February 6, 2024

Re: Public Comments on "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" released on December 8, 2023.

Submitter: The Texas Conservative Coalition Research Institute

The Texas Conservative Coalition Research Institute (TCCRI) submits this comment to express its concern over the "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights" released by the National Institute of Standards and Technology (NIST) on December 8, 2023 ("the Framework").[i] The Framework directs federal agencies to conduct a three-part analysis when contemplating the use of "march in" rights under the 1980 Patent and Trademark Law Amendments Act, often referred to as the Bayh-Dole Act ("the Act"):

1) Does the Act apply to the invention in question?
2) Is one (or more) of the four statutory grounds for exercising march-in rights satisfied?
3) Would exercising march-in rights support the policies and objectives of the Act?

The Framework makes clear that a federal agency may consider "high pricing" of a product in determining whether a statutory ground for exercising march-in rights is met (point #2 above).

NIST requested public comments on several topics, including the following: "Does [the Framework] sufficiently address concerns about public utilization of products developed from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?"[ii]

TCCRI believes that the answer to this question is "no," and that the Framework's allowance for pricing to be considered in deciding whether to exercise march-in rights is flawed in two respects. First, the Act was never intended to permit consideration of product pricing in analyzing whether the government should exercise march-in rights, a conclusion supported by the Act's text and legislative history. Second, even assuming that the Act does allow for such consideration, justifying the exercise of march-in rights on the basis of alleged high pricing is a short-sighted and counter-productive policy that would undermine the primary purpose of the Act: to spur commercialization of patents that will benefit the public.

Before addressing these two concerns in detail, it is instructive to briefly examine some background on the Act's purpose and the success of the Act to date. The primary purpose of the Act is evident from the Senate Judiciary Committee's report on S. 414, which would eventually become the Act.[1]

> One factor that can be clearly identified as part of this problem [i.e., a slowdown in American technological innovation] is the inability of the Federal agencies to deliver new inventions and processes from their research and development programs to the marketplace where they can benefit the public. A prime cause of this failure is the existence of ineffective patent policies regarding ownership of potentially important discoveries. In general, the present patent policies require contractors and grantees to allow the funding [federal] agency to own any patentable discoveries made under research and development supported by the Federal Government [unless a lengthy waiver process is navigated].
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> [Federal] Agencies which acquire these patents [developed with federal support] generally follow a passive approach of making them available to private businesses for development and possible commercialization through nonexclusive licenses. This has proven to be an ineffective policy as evidenced by the fact that of the more than 28,000 patents in the Government patent portfolio, less than 4 percent are successfully licensed. The private sector simply needs more protection to develop and commercialize new products than is afforded by a nonexclusive license.[iii]

By all accounts, the Act accomplished its goal. A 1987 report by the federal General Accounting Office (GAO), now the General Accountability Office, found that small business representatives and university administrators agreed that the Act had "a significant impact on their research and innovation efforts."[iv] Based on an admittedly small sample size of 25 universities, GAO found that university administrators believed that the Act had "'been significant in stimulating business sponsorship of university research, which has grown 74 percent' from FY1980 to FY1985."[v]

In 1980, only 23 universities had offices of technology licensing.[vi] Today, virtually all research universities have such an office.[vii]

A 2002 editorial in *The Economist*'s Technology Quarterly called the Act "Possibly the most inspired piece of legislation to be enacted in America over the past half-century."[viii] The editorial pointed out that patents generated by universities had increased tenfold since the bill's passage, creating more than 2,200 businesses and 260,000 jobs, and contributing $40 billion to the U.S. economy.[ix] According to a 2022 article by the Center for Strategic and International Studies, the Act has led to $1.3 trillion in economic growth, created more than 4 million jobs, and contributed to the success of over 11,000 startups.[x] The Information Technology and Innovation Foundation stated in a 2019 report that "More than 200 drugs and vaccines have been developed through public-private partnerships since the Bayh-Dole Act entered force in 1980."[xi]

Pharmaceutical drugs receive a great deal of attention in the context of the Act's record of spurring innovation. But the Act applies to many products other than pharmaceutical drugs. To name one

[1] S. 414 was eventually incorporated into a House Bill, HR 6933, which became law.

of many examples, Google obtained an exclusive license from Stanford University for its internet search engine, a product that had been developed by Google's founders when they were Stanford students.[xii]

Given the Act's track record of success, any attempt to dramatically alter the Act's provisions should be viewed with caution. For reasons discussed below, the Framework is flawed as a matter of both law and policy and should be rejected.

1. The Act was never intended to permit consideration of product pricing in contemplating the exercise of march-in rights

The text of the Act, codified at 35 U.S.C Section 200 et seq., begins with a recitation of policy and objectives. This recitation elaborates on the goal set forth in the legislative history discussed above and is worth quoting in full:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; 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; and to minimize the costs of administering policies in this area.

Notably, this recitation does not mention prices, affordability, or controlling the costs of products offered to the public. The reference to protecting the public refers only to "nonuse or unreasonable use of inventions." If Congress had wanted the Act to prohibit high pricing of covered inventions, it would have been logical to reference high prices when discussing the dangers to the public that the Act seeks to prevent.

The words "to promote the. . . public availability of inventions" might in isolation be interpreted as a call for affordable pricing, but that is a strained interpretation given that Congress could have easily mentioned price or affordability. Broadly interpreting an ambiguous statutory phrase in isolation could similarly lead one to incorrectly infer that the call "to promote free competition and enterprise" was an argument against patents (which effectively grant a company a temporary monopoly over a product), when in fact the purpose of the Act was to encourage the commercialization of patents by strengthening the rights of the company that undertook the necessary labor and assumed the corresponding risk to commercialize the product.

The Act (in 35 U.S.C. 203(a)) provides four grounds on which a federal agency can exercise march-in rights.

- The contractor or its assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention within the licensed field of use;
- Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- Action is necessary to ensure that products stemming from the subject invention be substantially manufactured in the United States unless a waiver is obtained.

Proponents of considering product pricing in the context of march-in rights- a view endorsed by the Framework- focus on the first of these four grounds. They point to the definition of "practical application" in 35 U.S.C. 201:

> [T]o 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** (emphasis added).

A product that is priced beyond a certain threshold, the argument goes, is not available to the public on reasonable terms; thus, the federal government can exercise march-in rights. But against this view, one can argue that the availability to the public on reasonable terms is aimed not at high pricing, but rather at licenses that allowed companies to "sit on" a valuable innovation to prevent its competitors from gaining an edge. In a written statement to the National Institutes of Health (NIH) in 2004, Senator Bayh pointed out that a key concern behind the inclusion of march-in rights was "that some companies might want to license university technologies to suppress them because they could threaten existing products."[xiii]

Without reference to wider context, whether the word "terms" incorporates "prices" is debatable. At least a few federal statutes treat those terms as having distinct meanings;[xiv] on the other hand, at least several court decisions have treated pricing as part of a transaction's terms.[xv] The following seven considerations, however, provide strong support for the idea that "terms" in the context of the Act was not intended to incorporate price.

First, Congress was capable of clearly specifying that it wished for inventions covered by the Act to be subject to some sort of price ceiling or control. Had it so wished, it could easily have done in a more straightforward way, such as (for example) by using the terms "pricing" or "affordability," rather than cross-referencing a definition in a separate section of the law that uses the ambiguous word "terms." When Congress has chosen to impose some sort of price limitation on products or services offered by the private sector, it has done so unambiguously. For example, the Emergency Price Control Act of 1942, provided that:

> Whenever in the judgment of the Price Administrator . . . the price or prices of a commodity or commodities have risen or threaten to rise to an extent or in a manner inconsistent with the purposes of this Act, he may by regulation or order establish such

> maximum price or maximum prices as in his judgment will be generally fair and equitable and will effectuate the purposes of this Act.[xvi]

Similarly, the federal statute authoring caps on late payment fees and over-the-limit fees states:

> The amount of any penalty fee or charge that a card issuer may impose with respect to a credit card account under an open-end consumer credit plan in connection with any omission with respect to, or violation of, the cardholder agreement, including any late payment fee, over-the-limit fee, or any other penalty fee or charge, shall be reasonable and proportional to such omission or violation.[xvii]

The Patient Protection and Affordable Care Act of 2010 did not impose price controls or set fees, but rather applied the concept of a "medical loss ratio," which required health insurance companies to provide rebates to enrollees if a certain percentage of revenue from the insurer's insurance premiums (generally 80 percent or 85 percent) was not spent on reimbursements for clinical services provided to enrollees or to improve health care quality.[xviii]

These three statutory examples (among others) illustrate that Congress is capable of providing clear directives on a private party's pricing, late fees, and profitability when it wishes to control or limit them.

A second indication that Congress did not intend to consider pricing in the context of march-in rights is that it would have faced a host of complex questions and factors in identifying impermissibly high pricing, yet the Act does not contain even a passing mention of these questions and factors. For example, Congress (or the federal agency to which it delegated rulemaking) would have had to take into account the risk that a company assumed in commercializing a product, with a great deal of assumed risk justifying higher pricing. Similarly, determining the percentage of development costs attributable to federal support would have been relevant in determining what constitutes high pricing, with greater federal support arguing for lower prices. Given these questions, the authorization for regulations under the Act very likely would have provided at least some general guidance to NIST on factors to weigh and questions to consider. For example, in the statute authorizing the Consumer Financial Protection Bureau to limit fees charged by credit card companies (discussed above), Congress instructed the agency to consider the cost incurred by the creditor from the cardholder's behavior, the deterrent effect on the cardholder, and the cardholder's conduct.[xix] Yet the directive in Section 203(a) to promulgate regulations on march-in rights offers no guidance to NIST whatsoever.

Third, the two authors of the bill, Senators Bayh and Dole, stated in a 2022 opinion editorial in *The Washington Post* that the Act was never intended to consider pricing in the exercise of march-in rights. This rebuttal was issued in response to a 2001 article by two law professors which made the case that the Act allows for considerations of pricing in that context.[xx] Dole and Bayh spoke unequivocally:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.[xxi]

Fourth, it strains credulity to believe that Congress would not have addressed (allegedly) excessively high pricing more clearly, had it intended to do so, given that it was easily foreseeable that the federal

government, through the Medicare program, would purchase many of the drugs which would be developed and commercialized as a result of the Act.

The fifth point concerns the Act's legislative history. In early versions of the Act, there were requirements for recoupment of windfall profits that universities reaped from taxpayer-supported research,[xxii] and "payback" requirements for licensees who profited from a successfully commercialized invention.[xxiii] These provisions would have ensured that government was compensated in some way for its support of research that yielded commercialized inventions. Both of these provisions were dropped from the Act before it was finalized, indicating that Congress had rejected them. Some have argued that march-in rights were included in the final version of the Act to achieve roughly the same general goal as the windfall and payback provisions- a public benefit to taxpayers- with the public benefit being capped prices rather than the government sharing in profits.[xxiv]

That conclusion is dubious. In a 2005 article, authors John Rabitschek and Norman Latker examined how the practice of march-in rights, prior to the Act, were set forth in memoranda in the Kennedy and Nixon administrations, and in institutional patent agreements used by certain federal agencies such as the National Institutes of Health.[xxv] But these authors note that march-in rights prior to their codification in the Act were hardly ever invoked, and when they were, the focus was not on pricing. As the authors note, the legislative history of H.R. 6933 indicates that the House Judiciary Committee included a provision on march-in rights, the purpose of which was "to continue existing practice . . . the [House Judiciary] Committee intends that [federal] agencies continue to use the march-in provisions in a restrained and judicious manner as in the past."[xxvi] While the Act incorporated the march-in rights provision of S. 414 in lieu of this portion of H.R. 6933, the legislative history of the latter makes clear that the House Judiciary Committee did not view march-in rights as authoring price caps as compensation for the federal government giving up a right to profits from successfully commercialized inventions. Moreover, even assuming that Congress viewed the inclusion of march-in rights as a sort of grand compromise under which price caps were accepted in lieu of windfall and payback provisions, it is remarkable that the text and legislative history of the Act would be so lacking in indications of that.

A sixth point is that the "practical application" ground in the Act- the basis for arguing that pricing is a factor in deciding whether march-in rights should be exercised- addresses the steps that a "contractor or assignee" has taken to achieve practical application of the invention. The term "licensee" does not appear in that statutory ground, but it does appear in the other three. If Congress had intended to address (allegedly) abusive pricing, the practical application prong presumably would have explicitly mentioned licensees, who generally are the parties that set the prices for the products sold to the public.

A seventh and final point provides still more evidence that the Act was not intended to target high pricing in the context of march-in rights. Since the enactment of the Act in 1980, the longstanding policy of federal agencies has been that pricing is not grounds for exercising march-in rights. Indeed, since the passage of the Act, march-in rights have never been invoked for any reason at all.[xxvii] An April 2019 paper by NIST stated that the National Institutes of Health over time had received a total of twelve march-in petitions, with ten requesting that march-in rights be invoked due to high drug pricing. In each of those ten cases, NIH decided that march-in rights were outside the "scope and intent of its authority."[xxviii]

While the practices of federal agencies do not create law, officials at these agencies are constantly exposed to the feedback of stakeholders and Congress. Had federal agencies been failing to incorporate pricing into decisions on march-in rights in a manner that Congress intended, Congress presumably

would have communicated this to the agencies, whether through legislation or less formal means. As the Supreme Court re-iterated in a recent decision, "established [regulatory] practice may shed light on the extent of power conveyed by general statutory language";[xxix] an agency dramatically altering its longstanding regulatory interpretation of a statute raises serious questions.[xxx]

The evidence offered above strongly indicates that Congress never intended for pricing to be a factor in a federal agency's decision to exercise march-in rights. Congress of course has the ability to amend the Act at any time to allow that, although TCCRI believes that doing so would be poor policy for the reasons discussed below. But if the Act is to be amended, it should be done by Congress, rather than being effectively amended by regulatory rulemaking. Federal agencies promulgating regulations without a clear grant of power from Congress can frustrate key principles of democratic governance. Most obviously, such regulation can be contrary to the public's will. In addition, it can limit the ability of voters to hold elected officials accountable (for better or worse) for their votes. Moreover, an improper exercise of regulatory rulemaking removes the subject matter of the regulations from the spotlight that accompanies congressional hearings, thereby limiting the public's ability to educate itself on the applicable matter.

2. Justifying the exercise of march-in rights on the basis of alleged high pricing is poor policy that undermines the primary purpose of the Act

Even if the Act did authorize NIST and other agencies to exercise march-in rights on the basis of high prices, invoking those rights for that reason would be a short-sighted and counterproductive policy. Capping prices dramatically reduces the incentive for companies to assume the costs and risks inherent in product development. According to a 2021 report by the Congressional Budget Office (CBO):

> Pharmaceutical research is inherently risky and canceled or failed projects are a normal part of any drug development program. Companies initiate drug projects knowing that most of them will not yield a marketable drug. Some drugs developed in the preclinical phase never enter clinical trials, and of those that do, only about 12 percent reach the market (recent estimates range from 10 percent to 14 percent).[xxxi]

The CBO also noted that research and development costs for the average new drug are high, with estimated average costs for new drugs ranging from less than $1 billion to more than $2 billion.[xxxii] According to a Deloitte study of 20 leading global pharmaceutical companies, the average expected return on investment for research and development expenditures was just 1.2 per cent in 2022, down from 6.8 percent in 2021.[xxxiii] The study estimated that, as of 2022, the average time from starting clinical trials to approval was over seven years, and the average cost of development was $2.3 billion.[xxxiv] The expense and time needed to develop new drugs, and the overall failure rate, adds necessary context to the claim that companies charge consumers excessive prices for groundbreaking treatments.

Some commentators have argued that not considering pricing in the context of march-in rights results in taxpayers being charged twice: the first time in the form of federal dollars supporting research that leads to new products, and then a second time in the form of high prices charged by businesses that successfully commercialized the research that was supported by federal funding. In fact, this criticism was made during the debate over the enactment of the Act, with Senator Russell Long arguing that there

is “absolutely no reason why the taxpayer should be forced to subsidize a private monopoly and have to pay twice: first for the research and development and then through monopoly prices.”[xxxv]

This “paying twice” claim has superficial appeal, but does not withstand analysis. Federal funding of research that is eventually used in developing a commercial product may account for only a small percentage of the total development costs. If federal funding accounts for only (for example) ten percent of total development costs, it is an oversimplification to claim that taxpayers have paid for it. Two economists authoring a 2001 report on the results of a survey of 62 research universities emphasized the gap that exists between a licensed invention and one that is ready to enter the stream of commerce:

> Our most striking [survey] result concerns the embryonic nature of the inventions that are licensed. Only 12 percent were ready for commercial use at the time of license, and manufacturing feasibility was known only for 8 percent. Over 75 percent of the inventions licensed were no more than a proof of concept (48 percent with no prototype available) or lab scale prototype (29 percent) at the time of license! Thus, an overwhelming majority of university inventions require further development once they are licensed.[xxxvi]

Proponents of federal agencies invoking march-in rights to manage pricing of products overlook not only the labor and expense to commercialize an invention, but also the fact that many drugs are protected by multiple patents, each of which is necessary to make the drug. To its credit, the Framework recognizes this, stating that:

> If only one of several patents necessary to produce a product is subject to march-in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product. On the other hand, if all the intellectual property needed to produce the product is a subject invention(s), that might result in a different licensee being able to produce [the] product quickly or efficiently.[xxxvii]

The problem with that approach, however, is that the number of drugs that are covered only by patent(s) subject to the Act is vanishingly small, which calls into question the usefulness of considering pricing in the context of march-in rights. A 2023 letter from numerous health care experts to several chairs of congressional committees cited a 2019 study for the claim that only two out of 197 top-selling drugs in the Food and Drug Administration’s (FDA’s) Approved Drug Products with Therapeutic Equivalence (the “Orange Book”) were completely covered by patents subject to the Act or were assigned to a government entity.[xxxviii]

Federal agencies exercising march-in rights to limit what they regard as excessive prices will have chilling effects on the willingness of companies to commercialize inventions which were produced due in part to federal funding. This outcome would be the opposite of what the Act intended. Moreover, it is an outcome that resulted when the federal government previously tried to restrict pricing in a very similar context; experience alone should lead the federal government to reject the idea that pricing is grounds for exercising march-in rights.

In 2021, NIH released an analysis of the attempt by the agency from 1990 to 1995 to address what it viewed as high drug prices through the use of “reasonable pricing clauses” (RPCS).[xxxix] The analysis

explained that "Under [an RPC], a company taking an exclusive license to bring an NIH invention to market could be compelled by the NIH to submit documentation showing a 'reasonable relationship between the pricing of the product, the public investment in that product, and the health and safety needs of the public.'"[xl] The analysis recounts how NIH began to receive negative feedback regarding RPCs from companies and researchers in the early 1990s. After public meetings, "a consensus [emerged] that companies were avoiding collaborations with the NIH because of the [RPCs]," and a decision to discard RPCs was made in 1995.[xli] The NIH analysis points to several factors supporting the causal link between RPCs and lack of commercial development of patents, such as dramatic growth in the number of collaborations in the five-year following elimination of RPCs compared to the 1990-1995 period.[xlii]

As noted in a *Wall Street Journal* editorial in early 2024, when NIH director Harold Varmus eliminated the use of RPCs in 1995, he observed that "'the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS (public health service) scientists' without offsetting benefits to the public. He called it "a restraint on the new product development."[xliii]

If pricing is allowed to factor in to a march-in rights analysis, it can be predicted with a high degree of confidence that NIST will experience the same result that NIH did with respect to RPCs. On the eve of the enactment of the Bayh-Dole Act, it was clear that the private sector did not have a strong enough incentive to commercialize inventions that had been discovered in part through federal funding. This state of affairs would likely appear again; given the time, expense, and labor to commercially develop many products, many companies will decline to make the necessary investments if the prices they charge for finished products can be capped.

As noted above, federal agencies have not exercised march-in rights since the Act's passage. On at least two occasions, the NIH has aptly used the following language in rejecting pricing as justification for exercising such rights:

> Finally, the issue of the cost or pricing of drugs that include inventive technologies made using Federal funds is one which has attracted the attention of Congress in several contexts that are much broader than the one at hand. In addition, because 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.[xliv]

Federal agencies exercising march-in rights on the grounds of product pricing offer a clearly defined benefit to a readily identifiable population: people in need of certain drugs will be able to obtain them at lower prices during the patent protection period than they otherwise would. On its face, exercising march-in rights in such cases may appear to yield a net public benefit. The drawbacks, however, in the form of forgone commercial developments of many patents, may be enormous, even if those drawbacks cannot be known with certainty, and even if the particular people who will be harmed by these innovations never being developed cannot be identified.

For the reasons discussed above, the Act was never intended to allow a federal agency to consider pricing in contemplating an exercise of march-in rights. Congress is free to amend the Act to allow for that, although doing so would almost certainly repeat the unfortunate experience of NIH in the first half

of the 1990s. TCCRI respectfully requests that NIST modify the Framework to make clear that pricing can not serve as a basis for march-in rights.

ENDNOTES

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[iii] S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979).
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[v] Id.
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[vii] Id.
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[xxii] See discussion at https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1399&context=chtlj (p. 163).
[xxiii] See discussion at https://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1754&context=fac_articles (p. 659).
[xxiv] Id.
[xxv] https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1399&context=chtlj
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