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IN FOCUS

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March-In Rights Under the Bayh-Dole Act: Draft Guidance

On December 7, 2023, the U.S Department of Commerce's National Institute of Standards and Technology (NIST) issued a request for information (RFI) on its "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights." The RFI seeks public comment on the draft guidance, which NIST envisions as a tool to help federal agencies evaluate when it is appropriate to exercise "march-in rights." March-in rights allow an agency to grant a compulsory license on a privately owned patent to third parties, if the invention was developed with federal funding and the agency finds that certain statutory criteria apply.

In the 40 years since Bayh-Dole's enactment, no federal agency has exercised its march-in rights. This In Focus provides background on march-in rights, analyzes NIST's draft guidance, and reviews select considerations for Congress.

Patents and the Bayh-Dole Act

U.S. patents give their owners the exclusive right to make, use, sell, and import a new and useful invention for approximately 20 years. Anyone else who wishes to use the invention in the United States needs to obtain a license (i.e., permission) from the patent holder and typically pays a royalty for the license. Patents are meant to encourage innovation by giving inventors a "temporary monopoly" on their inventions in exchange for disclosing their invention by filing a publicly accessible patent application.

To promote the utilization of inventions arising from federally supported research and development (R&D), Congress enacted the Patent and Trademark Act Amendments of 1980 (P.L. 96-517, as amended; commonly called the "Bayh-Dole Act" or "Bayh-Dole"). Bayh-Dole established a uniform federal patent policy for inventions supported by federal funding. Such R&D often has applications beyond the scope and goals of the original research, including commercial applications. Without further investment and sufficient private sector incentives, Congress was concerned that the commercial value of federally funded inventions might not be fully realized.

Under Bayh-Dole, federal contractors or grantees (collectively, federal contractors) may elect to retain the patent rights to an invention made with federal support. The federal contractor may then use the invention itself or license the patent(s) to industry partners. In exchange for retaining patent ownership, however, the federal contractor provides the federal agency with a government-use license—that is, permission for the government to use the patented invention without paying a royalty. The United States also retains the authority to grant compulsory licenses to third parties in certain circumstances, known as "march-in rights."

Statutory Bases for March-In Rights

Although Bayh-Dole generally allows federal contractors to take ownership of patents on inventions created with federal funding, the federal government has the power to "march in" and grant compulsory licenses to third parties in some circumstances. Specifically, the funding agency can require the federal contractor to grant a patent license to a third party if the agency determines that any of four statutory conditions listed in 35 U.S.C. § 203(a) apply:

> (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 . . . ;
>
> (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 . . . ; or
>
> (4) action is necessary because [the contactor or its licensee did not comply with the preference for domestic manufacturing of the invention under 35 U.S.C. § 204].

A license granted using march-in rights must have "terms that are reasonable under the circumstances," which may require the licensee to pay royalties to the patent holder.

The Debate over the Role of Pricing in March-In Determinations

NIST promulgates regulations governing agency implementation of Bayh-Dole, which are codified at 37 C.F.R. parts 401 and 404. Procedures governing the exercise of march-in rights are set forth in 37 C.F.R. § 401.6, which directs a funding agency to initiate a march-in proceeding when it "receives information that it believes might warrant" doing so.

Anyone may urge an agency to invoke march-in rights. Such stakeholder petitions are most often raised with respect to pharmaceutical drugs whose development was supported by federal funding. For example, a number of advocacy groups have petitioned the National Institutes of Health (NIH) to exercise march-in rights based on the high prices of certain drugs developed with federal funding, such as treatments for HIV/AIDS. NIH has rejected these petitions, contending that pricing concerns alone are an insufficient basis to exercise march-in rights—so long as the invention is on the market and available to patients.

In January 2021, NIST requested public comment on its proposal to revise Bayh-Dole regulations to state that march-in "shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services." In response, NIST received over 81,000 comments. Ultimately, the provisions of the proposed rule related to march-in rights and product pricing were not included in the final rule.

NIST's December 2023 Draft Guidance

NIST's December 2023 draft guidance aims to provide "clear guidance to an agency on the prerequisites for exercising march-in" rights and ensure the "consistent and predictable application" of Bayh-Dole. In contrast to the January 2021 notice of proposed rulemaking, NIST's new draft guidance treats price as an appropriate consideration in march-in determinations.

Drafted by NIST and the Interagency Working Group for Bayh-Dole (IAWBD), the proposed framework sets out a three-step process for agencies to use in determining whether to exercise march-in rights on a particular patented invention. First, the agency assesses whether Bayh-Dole applies to the invention at issue (i.e., was the invention conceived or reduced to practice using federal funds).

Second, the agency assesses whether one of the four statutory criteria (listed above) required to exercise march-in rights apply. The bulk of the draft guidance focuses on this step, providing a number of factors and questions agencies may consider when assessing whether a particular scenario meets one of the statutory march-in criteria. The draft guidance advises agencies to consider price as a factor in assessing whether the "practical application" and "health and safety needs" statutory criteria apply. As to practical application, the guidance considers "the reasonableness of the price and other terms" as a factor that may "unreasonably limit availability of the invention to the public." As to health and safety needs, the guidance would have agencies consider whether "the price is extreme, unjustified, and exploitative of a health or safety need," among other considerations.

Third, the guidance asks the agency to assess whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole, including whether invoking march-in rights would incentivize innovation and promote public access to that innovation.

NIST's proposed framework is a draft document. The guidance states that the responses to the RFI will inform NIST and IAWBD in developing a final framework. Even if finalized, the framework would be a guidance document that, unlike formal regulations, would lack the force of law.

Stakeholder Responses to the Draft Guidance

There is a long-running legal, academic, and policy debate over the appropriateness of considering a federally funded invention's price as a reason to exercise march-in rights. Some groups have urged federal agencies to march in when a federally supported invention is unduly expensive, noting that the statute defines "practical application" to require that the invention be "available to the public on reasonable terms." Other groups argue that Bayh-Dole was never intended to be a price-control statute and that market availability satisfies the "practical application" requirement, regardless of price.

Stakeholder responses to NIST's draft guidance have largely fallen along this existing divide. Groups such as the Bayh-Dole Coalition and AUTM (formerly known as the "Association of University Technology Mangers") have criticized the draft guidance's treatment of pricing. These groups argue that the government's threat to license patents to competitors on pricing grounds would discourage public-private partnerships and disincentivize critical investments required to make nascent technologies commercially viable.

Critics of the proposed guidance argue that it would discourage innovation across a range of industries. Representatives of the pharmaceutical industry argue that the proposal would especially diminish U.S. competitiveness in the pharmaceutical industry and undermine R&D and investment in new treatments for patients. The Biotechnology Innovation Organization stated that the draft guidance would especially hurt "smaller biotech companies, which are responsible for the bulk of medical innovation."

Groups that advocate for the use of march-in rights on the grounds of pricing have largely expressed qualified support. For example, the Center for American Progress issued a statement applauding the proposal. Other groups have questioned whether the framework goes far enough in encouraging federal agencies to exercise march-in rights. For example, Public Citizen stated that the guidance "must go further to challenge big pharma's monopoly power." The director of Knowledge Ecology International, which has petitioned NIH to exercise march-in rights to lower the price of some federally funded drugs, criticized the framework for not using drug prices in other countries as a metric for determining the reasonableness of drug prices.

Considerations for Congress

Congress might consider a range of actions in response to NIST's draft guidance. For example, Congress could consider legislation to amend 35 U.S.C. § 203 in a way that either explicitly requires or prohibits the consideration of specific factors, such as price, in march-in determinations. In considering possible responses, Congress may weigh the possible impacts that march-in rights have on pricing of patented products and incentives for innovation and R&D, as well as the potential effect the draft guidance may have on public-private partnerships.

Alternatively, Congress might choose to continue to engage in oversight, since it is unclear what effect the draft guidance would have on whether agencies exercise march-in rights. As such, Congress may choose not to pursue legislative action in order to see whether the agency's guidance is finalized, and to assess the guidance's practical effect, if any, on agency march-in proceedings and determinations.

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