February 6, 2024

Submitted via www.regulations.gov

Laurie E. Locascio
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

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

Dear Director Locascio:

Governing for Impact ("GFI") submits this comment on the National Institute of Standards and Technology (NIST) Notice, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" ("the RFI"). GFI is an organization dedicated to ensuring that the federal government operates more effectively for everyday working Americans.

The NIST is proposing a framework to guide agencies' use of march-in rights under the Bayh-Dole Act. Under the framework, consumer price is listed as one of several factors agencies should consider when determining whether to exercise their march-in rights under two circumstances.[1] We write in support of the draft framework—and to rebut industry commenters' assertion that the Bayh-Dole Act does not give the NIST the authority to encourage agencies to consider price as a factor when deciding whether to exercise their march-in rights.[2]

Moreover, as we explain below, a post-enactment opinion piece in the Washington Post by former Senators Birch Bayh and Bob Dole that industry groups have cited in support of their opposition to the framework[3] carries no legal weight and should not be considered.

I. The NIST draft framework

The Bayh-Dole Act governs the patent rights of government-assisted inventions made by certain federal contractors, including nonprofit universities.[4] Under the statute, the government retains

[1] *See* 88 FR 85598–85600, Criterions 1 & 2.
[2] See e.g. Bayh-Dole Coalition Comment on Docket No. 230831-0207, https://bayhdolecoalition.org/wp-content/uploads/2024/01/Bayh-Dole-Coalition-Comments-on-NIST-Draft-March-in-Framework-2.pdf, *4 (January 17, 2024)("NIST lacks the authority to direct federal agencies 'to further assess whether march-in is warranted' when "the contractor or licensee has commercialized the product, but the price or other terms at which the product is offered to the public are not reasonable."").
[3] *Id.* at *3.
[4] 35 USC 200 et seq. Regan's E.O. 12591 extended the application of Bayh-Dole to all federal contractors, not just nonprofits and small businesses. EO 12591, see also CRS, March-In Rights Under the Bayh-Dole Act (August 22, 2016).

"march-in" rights to certain privately held patents developed with federal resources, meaning that the funding agency can grant a license to a third party. March-in only applies under four statutorily-prescribed circumstances.[5]

Under Bayh-Dole, the NIST has issued a guidance document explaining the factors that agencies may consider when determining whether to use their march-in rights under the four criteria.[6] For two of the statutory criteria, the draft framework suggests that product price could, among other factors, lead an agency to invoke its march-in rights.[7]

The first statutory criterion, at 35 U.S.C. § 203(a)(1), authorizes an agency to use its march-in rights if it finds that: "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[.]"[8] "Practical application" is defined in 35 U.S.C. § 201(f) as: "...manufactur[ing] [a] product…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*."[9]

In assessing whether an invention is available to the public on "reasonable terms," the draft framework suggests that product price may be one factor — importantly, among a multi-factor assessment — that leads an agency to invoke its march-in authority.[10] The draft framework directs agencies to consider "[a]t what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.?" It elaborates:

> "Has the contractor or licensee made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors? Has the contractor or licensee provided any justification for the product's price or background on any extenuating factors which might be unreasonably limiting the availability of the subject invention to consumers or customers?"[11]

Beyond price, the draft framework advises agencies to consider additional factors under the first criterion, including whether the product is being sold to U.S. consumers, how the availability of the product benefits the public, and if its unavailability is harmful to the public.[12]

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[5] The statute lists four scenarios: (1) because the contractor has not "achieve[d] practical application" of the invention within a reasonable time, (2) to "alleviate health or safety needs" which are not reasonably met by the contractor, (3) to meet requirements for public use specified by Federal regulations, or (4) because of a breach of contract under section 204 (which places a preference for domestic industry). 35 U.S.C. 203.

[6] 88 FR 85593, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Dec. 8, 2023).

[7] *Id.* at 85598–99, Criterion 1 & Criterion 2.

[8] (emphasis added) 35 USC 203 (a)(1).

[9] (emphasis added)

[10] 88 FR 85598–99, Criterion 1.

[11] 88 FR 85599, Criterion 1., VI. D.

[12] *Id.*, at VI. A–C. ("In considering whether this criterion 1 applies to a product that is being commercialized, the agency may assess: A. Is the contractor or licensee marketing or selling to end-users or consumers in the U.S.? If not, why? B. Has the product utilizing the subject invention been sold or offered for sale in the U.S. using distribution channels (e.g., retailer, wholesaler, through a regulated intermediary, or direct to consumer) used for similar products? C. How does the availability of the product benefit the public, and how is the public harmed by limited availability of the product?")

The second statutory criterion, at 35 U.S.C. § 203(a)(2), directs agencies to invoke their march-in authority if "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees." Here, too, the draft framework directs agencies to consider price, again among other factors, instructing them to assess:

> "Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances? A. For example, has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk? *It should be noted that in reviewing this question, the agency is not limited to reviewing price increases; the initial price may also be considered if it appears that the price is extreme, unjustified, and exploitative of a health or safety need.*"[13]

Finally, the framework proposes several examples of scenarios where invoking march-in rights may be appropriate, some of which include the consideration of product price.[14]

II. The statutory text supports the draft framework's proposed role for price in evaluating march-in use cases

In choosing phrases like "reasonable terms" and "reasonably satisfied," Congress non-ambiguously afforded agencies a degree of interpretive discretion, which here includes the ability to use price as one factor in a multi-factor assessment.

To be clear, this is not a claim about statutory ambiguity and the *Chevron* doctrine, which may be revised in a pending case before the Supreme Court.[15] Rather, as Justice Kavanaugh has elaborated in his judicial and academic writings, certain common phrases — like "reasonable" — should be understood to reflect an affirmative congressional choice to allow agency discretion.

In a 2016 law review article, Kavanaugh explained how judges should undertake statutory interpretation, even outside of the *Chevron* context, for these kinds of phrases:

> "To begin with, courts should still defer to agencies in cases involving statutes using broad and open-ended terms like "reasonable," "appropriate," "feasible," or "practicable." In those cases, courts should say that the agency may choose among reasonable options allowed by the text of the statute. In those circumstances, courts should be careful not to unduly second-guess the agency's choice of regulation."[16]

Similarly, Kavanaugh's concurrence in *Kisor v. Wilkie* notes that "reasonable," in the regulatory context, is "open-ended" and tends to "afford agencies broad policy discretion, and courts allow an agency to reasonably exercise its discretion to choose among the options allowed by the text of the

[13] *Id.* at 85599, Criterion 2, V.
[14] *See id.* At 85603–85604, Scenarios 5 and 6.
[15] *See generally Chevron v. Natural Resources Defense Council, Inc.*, 467 US 837 (1984).
[16] Brett Kavanaugh, *Fixing Statutory Interpretation*, 129 Harv. L. Rev. 2118, 2153-2154. Earlier in the piece, he writes: "[f]or example, Congress might assign an agency to issue rules to prevent companies from dumping "unreasonable" levels of certain pollutants. In such a case, what rises to the level of "unreasonable" is a policy decision. So courts should be leery of second-guessing that decision." *Id.* at 2152.

rule."[17] He goes on to add that, "a judge should engage in appropriately rigorous scrutiny of an agency's interpretation of a regulation, and can simultaneously be appropriately deferential to an agency's reasonable policy choices within the discretion allowed by a regulation."[18]

Including price as one factor among many in an agency's march-in use assessment comfortably falls within this zone of discretion given the statute's purpose. Core legislative materials, such as committee reports, are silent on the precise question as to whether price should factor into march-in determinations, and so neither weigh for or against the NIST's proposed interpretation.[19] (Although, it's certainly the case that during legislative consideration, some clearly anticipated unreasonable pricing could justify invoking march-in rights under the statute).[20]

But other evidence about the statute's purpose is instructive. According to the statutory text, its purposes are to "...use the patent system to promote the utilization of inventions arising from federally-supported research or development…" and "to promote the *commercialization and public availability of inventions* made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or *unreasonable* use of inventions[.]"[21] According to the House committee report, the legislative purpose of the Act was two-fold: First, it sought to address the "bewildering array of 26 sets of agency regulations…" applied to patent rights involving government-funded R&D by creating a "...single, uniform national policy[.]"[22] And, second, the Act sought to facilitate the "*effective* commercialization of government financed research."[23]

As evidenced by the legislative history and statutory purpose, Congress was concerned with the commercialization and availability of inventions made through government-assisted research. And it reasonably follows that the public availability of drugs, for example, often depends on price. A drug cannot be publicly available if it fails to reach its intended beneficiaries, as evidenced by the wealth of research on the effects of drug pricing.[24]

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[17] 139 S. Ct. 2400, 2448 (2019) (J. Kavanaugh, concurring in the judgement).
[18] *Id.*
[19] *See e.g.*, House Report No. 96-1307, 96th Cong. 2d. Sess. (1980), Part 1; Government patent policy: Hearings before the Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, U.S. House of Representatives, 96th Cong. 1st Sess. (October 16, 17, 1979) [*hereinafcter*, "1979 Subcommitte House Report"]; Cong. Record: Proceedings and Debates, 96th Cong. 2d Sess., Volume 126–Part 22 (October 1–November 17, 1980), 28569–3000; Cong. Record: Proceedings and Debates, 96th Cong. 2d. Sess. (November 18 – December 1, 1980), 30001–31436.
[20] Expert witnesses also anticipated the issue of inflated consumer prices. Henry Manbeck, then the General Patent Counsel of GE, commented that if an government-funded invention "fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work." 1979 Subcomittee House Report, *supra*, note 19, at 48.
[21](emphasis added) 35 USC 200.
[22] House Report No. 96-1307, 96th Cong. 2d. Sess. (1980), Part 1. (emphasis added)
[23] *Id.* (emphasis added)
[24] *See*, *e.g.* Andrew Mulcahy, et al, *U.S. Prescription Drug Prices are 2.5 Times Those in other OECD Countries*, RAND (2021), https://www.rand.org/pubs/research_briefs/RBA1296-1.html; Junsoo Lee, *et al*, *Increases in Anti-infective Drug Prices, Subsequent Prescribing, and Outpatient Costs*, JAMA (2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781194; Ashley Kirzinger, *et al.*, *Public Opinion on Prescription Drugs and Their Prices*, KFF (2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

III. Lead drafters' post-enactment comments on the Act are irrelevant in determining the statutory authority or purpose.

In 2002, in response to a piece arguing that the government should invoke Bayh-Dole's march-in provision to mitigate exorbitant drug prices,[25] former Senators Birch Bayh and Robert Dole, co-sponsors of the Bayh-Dole Act, published an opinion piece in the *Washington Post* stating the bill "did not intend that government set prices on resulting products[,]" and that the omission of price considerations in the bill was intentional.[26] Criticism of the draft framework has often cited this piece as evidence that undermines the NIST's proposed interpretation.[27] As we explain below, this op-ed has no legal relevance.

As a threshold matter, Dole and Bayh's opinion piece, coming decades after the statute's enactment, was not part of the legislative record. As the Supreme Court has noted: "[p]ost-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation."[28] The focus should instead be on pre-enactment legislative history because it can resolve questions about what legislators understood at the time of passage.[29]

This principle makes sense. Decades after the fact, even the best-intentioned member of Congress is likely to misremember the nuances of a given congressional debate. Even more alarmingly, post-enactment assertions can be influenced by new motives.

In this case, at the time Bayh and Dole penned their *Washington Post* op-ed, both had left public service to spend years employed by firms that lobbied for pharmaceutical companies. According to Open Secrets, in 2002 Dole worked for Verner Liipfert et al.,[30] a lobbying firm that earned nearly

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[25] Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, Washington Post (March, 27, 2002), https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/.

[26] Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, Washington Post (April 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

[27] *See*, *e.g.,* Joseph P. Allen, *The Biden administration's plan to use march-in rights to address drug prices would kill future world-changing innovations*, StatNews (Dec. 15, 2023), https://www.statnews.com/2023/12/15/march-in-rights-bayh-dole-act-drug-prices-biden/; Bayh-Dole Coalition Comment on Docket No. 230831-0207, *supra*, note 2; Paul Michel and Kathleen O'Malley, *Opinion: Biden's Bayh-Dole Act proposal misuses 'march-in rights'*, Detroit News (Jan. 25, 2024), https://www.detroitnews.com/story/opinion/2024/01/25/opinion-bidens-bayh-dole-act-proposal-misuses-march-in-rights/72353556007/; Laura Hobbs, *March-In Rights: A Hostile Regulatory Environment*, American Action Forum (Dec. 20, 2023), https://www.americanactionforum.org/insight/march-in-rights-a-hostile-regulatory-environment/; Joel Zinberg, *Opinion: Biden Decides to 'March In' on Drug Patents*, Wall Street Journal (Dec. 12, 2023), https://www.wsj.com/articles/biden-decides-to-march-in-on-drug-patents-price-control-biotech-research-3e327f6b.

[28] *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242, (2011) (*citing Jones v. United States*, 526 U.S. 227, 238 (1999); *United States v. Mine Workers*, 330 U.S. 258, 281–282, (1947)); *see also* Peter Arno, Dana Neacsu, Kathryn Ardizzone, *March-In Rights Could Ensure Patient Access by Keeping Drug Prices in Check. They're Under Attack,* Health Affairs (April 30, 2021), https://www.healthaffairs.org/content/forefront/march-in-rights-could-ensure-patient-access-keeping-drug-prices-check-they-re-under.

[29] *Id.*

[30] *See Revolving Door, Employment History: Dole, Bob*, Open Secrets, https://www.opensecrets.org/revolving/rev_summary.php?id=14067 (accessed Feb. 5, 2024).

$500,000 from pharmaceutical and health product companies that year.[31] The next year, Dole moved to another firm, Alston & Bird, which took in over $600,000 from the sector between 2003-2004 (and over $1.5 million in 2023).[32] After leaving the Senate in 1981, Bayh worked for nearly three decades at two lobbying firms, Oppenheimer, Wolff & Donnelly and Venable LLP, which have represented pharmaceutical and health product companies according to Open Secrets.[33]

IV. Conclusion

In sum, the NIST's proposed use of price as a factor in assessing when agencies should invoke march-in authority comfortably fits within the discretionary grant Congress explicitly anticipated in the Bayh-Dole Act.

Sincerely,

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[31] *Lobbying Firm Profile: Verner, Liipfert et al., 2002*, Open Secrets, https://www.opensecrets.org/federal-lobbying/firms/summary?id=D000000183&cycle=2002.
[32] *See Lobbying Firm Profile: Alston & Bird, 2003*, Open Secrets https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2003&id=D000021817; *Lobbying Firm Profile: Alston & Bird, 2004*, Open Secrets, https://www.opensecrets.org/federal-lobbying/firms/summary?cycle=2004&id=D000021817; *Lobbying Firm Profile: Alston & Bird, 2023*, Open Secrets, https://www.opensecrets.org/federal-lobbying/firms/summary?id=D000021817&cycle=2023.
[33] *See* Revolving Door, Lobbyist Profile: Birch E Bayh, https://www.opensecrets.org/revolving/rev_summary.php?id=14669 (accessed Jan. 31, 2024).