AIPLA

American Intellectual Property Law Association

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*Via Federal eRulemaking Portal (*https://www.regulations.gov*), Notice* NIST–2023–0008.

Re: Response to Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights 88 Fed. Reg. 85593 (Dec. 8, 2023)

Dear Associate Director Bahar:

The American Intellectual Property Law Association ("AIPLA") is pleased to submit comments to the "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" published by the National Institute of Standards and Technology (NIST) on December 8, 2023, at 88 F.R. 85593-85605 ("RFI").

Founded in 1897, the American Intellectual Property Law Association is a national bar association of approximately 7,000 members including professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

The Notice

The RFI provides an extensive Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("proposed framework") that lists "factors that an agency may consider when deciding whether to exercise march-in rights," introduces definitions to be used with the Draft Guidelines, and provides hypothetical scenarios under which exercise of march-in rights may be warranted.

Summary of AIPLA Response

AIPLA's three overarching concerns are that the proposed framework is unnecessary, ambiguous, and would limit, rather than encourage, the development of federally funded

technology. AIPLA urges NIST to withdraw the proposed framework in its entirety for at least the following reasons:

(1) the Bayh-Dole Act (BDA) has a proven track record of overwhelmingly positive impact on the innovation ecosystem and increased public benefit of federally funded research, both of which should be preserved;

(2) the proposed framework is an extreme departure from the well-established understandings about the BDA and would erode the economically stimulating positive impacts of the BDA; and

(3) the proposed framework injects both uncertainty and unpredictability into the currently well-functioning innovation ecosystem, imposing an unnecessary chilling effect on important development and commercialization activities, i.e., is antithetical to "the policy and object" of Congress in enacting the BDA, which include, *inter alia*, "use [of] the patent system to promote the utilization of inventions arising from federally supported research or development."[1]

The RFI includes five specific questions regarding the criteria, questions, and examples set forth in the Draft Guidelines. AIPLA maintains that the proposed framework is not necessary, and therefore, questions relating to specific details of the proposed framework are difficult to answer. Nonetheless, AIPLA offers specific comments on the five questions posed in the RFI after briefly reviewing the BDA and its overwhelmingly positive economic and innovative impact on innovation in the U.S.

I. History and Positive Impact of the BDA

The BDA's text and its implementing regulations under 37 C.F.R. §§ 400 et seq. include both the congressional intent for the legislation and the factors to be considered when contemplating the exercise of march-in rights. Coupled with the existing government policy to avoid adding ambiguity to the scope of patent rights, the BDA has been overwhelmingly successful in fostering innovation and enabling the collaboration and investment necessary to bring innovative products to market across industries. It is critical that the United States government continues to pursue intellectual property (IP) policies supporting these important development and commercialization activities, and not upset the decades-long momentum towards innovative development propelled by the BDA, which is, in part, due to the fact that march-in rights have <u>never</u> been used.

Prior to the BDA's enactment, U.S. law dictated that the government retain ownership of inventions it had funded, a practice that many today agree stifled innovation.[2] While the U.S. government had accumulated more than 28,000 patents by 1978, less than 5% were commercially licensed.[3] At the time, many universities discouraged patenting and engagement

[1] 35 U.S.C. § 200.
[2] Stevens, A.J., "The Enactment of Bayh–Dole," *The Journal of Technology Transfer*, 29, 93–99 (2004).
[3] Paradise, Jordan, "COVID-IP: staring down the Bayh–Dole Act with 2020 vision," *Journal of Law and the Biosciences*, 7(1), 1-13, January-June 2020.

with industry,[4] and the U.S. was losing its innovative edge to competitors in Europe and Japan.[5] In that same decade, however, a new trend began taking shape in which universities increasingly sought patent protection for their inventions, which provided them with potential licensing opportunities with private industry.[6,7] This trend coincided with legal and financial changes in the country that increased venture capital availability, setting the stage for "possibly the most inspired piece of legislation to be enacted in America over the past half-century."[8,9,10]

On September 13, 1978, at a time when international pressures and the changing U.S. innovation landscape created a pressing need for U.S. policy to adapt, Senator Birch Bayh introduced a bill with words as pertinent today as they were back then:

> A wealth of scientific talent at American colleges and universities—talent responsible for the development of numerous innovative scientific breakthroughs each year—is going to waste as a result of bureaucratic red tape and illogical government regulations…. The problem, very simply, is the present policy … Government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public. It is not government's responsibility—or indeed, the right of government—to assume the commercialization function. Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle.[11] (Emphases added.)

The bill ultimately became the BDA, which is one of the foundational pieces of legislation promoting American innovation as we know it today.[12] A 2016 Congressional Research Service (CRS) report[13] summarized the BDA as a way for Congress to address concerns about the commercialization of technology developed with public funds by providing incentives to government contractors/grantees to actualize federal investment in research and early-stage development.[14]

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[4] Mowery, David C., and Bhaven N. Sampat, "University patents and patent policy debates in the USA, 1925–1980," *Industrial and Corporate Change*, 10(3), 781-814 (2001).
[5] Stevens, A.J., "The Enactment of Bayh–Dole," *The Journal of Technology Transfer*, 29, 93–99 (2004).
[6] Mowery, David C., and Bhaven N. Sampat, "University patents and patent policy debates in the USA, 1925–1980," *Industrial and Corporate Change*, 10(3), 781-814 (2001).
[7] Hughes, Sally Smith, *Genentech: The Beginnings of Biotech*, University of Chicago Press (2011).
[8] Mowery, David C., and Bhaven N. Sampat, "University patents and patent policy debates in the USA, 1925–1980," *Industrial and Corporate Change*, 10(3), 781-814 (2001).
[9] Stevens, Ashley J. "An emerging model for life sciences commercialization." *Nature Biotechnology,* 35(7): 608-613 (2017).
[10] Stevens, A.J., "The Enactment of Bayh–Dole," *The Journal of Technology Transfer*, 29, 93–99 (2004).
[11] *Id.*
[12] *Id.*
[13] Thomas, John R., "March In Rights Under the Bayh-Dole Act," *Congressional Research Service Report*, Aug., 22, 2016.
[14] The 2016 CRS report stated that "Congress approved the Bayh-Dole Act, P.L. 96-517, in order to address concerns about the commercialization of technology developed with public funds. This 1980 legislation awards title to inventions made with federal government support if the contractor consists of a small business, a university,

One aspect of the BDA permits the federal government to "march-in" and "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances" in limited situations enumerated in the statute.[15] March-in rights under the BDA are primarily intended to ensure patent owners commercialize their inventions. As Senator Birch Bayh explained:

> When Congress was debating our approach fear was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products. Largely to address this fear, we included the march-in provisions.[16]

March-in rights should be balanced with another one of the BDA's explicit policies and objectives, which is "to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery."[17] The BDA requires a careful balance between addressing fear of suppression and undue influence against free competition. In the 43 years since its enactment, the government has never found a situation meriting the exercise of the BDA's march-in provisions.

As enabled by the BDA and its accompanying policy and regulations over the past 43 years, the licensing of government-funded inventions has played a critical role in enabling the development of diverse products and services that benefit all of society. The BDA provides that "[e]ach nonprofit organization or small business firm may … elect to retain title to any subject invention."[18] A 1983 Executive Order expanded its scope to include large corporations.[19] Government funding typically supports early-stage research that may not yet be ready for commercialization but is nonetheless critical to the product development process. By allowing recipients of federal funds to patent and license the fruits of their research, the BDA decentralized technology management and increased the incentive for innovation-driven collaborations between government funded contractors and the private sector.[20]

The BDA works. To date, the existing and predictable framework of implementing the BDA has given innovators and their funders the incentive and confidence necessary to work with federally funded early-stage discoveries when making risky investments towards further development. Since its inception, the BDA has contributed almost $2 trillion to U.S. economic growth, sustained over 6 million jobs, and brought thousands of products to consumers.[21]

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or other nonprofit institution. A subsequent presidential memorandum extended this policy to all federal government contractors. . . . The Bayh- Dole Act endeavors to use patent ownership as an incentive for private sector development and commercialization of federally funded research and development (R&D)."

[15] 35 U.S.C. § 203(a) (emphasis added).

[16] Bayh, B., "Statement of Senator Birch Bayh to the National Institutes of Health. May 25, 2004." (2004).

[17] 35 U.S.C. § 200.

[18] *Id.*

[19] Treasure, Carolyn L., Jerry Avorn, and Aaron S. Kesselheim. "Do march-in rights ensure access to Medical products arising from federally funded research? A qualitative study." *The Milbank Quarterly,* 93(4): 761-787 (2015).

[20] Gabrielle Athanasia, "The legacy of Bayh-Dole's Success on US Global Competitiveness Today." *Center for Strategic and International Studies*, January 12, 2022, https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today.

[21] Bayh-Dole Coalition Statement on Biden Administration's Proposed March-in Framework, December 7, 2023, https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-biden-administrations-proposed-march-in-

The widespread opening of university technology transfer offices since the enactment of the BDA is another metric of its success in promoting the commercialization of federally funded inventions.[22] Spurred by government grants and the promise of title retention, entrepreneurial universities began patenting, assigning, and licensing at an unprecedented rate in the 1980's.[23] The resulting collaborations, and investments made by academic licensees, have contributed hundreds of millions of dollars to U.S. gross domestic product.[24] This enabled even more innovation. The BDA has directly contributed to the creation of 11,000 new university startups.[25] Although not explicitly mentioned in the BDA, licensing royalties now fund further research and education in universities and hospitals and provide yet another testament to its benefits.[26] The model has been adopted by several other countries in the hopes of increasing institutional research revenue from royalties, diversifying their economies, and attracting foreign investment.[27]

II. Response to Specific RFI Questions

Question 1

After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?

Response 1

a. AIPLA urges NIST to withdraw the proposed framework in its entirety. The proposed framework represents an unprecedented change in public policy and would enable unjustified and/or unwise takings of rights in technology, and thereby detrimentally impact the ability to transform early research into useful products across sectors.

AIPLA submits that the proposed guidance framework is unnecessary and, if implemented, would increase ambiguity rather than clarify march-in rights under the BDA. The factors to be weighed when considering use of the march-in provisions of the BDA are

framework/#:~:text=In%20response%2C%20Joseph%20P.,uncertainty%20over%20America%27s%20innovation%20system.

[22] Link, Albert N., and Martijn van Hasselt. "On the transfer of technology from universities: The impact of the Bayh–Dole Act of 1980 on the institutionalization of university research." *European Economic Review,* 119: 472-481 (2019).

[23] Fleming, Lee, et al. "Government-funded research increasingly fuels innovation." *Science,* 364(6446): 1139-1141 (2019).

[24] Pressman, Lori, Robert Yuskavage, and Sumiye Okubo. "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2015." *Biotechnology Industry Organization*, date 18 (2017): 2018. (retrieved from https://www.autm.net/AUTMMain/media/Partner-Events/Documents/Economic-_Contribution_University-Nonprofit_Inventions_US_1996-2015_BIO_AUTM.pdf).

[25] Copan, Walter, "Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation." *IPWatchdog.com*, November 2, 2020, https://ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/id=126980/.

[26] Colaianni, Alessandra, and Cook-Deegan, Robert, "Columbia University's Axel Patents: Technology Transfer and Implications for the Bayh-Dole Act." *The Milbank Quarterly,* 87(3): 683-715 (2009).

[27] Stevens, Ashley J. "An emerging model for life sciences commercialization." *Nature Biotechnology*, 35(7): 608-613 (2017).

embedded in the statute itself.[28] To the extent that the proposed framework quotes from the existing law and regulations, it adds nothing that doesn't already exist. The language and tone of the proposed framework, however, render it more permissive of the use of the BDA's limited provision for government march-in rights than the limited situations provided in the statute. This would be a marked departure from the statute's plain language, its policy underpinnings, and the government's application of it over the past 43 years.

AIPLA believes that policy changes that alter the robust and predictable landscape upon which innovators are incentivized by the patent system should be left to Congress. The proposed framework appears to expand or alter the statute without authority. It includes changes to existing terms defined in statute without explanation as to why such changes are necessary. The lack of consistency between the proposed framework and the statute would further increase ambiguity rather than provide clarification. To the extent that any ambiguity exists in the BDA, clarification would require congressional action.

In the 43 years since the enactment of the BDA, the government has never found a situation that would merit the exercise of the BDA's march-in provisions. The proposed framework, however, seems to deviate from the decades-long implementation of the BDA and seeks more permissive application of government march-in rights. To this end, the proposed framework adds non-exhaustive examples regarding whether to exercise march-in rights. Interestingly, of the 8 specific examples, 5 suggest the real possibility of exercising the rights (S1: psoriasis treatment, S5: water treatment; S6: pandemic vaccine; S7: vehicle communications; S8: Alzheimer's treatment). While the guidelines do not force any conclusion, they suggest that, in 5/8 of the scenarios, march-in might be appropriate and therefore add uncertainty to IP rights and the related public benefits resulting therefrom.

The proposed framework would create a new environment with an increased expectation that federally funded inventions be subject to march-in rights. This new environment would increase innovation investment risk and inhibit commercialization of products in every sector, including but not limited to, pharmaceutical/biotechnology (S1, S6, S8), environmental (S5), automotive, and communications (S7) industries (exemplified in the RFI). These examples provided by the RFI appear to suggest that as early-stage research progresses through private investments into useful products that benefit the public, there would be an increased risk for such products to be subject to march-in rights. Even if the federally funded early-stage research does not yield a successful commercial product, patentees/licensees may still be required to furnish the fruits of their investments (e.g., technical data generated by private investments) to retroactively justify business decisions, later being challenged in a march-in proceeding with the benefit of hindsight. The risk is even more pronounced in the pharmaceutical field, where technology development is highly front-end loaded with billion-dollar investments needed to bring new medicines to market. This area of technology is also highly unpredictable and many of the early-stage technologies associated with government research never mature into viable pharmaceutical products despite years of diligent research.

If public policy shifts and IP rights are made more tenuous, new technologies, especially medicines, may never be developed in the first place.

[28] *See* 35 U.S.C. § 203.

Furthermore, it has been a longstanding position of the U.S. to avoid the use of march-in, compulsory licensing, and international IP flexibilities (such as the flexibilities provided under the terms of TRIPS).

The BDA relies upon innovative collaborators, in all sectors across the economy, for additional investments that bring federally funded nascent inventions to a product or applied system that benefits the public. These innovative collaborators spend billions of dollars on high-risk investments in R&D with no guarantee of marketplace success. Any new framework should clarify any deviations from already well-established U.S. public policy that would erode the incentives provided by the BDA upon which the innovation ecosystem has come to rely for mitigating these high-risk investments in R&D.

b. AIPLA submits that the statutory language of the BDA does not permit price as a basis for the government to dilute IP rights. Such an extreme policy shift that alters the robust and predictable landscape statutorily provided by the BDA, upon which innovators are incentivized, should be left to Congress.

The proposed framework introduces various factors related to pricing of a product as criteria for determining whether the statutory requirements for exercising march-in rights under 35 U.S.C. §203(a) have been met. However, pricing was never intended to be a basis for march-in under the BDA and should be removed from consideration of march-in rights. This is self-evident from the text of the statute, which makes no reference to "price" whatsoever. Nor does the statute provide any factors to be considered by an agency in determining a "reasonable price." Moreover, establishing pricing as a march-in factor, as proposed in the draft guidance, would undermine predictability and certainty of the protections necessary to incentivize public-private collaborations that advance product commercialization, which are the policy underpinnings of the BDA that have allowed innovative collaborations in the United States to thrive.

Consistent with the statutory language and the statements of Sens. Bayh and Dole, the government has repeatedly and consistently rejected the notion of pricing as a basis for march-in. In fact, the titular Bayh-Dole sponsors themselves explained that the BDA:

> "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.… The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-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."[29] Emphasis added.)

The price of a successfully commercialized product, whether it is a drug, a filtration system, or a vehicle, cannot be the basis for government to exercise its march-in rights. In

[29] Bayh, Birch, and Robert Dole, "Our law helps patients get new drugs sooner," *Washington Post* 11 (2002).

particular, march-in rights petitions based on pricing of pharmaceutical products have been repeatedly presented in the past and were turned down on every occasion.[30] The price of pharmaceutical products experienced by consumers is the result "of the complex web of federal and state laws and regulations that govern the manufacture, sale, distribution, and pricing of pharmaceuticals," and is not solely controlled by patent rights.[31] In fact, according to a recent study, generic approval occurred in 28% of cases where exclusivity remained, and generic approval did not follow patent expiration in 32% of cases.[32] Pricing issues, while oft-times comingled with patent rights, should be independently considered rather than compromising innovative technology development in the first instance.

As shown in the examples below, the NIH has repeatedly concluded that march-in is an inappropriate or ineffective means for price control in the context of pharmaceutical products.

In 1997, addressing one march-in petition, then Director of the National Institutes of Health (NIH), Harold Varmus, noted that NIH was wary:

> "of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research." (Emphases added.)[33]

In 2004, Elias Zerhouni, Dr. Varmus' successor at NIH, added that "the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress ... because the market dynamics for all products developed pursuant to licensing rights under the BDA could be altered if prices on such products were directed in any way by the NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[34] (Emphases added.) This policy observation regarding the global

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[30] Thomas, John R., "March In Rights Under the Bayh-Dole Act," *Congressional Research Service Report*, Aug. 22, 2016.

[31] Joseph Antos and James C. Capretta, "Prescription Drug Pricing: An Overview of the Legal, Regulatory and Market Environment, *AEI Economic Perspectives*, July 2018, https://www.aei.org/wp-content/uploads/2018/07/Prescription-Drug-Pricing.pdf?x91208 (indicating that "the pharmaceutical supply chain is complex, with various intermediaries, each of whom have a financial interest and considerable influence over the distribution and pricing of prescription drugs," and third-party payers – including private insurance and public programs – have their own financial incentives that determine their willingness and ability to negotiate prices and control access to drugs.")

[32] Darrow, Jonathan J., and Daniel TC Mai, "An Orange Book Landscape: Drugs, Patents, and Generic Competition." *Food & Drug L.J.,* 77: 51 (2022).

[33] Harold Varmus, Director, NIH, *Determination in the Case of Petition of CellPro,Inc.*, Aug. 1, 1997, http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[34] Elias A. Zerhouni, Director, NIH, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.*, July 29, 2004, http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

implications of exercising march-in rights remains in place today and is not limited to pharmaceuticals.

Most recently, in March 2023, only nine months prior to the proposed framework, the NIH declined a march-in petition for Xtandi (enzalutamide) based on pricing.[35] Dr. Lawrence A. Tabak, Performing the Duties of the NIH Director, stated that "given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that the use of the march-in authority would be an effective means of lowering the price of the drug." (Emphasis added.) The mere fact that the drug is manufactured and on the market in the manner of other prescription drugs was considered sufficient to meet the requirement for bringing Xtandi to practical application and avoid exercise of the government's march-in right under 35 U.S.C. § 203(a). Dr. Tabak noted that:

> "This decision is consistent with the NIH's determination in 2016, in which [the same parties] requested NIH and the Department of Defense march-in based on the price of Xtandi but each declined. In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013) and Xalatan (2004), practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public…."[36]

The inclusion of pricing in assessing march-in under the BDA is inconsistent with the statutory requirements of 35 U.S.C. § 203(a) and is an extreme departure from the government's consistent implementation of the BDA since at least 1997 until 2023.

AIPLA urges NIST to remove pricing as a factor in any framework for assessing march-in rights.

c. AIPLA is concerned that the proposed framework would introduce uncertainty and unpredictability into the innovation ecosystem that would disproportionally impact, basic, embryonic stage research by universities, start-ups, and small companies and should therefore be withdrawn.

AIPLA views the proposed framework as inadvisable because it injects uncertainty and unpredictability into the well-functioning patent/licensing system described above. One of the core policy objectives of the BDA was to provide government funding recipients, and their licensees, the means, predictability, and certainty necessary to enter into licensing agreements. This is critical in a competitive innovation ecosystem where larger companies have a choice of where to invest their R&D dollars and with whom they partner. Licensees who make the considerable R&D investments necessary to transform licensed inventions into products rely upon this predictability and certainty. If the proposed framework were to be finalized, it would place all government funding recipients at a competitive disadvantage when seeking to license their inventions as compared to privately funded early-stage research.

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[35] Lawrence A. Tabak, Performing the Duties of the NIH Director, Letter regarding request for exercise of the march-in authority under the Bayh-Dole Act (35 USC §203) to lower the prices of Xtandi (enzalutamide), of March 21, 2023, https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf.

[36] *Id.* (second alteration in original) (footnote omitted).

The adverse impacts described above would be disproportionally felt by universities, start-ups, and small companies that typically receive government funding to support early research and would result in loss of significant revenue in the form of licensing royalties. One study found that 34.6% of patents assigned to venture-backed startups between 1976 and 2016 cite federally funded research, compared to only 21.7% of corporate patents from the same period.[37] Additionally, the proposed framework would disproportionately affect basic, embryonic stage innovation across sectors. A 2013 CRS report found that the "issuance of compulsory licenses may … negatively impact the U.S. economy" as a whole.[38] Startups, universities, and small companies are also most reliant upon their intellectual property since they typically do not possess the R&D or manufacturing resources of larger companies. These same stakeholders rely fundamentally on the strength of their IP and would be far more susceptible to changes in patent protection standards than larger established companies.[39] Their intellectual property therefore may represent their primary, if not sole, commercially valuable asset.

Policymakers need not speculate about potential impacts of introducing pricing as a basis for march-in, as we have clear precedent to reference, and prior learnings to draw from. In 1989, the NIH adopted a "reasonable pricing" clause in its research agreements.[40] After widespread criticism that this policy discouraged the industry from collaborating with government scientists, it was repealed in 1995.[41] The year following its repeal saw a 500% increase in agreements between the NIH and the private sector.[42] This past experience shows that, ironically, the threat of march-in under the proposed framework would thwart one of the main policy aspirations of the BDA, which is to ensure that inventions universities, start-ups, and small companies "are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery."[43]

In summary for Question 1, the proposed Guidelines could only be made clearer by withdrawing them entirely.

Question 2

> ***The framework contains many terms which have specific meanings under Bayh-Dole or in technology development and commercialization. Are the definitions provided at the beginning of the framework easy to understand? Do they aid in your ability to interpret the framework?***

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[37] Fleming, Lee, et. al., "Government-funded research increasingly fuels innovation." *Science*, 364.6446 (2019): 1139-1141.
[38] Thomas, John R. Compulsory licensing of patented inventions. *Congressional Research Service*, 2013.
[39] Bayh-Dole Coalition Statement on Biden Administration's Proposed March-in Framework, December 7, 2023, https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-biden-administrations-proposed-march-in-framework/#:~:text=In%20response%2C%20Joseph%20P.,uncertainty%20over%20America%27s%20innovation%20system.
[40] Treasure, Carolyn L., Jerry Avorn, and Aaron S. Kesselheim, "Do march-in rights ensure access to Medical products arising from federally funded research? A qualitative study," *The Milbank Quarterly*, 93(4): 761-787 (2015).
[41] *Id.*
[42] *See* The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995, Nov. 15, 2021, https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.
[43] 35 U.S.C. § 200.

Response 2

Some of the definitions modify terms and phrases codified in the BDA or its implementing regulations. Expanding or otherwise altering definitions adds ambiguity in statutory interpretations. To the extent that the proposed guidelines are merely interpretive, their alteration and expansion of the literal language set forth in, e.g., 35 U.S.C. §§ 203(a) et al. are inappropriate because it is unclear how to reconcile the statute's explicit language with that proposed by the guidance framework.

The RFI offers specific definitions of such terms as "Agency," "Head of Agency," "contractor," "shelving," et al. Those definitions are not concordant with those provided under the BDA or its implementing regulations under, e.g., 37 C.F.R. § 401.2. Consider the following:

- The RFI changes the word "This" to "Such" in defining a "Funding Agreement." This change is inconsistent with 37 C.F.R. § 401.2(a).

- The term "contractor" is incorporated into the RFI's definitions in a way that is not coextensive with its definition in the regulation under 37 C.F.R. § 401.2(b).

- The RFI introduces the term "shelving" as a factor weighing in favor of exercising government march-in rights. The term "shelving" is defined as "[w]hen an entity holds a patent or has a license to make, use or sell an invention, but they do not develop, use or sell that invention (or a product embodying the invention) or seek out third parties to do so for an extended period of time." This term is not present in 35 U.S.C. § 203(a), and the definition provided by the proposed framework introduces ambiguity to the statutory standard for determining whether the contractor or assignee has taken or is expected to take "within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."[44] (Emphasis added.)

- Finally, the last paragraph of the proposed definitions states that the definitions must be interpreted to be consistent with the BDA and 37 C.F.R. § 401 et seq. Again, if the definitions are the same in existing related statutes and regulations, the proposed framework only serves to add ambiguity.

Question 3

How could the framework be improved to be easier to follow and comprehend?

Response 3

AIPLA maintains that this framework document is unnecessary. The framework sets forth definitions and considerations beyond what is set forth in the statute. Limiting the framework to the considerations and definitions set forth in the BDA and its accompanying regulations would not alleviate this conflict, but also render the framework unnecessary.

[44] *Id.* § 203(a).

Question 4

> ***Does this framework sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?***

Response 4

As discussed above, the BDA seeks to promote free competition and enterprise without unduly encumbering future research and discovery. It is not meant to be used as a tool to interfere with free competition through price control of inventions that have already been made publicly accessible. The proposed framework would inject uncertainty into government-funded inventions and have a chilling effect on further investments for late-stage development and commercialization that are necessary to bring a product to market – contrary to the policy and object of the BDA.

Question 5

> ***The framework is not meant to apply to just one type of technology or product or to subject inventions at a specific stage of development. Does the framework ask questions and capture scenarios applicable across all technology sectors and different stages of development? How could any gaps in technology sectors or stages of development be better addressed?***

Response 5

The scenarios provided by the proposed framework suffer from the same defects as any other attempt to use broad hypotheticals, rather than specific facts, to address specific technology and legal matters. Each innovation subject to the BDA was and will be unique, and whether to exercise march-in rights would require consideration of the specific subject matter infrastructure in which the technology resides. Situation- and technology-specific fact-finding will be needed. To the extent that broad guidance is needed, it is provided by statute. To the extent that specific guidance is needed, the framework scenarios are not specific enough.

III. Conclusion

AIPLA believes that the proposed Guidance Framework is unnecessary and would have a chilling effect on all industries in which the federal government funds research because it will increase uncertainty, unpredictability, and confusion as to if, or when, the government will exercise march-in rights. The RFI fails to justify a need or desire for further guidance on a subject that has already stood the test of 43 years of practice and contributed almost $2 trillion to U.S. economic growth. The proposed framework represents a policy shift that will disproportionately diminish the positive benefits of the BDA to startups, universities, and small companies, because private sector collaborators will become more reluctant to license early-stage federally funded technologies. Finally, AIPLA maintains that the proposed guidance framework would, at a minimum, change the dialogue on exercise of march-in rights from non-advisable to permissive, which is a radical change that should only be done by appropriate statutory change.

Sincerely,

Ann M. Mueting
President
American Intellectual Property Law Association