights of use to a contractor's privately funded inventions. Such clarification makes doing business with the government more attractive. This provision would protect all privately funded inventions from the government using contractors' other inventions beyond the "subject invention," thereby aligning with the process of discovery and invention and respecting contractors' work on other projects using private investment.

Finally, Section 401.14(d)(2) as proposed would allow agencies to waive taking title to a contractor's invention in instances of noncompliance with certain requirements, such as reporting deadlines. This enables agencies to cure noncompliance of form-and-manner and similar minor violations. EFELDF supports this revision, viewing it as constructive and reasonable. Loss of title to intellectual property often has a significant, detrimental impact on a contractor. This is especially so for small businesses and entrepreneurs building an IP-centered business. We favor this recommendation.

The Broader Context

As with other areas of law and regulation, these matters do not occur in a vacuum. These laws, policies, and related judicial decisions have real-world effects for the United States and its competitive, economic, and national security status vis-a-vis other nations.

The Bayh-Dole Act set out to democratize the commercialization of the 28,000 U.S. government-owned patents in 1980 and inventions to follow. The Senators faced a situation of federally funded research yielding discoveries, while commercial entities

used only 5 percent of those patents because of government policies that made it difficult, nonexclusive, and unattractive to license them. Bayh-Dole deliberately democratized secure IP protection and commercialization decisions. The certainty, exclusivity, and secure IP rights Bayh-Dole has provided launched many thousands of inventions. patents, startups, and new products, millions of new jobs, and trillions in economic benefit.[7]

Yet, the context for the fruits of Bayh-Dole extend even more broadly. The United States faces global competition with both allies and adversaries. The greatest challenges pertain to China, which has been playing for keeps for many years now and has continued to escalate the stakes for global domination. China intends to surpass the United States and the West. A global microchip shortage, renewed focus on expanding U.S. manufacturing capacity, and technological races in 5G wireless, biopharmaceuticals, quantum computing, and artificial intelligence, for instance, have brought to light the degree to which the United States relies on China for finished products, manufacturing, critical minerals, and the like. As Congress and courts have weakened the U.S. patent system, China has strengthened its own. While special interests and politicians are intent on raiding the fruits of R&D's innovative labor, China is marshaling its whole society in executing a military-civil fusion strategy. The stakes are too high for self-inflicted policies that cut into our innovative edge, of which Bayh-Dole plays a part.

As we said in our comments on the draft Green Paper:

> [W]e reiterate the connection of economic competitiveness to our national security. The daily news reports of Chinese expropriation of U.S. IP, forced tech transfer and joint ventures in China, Chinese theft and espionage schemes that result in stolen sensitive U.S. information and Chinese agents proliferating throughout the United States demonstrate how true this is — and how serious the Chinese are about winning this competition for technological dominance. We appreciate the following from page 35 of the Green Paper:
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> "The September 2018 Department of Defense report to the President 'Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States' in response to Executive Order 13806 makes the case for protecting American manufacturing. This report notes that it is imperative to maintain domestic manufacturing capability to meet more than

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[7] Biotechnology Innovation Organization and Association of University Technology Managers, "The Economic Contribution of University/Nonprofit Inventions in the United States, 1996-2015," June 2017. Also, see p. 2, EFELDF January 9, 2019, comment letter, RFI Response: Federal Technology Transfer Authorities and Processes, Docket No. 180220199-819-01.

current production needs with the conclusion that: 'Above all, America's manufacturing and defense industrial base must support economic prosperity, be globally competitive, and have the capabilities and capacity to rapidly innovate and arm our military with the lethality and dominance necessary to prevail in any conflict.'"[8]

We commend NIST for the excellent job it has done on this initiative. The bulk of the recommendations align with the fundamental elements of the Bayh-Dole Act and its 40-year track record of success. With the exception of march-in, it may be expected that these regulatory revisions will serve our nation's innovation needs well, contributing to our economic and military security — two sides of the same coin. It is imperative to allow innovation to flourish and be used in our economy, given China's rapid ascent.[9]

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Eagle Forum Education and Legal Defense Fund appreciates the opportunity to provide comments on the proposed regulatory revisions. We commend NIST's proposals intended to improve obtaining practical returns from federal research investments and to realize America's potential economic and national security benefits. We support this initiative, except for the march-in provision discussed above.

Respectfully submitted,

/s/ Andrew L. Schlafly

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[8] At p. 5, EFELDF January 9, 2019, comment letter.

[9] A report by the Alliance of U.S. Startups and Inventors for Jobs (USIJ) report, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, August 2020, found a significant decline in the share of investment in patent-intensive industries; Bloomberg Innovation Index, in which the U.S. fell out of the top 10, to 11th, while China ranked 16th (Michelle Jamrisko, Wei Lu, and Alexandre Tanzi, "South Korea Leads World in Innovation as U.S. Exits Top Ten," *Bloomberg*, February 2, 2021); William A. Galston, "How to Step Up the Tech Fight Against China," *Wall Street Journal*, March 3, 2021.