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Client Alert

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The Administration Takes Aim At Drug Prices Again – This Time Through A Controversial Framework for Exercising March-In Rights

The Biden Administration recently announced a plan to leverage an old tool in a new way to try to reduce drug costs: exercising "march-in rights" under the Bayh-Dole Act for drugs that were supported by government funding. These march-in rights have existed for more than forty years, but have never been utilized—let alone leveraged to attempt to reduce the price of a marketed drug. Here, we explain the history of the march-in rights in question, the Framework proposed by the Administration (through the National Institute of Standards and Technology ("NIST")), and how it could impact drug prices, if at all.

BACKGROUND

The Bayh-Dole Act,[1] enacted in 1980, revolutionized the commercialization of federally funded research, leveraging the "patent system to promote the utilization of inventions arising from federally supported research or development."[2] To do so, the Bayh-Dole Act awarded ownership in those funded inventions to government contractors,[3] providing a powerful incentive for industry (especially small players) to invest in research and innovation. Notably, for every dollar spent on government research, at least ten dollars of industry development is needed to bring a product to market.[4]

At the same time, Congress sought 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."[5] The Bayh-Dole Act thus reserved a non-exclusive license to the government for its own benefit.[6] The statute separately also provided for "march-in rights," under which in certain,

enumerated circumstances, the government can request the contractor (or its assignee or exclusive licensee) to grant a license—or, if that request is refused grant a license *unilaterally*—to a third party.[7]

The enumerated circumstances include:

- 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;
- 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 because the agreement required by the Bayh-Dole Act has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.[8]

In particular, achieving "practical application" of the invention in the first criterion, by definition, includes actions like manufacturing the drug, practicing the method, or operating the machine—all so the invention is utilized and available to the public on reasonable terms.[9] The "practical application" criterion was motivated, at least in part, to counter the possibility that industry may seek to license technologies only to suppress them and limit competition to existing products.[10] When a license is granted to a third-party under these circumstances, the Bayh-Dole Act requires only that the terms be "reasonable."[11]

MARCH-IN RIGHTS AND DRUG PRICING HISTORICALLY

The debate over whether march-in rights could be exercised to affect pricing (and, in particular, drug pricing) has been ongoing for decades. In 2001, two professors published an article asserting that the march-in rights provisions of the Bayh-Dole Act could be used as a price-control mechanism for drugs that benefitted from federal funding.[12] Senators Bayh and Dole, the architects of the law, disagreed. They explained in an opinion piece that the Bayh-Dole Act "did not intend that government set prices on resulting products" and that the law made "no reference to a reasonable price that should be dictated by the government."[13]

To date, march-in rights have never been exercised by any agency, though the National Institutes of Health ("NIH") have received multiple requests. Yet that agency consistently has concluded that the availability and public use of a product suffices to demonstrate "practical application"—including as recently as March 21, 2023.[14] For example, in 2004, NIH publicly discussed its decision to decline requests to exercise march-in rights related to concerns over the price of AIDS/HIV treatment, explaining that the drug in question had been on the market since 1996 and, accordingly, the "practical application" standard had been satisfied.[15] NIH further explained that "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," and that "the extraordinary remedy of march-in [rights] is not an appropriate means of controlling prices."[16]

NIST, which is responsible for managing and licensing federally funded inventions, historically has taken a similar view. In a 2018 Draft Green Paper discussing reducing and removing barriers that hinder transitioning federally funded innovations from the laboratory to the marketplace, NIST explained that march-in rights "should not be used as a mechanism to control or regulate the market price of goods and services."[17] The 2019 Final Green Paper, though

omitting that express statement, nevertheless again acknowledged that "stakeholders agreed that the march-in authority should not be broadened, and that doing so would create uncertainties in the U.S. innovation system."[18] Similarly, in 2021, NIST issued a notice of proposed rulemaking that would have specified that "march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services."[19]

Meanwhile, pressure has continued for agencies, including the Department of Health and Human Services in particular, to exercise march-in rights and, in doing so, to consider product price in determining whether a product is available to the public on the requisite "reasonable terms" to satisfy the practical application requirement.[20] Indeed, after NIST's proposed rule was published, Executive Order 14036 directed NIST to consider *not* finalizing that provision.[21] And, days after NIH's March 21, 2023 decision against pursuing march-in rights, described above, NIST announced its intent to engage with stakeholders to develop a comprehensive framework for agencies considering to use the march-in rights provisions.[22]

This pressure culminated when, on December 8, 2023, NIST announced the availability of its Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (the "Framework").[23]

THE NIST DRAFT MARCH-IN FRAMEWORK

As described by NIST, the Draft March-In Framework sought to provide clear guidance to agencies on the prerequisites for exercising march-in rights—and to ensure that agencies gather appropriate facts and use march-in rights consistent with underlying policy.[24]

To do so, the Framework set forth three overarching questions:

1. Does the Bayh-Dole Act apply?
2. Is a statutory criterion (*i.e.*, one of the four enumerated criteria in 35 U.S.C. § 203(a)) met?
3. Would march-in support the policy and objectives of the Bayh-Dole Act?[25]

For purposes of this Client Alert, we focus on the Framework's approach to product pricing—in particular, in the context of evaluating what it means to achieve "practical application" and whether a contractor (or its assignee) has taken effective steps to achieve such practical application of the invention (or, in the inverse, when an agency might justifiably determine that a contractor or assignee has not taken or is not taking effective steps to achieve such "practical application").

In addressing the "practical application" criterion, the Framework observes that if a product has been commercialized, "but the price or other terms at which the product is currently offered to the public are not reasonable," an agency may need to further assess whether march-in is warranted.[26] In other words, the "reasonableness of the price and other terms at which the product is made available to end-users" may be considered in determining whether action is needed to meet the needs of the government or "protect the public against nonuse or unreasonable use."[27] Accordingly, when an agency is considering exercising march-in rights for a commercialized product using the "practical application" statutory criterion, the questions it should ask include not only whether the product is available to end-users, but also at "what price and on what terms has the product … been sold or offered for sale in the U.S."[28] Yet, the Framework is conspicuously silent regarding how to determine the reasonableness of the price.

"Practical application" notwithstanding, the Framework also directs agencies to consider whether march-in rights support the policy and objectives of the Bayh-Dole Act, considering both the specific case and the broader context.[29]

As described in the framework, the Bayh-Dole Act incorporates two policy goals: "incentivizing U.S. innovation and promoting access to the fruits of that innovation in the U.S."[30] Agencies therefore should consider the following when evaluating whether to exercise march-in rights:

- The practical value, particularly in terms of increasing access, including:
    - **Potential Licensees**. Could other interested and willing licensees practice the subject invention in sufficient time to address access, and, if so, at what price would another licensee be able to make the product available?[31]
    - **Intellectual Property**. Is there intellectual property (beyond the subject invention(s)) that could possibly prevent other licensees from making the product? A "complicated intellectual property landscape could reduce the likelihood of successful licensing and weigh against march-in."[32]
    - **Timeframe**. Do the patents in question have useful life and are the products subject to regulatory exclusivity? The Framework instructs agencies to consider patent expiration before the march-in process is completed and whether another licensee could bring another product to market during that time. Relatedly, agencies should also consider whether existing regulatory exclusivity could interfere with approval or marketing of a product by another licensee.[33]
- The existence of alternatives to address the specified problem. These include whether the contractor (and its licensees) are willing to take action to remedy the matter without further government invention and whether patent litigation or other legal tools could more expeditiously facilitate market entry. The Framework states, however, that the availability of alternatives does not necessarily mean that march-in would be inappropriate.[34]
- The broader implications of using march-in rights, including "the potential impact on the broader R&D ecosystem."[35] The Framework directs agencies to ensure that any individual march-in exercise "does not have broad and unintended consequences on U.S. competitiveness and innovation" and would not "unduly encumber[] future R&D."[36] The Framework acknowledges that answering these questions *ex ante* may be challenging (and we note that this is particularly the case in light of the landscape shifts caused by the Inflation Reduction Act[37]), but agencies nevertheless should consider "the potential chilling effect on the agencies' existing relationships with industry" and whether prospective licensees may "avoid future collaborations with federally funded research institutions."[38]

The Framework provides a number of scenarios and examples, though none in which march-in rights would be exercised based exclusively on drug pricing under the practical application criterion. We glean instruction from Scenario 6, in which a government contractor developed a mask that filters out viral particles and filed a patent on the invention during the early stages of a respiratory virus pandemic. The contractor continued to increase the price of its masks (a total 400% increase) and also sent letters to other manufacturers, flagging the pending patent application and threatening lawsuits once the patent issues. The Framework notes that that two march-in criterion could be relevant—the contractor's actions may promote nonuse or unreasonable use (the practical application criterion) and there may be a health and safety need that is not reasonably being satisfied by the contractor. In determining whether to exercise march-in rights, the Framework explains, the agency would seek information from the contractor regarding the price increases, including how the increase in price compares to other masks and "how that price point compares to the cost of developing and manufacturing the masks." Moreover, as suggested by the Framework, "[b]y rapidly increasing the price of masks and threatening other manufacturers with litigation during an urgent public health emergency, the

contractor seems focused on keeping prices unusually high while not satisfying demand," which could weigh in favor of march-in. Nevertheless, the agency would still need to obtain additional information to better understand the unmet need, how march-in would impact it, and any justification for the contractor's actions, as well as how march-in would impact the policy and objectives of the Bayh-Dole Act.[39]

IMPLICATIONS

On the one hand, the Framework can be seen as an about-face by the government regarding the availability of march-in rights based on considerations related to drug price alone. Indeed, as noted above, historically, the availability of a product was sufficient to demonstrate "practical application," with the government consistently declining to take price into account. Now, however, price could factor into whether the invention has been made available to the public on reasonable terms, with scant guidance from NIST regarding how agencies should determine whether a drug's price is reasonable—let alone how they should do so with the threat of imposed prices under the Inflation Reduction Act. Additionally, the mere threat of march-in could potentially impact patent negotiations between competitors (*e.g.*, generics and biosimilars)—especially given that the presence of a near-marketable competitor would tick many of the practical value boxes in favor of march-in.

At the same time, as recognized in the Framework, there remain a number of practical limitations and downstream policy impacts (including on incentives to innovate) that may still disfavor march-in rights. For example, the intellectual property landscape of drugs is rarely straightforward; rather, drugs are often protected by multiple patents, some of which may be covered by the Bayh-Dole Act, but others may not be. A compulsory license to only a subset of patents would not facilitate more access and would weigh against march-in rights under the Framework. Additionally, any agency decision to exercise march-in rights based on the practical application criterion must be held in abeyance pending the exhaustion of appeals or petitions[40]—a factor NIST recommends considering in evaluating march-in. The fact-specific nature of the analysis, and the absence of any meaningful guidance regarding how to assess whether a price is reasonable or to ensure that march-in would not deter innovation, all point to a lengthy process.

As a whole, the Administration's announcement to rely upon the march-in rights under the Bayh-Dole Act does not appear to pose an immediate threat to drug pricing, at least because the "practical application" criterion has never been applied to price alone, and because a host of countervailing criteria likely weigh against an Agency's decision to march-in on drug patents. This action by the Administration, however, is yet another signal to drug companies—along with the Inflation Reduction Act and the Federal Trade Commission's recent actions regarding certain Orange Book listed patents—that the government is sharpening all of its tools to attempt to reduce drug pricing.

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Comments on the Draft March-In Framework are due to NIST by February 6, 2024. Please let us know if you have any questions regarding the Draft March-In Framework or are interested in submitting a comment. King & Spalding would be happy to assist.

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[1] Pub. L. No. 96-517, 94 Stat. 3015 (Dec. 12, 1980).
[2] 35 U.S.C. § 200.
[3] Although the statutory language refers only to nonprofit organizations and small businesses, a 1983 Presidential Memorandum extended the policy to all federal government contractors, regardless of size. This policy was later incorporated into the Department of Commerce's implementation of the Bayh-Dole Act (*see* 37 C.F.R. pt. 401), though the statutory language remains unchanged.
[4] Birch Bayh & Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ [hereinafter Bayh Dole Op-Ed].
[5] 35 U.S.C. § 200.
[6] *See id.* § 202(c)(4).
[7] *See id.* § 203.
[8] *Id.*
[9] *Id.* § 201(f).
[10] *See* STATEMENT OF SENATOR BIRCH BAYH TO THE NATIONAL INSTITUTES OF HEALTH (2004), https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf.
[11] *See* 35 U.S.C. § 203.
[12] Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631 (2001); *see also* Peter Arno & Michael Davis, *Paying Twice For the Same Drugs*, WASH. POST (Mar. 27, 2002), https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/ (stating that if a drug is not available to the public under a reasonable price, the government can insist the drug be licensed to "more reasonable manufacturers" under the Bayh-Dole Act).
[13] Bayh Dole Op-Ed, *supra* note 4.
[14] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Dir., to Robert Sachs and Clare Love (Mar. 21, 2023), https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-21march2023.pdf (referring to NIH's six prior decisions, spanning 1997 to 2016).
[15] *See* NIH, OFFICE OF THE DIRECTOR, IN THE CASE OF NORVIR® (July 29, 2004), https://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf.
[16] *See id.* NIH also concluded that the health or safety needs criterion had not been met, and there was "[n]o evidence" that "march-in could alleviate any health or safety needs that are not reasonably satisfied" by the Norvir manufacturer. *Id.*
[17] *See* NIST, RETURN ON INVESTMENT INITIATIVE: DRAFT GREEN PAPER (2018), https://www.nist.gov/system/files/documents/2018/12/06/roi_initiative_draft_green_paper_nist_sp_1234.pdf.
[18] NIST, RETURN ON INVESTMENT INITIATIVE, FINAL GREEN PAPER (2019), https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf.
[19] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35, 37 (proposed Jan. 4, 2021).
[20] *See, e.g.*, Letter from Senators Elizabeth Warren and Angus S. King, Jr. and Congressperson Lloyd Doggett to Xavier Becerra, Sec'y, U.S. Dept. of Health & Hum. Servs. (Feb. 17, 2022), https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf.
[21] Exec. Order No. 14036, 86 Fed. Reg. 36987 (July 14, 2021).

[22] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 88 Fed. Reg. 17730, 17730–31 (Mar. 24, 2023).
[23] Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023).
[24] *See id*. at 85594.
[25] *See id*. at 85596–97.
[26] *Id*. at 85598.
[27] *Id*.
[28] *Id*. at 85599; *see also id*. ("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?").
[29] *See id*. at 85600 (referencing 37 C.F.R. § 401.6(a)(6)).
[30] *Id*.
[31] *See id*.
[32] *Id*.
[33] *See id*.
[34] *See id*.
[35] *Id*.
[36] *Id*.
[37] *See generally* Inflation Reduction Act of 2022, Pub. L. No. 117-169 (Aug. 16, 2022); *see also* David J. Farber et al., *Price Negotiation, Medicare Rebates, and Benefit Reform*, KING & SPALDING (Aug. 15, 2022), https://www.kslaw.com/news-and-insights/price-negotiation-medicare-rebates-and-benefit-reform.
[38] 88 Fed. Reg. at 85600–01.
[39] *See id*. at 85603–04.
[40] *See* 35 U.S.C. § 203(b) (describing an administrative appeals process as well as a petition to the United States Court of Federal Claims).