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VIA ELECTRONIC FILING

National Institute of Standards and Technology (NIST)
U.S. Department of Commerce
100 Bureau Dr.
Gaithersburg, MD 20899

Re: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions (Docket No. 201207–0327)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments in response to NIST's January 4, 2021 Notice of Proposed Rulemaking (NPRM) on 37 C.F.R. Parts 401 and 404, the implementing regulations of the Bayh-Dole Act (hereinafter "Bayh-Dole" or "the Act").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

PhRMA's comments in response to the NPRM focus on two sections in the proposed rulemaking:

- 37 C.F.R. § 401.6, in which NIST seeks to clarify the procedures that govern the exercise the march-rights of agencies as set forth in 35 U.S.C. § 203; and
- 37 C.F.R. § 401.14, in which NIST seeks to clarify the standard patent rights clause to be used in each federal funding agreement pursuant to 37 C.F.R. § 401.3.

The biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling diseases like Alzheimer's, heart disease, and, most recently, COVID-19. This is made possible by America's system of intellectual property (IP) protections. Strong and predictable intellectual property (IP) protections in the United States are essential to the United States' economic well-being, and signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. IP-intensive manufacturing industries drive

[1] NIST, Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 37 C.F.R. Parts 401 and 404, RIN 0693-AB66; Docket No. 201207-0327 (Jan. 4, 2021).

economic progress and collectively support 57.6 million American jobs and the biopharmaceutical industry supports a total of more than 4.7 million jobs, contributing $1.3 trillion in economic output when direct and indirect effects are considered.[2]

The Bayh-Dole Act helped establish a culture of entrepreneurship in America's universities and research institutes by creating a well-defined path for ownership and development rights for university researchers and spin-offs.[3,4] As a 2012 Congressional Research Service report stated, "one of the major factors in the reported success of the Bayh-Dole Act is the *certainty it conveys concerning ownership of intellectual property*."[5] In addition, as the then Director of the United States Patent and Trademark Office (USPTO) previously noted, "when patent owners and the public have confidence in the patent grant, inventors are encouraged to invent. Investments are made. Companies are created and grown. Jobs are created and science and technology advance."[6] Collectively, clear IP ownership by the grantee along with the certainty of exclusive licensing terms established under the Bayh-Dole Act have helped foster licensing of technology resulting from federal funding for use by private sector entities to advance biomedical research.

We believe the proposed changes to the implementing regulations of Bayh-Dole help maintain the balance of rights between innovators, contractors, licensees, and the federal agencies that contribute funding for early-stage research.

The NPRM Helpfully Clarifies the Scope and Procedures for the Exercise of March-In Rights.

PhRMA welcomes NIST's implementation of its findings and strategies developed from its 2018 "large-scale stakeholder engagement effort to inform" in order to "improve the transition of federally funded innovations from the laboratory to the marketplace by reducing the administrative and regulatory burdens for technology transfer and increasing private sector

[2] PhRMA, IP in the Economy, *available at* https://www.phrma.org/Advocacy/Intellectual-Property; TEConomy Partners, The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners (Nov. 2017).
[3] President's Council of Advisors on Science and Technology (PCAST), Report to the President — Transformation and Opportunity: The Future of the U.S. Research Enterprise (Nov. 2012), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf.
[4] D'Este P, Perkmann M., Why do academics engage with industry? The entrepreneurial university and individual motivations, 36 J. Technol. Transf. 316–39 (2011).
[5] Schacht, W., The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service Report 7-5700 (Dec. 3 2012), *available at* https://fas.org/sgp/crs/misc/RL32076.pdf.
[6] Andrei Iancu, Director of U.S. Patent and Trademark Office, Comments at NIST Symposium Presentation (Apr. 19, 2018), *available at* https://www.nist.gov/tpo/return-investment-roi-initiative/unleashing-american-innovation-symposium.

investment in later-stage research and development (R&D)"[7] by addressing concerns raised by stakeholders in regards to march-in rights.[8]

PhRMA supports NIST's efforts to improve certainty afforded to stakeholders regarding the use of march-in rights and the process for exercising march-in rights by its proposed changes to 37 C.F.R. § 401.6. As discussed further below, such changes (1) clarify the statutory bases for initiating march-in proceedings, (2) codify the "informal consultation" process when a funding agency is considering the exercise of march-in proceedings, and (3) amend the timeline for the agency deliberation period.

1. Proposal to clarify Section 401.6 in Regards to Pricing Decisions as an Exclusive Basis for March-In

NIST has helpfully proposed to "[c]larify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention."[9] This proposal is in line with Strategy 1 of NIST's "Return on Investment Initiative" Final Green Paper (hereinafter "Final Green Paper"),[10] which PhRMA supports. As discussed by the Final Green Paper and reflected in the plain language of the statute itself, Congress specified the limited conditions that must be met in order for the funding agency to exercise its march-in rights, none of which include the pricing of a Bayh-Dole subject invention.[11] Yet, despite the limited grounds for march-in provided by Congress, of the twelve requests to initiate march-in proceedings that the National Institutes of Health (NIH) has received, ten were based solely upon pricing decisions made in relationship to the subject invention price.[12]

NIH has consistently "determined that the use of march-in to control drug prices was not within the scope and intent of its authority"[13] and yet NIH has had to repeatedly consider whether the pricing of a drug embodying a subject invention alone provides sufficient grounds for march-in. This creates additional burden on the funding agencies to consider the question anew, which wastes agency resources. It also creates uncertainty for contractors and their licensees given the unknowns of adjudicatory proceedings and the possibility of an agency making a determination that is inconsistent with prior NIH determinations. Requiring funding agencies to

[7] RIN 0693-AB66 at 36.
[8] NIST, "Return on Investment Initiative: Final Green Paper," NIST Special Publication 1234, 31-32 (Apr. 2019), *available at* https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf.
[9] RIN 0693-AB66 at 37.
[10] NIST, "Return on Investment Initiative: Final Green Paper," NIST Special Publication 1234, 28 (Apr. 2019), *available at* https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf.
[11] 35 U.S.C. § 203(a).
[12] NIST, Final Green Paper at 29.
[13] NIST, Final Green Paper at 29.

consider non-statutory bases for march-in proceedings introduces market uncertainty in collaborations with publicly-funded entities that could ultimately reduce the licensing and development of early-stage technologies, a scenario the Bayh-Dole Act was enacted to eliminate.

The original sponsors of the Act, Senators Birch Bayh and Bob Dole, have published statements noting that the "Bayh-Dole [Act] 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…The ability of the government to revoke a license granted under the [Act] is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from [federally] funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product," among other circumstances."[14] These post-enactment statements are consistent with the stated original intent of the Act, which was to ensure commercial access to subject inventions made by research entities that may have received federal funding but were not equipped to commercially launch a product.[15] At the time of Bayh-Dole's enactment, the U.S. government owned 28,000 patents, of which only 4% had been developed as a product for use by American consumers.[16] This left a state of affairs where "[t]he taxpayers were getting no benefit whatsoever" from taxpayer funded research that resulted in "embryonic stages of development" and often required "millions of dollars [] to produce the sophisticated products necessary for marketability."[17] The concern that early-stage research into biopharmaceutical or medical fields was gathering dust on university shelves led President Johnson to state, "[w]e must make sure that no life-giving discovery is locked up in the laboratory."[18]

To remedy this state of affairs, the Senate identified the important role private industry partners could play to commercialize Bayh-Dole subject inventions that were often in the early-stages of development. Congress noted that much of federal funding provided in support of research "is spent in basic research," which is "not specifically geared to producing new inventions, but seeks to expand the frontiers of knowledge."[19] Although, "[p]atentable inventions often arise as unexpected by-products of this research effort…[t]he funding agency is rarely in a position to develop these reported inventions."[20] However, collaborating with or licensing to industry partners who have the experience and resources needed allows the transformation of a product from early-stage research to a commercially-available product. And

[14] NIST, Final Green Paper at 30, *citing* Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Wash. Post (Apr. 11, 2002).
[15] *See* Report of the Committee on the Judiciary of the United States Senate on S.414 (Dec. 12, 1979).
[16] Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004).
[17] Report of the Committee on the Judiciary of the United States Senate on S.414 (Dec. 12, 1979).
[18] Sen. Jud. Comm. Report at 20.
[19] Sen. Jud. Comm. Report at 19.
[20] Sen. Jud. Comm. Report at 19.

it is in this conceived goal of commercially-available subject inventions that the scope of march-in rights is correctly understood.

As such, PhRMA supports NIST's proposal to create a clarification consistent with the original intent and plain language of the statute in Section 401.6. NIST's articulation of the lack of statutory basis to exercising march-in rights on the basis of pricing decisions helpfully provides clarity and certainty to stakeholders. Indeed, the statute provides authority for a Federal agency to exercise march-in rights when it determines action is needed for a list of specific reasons that notably does not include pricing decisions. Accordingly, PhRMA believes that NIST should remove the word "exclusively" from the proposed language. Further, in order to reflect the full scope of stakeholders in transforming subject inventions into commercially available products, PhRMA proposes modifying the provision to include subject-invention licensees as follows (proposed changes are in **bold and strikethrough**):

- 37 C.F.R. § 401.6(e): "March-in rights shall not be exercised ~~exclusively~~ based on the business decisions of the contractor **or licensee** regarding the pricing of commercial goods and services arising from the practical application of the invention."

In summary, we appreciate NIST's clarification of the current and long-standing understanding of the scope of march-in rights to be based on the commercial availability of a subject invention and the lack of statutory support for march-in proceedings to be initiated on the basis of pricing decisions. We respectfully ask that NIST consider our suggestions which clarify the applicability of the provision to contractors and licensees.

2. Proposal to clarify the informal consultation process prior to initiating march-in proceeding

We commend NIST's proposed requirement that Federal agencies request "an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue and consider possible actions other than exercising march-in rights."[21] NIST's proposed change provides an opportunity to include contractors' perspective, increases communication between private industry title-holders or licensees and funding agencies, and reduces the burden placed on funding agencies that receive march-in requests by bringing the contractor or title holder into the fact-finding process. Further, it codifies an existing agency process[22] and creates opportunities for collaborative discussions regarding any potential consumer access issues. Additionally, this proposal furthers the purposes of Bayh-Dole by

[21] RIN 0693-AB66 at 36.

[22] *See, e.g.,* Francis Collins, *Determination in the Case of Fabrazyme®*, Nat'l Inst. of Health (Dec. 1, 2010) (NIH worked with the manufacturer to provide a timeline for the increase of production, monitored patient access to *Fabrazyme®*, and worked with third parties to provide monthly reports on the status of patient access).

incentivizing the commercialization of Bayh-Dole products while reserving march-in for a last resort after a fulsome agency process.

PhRMA also respectfully requests that NIST consider modifying the final provision to include consultation with other title holders, including exclusive licensees, of which they are aware:

- 37 C.F.R. § 401.6(a)(1): Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor **and/or the exclusive licensee if known** in writing (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor **and/or known exclusive licensee** to understand the nature of the issue and consider possible actions other than exercising march-in rights.

In many instances, exclusive licensees possess important information demonstrating efforts to commercialize a subject invention or the successes achieved in a commercial product incorporating a subject invention. Although Federal agencies may be willing to engage with title holders, in some instances there have been situations where such agencies have expressed hesitancy to engage exclusive licensees. Allowing all subject invention title holders, including exclusive licensees, to participate facilitates and accelerates the exchange of information, improving the results of the informal consultation for all stakeholders.

3. ***Proposal to increase the allowable time frame an agency has to respond to the contractor following informal consultation***

We support NIST's proposal to increase the allowable time frame an agency has to respond to the contractor or potentially exclusive licensee following the informal consultation from 60 days to 120 days.[23] We also respectfully request that the allowable time frame for a contractor, or the exclusive licensee if appropriate, respond to the agency request be increased a proportional amount from 30 days to 60 days as proposed below.

[23] RIN 0693-AB66 at 36-37.

- 37 C.F.R. § 401.6(a)(1): "… In the absence of response from the contractor **and/or the exclusive licensee if known** to the agency request for informal consultation within **60** days, the agency may, at its discretion, proceed with the procedures below. If informal consultation occurs within **60** days, or later if the agency has not initiated the procedures below, then the agency shall, within 120 days after informal consultation, either notify the contractor **and/or the exclusive licensee if known** of the initiation of the procedures below with a summary of the efforts taken, or notify the contractor **and/or the exclusive licensee if known**, in writing, that it will not pursue march-in rights on the basis of the available information."

The proportional and commensurate additional time provided to contractors, or exclusive licensees if appropriate, will allow a more fulsome response from contractors or their exclusive licensees to funding agency requests, increasing the efficiency of the informal consultation. Further, if a contractor needs additional information from their exclusive licensee in order to respond to the funding agency request, the additional time will facilitate the further exchange of information and can reduce subsequent delays that may result from hastily prepared or incomplete responses.

Overall, we appreciate NIST's clear and correct articulation of the limited circumstances under which the government may exercise march-in rights and commend NIST for its efforts to help stakeholders correctly understand the provisions of the Bayh-Dole Act. We respectfully ask that NIST consider our proposals that we believe would offer greater clarity and increase the positive impact of the changes for both private and public stakeholders.

The NPRM Helpfully Clarifies the Scope and Processes of the Standard Patent Rights Clauses within Funding Agreements.

PhRMA supports NIST's efforts to clarify the scope of the standard patent rights clause definition of "subject invention" and its efforts to provide for agency discretion to waive the requirement for the contractor to convey title to any subject invention.

4. Proposal to revise the definition of "subject invention"

NIST proposes to revise the current definition of "subject invention" contained within 37 C.F.R. § 401.14 to "any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement…An invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention."[24] The proposal rightfully seeks to clarify that background inventions are not "subject inventions."

[24] RIN 0693-AB66 at 42.

PhRMA welcomes the additional clarification and certainty that privately-funded, proprietary technology of contractors or their exclusive licensees are not subject to the rights and obligations of Bayh-Dole.

5. Proposal to clarify the conditions of when the government may obtain title to the subject invention resulting from potential reporting failures

PhRMA welcomes NIST's proposal to amend 37 C.F.R. § 401.14(d)(1) to state that "[a] Federal agency may require the contractor to convey title to the Federal agency of any subject invention—[i]f the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title."[25] PhRMA also welcomes NIST's proposal to amend 37 C.F.R. § 401.14(d)(2) to codify current agency discretion to waive the requirement for the contractor to convey title to any subject invention. These proposed changes will allow an agency to work with title holders to cure any reporting deficiencies.

Although contractors should and do aim for strict compliance with Bayh-Dole's reporting requirements, the proposal formalizes agency discretion to work with contractors who were unaware of the Bayh-Dole obligations pertaining to a product or who otherwise inadvertently missed the reporting window. In PhRMA's view, this proposal supports Bayh-Dole's goals of incentivizing commercialization of federally-funded products by vesting title in the contractor and ensuring that subject inventions will be available for the marketplace. Further, it incentivizes greater reporting by entities who were unaware of a subject invention status by allowing those less familiar with complex, administrative requirements, including small businesses and universities, to cure inadvertent errors. Greater reporting provides funding agencies increased notice of their rights in commercialized subject inventions. As such, PhRMA believes this proposal benefits all Bayh-Dole stakeholders.

[25] RIN 0693-AB66 at 42.

Conclusion

PhRMA appreciates the opportunity to comment and address the proposals NIST has provided in the Notice of Proposed Rulemaking. We particularly welcome NIST's efforts to make clear the requirements of the Bayh-Dole Act concerning government march-in rights and the processes afforded to stakeholders. In the research-based biopharmaceutical industry, clearly-defined IP rights are critical to fostering innovation, ensuring continued R&D, and facilitating the successful transfer of technology. To that end, NIST's proposed changes can play an important role in providing further clarity to stakeholders who rely on the protections that the Bayh-Dole Act provides to government-funded IP.

Respectively submitted,

/s/	/s/	/s/
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