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February 6, 2024

VIA ELECTRONIC SUBMISSION

National Institute of Standards and Technology
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Comments to Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (NIST–2023–0008), 88 Fed. Reg. 85593

On behalf of its member companies and organizations, the Biotechnology Innovation Organization (“BIO”) extends its appreciation to NIST for considering these comments in response to the agency’s Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (the “draft framework”).

BIO is the world’s largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO’s members, most of which are small and medium-sized innovative businesses, develop biopharmaceutical drug therapies, modern bioengineered seed and agricultural products, and important applications of biotechnology in industrial processing, material science, environmental remediation and sustainability. BIO’s members routinely collaborate and interact with publicly funded research institutions and small businesses, and have long supported government agencies such as NIH, DOA, DOE and others in their important role of funding and advancing biotechnology in the United States and throughout the world.

As explained below, BIO believes that expanding the use and scope of the march-in authority of 35 U.S.C. § 200 in the manner being proposed in the draft framework is contrary to both the objectives and language of the Bayh-Dole Act. BIO is concerned that adoption of the draft framework will diminish private sector interest in the partnerships necessary to develop and commercialize products and services based on federally funded inventions. Accordingly, BIO urges NIST to withdraw the draft framework and avoid similar initiatives that undermine the objectives and success of the Bayh-Dole Act.

I. The Bayh-Dole Act Is a Success Story

The path from an invention to a marketed product or service is not linear. Nearly every product or service that reaches the market results from an amalgamation of different inventions, preexisting technology and technological know-how. This is particularly true in the industry sectors in which BIO members are active. Commercialization of new products and services thus



requires collaborations between many different stakeholders having different roles and interests. This is true for both privately developed and federally funded inventions.

Partnerships with the private sector are thus essential to converting federally funded inventions into commercially viable products and services. Private sector partners, however, require not only compelling incentives and safeguards, but also substantial commercial certainty to validate their investment of time, effort, and money in developing and commercializing innovations. Crucially, this certainty encourages them to undertake the risk of potential commercialization failure.

Prior to the Bayh-Dole Act, the government claimed ownership of inventions resulting from government-funded research. Having less than all of the rights in a patent impeded licensing of rights to private sector partners hoping to bring products and services based on the invention to market. The impact was stifling; due to the excessively restrictive conditions, agencies or recipients of funding struggled to attract interest from private sector companies for commercial development partnerships.

This problem was the impetus for the Bayh-Dole Act, which, since its enactment in 1980, has done precisely what it was designed to do: effectively stimulate formation of partnerships with the private sector to commercialize federally-funded inventions. By allowing recipients of federal funding to claim title to patents, and then license them in commercially conventional ways to private sector partners, the Bayh-Dole Act removed the primary obstacle to commercialization of federally funded inventions. This enabled private sector partners to use their investments, know-how, and other resources to bring products and services arising out of these federally supported inventions to American consumers.

The Bayh-Dole Act provided a focused solution that addressed the “failure of the American industry to keep pace with the increased productivity of foreign competitors,”¹ and removed the economic, political, and bureaucratic “roadblocks” that had led to decline in research and development and innovators’ ability to secure investment capital. Experiences under the Bayh-Dole Act have shown that private industry is best positioned both technically and financially to take on the risky and prolonged commitment necessary to bridge the gap from a nascent concept (the federally funded invention) to actual commercial products and services. By any measure, the Bayh-Dole Act has consistently achieved its legislative purpose of being a stimulus for commercialization of federally funded inventions; studies show that it has contributed between \$631 billion and \$1.9 trillion to U.S. industry gross output, has catalyzed the formation of 17,000

¹ H.R. Rep. No. 96-1307 (Part I), at 1.



startup businesses, and supported between 2.4 and 6.5 million jobs in the United States over the past 25 years alone.²

II. The Draft Framework Will Undermine the Objectives and Success of the Bayh-Dole Act

The draft framework threatens to undermine the substantial progress made over the past 43 years under the Bayh-Dole Act in promoting commercialization of federally funded inventions. It does so by endorsing a liberal and expansive use of the limited “march-in” authority, creating uncertainty about when, whether and how the government might exercise the march-in authority of the Act. Equally concerning, comments in the draft framework suggest that the government believes that its authority is much broader than what the statute allows. For example, the draft framework incorrectly suggests that federal agencies have broad authority to invoke march-in authority to manipulate conditions of commercialization of a product or service resulting from the successful commercialization of a federally funded invention (*e.g.*, to set prices or alter manufacturing conditions).

The ambiguities and uncertainty in the draft framework, if adopted, would create unacceptable commercial risks and uncertainty for potential private sector partners, which, in turn, would chill (if not substantially eliminate) interest from the private sector in forming the partnerships necessary to commercialize products and services based on federally funded inventions. While the Request for Information (RFI) states that one of the objectives of the draft framework is to “[e]ncourage the consistent and predictable application of the Bayh-Dole Act’s march-in authority” (85 Fed. Reg. at 85594), the draft framework does exactly the opposite, creating far more questions than it answers.

A. A More Expansive Use of the March-In Authority Will Diminish Private Sector Interest in the Partnerships Necessary for Commercialization of Federally Funded Inventions

Rather than being a system of direct regulation, the Bayh-Dole Act authorizes and enables a contract-based mechanism for technology transfer under which immature inventions supported by federal funding are licensed for development and commercialization via collaborations between parties at different stages of the innovation and commercialization chain. Congress wanted the participants of Bayh-Dole-mediated collaborations to follow normal, free-market principles: it instructed that “inventions made by nonprofit organizations and smalls business

² Pressman, *et al.*, Economic Contributions of University/Nonprofit Inventions in the United States: 1996–2020, available at https://autm.net/AUTM/media/About-Tech-Transfer/Documents/BIO-AUTM-Economic-Contributions-of-University-Nonprofit-Inventions_14JUN2022.pdf; *see also* <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf>.



firms” were to be “used in a manner to promote free competition and enterprise...”³ It then vested contractors with title and control of patents on those inventions to give them the ability to contractually transact with private sector partners on commercially reasonable terms and conditions, applying only normal commercial law principles of good faith, fair dealing, and generally accepted and practiced terms and conditions in the relevant industry.

Exercising march-in rights pursuant to the principles in the draft framework would disrupt this well-established, contract-based licensing environment between contractors and their licensees and commercial partners. For example, the draft framework contemplates that an agency could determine to exercise march-in rights in connection with a patent on a federally funded invention, even though it was part of a successful collaboration that yielded products or services that are meeting market demand, and despite the absence of any contractual breach. The draft framework thus would improperly encourage agencies to engage in commercially disruptive conduct that contravenes the contractual rights and obligations of parties in a Bayh-Dole related partnership. Encouraging this type of arbitrary and capricious agency conduct is not only undesirable and contrary to the goals of the Bayh-Dole Act, it raises serious questions under the Administrative Procedure Act.

The draft framework risks materially undermining the goals and viability of the Bayh-Dole Act in two particular ways.

First, the possibility of a more expansive use of the march-in authority in a way that affects marketing of products and services arising from the successful commercialization of federally funded inventions will substantially diminish future interest by private sector companies in the partnerships necessary to develop those products and services. Commercially-focused companies require predictable, certain rights delivered from their partners who own the licensed patents. Indeed, a substantial focus of pre-agreement due diligence is on assessing whether eventual products or services will be effectively protected by intellectual property rights, and that the licensee will have the freedom to commercialize the product and realize its success without undue interference. By introducing the possibility that government agencies will unpredictably march in and reclaim title to patents many years after investments were made, and after products or services are being commercially marketed, the draft framework introduces a level of uncertainty that will make licensing and use of federally supported inventions far less attractive than patented inventions not encumbered with such risks.

³ 35 U.S.C. § 200. The statute also provides that the government retains limited rights to use the patented invention for “future research and discovery,” thus emphasizing this reservation is not being done to enable commercial competition with the partnership that has successfully commercialized an invention.



Second, the more expansive use of march-in authority would impair the ability of universities, small businesses and their licensees to secure funding from the private capital markets for commercial development of products and services if they are related to inventions supported by federal funding. The private capital markets are intensely competitive, and partnerships to develop federally funded inventions must compete with other early-stage inventions for the same limited pool of private capital. Provisions that make licensing and commercial development of products or services arising from Bayh-Dole related partnerships less viable or riskier will put those initiatives at a competitive disadvantage for securing funding from the private capital markets relative to initiatives that are not encumbered those risks. Unfortunately, the greatest impact of this disadvantage will be felt by the Bayh-Dole “contractors” (e.g., universities and small business grantees) who are more dependent on funding to generate commercial interest in their untested and immature inventions.

By diminishing private sector interest in collaborations to develop federally funded inventions, the draft framework could undermine a variety of federal innovation initiatives that depend on private sector activity in development of federally funded inventions, such as the CHIPS and Science Act, the Small Business Innovation Research (SBIR) program, and the Small Business Technology Transfer (STTR) program. All of those programs depend on robust interest in and participation by the private sector.

B. The March-In Authority Was Not Designed to and Cannot Realistically Regulate Pricing of Final Commercial Products

A central goal of the Bayh-Dole Act was to ensure the “practical application”⁴ of subject inventions developed with federal support. To that end, the drafters of the statute included a “march-in” provision designed as a failsafe to prevent shelving of licensed “subject inventions.” The legislative history of the Act makes it clear that march-in rights were meant and expected to be *rarely invoked*, except in commercially unusual circumstances that are enumerated in the statute.⁵ More frequent exercise of the march-in right, especially when guided by principles not grounded in the statute, would frustrate the goal of incentivizing partnerships to commercialize

⁴ 35 USC § 201(f): “The term ‘practical application’ means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.”

⁵ *See, e.g.*, Senate Judiciary Committee Report on S. 414 (96-480), at 28 (“The presence of ‘march-in rights’ in the licensing program (where the agency could issue additional licenses to competitors if such licensing were required to meet a public need) should be a sufficient safeguard to protect public welfare requirements and prevent any undesirable economic concentration. S. 414, however, does not actually mandate more extensive Government licensing programs.”).



subject inventions. The march-in authority was not designed, for example, to regulate commercial conditions for marketing products or services, *e.g.*, pricing or conditions of sale. Instead, its primary purpose was to rectify the unusual situation where there has been an inexcusable *failure* to commercialize the subject invention, *i.e.*, lack of “practical application.”

The suggestions in the draft framework that agencies use the march-in authority to regulate the pricing of successfully commercialized products, particularly complex products like biopharmaceutical products, is not only inconsistent with the statute, it is unrealistic.

In the biopharmaceutical sector, for example, patents on inventions supported by federal funding only infrequently have a connection to a finished, marketed biopharmaceutical product, and when they do, that connection is usually attenuated.⁶ That is because the focus of the public sector is overwhelmingly on basic research, while the focus of the private sector is on the creation and development of specific products and therapies, clinical testing of those products, development of manufacturing technologies and other commercially focused activities. Studies have shown that public institutions infrequently perform the applied research required to create and develop a specific biopharmaceutical product.⁷ Instead, the vast majority of applied research performed in connection with a new biopharmaceutical product (including discovery, characterization, manufacturing and clinical testing) is led by private companies. One study estimates that “biotechnology companies invest \$100 in development for every \$1 the

⁶ Very few FDA approved drugs and therapeutic products have any link to federally funded inventions. One recent study found that only 8% of approved drug therapies are associated with at least one patent that has a government interest statement or was supported by a federally funded program. Vital Transformation, *March-in rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents* (Nov. 30, 2023), available at <https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/>. Another study found that out of 313 drugs approved by FDA between 2010 and 2019, only about 10% of these included at least one patent listed in the Orange Book that had NIH-funding. Ledley *et al.*, *NIH funding for patents that contribute to market exclusivity of drugs approved 2010–2019 and the public interest protections of Bayh-Dole*, *PLOS One* 18(7) (July 26, 2023). Patents licensed under the Bayh-Dole Act or directly owned by the government were found to constitute only 2.6% of all patents listed in the Orange Book for 197 top-selling drugs from the years 2013-2017. Genia Long, *Federal government-interest patent disclosures for recent top-selling drugs*, *J. Med. Econ.* 22:12, 1261-1267 (2019). Approximately two-thirds of these patents do not claim the drug substance, but instead are directed to formulations or methods of using the drug. *Id.*

⁷ NIH provided over \$164 billion in funding for research relating to drugs approved between 2010-2019, but less than 1% (0.59%) of this funding was associated with the corresponding patents for those drugs. *See* Ledley *et al.*, at 6-8.



government invests in research that leads to an innovation.”⁸ A retrospective study of over 23,000 NIH grants during FY 2000, representing \$7.1 billion in public funding, showed that only a small fraction of those grants were linked to 18 new drug approvals over two decades.⁹ And while the government’s contribution to development of those 18 drug products was \$640 million, that was a small fraction of the \$44.3 billion that private companies invested to develop those products.¹⁰

The draft framework also fails to acknowledge that the march-in authority only applies to “subject inventions,” not finished commercial products. NIH has recognized this important distinction:

By law, the funding agency retains residual interest in grant- and contract-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes. This right does not extend to a licensee's final commercial product, nor does it extend to proprietary information or trade secrets that belong to another party and may be incorporated in the final product.¹¹

In other words, the Government’s residual march-in authority is limited to patents on the federally funded inventions and does not extend generally to a final commercial product, much less give rights to produce that product where it is covered by independently owned intellectual property rights. Given that most complex products, like biopharmaceuticals, reflect and embody many different inventions and technologies, and are covered by many independently owned intellectual property rights, the march-in authority does not have the ability to authorize a third party to manufacture and market a copy of the final commercial product. This inherent limitation on the march-in authority is unsurprising, given that it was devised as a remedy for failed commercialization efforts, not successful ones.

The only observation in the draft framework about this very common scenario is that it could counsel an agency to *not* exercise the march-in authority. That passing observation provides little assurance that legitimate rights and interests of private sector partners in “real world”

⁸ Stephen Ezell, *The Bayh-Dole Act’s Vital Importance to the U.S. Life-Sciences Innovation System*, ITIF Center for Life Sciences Innovation (2019).

⁹ Schulthess *et al.* *The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals*, *Ther. Innov. Regul. Sci.* 57, 160–169 (2023)..

¹⁰ *Id.*

¹¹ Dept. of Health and Human Services, *NIH Response to the Conference Report Request for A Plan to Ensure Taxpayers’ Interests are Protected*, July 2001, available at: <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf>.



collaborations will be respected. The draft framework could and should have simply confirmed that the government has no rights in other proprietary technology alongside of a subject invention and will not seek to exercise its march-in authority where there has been a successful commercialization in such settings.

The draft framework also operates under impractical assumptions about the industry and the actors involved in tech transfer deals. Licensing government-supported IP under the draft framework would become a calculated risk, and licensees would be forced to explore options to minimize or avoid that risk, for example by independently developing and commercializing the technology without a license, designing-around, collaborating with other entities that own alternative proprietary technology, or invalidating government-supported patents in the Patent Trial and Appeal Board. Second, the draft framework unrealistically assumes that after revoking a license, there would be another licensee willing to step in and take on risks from commercializing products linked to the patent on the federally funded invention, including independently owned patents covering the commercial product. Third, the draft framework assumes that an agency exercising march-in can feasibly order the patent owner (the contractor) to effectively sever its longstanding ties with its licensee and enter into a business relationship with a different commercial partner of the government's choosing. Even if this could happen, there is no reason to believe the new licensee would be willing to commercialize that product under terms less favorable or for lower returns on its investment than the original licensee.

The draft framework thus rests on an oversimplified and inaccurate set of assumptions about the ability of the march-in authority to regulate the commercial marketing of products and services that derive from a successful commercialization effort under the Bayh-Dole Act.

C. The Draft Framework Rests on Incorrect Interpretations of the Bayh-Dole Act

BIO is concerned that many aspects of the proposed draft framework are based on misinterpretations of the Bayh-Dole Act and depart from well-established administrative precedent.

The Bayh-Dole Act has a narrow window of application. It is directed to "subject inventions" which require conception or first actual reduction to practice under a federal funding agreement. The draft framework improperly conflates "subject inventions" with "the product," ignoring that the commercial and technical reality that most subject inventions are tools that can be used to discover or produce a complex downstream commercial product, or become components, constituent parts, or uses of those downstream commercial products, as discussed above.

Despite this narrow scope, the draft framework suggests that product pricing can justify exercise of march-in rights, an assertion that is flatly inconsistent with the statute and historical practices



under it.¹² Under the statute, the “practical application” requirement is met if products or services reach the market and satisfy market demand for them—the criterion for achieving a practical application thus has nothing to do with pricing of products that have actually reached the market.

The “public health and safety” requirement is also not determined by simply evaluating market prices of products resulting from a successful commercialization of a federally funded invention. Indeed, as the sponsors of the Act (Senators Bayh and Dole) explained:

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.¹³

The statute thus again focuses on whether market demand for the products is being met.

In short, the statutory language identifying the objective of benefits of the commercialization of Bayh-Dole inventions being “available to the public on reasonable terms” was never intended to be measured by simply evaluating the price of goods or services derived from use of the subject invention, but whether a product or service based on or arising from the use or licensing of the invention reaches the market in the ordinary course of commerce, and whether market demand for that product or service is being met.

The draft framework also fails to acknowledge that the march-in authority in 35 U.S.C. § 203(a)(1) only concerns conduct by a contractor or assignee, not an exclusive licensee. This point is significant because the entity that actually commercializes and sells a marketable product or service derived from a subject invention is not the contractor or assignee, but a licensee or a downstream partner of that licensee. By limiting the march-in authority to address conduct of universities or small business grantees, *i.e.*, the “contractor[s],” Congress plainly did not intend to set the terms under which downstream commercial products are marketed by the licensee or its partners. Simply put, the statutory language of § 203 cannot be read as imposing an authority on an agency to set the terms for commercial marketing of products or services derived from licensing of subject inventions.

¹² The draft framework appears to suggest that march-in rights may be exercised if the terms on which “the product” is offered to the public are not deemed “reasonable.” 88 Fed. Reg. at 85598 (“If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered [sic!] to the public are not reasonable, agencies may need to further assess whether march-in is warranted.”).

¹³ Sens. Bayh and Dole, Our Law Helps Patients Get New Drugs Sooner, *Wash. Post* (Apr. 11, 2002).



D. As Written, the Proposed Draft Framework Would Disrupt Settled Expectations Regarding the March-In Authority

Prior agency decisions provide the best guidance on the scope and applicability of the march-in provision, as they address the particular facts, circumstances and parties involved. The draft framework, unfortunately, makes no attempt to reconcile its guidance with past agency rulings on march-in petitions, and appears to be inconsistent with those past agency decisions.

For example, NIH has received multiple march-in petitions and has denied all of them, under both democratic and republican administrations. The agency's reasoned determinations in each of these cases reflected the fact that commercial prices and price comparisons with other countries are an insufficient justification for finding that there has been a failure to bring the invention to practical application, or to reasonably satisfy health and safety needs.¹⁴ Specifically, the agency has held that "the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients."¹⁵ Moreover, NIH's past experience with its short-lived "reasonable pricing clause"¹⁶ shows that efforts to regulate drug pricing through the use of federally funded research are difficult to enforce and negatively impact innovation and public-private collaborations, while providing no net benefit to public welfare.¹⁷

¹⁴ See, e.g., In the Case of Norvir, NIH Office of the Director (July 29, 2004), 5-6, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf> ("[B]ecause the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by 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."); In the Case of Norvir Determination, NIH Office of the Director (Nov. 1 2013), at 6, available at <https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf> ("We do not think that the AbbVie pricing policies and pricing disparities between the United States and other countries trigger any of the four Bayh-Dole march-in criteria.")

¹⁵ In the Case of Norvir (2013), at 7.

¹⁶ NIH established a "reasonable pricing clause" in 1989 which was then eliminated in 1995. The clause applied to products developed through collaborative public-private research grants (called CRADAs), and required a "reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public," supported by "reasonable evidence." Reports of the NIH Panels, Cooperate Research and Development Agreements (July 21, 1994 and Sept. 8, 1994), page 15, available at https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf.

¹⁷ *Id.* at 16-18; see also Conti et al., Public research funding and pharmaceutical prices: do Americans pay twice for drugs?, F1000 Res. 9:707 (2020).



Experiences under the Bayh-Dole Act also have shown that safeguards in the law (such as “march-in rights”) are rarely relevant, and when they are implicated, they can be administered using the plain language of the statute. As recently as 2016, DHHS Secretary Burwell, under the then-Obama administration, stated that it is the position of DHHS and NIH that “the statutory criteria [for march-in] are sufficiently clear and additional guidance is not needed.”¹⁸ BIO is unaware of any significant changes in law or the nation’s economic circumstances that would necessitate the drastic change in use of the march-in authority reflected in the draft framework. The agency should explain the specific events or developments that it believes warrant altering longstanding administration policies on use of the march-in authority and whether the agency intends this draft framework to supersede past agency rulings on march-in petitions. NIST should also explain whether it has identified instances since 1980 (or at the very least since Secretary Burwell’s statement in 2016) where agency march-in authority should have been exercised but was not.

III. The Draft Framework Can and Will Create Confusion

The draft framework contains numerous ambiguities and relies on a number of impractical examples. Collectively, its elements would introduce a significant potential for misapplication and misuse of the statutory march-in authority.

Most significantly, the draft framework fails to account for the complexity of marketing and distribution of products in a wide range of manufacturing and service industries. Commercial products, including biopharmaceutical products, flow through the chain of commerce in a myriad of ways, being offered to different actors along the chain of commerce on different terms. What would be the relevant price, for example, for a product that is sold to national wholesalers, who sell it to regional wholesalers, who sell it to retailers, who sell it to end-users and consumers? How are rebates, discounts, and mark-ups along the chain accounted for? How would one account for differential pricing at any given level in the distribution chain; would it be an average of all prices, or the highest or the lowest price, or some other measure? Who, even, is the relevant “public” – wholesalers, retailers, end users, added-value manufacturers, other resellers, consumers, public and/or private buyers? What constitutes “reasonable terms” for these actors when all are virtually certain to transact on different terms, including pricing? Congress must have been aware of the commercial realities under which products are distributed and sold in the marketplace, and could not reasonably have expected public, science-based agencies to adjudge the reasonableness of such market-driven terms and transactions, simply because they provided some amount of funding to a upstream contractor.

¹⁸ HHS Ltr. to Hon. L. Doggett re: March-in Rights, available at <https://bayhdolecoalition.org/wp-content/uploads/2023/05/302959645-HHS-Letter-to-Doggett-Re-March-In-Rights.pdf>.



Similar uncertainty is inherent in the draft framework’s consideration of “shelving.” The reservation of march-in rights was intended to protect the government against the unusual situations in which a commercial partner made no good-faith efforts to develop the technology created under their agreement, but rather “shelved” the technology to prevent any development by any other interested party. In the 43 years since Bayh-Dole was enacted, the government has never found such a situation to exist. This is for good reason. Technology licenses, including under the Bayh-Dole framework, generally contain carefully-drafted milestone and due diligence obligations to ensure that development of the licensed invention is being advanced, as well as reversion clauses that enable the licensing institution to take the licensed invention back in case of inexcusable inaction by the licensee. In this way, the Bayh-Dole Act commits the assessment of development delays or inaction to the licensing institution in the context of its ongoing relationship with the licensee. Unfortunately, the draft framework invites funding agencies to substitute their own judgment for that of the licensor-institutions, and it includes a definition of “shelving” which provides an unacceptably vague and uncertain standard for what constitutes inexcusable inaction in bringing the invention to practical application. This lack of clarity will lead to inconsistency across agencies and among potential collaborators.¹⁹

Another source of confusion lies in the draft framework’s invocation of the march-in authority to enforce the Act’s domestic manufacturing requirement. The statute requires that “products embodying the subject invention or produced through the use of the subject invention” be substantially manufactured in the United States, with potentially severe penalties for failure to do so absent a waiver or other exemption.²⁰ The Act’s domestic manufacturing requirement has given rise to numerous questions over the years, and the heads of funding agencies are currently in the process of coordinating on a unified set of policies and guidance pursuant to President Biden’s July 28 Executive Order on domestic manufacturing.²¹ The draft framework provides no guidance on the proper interpretation of the domestic manufacturing requirement, increasing the

¹⁹ For example, how would an agency determine when development, use, or sale of the invention or product embodying it has not occurred “for an extended period of time;” or when the pace or delay in developing, using, or selling the invention or product is justified or excused? What deference is to be given to a university’s or small business licensor’s position regarding appropriate pace or direction of development? Would the agency consider whether there is available capacity in the U.S. market to develop, use, or sell the invention faster than the status quo? Inter-agency inconsistency or disagreement on the meaning of the framework and its new definitions will create increased uncertainty and risk for private industry, as companies may find themselves subject to a variety of conflicting and ever-changing standards.

²⁰ 35 U.S.C. § 204; *see also* 35 U.S.C. § 203(a)(4).

²¹ Exec. Order on Federal Research and Development in Support of Domestic Manufacturing and United States Jobs (July 28, 2023), available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/07/28/executive-order-on-federal-research-and-development-in-support-of-domestic-manufacturing-and-united-states-jobs/>.



uncertainty among stakeholders in the Bayh-Dole system. Rather than discussing the use of the march-in authority in an unclear and evolving environment, NIST should await forthcoming regulatory clarification on the scope of “substantial” domestic manufacturing and the criteria for granting a waiver.

The eight scenarios are described in the RFI as “presenting a variety of hypothetical scenarios where march-in could emerge”²² and include various factors and questions (including considering the subjective factors of the “policy and objectives of Bayh-Dole”) without coming to any useful conclusions. Although the scenarios rightfully recognize the complexity and fact-specific nature of the questions that must be answered, the approach reflected in these examples is directly contrary to the stated goal of the draft framework of encouraging consistent and predictable application of the march-in authority. Moreover, the hypothetical scenarios provided in the draft framework offer extreme examples that assume a serious market failure and/or failure of parties to fulfill their contractual obligations. In the real world, such problems would be resolved by resort to conventional contract terms, not by the extraordinary step of an exercise of the march-in authority. NIST has not provided its proposed resolution to any of these scenarios, much less explained how such scenarios can only fall outside of issues addressed by contract law. And in the scenario where a contractor and licensee have both fulfilled their obligations and have successfully commercialized a product, the draft framework fails to explain the basis under which an agency could substitute its own judgement in place of the terms of a license.

BIO respectfully requests that NIST reconsider the necessity of developing a framework on the exercise of the march-in authority. The clarity of the statutory language, coupled with the effectiveness of conventional contract language to remedy failures of a licensee to advance development of a licensed “subject invention,” demonstrate that there is no need for the draft framework. Moreover, for the reasons set forth above, the draft framework, if adopted, will discourage public-private collaborations and innovations that the Bayh-Dole Act was intended to promote. Withdrawing the draft framework would preserve the complex, but balanced, ecosystem of biopharmaceutical development that advances the goals of the Bayh-Dole Act and which continues to demonstrate its success to this day.

Respectfully submitted,

Biotechnology Innovation Organization

²² 88 Fed. Reg. at 85601.