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January 9, 2019

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

Re: NIST Return on Investment Initiative for Unleashing American Innovation: December 2018 Draft Green Paper

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments in response to NIST's December 2018 *Return on Investment Initiative for Unleashing American Innovation* Draft Green Paper (Green Paper).[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 $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA's comments focus on the first two components of NIST's Strategy 1, *Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices*, as presented in the Green Paper:[2]

(1) "Government Use License: Define the scope of the 'government use license'"; and
(2) "March-In Rights: Define the circumstances under which the government may exercise march-in rights to license further development of an invention to achieve practical application."

PhRMA is committed to ensuring the continued health and competitive strength of a biomedical research and development (R&D) ecosystem that fosters innovation, incentivizes competition, and benefits U.S. consumers. Moreover, 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. The IP-intensive biopharmaceutical industry supports a total of more than 4.7 million jobs across the

[1] NIST Return on Investment Initiative for Unleashing American Innovation Green Paper (Dec. 2018), https://www.nist.gov/sites/default/files/documents/2018/12/06/roi_initiative_draft_green_paper_nist_sp_1234.pdf [Hereinafter, "Green Paper"].
[2] *Id.* at 7.

U.S. economy and contributes $1.3 trillion in economic output when direct and indirect effects are considered.[3]

The Bayh-Dole Act helped establish a culture of entrepreneurship in America's universities and research institutes by creating a well-defined path to ownership and development rights for university researchers and spin-offs.[4,5] As a 2012 Congressional Research Service report found, "one of the major factors in the reported success of the Bayh-Dole Act is the *certainty it conveys concerning ownership of intellectual property*."[6] In addition, as the Director of the United States Patent and Trademark Office (USPTO) recently 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."[7] Collectively, clear IP ownership by the grantee along with the certainty of exclusive licensing terms established under the Bayh-Dole Act have helped advance biomedical research by fostering the licensing of technology developed at least in part with federal funding for use by private sector entities. Such collaboration supports further significant innovation by private biopharmaceutical companies.

While we do not believe it is necessary to modify the regulations, NIST's proposal clearly and accurately articulates federal agencies' current interpretation of and approach to the "government use license" and "march-in rights" provisions of the Bayh-Dole Act. In doing so, NIST's efforts serve the important goals of that Act. We also offer additional suggested changes to NIST's proposals to provide greater clarity and certainty surrounding these issues.

NIST's Intended Action Would Be Consistent With the Current Scope of the "Government Use License" Under the Bayh-Dole Act.

Intended Action 1 of the Green Paper proposes changing the Bayh-Dole Act regulations to define the scope of the government's license "to practice or have practiced for or on behalf of the United States any Subject Invention," the so-called "government use license."[8] Neither of the two proposed changes alters the state of the law, but rather accurately re-articulates the already-operative definition of the government license in a clear way. This proposal would make explicit the current understanding of the license and provide clarity regarding the scope of the license in the context of the Bayh-Dole Act regime.

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[3] TEConomy Partners, The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; November 2017.

[4] 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.

[5] D'Este P, Perkmann M. Why do academics engage with industry? The entrepreneurial university and individual motivations. J Technol. Transf. 2011;36(3):316–39.

[6] 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)(emphasis added), *available at* https://www.fas.org/sgp/crs/misc/RL32076.pdf.

[7] 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.

[8] *See* Green Paper at 28; s*ee also* 35 U.S.C. § 202(c)(4); 37 C.F.R. § 401.14(b).

The proposed changes are as follows:[9]

- Insert a new definition in 37 CFR 401.2: "The term ***government use*** is defined as use directly by the government for a government purpose and the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included."
- Insert new language into the existing standard patent rights clause in 37 CFR 401.14(b) "Allocation of Principal Rights" clause: "The government use license is restricted by the following conditions: (A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract."

Of particular importance, under NIST's proposal, the term "government use license" means "use directly by the government—or a government contractor in performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government."[10] NIST rightly observes that the license "should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services."[11] NIST's proposals reflect existing interpretations of this term, by making clear that the license only extends to third-party goods or services *directly* used or consumed by the government.[12]

NIST's proposals capture and define Federal agencies' two-decade old understanding of and approach to the government use license, and this change will benefit all stakeholders seeking greater clarity and certainty in the scope of the government use license. For example, a report by the Government Accountability Office (GAO) describes the government use license as giving the government the right to use a subject invention in two situations: (1) when contracting with a third party to make a product that incorporates the invention for or on behalf of the government, provided use of the government's license satisfies a legitimate federal governmental need in support of a congressionally authorized program; or (2) when the government or a recipient of federal financial assistance uses the invention in further government-funded research, provided that such research serves a legitimate government need for the agency exercising the license.[13] This understanding by GAO is consistent with the long-

[9] Green Paper at 29, n. 43.
[10] *Id.* at 28.
[11] *Id.*
[12] *Cf. Innovative Concepts, Inc. v. Symetrics Indus., Inc.*, No. 02-1040-A (E.D. Va. 2003) (direct sale to a foreign government by a third party that had obtained computer software with government purpose rights was not a "government purpose"); *Aktiebolaget Bofors v. United States*, 139 Ct. Cl. 642 (1957) (license to use drawings "for United States use" barred use to manufacture guns for supply to other countries).
[13] *See* General Accounting Office, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions*, 5–6 (July 2003), *available at* http://www.gao.gov/assets/240/238890.pdf.

standing approach of the government use license from the Department of Defense and the National Institutes of Health (NIH), which refer to it as a license "for government purposes."[14]

We appreciate NIST's clear restatement of the current and long-standing operative definition of the government use license, and its efforts to provide greater certainty and clarity to stakeholders in understanding the provisions of the Bayh-Dole Act. NIST's proposals would provide greater certainty and clarity to the scope of the government use license.[15]

NIST's Intended Action Would Reflect Current Appropriate Interpretations of the "March-in Rights" Provisions of the Bayh-Dole Act.

NIST's proposals regarding march-in rights would codify the existing approach of Federal agencies to march-in rights, and we support NIST's efforts to provide greater clarity and certainty regarding the current state of the law.

NIST's Intended Action 2 proposes changing the Bayh-Dole Act regulations to (a) make explicit that the actionable bases for exercising march-in rights in 35 U.S.C. § 203(a) would be reserved for uses that address a compelling national issue or a declared national emergency when other remedies have failed; (b) specify that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services; (c) provide a clear and consistent definition for "reasonable terms" contained within the existing statutory definition of "practical application," including clarifying that the intent of reasonable licensing terms is to allow a product or service to reach the marketplace but not as terms for consumer use (i.e., price control mechanism); and (d) require that an agency first conduct an informal consultation with the contractor, grantee, or licensee when it receives information that it believes might warrant march-in to understand the nature of the issue and consider other potential alternatives.[16]

Each of the changes proposed by NIST accords with the understanding of the original sponsors of the Bayh-Dole Act, whose "intent was to ensure that products were licensed for reasonable terms rather than being used as a price control."[17] Further, the proposed changes align with the current, long-standing state of the law. As NIST indicates, in all six publicly

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[14] *See* Dep't of Defense, *Intellectual Property: Navigating Through Commercial Waters, Department of Defense*, 2–3, *available at* http://www.acq.osd.mil/dpap/Docs/intelprop.pdf (stating that "the Government receives a nonexclusive license to use [the subject] invention for Government purposes."); Nat'l Institute of Health, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interest are Protected*, 5 (July 2001), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf ("By law, the funding agency retains residual interest in grant- and contracts-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes."); *see also* DFARS 252.227-7013(a)(12) (explicitly excluding use of a government purpose license in data for commercial purposes); DFARS 252.227-7014(a)(11) (same); DFARS 252.227-7018(a)(14) (same).

[15] In line with NIST's proposed regulatory changes, it also would be worth noting in any regulatory amendment that the government use license must be in furtherance of a legitimate agency need authorized by Congress, as discussed in the GAO report.

[16] Green Paper at 33–34.

[17] *Id.* at 31. *See also* Statements by Senators Bayh and Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002.

reported cases where NIH received formal petitions to initiate march-in proceedings, it has determined that the criteria for exercising march-in rights were not met.[18]

NIST's articulation of the government's current approach for exercising march-in rights would provide clarity and certainty to stakeholders. NIST's approach also addresses important concerns stakeholders voiced in response to its RFI, including that using march-in rights as a price control would "impede[] the creation of new drugs and discourage[] university and medical school licensees from making the substantial additional investments necessary to develop and commercialize new drug discoveries," as well as create "uncertainties in the U.S. innovation system" and lead to "lack of confidence that patents will be enforceable in fair court proceedings or in the U.S. Patent and Trademark Office's Patent Trial and Appeal Board."[19] Importantly, NIST notes that some of its RFI respondents "report that the threat of march-in has prevented licensing deals that would have otherwise occurred, leading to technologies languishing in contravention to the law's stated purpose."[20] Our hope is that with greater certainty brought by NIST's proposals, licensing deals in the future will no longer fail to materialize due to uncertainty in the scope of march-in rights.

Additionally, we commend NIST's proposed requirement that Federal agencies coordinate with organizations (i.e., contractors) holding title to Subject Inventions or exclusive licensees of those inventions upon receiving a march-in request. NIST's proposed change could provide useful industry perspective, increase communication between private industry title-holders or licensees and funding agencies, and reduce the government's burden of responding to third-party march-in requests. We suggest that in addition to consulting title holders, Federal agencies should also seek consultation with any exclusive licensees. 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. However, to date, Federal agencies have expressed hesitancy to engage exclusive licensees concerning Bayh-Dole Act matters. We would also suggest adding clarifying language to any relevant regulatory change to make clear that the informal discussions are for the agency and Subject Invention title holder and/or exclusive licensee only, and not the organization submitting a march-in petition, as such organizations have the opportunity to provide supporting information when submitting a march-in petition.

We applaud NIST's clear and correct articulation of the limited circumstances under which the government may exercise march-in rights. While not necessary, to the extent NIST seeks to introduce regulatory amendments to clarify the march-in rights provisions, PhRMA respectfully asks that NIST make changes consistent with what is proposed in the Green Paper.

[18] Determination in the Case of Petition of CellPro, Inc. (1997); Determination in the Case of Norvir (2004); Determination in the case of Xalatan (2004); Determination in the Case of Fabrazyme (2010); Determination in the Case of Norvir II (2013); Determination in the Case of Xtandi (2016).
[19] Green Paper at 31–33.
[20] *Id.* at 32.

Conclusion

PhRMA appreciates the opportunity to comment on the proposals NIST provides in the Green Paper. We particularly welcome NIST's efforts to make clear the existing requirements of the Bayh-Dole Act concerning government use licenses and march-in rights. 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 by providing further clarity to stakeholders who rely on the protections that the Bayh-Dole Act provides to government-funded IP.

Sincerely,

/s/
Anne McDonald Pritchett, PhD
Senior Vice President, Policy and Research

/s/
David E. Korn
Vice President, Intellectual Property and Law