BEFORE THE

United States Department of Commerce
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, Maryland 20899

In the Matter of:	)	
Notice of Proposed Rulemaking Regarding	)	**Docket No.: 201207-0327**
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions	)	

COMMENT OF CENTER FOR INDIVIDUAL FREEDOM
ON PROPOSED CHANGES TO REGULATIONS THAT SUPPORT THE UNIVERSITY AND SMALL BUSINESS PATENT PROCEDURES ACT OF 1980, COMMONLY KNOWN AS THE "BAYH-DOLE" ACT OF 1980"

April 5, 2021

I. Introduction

"Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with taxpayers' money."[1]

That was *The Economist* magazine's assessment of the Small Business Patent Procedures Act of 1980, 35 U.S.C. §§200, *et seq.*, commonly known as the Bayh-Dole Act, the statute at issue in the instant Notice of Proposed Rulemaking. It is in that same spirit that the Center for Individual Freedom

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[1] https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose

(hereinafter "CFIF") submits this Comment. CFIF is a non-profit, non-partisan 501(c)(4) organization with over 300,000 grassroots supporters and activists across the United States, established in 1998 for the purpose of safeguarding and advancing Constitutional rights, technological innovation, free market principles and fidelity to the rule of law.

As a central part of that mission, CFIF advocates for public policies that preserve the United States of America's standing as the world's most innovative nation for, among other things, pharmaceutical advances, and that ensure the American public maintains access to the safest, most effective and most comprehensive array of life-saving and life-improving pharmaceuticals possible. The Bayh-Dole Act at issue in this Proposed Rulemaking advances those objectives, and it is on that basis of preserving its ongoing value that CFIF respectfully submits this Comment.

II. Discussion

Strong patent protections provide the foundation for American pharmaceutical innovation, which continues to account for a remarkable two-thirds of all new drugs introduced to the world.[2] In the famous words of former patent attorney Abraham Lincoln, strong U.S. patent rights "added the fuel of interest to the fire of genius."

In addition to patent protections deliberately inserted into the text of Article I of our Constitution by the Founding Fathers, that legacy rests significantly on the Bayh-Dole Act, passed in 1980 to grant universities, nonprofit organizations and small business the right to patent and license inventions funded partly by federal funding. Prior to passage, ownership rights remained with the federal government itself, which brought less than 5% of its tens of thousands of patents to consumer

[2] Macher, J.T. and Mowry, D.C., Innovation in Global Industries: U.S. Firms Competing in a New World, Washington, D.C., The National Academies Press (2018).

markets.[3] The Bayh-Dole Act quickly remedied that shortcoming, as celebrated by *The Economist* and detailed by Information Technology and Innovation Foundation (ITIF) Vice President Stephen Ezell:

> *Prior to the Bayh-Dole Act, when the federal government retained ownership of the innovations it funded, very few were ever commercially produced. Only 390 patents were awarded to universities in the year the act was passed. But in 2017, that number had increased to nearly 7,500. In fact, more than 100,000 patents have been issued to U.S. universities or nonprofit research institutes between 1996 and 2017, resulting in more than 420,000 inventions and 13,000 startup companies formed.*[4]

The Bayh-Dole Act – which counted then-Senator Joe Biden among its sponsors – succeeded so remarkably because it incentivized innovation by expanding patent rights and unleashing free market cooperation.

Alarmingly, however, some political leaders and commentators seek to undermine patent rights by exploiting a "march-in" provision within Bayh-Dole to empower the federal government to commandeer new drugs and license the patents on inventions partially funded by federal dollars to third parties. In that vein, two isolated terms included in the Proposed Rule as currently drafted could open a counterproductive window for future disruption, with potentially harmful consequences. According to their flawed logic, the market prices of some drugs render them insufficiently available to the general public, and on that basis they encourage federal bureaucracies to forcibly license those drugs' patent rights to other third parties for manufacture and sale.

That would constitute a frontal assault against private pharmaceutical innovators, disregarding their patent rights and the enormous investments they've made over years and decades to conceive,

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[3] http://web.mit.edu/lawclub/www/Bayh-Dole%20Act.pdf

[4] https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system

perfect, produce and distribute those drugs. It would also contravene the statutory terms of Bayh-Dole itself, which allows four bases for "march-in" authority, none of which include pricing:

(1) Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) Action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.[5]

Indeed, Senators Birch Bayh and Bob Dole jointly and unequivocally confirmed that the law bearing their names did not intend or allow cost to become a mechanism for imposition of *de facto* drug price controls:

> *Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. 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.*[6]

That straightforward truth explains why the National Institutes of Health (NIH) has rejected every one of the twelve march-in petitions that it has received during the Bayh-Dole Act's 41-year

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[5] 35 U.S.C. § 203.

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

existence. It has consistently and correctly ruled that attempts to leverage price allegations to justify march-in would undermine the very goal of the act and ultimately harm American consumers.

Critics nevertheless allege that federal funding toward pharmaceutical research justify government march-in intrusion, falsely claiming that pharmaceutical innovators somehow enjoy a free ride at taxpayer expense. The truth is very different. Private funding for research and development actually dwarfs public funding. According to the NIH itself, private sector R&D amounted to five times NIH funding in 2015 alone, $150 billion to $30 billion.[7] In 2018, as another example, the NIH spent $3 billion on clinical trials involving new or existing drugs, compared to $102 billion in R&D by the U.S. biopharmaceutical industry.[8] Indeed, the pharmaceutical industry stands as the single largest source of business R&D funding in the U.S., accounting for 17.6% of all U.S. business R&D. The next-closest counterpart is the software sector at 9.1%, with the automobile industry at 5.9% and the aerospace industry at 4.1%.[9]

Accordingly, the real-world R&D data reveal that Bayh-Dole has fueled pharmaceutical R&D investment, not provided it some sort of free ride. There is simply no textual or logical basis for advocating march-in actions under Bayh-Dole on the basis of market prices. Pharmaceutical innovation demands billions of dollars in sunk costs of investment, not to mention potential product liability lawsuits for any errors. Strong patent protections, which Bayh-Dole codifies, help ensure that those costs and risks will be fairly and sufficiently rewarded. They provide innovators and investors the incentives to create pharmaceuticals that save millions and even billions of lives worldwide.

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[7] National Institutes of Health, 2015, *Funding Facts, All NIH*, Fiscal Year 2015 – Awards – Funding (Total Cost) – All (In Aggregate), https://reports.nih.gov/fundingfacts/fundingfacts.aspx.

[8] https://grants.nih.gov/policy/clinical-trials/why-changes.htm; https://catalyst.phrma.org/study-finds-the-pharmaceutical-industry-retains-a-smaller-share-of-revenue-than-research-intensive-industries.

[9] https://www.phrma.org/en/Advocacy/Research-Development; https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf.

The Proposed Rule currently at issue explicitly seeks to provide clarifications on the scope of march-in rights. More specifically, it formally codifies the text and intent of Bayh-Dole that march-in rights cannot be used as a means to impose drug price controls, stating 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 the practical application of the invention."

Inclusion of the terms "exclusively" and "of the contractor" unfortunately open the door for critics to suggest that business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of inventions may serve as one basis for exercising march-in rights. On that basis we urge that the Proposed Rule omit those terms. It would contravene the very text of Bayh-Dole, as well as its underlying intent as expressed by Senators Bayh and Dole themselves, and potentially undermine the innovation that the act sought to advance.

Apart from that potentially detrimental terms "exclusively" and "of the contractor," the Proposed Rule can provide greater clarity and certainty to universities and other private innovators that Bayh-Dole will continue to protect patent rights and expectations. That can propel investment and innovation in future decades, in the same way that it has since passage in 1980. As *The Economist* highlighted, Bayh-Dole stands among the most beneficial statutes in recent American history, and the Proposed Rule must be crafted in a manner that extends that legacy, rather than undermines it.

III. Conclusion

For the reasons set forth herein, CFIF supports full implementation of the Proposed Rule in accord with the Bayh-Dole Act's underlying provisions and intent, which prohibits cost as a basis for march-in actions whether "exclusively" or otherwise, and offers the invaluable legal certainty upon which universities and private companies rely to invest more robustly in research and development of publicly funded concepts, which in turn results in lifesaving pharmaceutical innovations for the United States and the world.

Respectfully submitted,

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