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Vice President,
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February 6, 2024

VIA ELECTRONIC SUBMISSION

Alicia Chambers
Executive Secretariat
National Institute of Standards and Technology
Attention: Mojdeh Bahar, Associate Director for Innovation and Industry Services
100 Bureau Drive
Gaithersburg, MD 20899

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No. 230831-0207, NIST-2023-0008

Dear Ms. Chambers:

The National Association of Manufacturers (“NAM”) appreciates the opportunity to respond to the *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (“Proposal”) issued by the National Institute of Standards and Technology (“NIST”).¹

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturers make significant investments in research and development (“R&D”), accounting for more than half of all private-sector R&D in the United States. This research results in groundbreaking inventions that improve the quality of life for all Americans; it also supports well-paying jobs for the 13 million people who make things in America. Manufacturers therefore rely on a strong U.S. patent system for the certainty and protection that it brings to the products and technologies that these companies patent and license.

The NAM strongly opposes the proposed expansion of the government’s ability to march in and seize manufacturers’ intellectual property (“IP”) rights. Manufacturers respectfully urge the Administration to immediately and unequivocally withdraw the Proposal.

The Proposal contemplates an expansion of the Bayh-Dole Act’s march-in provision, which has *never* previously been used during the 44 years since the law’s enactment.² This unlawful expansion of a 44-year-old statutory provision would prompt the government to exercise march-in rights to force patent licenses to private-sector inventions that are derived at least in part from federal funding. This price control measure would impact innovative companies of all kinds across the manufacturing sector; by its own terms, the Proposal “is not meant to apply to just one type of technology or product.”³ Undermining manufacturers’ IP rights would have sweeping ramifications for innovation in the United

¹ See National Institute of Standards and Technology, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, 88 Fed. Reg. 85,593 (Dec. 8, 2023) [hereinafter, “Proposal”].

² See The Patent and Trademark Law Amendments Act, Pub. L. 96-517, 94 Stat. 3015 (1980) (codified as 35 U.S.C. §§ 200-212) [hereinafter, “Bayh-Dole Act”].

³ Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,595.

States and America's world-leading innovation economy. In particular, start-ups and small businesses would bear the brunt of the drastic changes proposed by the Administration, as the spectre of government march-in would disincentivize early-stage entrepreneurship and dissuade much-needed capital formation from outside investors.

If the Administration moves forward with the Proposal, the unprecedented expansion and use of the Bayh-Dole Act's march-in provision would impede R&D, investment, and the commercialization of innovative technologies. It would cause significant market uncertainty as to current and future patent licenses that are derived in any part from federal funds—directly contradicting the intent and purpose of Bayh-Dole. And it would hinder industry collaborations with research universities and laboratories across the country, stymieing manufacturers' efforts to develop the products and technologies of the future and bring them to the public. Undermining the U.S. innovation economy would harm American competitiveness at a time when China has made no secret of its desire to lead the world in advanced manufacturing and the technologies of the future.

Moreover, as a matter of law, the Administration's attempt to expand the Bayh-Dole Act's limited-in-scope and never-used march-in provision represents a stark and alarming departure from the Act and bedrock tenets of sound policymaking. Indeed, the Proposal is wholly inconsistent with the statute, as it includes price as a consideration in the government's march-in analysis—when the Act's bipartisan authors *intentionally* omitted price from the Act.⁴ The Proposal further contravenes Congress's intent by creating considerable uncertainty about IP rights for federally funded patents through its use of hypothetical examples that lower the statutory thresholds for march-in. If enacted, the Proposal's disregard for the will of Congress would also raise separation of powers questions under the major questions doctrine. Finally, the Proposal's lack of any economic or cost-benefit analysis, and its failure to consider any reasonable alternatives, all depart from the lawful rulemaking processes required by the Administrative Procedure Act ("APA").

All told, the Proposal is fundamentally flawed and would have disastrous consequences on manufacturers, American innovation, and the U.S. economy. The NAM respectfully encourages the Administration to provide certainty to manufacturers and other stakeholders in the innovation economy by affirmatively and unequivocally withdrawing the Proposal and making clear that the Administration will not implement any of its recommendations. Abandoning and disclaiming the Proposal's attempts to impose price controls and undermine the Bayh-Dole Act will ensure that manufacturers in the United States can continue to lead the world in R&D and innovation—and continue to create and support well-paying jobs vital to the success of the U.S. economy.

⁴ U.S. Sens. Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASHINGTON POST (Apr. 11, 2002), available at <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>.

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I. The Bayh-Dole Act And The Government's Consistent Refusal To March In Have Led To America's Economic, Industrial, And Innovative Revitalization.

A. The Bayh-Dole Act has been a resounding success.

In 1980, Congress passed the Bayh-Dole Act during a time of heightened international competition and American economic, industrial, and innovative stagnation. To bolster American competitiveness in the face of increased competition for economic leadership on the world stage, the United States launched a range of policies to encourage industrial innovation, one of which was the Bayh-Dole Act.⁵

Senators Birch Bayh (D-IN) and Bob Dole (R-KS) authored the bipartisan Bayh-Dole Act. As explained by the Senators: "Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. . . . [T]he primary purpose of the [A]ct was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."⁶ To achieve this purpose, the Act allowed researchers or the institutions sponsoring federally funded research, such as private businesses or universities, "to use the patent system to promote the utilization of inventions arising from federally supported research or development."⁷ In other words, the Act permitted private persons, companies, and universities to obtain title to patents covering products and technologies derived from federal funding.

Prior to the Act's passage, the government held approximately 28,000 patents—yet fewer than 4% of those patents were licensed to the private sector.⁸ This is because private-sector participants viewed these patents as "[c]ontaminated by government funding" since the patents were licensed on a *nonexclusive* basis.⁹ Private-sector participants largely avoided these nonexclusive licenses because they could not be assured of returns on their investments in bringing the resulting products and technologies to market.¹⁰ To put it simply, before Bayh-Dole's passage, the private sector had no incentive to collaborate with research universities and laboratories when federal funding was present. In fact, the private sector was *disincentivized* to engage in such collaborations. This resulted in government-funded research being left "on the shelf" in laboratories across the country, with potentially life-changing or life-saving innovations never able to reach commercialization.

The Act reversed the trend of private-sector actors being forced to avoid "[c]ontaminated," government-licensed patents. As a result, the Act has sparked tremendous innovation and economic growth, including throughout the manufacturing sector. Bayh-Dole's success led *The Economist* to remark that the Act is "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century. . . . [The Act] unlocked all the inventions and discoveries that had been made in

⁵ Gabrielle Athanasia, *The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today*, CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES (Jan. 12, 2022) ("Japan's modernization of its industrial production process began to yield tangible gains. Advances in precision machining technologies gave Japanese cars and electronics an edge over the American products in the global market. To rise to the challenge posed by Japan's industry, the U.S. launched a range of policy experiments that sought to encourage innovative small firms and start-ups [to] grow and compete in global markets."), *available at* <https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today>.

⁶ U.S. Sens. Bayh & Dole, *supra* n.4.

⁷ Bayh-Dole Act, *supra* n.2, 35 U.S.C. § 200.

⁸ Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, at 1, SCIENCE (Oct. 6, 2010), *available at* <https://www.science.org/doi/pdf/10.1126/scitranslmed.3001481>.

⁹ See David Kappos & Andrei Iancu, *Opinion: President Biden's domestic technology seizure plan*, THE HILL (Jan. 14, 2024), *available at* <https://thehill.com/opinion/4407846-president-bidens-domestic-technology-seizure-plan/>.

¹⁰ See Loise & Stevens, *supra* n.8, at 1.

laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."¹¹ Indeed, by 2020, there were more than 7,911 Bayh-Dole-licensed patents.¹² The use of these patents has sustained over 6 million jobs and added nearly \$2 trillion to U.S. GDP since the Act's inception.¹³

The Act achieved its goal of fostering public-private partnerships between industry, universities, and laboratories—partnerships that were essentially nonexistent in the decades prior to 1980. These partnerships have contributed to innovation, funding for universities through patent licenses, and the overall success of the industrial economy and educational system in the United States. For example, since the Act's passage, over 11,210 start-ups have been created through technology transfer activities between universities, laboratories, and industry.¹⁴ Now, universities create approximately two start-ups each day, which add American jobs and support local economies.¹⁵

Bayh-Dole is a uniquely American success story that many countries have sought to emulate. Indeed, "America's Bayh-Dole legislation has been copied by more than two-dozen countries," including most developed countries, given the Act's success in sparking innovation.¹⁶ The reason is simple: Countries with "[r]obust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks."¹⁷ Congress understood the benefits of strong IP rights when it passed the Act, and the American innovation economy has reaped the rewards of this insight.

B. Bayh-Dole's statutory march-in provision is intentionally narrow in scope.

The Bayh-Dole Act contains a march-in provision that allows the government to march in on the IP rights associated with federally funded patents in very limited circumstances. The Act allows a federal agency to exercise this right only if the agency determines that: (1) "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;" (2) "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;" (3) "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee,

¹¹ *Innovation's golden goose*, THE ECONOMIST (Dec. 14, 2002), available at https://bayhdolecoalition.org/wp-content/uploads/2023/05/The-Economist-December-14-2002-Innovation_s-Golden-Goose-Article.doc.pdf.

¹² Sara Abdulla & Jack Corrigan, *Bayh-Dole Patent Trends 2*, GEORGETOWN UNIVERSITY CENTER FOR SECURITY AND EMERGING TECHNOLOGY (Aug. 2023), available at <https://cset.georgetown.edu/publication/bayh-dole-patent-trends/>.

¹³ Press Release, *Bayh-Dole Coalition Statement on Biden Administration's Proposed March-in Framework*, BAYH-DOLE COALITION (Dec. 7, 2023), available at <https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-biden-administrations-proposed-march-in-framework/>.

¹⁴ *The Role Of The Bayh-Dole Act In Fostering Technology Transfer And Implications for Innovation* 12, PHRMA (Feb. 2020), available at <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Bayh-Dole-Whitepaper-FINAL---21820.pdf>.

¹⁵ *Id.*

¹⁶ See *National Innovation Policies: What Countries Do Best And How They Can Improve* 5, GLOBAL TRADE & INNOVATION POLICY ALLIANCE (June 2019), available at <https://www2.itif.org/2019-national-innovation-policies.pdf>; see also Michael S. Mireles, *Adoption Of The Bayh-Dole Act In Developed Countries: Added Pressure For A Broad Research Exemption In The United States?* 260, MAINE L. REV. Vol. 59:2 (2007) ("Numerous developed countries, most if not all members of the Organisation of Economic Cooperation and Development [], including Japan, France, the United Kingdom, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland, have or are considering adopting legislation similar to the Bayh-Dole Act.").

¹⁷ See, e.g., Stephen Ezell & Nigel Cory, *The Way Forward for Intellectual Property Internationally* 6, INFORMATION TECHNOLOGY & INNOVATION FOUNDATION (Apr. 2019) (internal quotation marks omitted) (collecting studies), available at <https://www2.itif.org/2019-way-forward-ip.pdf>.

or licensees;” or (4) “action is necessary” because a licensee has not met the Act’s preference for federally funded inventions to be “manufactured substantially in the United States.”¹⁸

These four statutory factors are intentionally meant to be narrow in application. They are meant to serve as an emergency ripcord for the government to act in times of crisis or to prevent “companies from licensing academic know-how merely to block rival firms from doing so.”¹⁹ The reason for such a narrow application of these factors has to do with the intent behind the Act. In order to spark public-private collaboration, the private sector has to be assured that the government will not strip their IP rights at its arbitrary choosing. Otherwise, the exceptions swallow the rule, and companies will not be “willing to invest millions . . . of their own money to turn a raw research idea into a marketable product.”²⁰ As noted by Senators Bayh and Dole, the Act is intended to allow “the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product,” in consideration of the four factors described above.²¹

For 44 years, none of these egregious circumstances has ever materialized. And successive administrations of both parties honored Congress’s intent by narrowly applying any relevant factor—and thus have rejected every march-in petition to date. This administrative restraint is a direct contributor to the Act’s dramatic success over the past four decades because it has provided the private sector with the certainty needed to take federally funded licenses and engage in public-private collaboration. Now, for the very first time, the Proposal would dramatically expand the government’s ability to march in, well beyond the limited “crisis” scenarios contemplated by the Act—and, in so doing, would provide federal agencies with a roadmap to seize manufacturers’ patent rights across a wide range of scenarios and circumstances. The Proposal effectively vitiates the purpose of the Act, and as a result poses an immediate and concrete threat to the innovation and technology transfer ecosystem—and the millions of American jobs it supports—that the Act carefully and thoughtfully created.

II. The Proposal Contradicts The Statutory Text And Legislative Intent Of The Bayh-Dole Act.

The Proposal risks unwinding 44 years of benefits to American innovation and the industrial economy generated by the Bayh-Dole Act and the robust technology transfer ecosystem that has developed in the decades since the Act’s enactment. The Proposal does this by improperly and impermissibly adding price into the government’s march-in analysis. The Proposal further ignores the Act’s intent by lowering the threshold for the statutory criteria enabling the government to march in, and by injecting uncertainty into the innovation ecosystem by seeking to regulate via hypothetical scenarios that grant federal agencies significant latitude to use subjective criteria to march in. All of this will result in the amorphous threat of march-in hanging over innovators throughout the economy. The Proposal’s new, atextual approach would result in federal agencies empowered to pursue unbridled, subjective, and arbitrary march-in decision-making processes—undermining the U.S. patent system and the innovation economy it supports.

¹⁸ Bayh-Dole Act, *supra* n.2, 35 U.S.C. § 203(a); *see also id.* at 35 U.S.C. § 204 (explaining preference for inventions to be manufactured in the United States).

¹⁹ *See Innovation’s golden goose*, *supra* n.11.

²⁰ *Id.*

²¹ U.S. Sens. Bayh & Dole, *supra* n.4.

A. The Proposal atextually and improperly considers price.

“[A]n agency’s power is no greater than that delegated to it by Congress.”²² Thus, an agency must not regulate outside of the authority given to it by Congress. The Proposal does so here because it atextually and improperly considers price as a factor in the government’s march-in analysis. Specifically, the Proposal centers on “the reasonableness of [] price,” which is a term nonexistent in the Act’s text and undefined by the Proposal.²³

By the Act’s plain text, the price of a product or technology should not factor into the government’s march-in analysis.²⁴ Indeed, a price consideration is wholly absent from the Act’s statutory language. As Senators Bayh and Dole explained, the Act “did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. *This omission was intentional*[.]”²⁵ The Senators went further, stating: “The ability of the government to revoke a license granted under the [A]ct 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.”²⁶ Otherwise, as explained by the Senators, the private sector would not be “entice[d] . . . to seek public-private research collaboration,” which would defy the “primary purpose” of the Act.²⁷

Adding price as a consideration amounts to government price controls for the relevant products and technologies. As with other price controls in a free-market economy, this will have grave consequences for industry. Among other things, any price consideration by the government would be wide-ranging and subjective. Companies would be forced to ponder the prices at which the government might march in and any views the government might have about an “appropriate” level of profitability. In turn, business decision-making would become skewed and distorted. As a result, companies would not be willing to take the risks on developing and commercializing inventions, knowing that the government might march in at any time based on constantly shifting political whims as to what price might be considered appropriate or inappropriate. Speculative pondering and distorted decision-making is not conducive to supporting public-private collaboration or sparking innovation. That is exactly why Congress intentionally omitted a price consideration from the Act’s march-in analysis.

The flaws of this approach are highlighted in many of the scenarios contained in the Proposal. Scenarios 5 and 6, for example, focus on product prices. Yet there is no discussion as to what aspects of price an agency considering march-in might take into account, or what pricing decisions by a company might or might not invite march-in. The simplistic examples in the Proposal evoke hypothetical and opportunistic price increases amidst acute crises, but it is not at all clear how or why an agency should march in under such scenarios—or what the scenarios’ limiting principle(s) might be when applied to other fact patterns. Rather, the focus on price both within the Proposal and throughout the Administration’s justifications for it evince an overarching effort to impose price controls on a wide range of innovative products—without any guidance for companies or guardrails for agencies.²⁸ Such an approach is clearly outside the Administration’s authority under the Bayh-Dole

²² *Lyng v. Payne*, 476 U.S. 926, 937 (1986).

²³ Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,598.

²⁴ See Kappos & Iancu, *supra* n.9.

²⁵ U.S. Sens. Bayh & Dole, *supra* n.4 (emphasis added).

²⁶ *Id.*

²⁷ *Id.*

²⁸ See, e.g., @POTUS, X (formerly, Twitter) (Dec. 7, 2023) (“[M]y Administration is proposing that if a drug made using taxpayer funds is not reasonably available to Americans, the government reserves the right to ‘march in’ and license that drug to another manufacturer who could sell it for less.”).

Act, and it would undermine the innovation-to-commercialization pipeline at the core of the Act's success. Any attempt to graft this new consideration onto the march-in analysis is extra-statutory and unlawful.

To get around the fact that the Act does not mention price as a criteria for march-in, the Proposal invokes the Act's reference of march-in action "necessary to alleviate health or safety needs" and to increase the supply of the products in question.²⁹ The Proposal suggests that the government has unbridled, subjective, and arbitrary discretion to define what constitutes a health or safety need, despite a lack of congressional direction, and to march in in any scenario where such a need has been identified. Furthering this extra-statutory misinterpretation of the "health and safety" provision of the Act, the Proposal emphasizes *price* as the trigger for march-in in such scenarios. This atextual approach gives away the game: illustrating the Proposal's desire to impose price controls absent any authorization to do so in the text of the Bayh-Dole Act.

Agencies have wrestled with questions of price in the context of march-in for years, *always* determining that they lacked the authority to consider price—and rejecting march-in petitions based on price accordingly. For example, in 2004 petitioners asked the National Institutes of Health ("NIH") to march in "due to concerns over the high price of an HIV/AIDS treatment, Norvir/ritonavir."³⁰ The NIH under the Bush Administration refused, saying: "[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. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."³¹ Similarly, less than a year ago, the NIH under the Biden Administration denied a march-in petition related to the prostate cancer drug Xtandi, which petitioners argued was too expensive. Here, the NIH stated: "NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug."³² In these examples, two administrations of different political parties came to the same and correct conclusion: that march-in should not and cannot be used to control price.

If the Proposal is adopted, and price is a factor in the government's march-in analysis on a going-forward basis, industry will be forced to read the tea leaves as to when the government plans to march in and seize an innovator's patent rights—which could theoretically be any time when there is a profit margin. Put simply, the uncertain nature of the Proposal could lead to march-in petitions any time a company makes a profit of any size on any product. Such an approach would incentivize petitions from a wide range of market actors seeking to influence price, and it would serve as a threat on the part of the government to force companies to adhere to price controls to avoid potential march-in petitions—and march-in itself from the government. This uncertainty will harm R&D and investment decisions and distort markets, which may affect the development of products and technologies that will solve the problems of the future—from health care to green energy to cybersecurity to aerospace products and technologies. Ultimately, attempting to impose price controls via the Bayh-Dole Act will prevent the

²⁹ Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,603; see also Bayh-Dole Act, *supra* n.2, 35 U.S.C. § 203(a)(2).

³⁰ Alexander Kersten & Gabrielle Athanasia, *March-In Rights and U.S. Global Competitiveness*, CENTER FOR STRATEGIC & INTERNATIONAL STUDIES (Mar. 24, 2022), available at <https://www.csis.org/analysis/march-rights-and-us-global-competitiveness>.

³¹ *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.* 5-6, NATIONAL INSTITUTES OF HEALTH (July 29, 2004), available at <http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf>.

³² *Letter re: Xtandi Petition 2*, NATIONAL INSTITUTES OF HEALTH (Mar. 21, 2023), available at <https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-21march2023.pdf>.

development of the very groundbreaking technologies the law was enacted to encourage and support, harming consumers, universities, and the economy alike.

B. The Proposal contravenes the Bayh-Dole Act's intent by lowering the thresholds for march-in and increasing uncertainty.

The Proposal represents the most significant government discussion of the Act's march-in provision since its enactment. After 44 years with zero instances of march-in, the Proposal identifies eight hypothetical scenarios that could potentially justify it. The hypothetical scenarios demonstrate a dramatic lowering of the thresholds for when the government might exercise its march-in right when viewed in the context of the Act's intent and subsequent implementation. Under the Proposal, any entity, including a foreign entity, can petition the government to exercise its march-in rights based on these hypothetical scenarios. With no check on entities petitioning the government, and the fact-intensive and subjective discretion given to the government, the Proposal would result in a free-for-all, leading the government to become mired in the operations of private-sector companies.

All of this would be based on federal agencies, patent owners, investors, and those considering seeking a federally funded patent license trying to make sense of the eight hypothetical scenarios and applying these scenarios to factually different situations. Thus, the Proposal puts a thumb on the scale in favor of petitioners, including those who may not actually intend to produce competing products, who could use the compliance and potential litigation costs associated with march-in petitions as leverage in licensing negotiations, thereby distorting the market. If the Proposal moves forward, petitioners would seize upon the expanded march-in criteria to file petitions to their advantages. The government very well might entertain these petitions given the lowered thresholds for march-in after four decades of the government never marching in.

Further, the Proposal effectively constitutes regulation by hypothetical. That alone creates massive uncertainty. As discussed above, these hypotheticals are inherently vague and are difficult to apply to real-life situations involving specific patents. Indeed, under the scenarios, patent owners and industry cannot readily discern how the government will use them and when it will apply them in its march-in analysis, which creates both real and legal uncertainty.³³ Undoubtedly, these hypothetical scenarios would lead to a waterfall of unpredictable litigation involving specific products.

In sum, neither the text of the Act nor Senators Bayh and Dole intended for the Proposal's increased government involvement in federally funded patents, thumb on the scale in favor of petitioners, or the inherent uncertainty caused by the use of vague hypothetical scenarios. To the contrary, the Act was intended to reduce government involvement and uncertainty in federally funded patents "to promote the utilization of inventions arising from federally supported research or development."³⁴ That march-in rights have never been exercised to date increases confidence in the investment necessary to bring such innovative technologies to market, and has been a direct contributor to the Act's success—but that confidence and market certainty would be significantly undermined by the Proposal.

³³ See, e.g., *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (Courts will "uphold a decision of less than ideal clarity" only "if the agency's path may reasonably be discerned.") (citation omitted).

³⁴ Bayh-Dole Act, *supra* n.2, 35 U.S.C. § 200.

III. The Proposal Is Arbitrary and Capricious and Exceeds NIST's Statutory Authority.

As explained by various commenters, there are other fundamental legal concerns with the Proposal.³⁵ For example, among many others, the Proposal, if enacted, would raise serious separation of powers concerns and implicate the major questions doctrine. The major questions doctrine prevents agencies from “asserting highly consequential power beyond what Congress could reasonably be understood to have granted.”³⁶ Courts have found that an agency violates the major questions doctrine on matters of significant economic importance when the agency cannot “point to clear congressional authorization for the power it claims.”³⁷ The government’s ability to seize private-sector IP is undoubtedly a topic of vast economic and political significance; as discussed, America’s robust patent system lies at the heart of the innovation economy in the United States—and the Proposal would threaten the financing of that innovation ecosystem and the economic viability of many of its key participants (including start-ups, entrepreneurs, small- and medium-sized businesses, universities, and more). The effects of the Proposal would be felt in every state and every congressional district. Yet the Proposal cannot point to “clear congressional authorization” for including a price consideration in the government’s march-in analysis because it does not exist; as explained above, price is wholly absent from the Bayh-Dole Act’s text. More broadly, the Act was enacted to support public-private partnerships and bolster the innovation economy in the United States—yet the Proposal would undermine and endanger American innovation. It is unlikely that Congress, in passing the Bayh-Dole Act, “could reasonably be understood to have granted” the Administration the power to vitiate the primary goal of the Act itself.

If finalized, the Proposal also would fall short of NIST’s obligation to employ appropriate rulemaking procedures under the APA. Regulation is “arbitrary and capricious” if an agency “has relied on factors which Congress has not intended it to consider.”³⁸ As discussed, the Proposal includes price as a factor, which Congress clearly did not intend. Among other APA issues, the Proposal also “failed to consider . . . important aspect[s] of the problem[s]” it purportedly seeks to address by not conducting any sort of economic or cost-benefit analysis of the downstream consequences that it will have on the innovation ecosystem and the U.S economy.³⁹ See *infra* pp. 11-14.

Additionally, the Proposal did not consider any reasonable alternatives, including, for example, ways to limit its scope.⁴⁰ Indeed, the Proposal has no limiting principle whatsoever. All products and technologies and all industries would be impacted by the Proposal, no matter the relative size of the contribution of federal funds to inventions. This is particularly arbitrary given the magnitude of private investment needed to bring a product to market. For example, studies have shown that industry can contribute as much as 66 times more in funding as compared to the government’s contribution to innovative new therapies.⁴¹ Specifically, a 2022 study found that “NIH funding for . . . 18 FDA-

³⁵ See, e.g., *Letter re: December 8, 2023 Request for Information Regarding Draft Interagency Guidance Framework for Considering the Exercise of Bayh-Dole Act “March-In Rights,”* AM. BAR ASSOC. INTELLECTUAL PROP. L. SECTION (Jan. 31, 2024).

³⁶ *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 724 (2022); see also *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (“When Congress intends to “assign to an agency decisions of vast ‘economic and political significance,’” Congress “speak[s] clearly.”) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)).

³⁷ *W. Virginia*, 597 U.S. at 723 (internal quotation marks omitted).

³⁸ *Motor Vehicle Mfrs. Ass’n of U.S.*, 463 U.S. at 43.

³⁹ *Id.*

⁴⁰ See *id.* at 48 (“At the very least this alternative way of achieving the objectives of the Act should have been addressed and adequate reasons given for its abandonment.”).

⁴¹ See, e.g., Gwen O’Loughlin & Duane Schulthess, *What is the Bayh-Dole Act* 19, VITALTRANSFORMATION (Nov. 30, 2023), available at https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

approved therapies” since 2000 “totaled \$0.670 billion, whereas private sector funding (excluding post-approval funding) totaled \$44.3 billion.”⁴² This is true in general: on average, industry contributes significantly more to the development and commercialization of inventions in virtually all areas of technology. “A dollar’s worth of academic invention or discovery requires upward of \$10,000 of private capital to bring to market.”⁴³

Thus, the invocation of the government’s march-in right, no matter the size of the government’s contribution to the underlying product or technology, would impact thousands of patent owners and their manufacturing partners, and threaten the sanctity of patents—a right guaranteed by the Constitution—and the U.S. patent system. Indeed, knowing that the government might march in no matter how small the federal contribution and with little clarity as to what fact patterns might lead to the government actually marching in would lead to private businesses being less willing to take risks to invest and commercialize the products of *any* federally funded research.

For all of these reasons and more, the Proposal is arbitrary and capricious and exceeds NIST’s legal authority. As such, it should be unequivocally withdrawn.

IV. The Proposal Would Have Negative Effects On All Technologies And Industries, Especially Small Businesses And Research Universities And Laboratories.

If finalized, the Proposal would disproportionately harm start-ups and small- and medium-sized businesses. It would hamper investment and R&D decisions at a time of intense global competition. And it would hinder public-private collaboration between industry and the academic and research communities.

A. The Proposal would negatively and disproportionately impact start-ups and small- and medium-sized businesses.

While the Proposal would affect all companies, start-ups and small- and medium-sized businesses would be disproportionately harmed for at least four reasons. First, smaller companies depend more on federally funded technologies than larger companies. Indeed, start-ups license approximately 70 percent of patents associated with federally funded university research.⁴⁴ Moreover, smaller companies often are dependent on *one* product or technology from *one* patent or related patent portfolio. As such, march-in could make or break a smaller company because it might not have the benefit of a large and diversified product portfolio. Second, smaller companies face significant capital formation challenges, which in turn demands stable patent rights so that investors have the required certainty needed to support their investment. Because the Proposal would create significant uncertainty about these companies’ IP rights, it would reduce the ability of small businesses to attract investors. Third, under the Proposal, more-established competitors could argue in march-in petitions that they could bring products to market more quickly and with less expense than smaller companies. This would result in a vicious cycle that would stymie innovation, as smaller companies with the most successful and innovative products would find themselves subject to march-in petitions and potential litigation that would increase their operating costs and undermine their IP rights. Fourth, and relatedly, smaller companies have fewer resources to defend against march-in petitions in the first place—so

⁴² Duane Schulthess, et al., *The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals* 160, THERAPEUTIC INNOVATION & REGULATORY SCIENCE, 57:160–169 (Sept. 3, 2022).

⁴³ See *Innovation’s golden goose*, *supra* n.11.

⁴⁴ Joseph Allen, *New March-In Guidelines Threaten U.S. Innovation*, IPWATCHDOG (Dec. 10, 2023), available at <https://ipwatchdog.com/2023/12/10/new-march-guidelines-threaten-u-s-innovation/id=170491/>.

any resources to protect their IP rights would be directly diverted from critical priorities like R&D and job creation.

To put the effects of the Proposal into perspective, it could impact the development of future technologies that Americans might find ubiquitous and helpful to everyday life. For example, ground-breaking and well-known companies like Google were either founded or relied in part on federally funded patents for their success.⁴⁵ This is not surprising as the technology-transfer ecosystem that the Bayh-Dole Act created has led to the creation of over 11,210 start-ups.⁴⁶ Under today's Proposal, these companies might never have gotten off the ground. And the two start-ups that universities create each day based on the technology-transfer ecosystem might never have the opportunity to become the Googles of the future.⁴⁷

The Proposal's effect on start-ups and small- and medium-sized companies is not conjecture. Indeed, by its own terms, the Proposal concedes that it will apply to these businesses. For example, Scenario 2 involves an "advanced manufacturing startup," Scenario 3 involves a "medium-sized company that is seeking to grow," and Scenario 4 involves a "small pharmaceutical startup."⁴⁸ And, both Scenarios 2 and 4 highlight the fact that more-established competitors could petition the government to march in based on the rationale that they could bring products to market more quickly, given their resources.⁴⁹

Ultimately, the Proposal's focus on start-ups and small- and medium-sized businesses would have disastrous economic consequences on a vanguard of innovation in the United States. Indeed, these smaller companies would find themselves directly in the Proposal's crosshairs if the Proposal is finalized.

B. The Proposal would negatively impact investment and R&D decisions.

Just as in the decades before the Bayh-Dole Act was passed into law, if the Proposal is not withdrawn, investors would not be incentivized to invest in companies that hold federally funded patent licenses. This is because march-in rights as interpreted by the Proposal would swallow all the benefits of the Bayh-Dole Act, as investors would not know when the government might march in on a portfolio company's products or technologies, thereby placing investments at risk. The Proposal increases uncertainty about IP rights through both its extra-statutory consideration of price—which the government has never used as a factor to march in before—and its vague hypothetical scenarios.

Innovation is difficult and risky. By definition, innovative technologies are new and often fail. If they succeed technically, they might fail commercially or might be easily replicated when brought to market. This is why "venture capital investors are drawn to sectors in which . . . uncertainty can be reduced."⁵⁰ The uncertainty caused by the Proposal would dissuade private-sector participants and investors from engaging in investment and R&D decisions—that typically occur years, if not decades, before a

⁴⁵ See Kappos & Iancu, *supra* n.9.

⁴⁶ *The Role Of The Bayh-Dole Act In Fostering Technology Transfer And Implications for Innovation*, *supra* n.14, at 12.

⁴⁷ *Id.*

⁴⁸ Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,601-85,602.

⁴⁹ *Id.*

⁵⁰ Josh Lerner & Ramana Nanda, *Venture Capital's Role in Financing Innovation: What We Know and How Much We Still Need to Learn* 255, J. ECON. PERSPECTIVES, Vol. 34, No. 3 (2020).

product or technology is brought to market—at a time when strategic competitors like China are boosting their own R&D efforts.⁵¹

Again, the Proposal’s ramifications are not conjecture. The National Venture Capital Association (“NVCA”) has directly explained the dire consequences that the Proposal would have on investment in the United States. As the NVCA explained, the Proposal would: (1) “destroy the remaining [venture capital] trust in the patent system;” (2) “make public funding toxic for [venture capitalists];” (3) “harm[] small businesses competitiveness;” and (4) “hurt development of critical industries.”⁵² All of these things would threaten American innovation and economic growth. Indeed, venture-capital funding is “positively associated with firm innovation and growth in the United States.”⁵³ And nearly half of initial public offerings in the United States are made by venture-backed firms.⁵⁴ As of 2020, seven of the eight top publicly traded companies, measured by market capitalization, had been backed by venture-capital funding before their initial public offerings.⁵⁵ Thus, companies that traditionally benefit from venture-capital funding, and especially start-ups and small- and medium-sized businesses, might not ever get the chance to become tomorrow’s publicly traded companies. This would include the many manufacturers that rely on outside investments. The result of the Proposal would be a return to the conditions that contributed to “the technological malaise that befell America in the late 1970s” when other countries were “busy snuffing out Pittsburgh’s steel mills, driving Detroit off the road, and . . . assault[ing] . . . Silicon Valley.”⁵⁶

C. The Proposal would negatively impact public-private collaboration and the academic and research communities.

The Proposal would also reverse the Act’s success in cultivating relationships between the private sector and the academic and research communities that has brought great benefits to the country’s higher education and innovation ecosystem. In 1979, the year before the Act was passed into law, only 30 universities had technology transfer offices.⁵⁷ Today, in contrast, most of research universities have such offices, where experienced employees craft patent licensing deals with the private sector. These deals help supplement federal funding for research universities through licensing fees. In a typical deal between a university and a private-sector participant, the deal includes development and commercialization milestones that allow for the university to terminate the deal if these milestones are not met by the private-sector participant. Thus, the university not only benefits from licensing fees, but the university also reserves the right to terminate the deal and reissue a license to another member of

⁵¹ See Organisation for Economic Co-operation and Development, *Main Science and Technology Indicators*, Vol. 2022/2, at 21, Table 12 (June 22, 2023) (noting the PRC’s closing in on the United States when it comes to government-financed gross domestic expenditure on R&D), available at https://www.oecd-ilibrary.org/science-and-technology/main-science-and-technology-indicators/volume-2022/issue-2_1cdcb031-en.

⁵² See generally, *Letter to President Biden*, NATIONAL VENTURE CAPITAL ASSOCIATION (Jan. 23, 2024), available at https://nvca.org/wp-content/uploads/2024/01/NVCA_WH-Letter-on-March-In.pdf?mc_cid=5e95e9609f&mc_eid=3f00fdb77.

⁵³ See, e.g., Jeremy Greenwood, Pengfei Han & Juan M. Sánchez, *Venture Capital: A Catalyst for Innovation and Growth* 11, FEDERAL RESERVE BANK OF ST. LOUIS (2022), available at <https://files.stlouisfed.org/files/hdocs/publications/review/2022/04/06/venture-capital-a-catalyst-for-innovation-and-growth.pdf>.

⁵⁴ William Janeway, Ramana Nanda & Matthew Rhodes-Kropf, *Venture Capital Booms and Startup Financing 2*, HARVARD BUSINESS SCHOOL (2021), available at https://www.hbs.edu/ris/Publication%20Files/21-116_c8365ab5-7cad-4ba3-9e02-ddec0191413f.pdf.

⁵⁵ Lerner & Nanda, *supra* n.50, at 237.

⁵⁶ See *Innovation’s golden goose*, *supra* n.11.

⁵⁷ Walter D. Valdivia, *University Start-Ups: Critical for Improving Technology Transfer* 6, CENTER FOR TECHNOLOGY INFORMATION AT BROOKINGS (Nov. 2013), available at https://www.brookings.edu/wp-content/uploads/2016/06/Valdivia_Tech-Transfer_v29_No-Embargo.pdf.

the private sector if the licensee does not engage in the productive and successful use of the patented technology.

The Proposal would throw these licensing agreements into disarray. It would replace universities' rights to evaluate licensing deals with private-sector participants with the government's subjective decision-making as to whether to march in. In turn, the private sector would avoid collaborations with research universities because of the increase in uncertainty that comes with enhanced government involvement in the federally funded patent space. This would have severe consequences for innovation when it comes to products and technologies in countless fields.

V. The Proposal Undermines The Administration's Efforts To Boost American Manufacturing.

The Administration has rightly prioritized boosting American manufacturing in a time of global competition. President Biden has touted the fact that the Administration has “created close to 800,000 manufacturing jobs” since he took office.⁵⁸ And that the Administration has sought to “revitalize American manufacturing and secure critical supply chains.”⁵⁹ But the Proposal would undermine the manufacturing industry in the U.S. by disincentivizing the use of federally funded patents and public-private collaboration, to the detriment of American manufacturing and workers.

For example, the Proposal would undermine the aims of the CHIPS and Science Act. Through the CHIPS and Science Act, Congress and the Administration have sought to ensure that America can compete in the incredibly important semiconductor field and not have to rely on other countries to develop and manufacture semiconductors. To this end, the Administration is poised to distribute tens of billions of dollars to industry to spur semiconductor development in the United States.⁶⁰ But if the Administration's march-in Proposal goes forward, it will undermine interest in these critical R&D funds—lest accepting government funding jeopardize any patent that might become associated with the use of these funds. Similarly, the Proposal would weaken the commercial attractiveness of the patents stemming from the R&D labs funded by the CHIPS program. For the same reasons, the Proposal would threaten the “Tech Hubs” envisioned by the CHIPS and Science Act, as the private sector would become reluctant to collaborate with any recipients of federal funding, just as before the enactment of the Bayh-Dole Act.⁶¹

The Proposal also would threaten any future initiatives that seek to foster public-private collaboration. All of this comes at a time when China has prioritized becoming a leader in the products and technologies of the future, such as semiconductors and products and technologies that utilize semiconductors, as well as a leader in manufacturing. If the Proposal is enacted and IP rights are

⁵⁸ See @JoeBiden, X (formerly, Twitter) (Dec. 4, 2023) (“We’ve created close to 800,000 manufacturing jobs since I’ve taken office.”).

⁵⁹ The White House, *The Biden-Harris Plan to Revitalize American Manufacturing and Secure Critical Supply Chains in 2022* (Feb. 24, 2022), available at <https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/24/the-biden-harris-plan-to-revitalize-american-manufacturing-and-secure-critical-supply-chains-in-2022/>.

⁶⁰ See Yuka Hayashi, *Eager for Economic Wins, Biden to Announce Billions for Advanced Chips*, THE WALL STREET JOURNAL (Jan. 27, 2024), available at <https://www.msn.com/en-us/money/markets/eager-for-economic-wins-biden-to-announce-billions-for-advanced-chips/ar-BB1hlcxv>.

⁶¹ The White House, *Fact Sheet: Biden-Harris Administration Announces 31 Regional Tech Hubs to Spur American Innovation, Strengthen Manufacturing, and Create Good-Paying Jobs in Every Region of the Country*, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/23/fact-sheet-biden-harris-administration-announces-31-regional-tech-hubs-to-spur-american-innovation-strengthen-manufacturing-and-create-good-paying-jobs-in-every-region-of-the-country/>

weakened in the United States, companies would be *incentivized* to look to other jurisdictions with friendlier IP policies, ultimately harming American competitiveness.

VI. The Proposal's Costs Far Outweigh Its Claimed Goals.

The Proposal outlines several objectives of the new march-in framework, including: “(1) Provide clear guidance to an agency on the prerequisites for exercising march-in, and, if those prerequisites are met, on facts to be gathered by the agency and factors to consider in determining whether to march-in; (2) Ensure that decisions to exercise march-in support the policy and objectives of Bayh-Dole; (3) Encourage the consistent and predictable application of the Bayh-Dole Act’s march-in authority; and (4) Balance the need to incentivize industry investment in the development and commercialization of subject inventions with the need to promote public utilization of subject inventions.”⁶²

As discussed, the Proposal does not achieve any of these goals, and, in fact, will likely result in the opposite. Specifically, the Proposal (1) does not provide clear guidance for the countless real-world circumstances that will arise in the future, (2) violates the letter and spirit of the Bayh-Dole Act, (3) will result in inconsistent and arbitrary application of march-in rights, and (4) will depress most industry investment in federally funded inventions. There are virtually no benefits for the United States to moving forward with any aspect of the Proposal—and the costs the Proposal would impose on the economy are substantial. Indeed, if there is an imperative national need for a particular technology, and industry indeed fails to supply that need, the existing march-in rights contemplated by the Bayh-Dole Act would suffice without subjecting the nation to broader harms imposed by the Proposal. In short, the costs of the Proposal far outweigh any possible benefit.

VII. Conclusion

The NAM respectfully requests that the Administration unequivocally withdraw the Proposal, and that the Administration affirmatively state that the framework outlined in the Proposal will not be adopted in any part.

The Proposal would damage innovators in all sectors of the U.S. economy and would represent a significant threat to R&D, capital formation, and the development and commercialization of groundbreaking products—and the manufacturing job creation that results from these critical investments. The Administration must withdraw the Proposal so that members of the innovation ecosystem regain the certainty needed to continue their R&D efforts and investments in the technologies of the future, just as the Bayh-Dole Act and the government’s consistent restraint against using its march-in rights has provided over the last 44 years.

Sincerely,



Charles Crain
Vice President, Domestic Policy

⁶² Proposal, *supra* n.1, at 88 Fed. Reg. 85,593, 85,594 (numbers added).