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IN FOCUS

Updated December 3, 2024

Pricing and March-In Rights Under the Bayh-Dole Act

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 that allows funding recipients to retain patent rights on inventions made with federal funding, subject to certain conditions.

One of those conditions is known as "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 that agency's funding and the agency finds that certain statutory criteria apply. In the more than 40 years since Bayh-Dole's enactment, no federal agency has ever exercised its march-in rights.

There is a long-running legal, academic, and policy debate over the appropriateness of considering an 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, while other groups argue that Bayh-Dole was never intended to be used as a price-control statute. This In Focus explains the debate as well as key policy developments, including the 2023 draft guidance on march-in rights released by the National Institute of Standards and Technology (NIST), and reviews select considerations for Congress.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 them in a publicly accessible patent application.

The Bayh-Dole Act applies only to patents on inventions conceived or reduced to practice under a federal funding agreement. Without further investment and sufficient private-sector incentives, Congress was concerned that the full value of federally funded inventions might not be realized. Bayh-Dole aims to promote the utilization of federally supported R&D, which often has applications beyond the scope and goals of the original research, including commercial applications.

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.

Statutory Bases for March-In Rights

Bayh-Dole also gives the federal government authority to "march in" and grant compulsory patent licenses to third parties in some circumstances. Specifically, the funding agency can require a federal contractor to grant third-party licenses on patents covered by Bayh-Dole, 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 [based on a failure to comply with the preference for domestic manufacturing of the invention under 35 U.S.C. § 204].

Procedures for March-In Determinations

NIST promulgates regulations governing agencies' 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. At this point, the agency must notify the contractor and may use informal consultations to determine whether to begin a formal march-in proceeding.

If the agency decides to begin a formal march-in proceeding, it must give written notice to the contractor of the proposed basis for march in. If necessary, the agency may conduct fact-finding, receive evidence, take testimony, and hear argument in a proceeding closed to the public. Should the agency decide to march in, the contractor may appeal the decision to the U.S. Court of Federal Claims.

The Debate over Pricing and Past March-In Petitions

The price of the patented product is not explicitly mentioned in Bayh-Dole as a basis for march-in rights. Proponents of using march in note that the statute defines the "practical application" of an invention as being

"available to the public on reasonable terms." On this view, excessively high prices for a patented invention may be an "unreasonable term" that justifies march in. Other groups argue that the text, history, and purpose of Bayh-Dole demonstrates that it was never intended to be a price-control statute. On this view, availability for purchase on the market satisfies the practical-application requirement, regardless of the pricing decisions of the patent holder.

Anyone may urge an agency to invoke march-in rights. Stakeholder petitions most often have been 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 drugs developed with federal funding, such as certain treatments for cancer or HIV/AIDS. NIH has rejected all of these petitions, concluding 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.

Recent Policy and Regulatory Actions

In 2018, President Trump's Management Agenda charged NIST with engaging stakeholders to identify regulatory impediments and administrative improvements to federal technology transfer policies and practices. Later that year, NIST released a draft "green paper" called the *Return on Investment Initiative for Unleashing American Innovation*. This discussion document, based on stakeholder feedback, identified many short- and long-term actions to enhance U.S. innovation and promote technology transfer of federally supported R&D. One of the proposed "intended actions" was for NIST to define the circumstances justifying march in to make clear that it should not be used as a "regulatory mechanism" to "control the market price" of patented products. NIST's final 2019 green paper found that a lack of clarity regarding march-in rights (and its potential use as a means to control price) created detrimental "market uncertainty."

In January 2021, NIST requested public comment on a proposal to formally revise Bayh-Dole regulations to (among other things) 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, many of which opposed the proposed rule on march in and pricing. Ultimately, that provision was not included when the final rule issued in 2023.

NIST Draft Guidance

In December 2023, NIST issued a request for information (RFI) on a "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights." NIST's December 2023 draft guidance aimed 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 2023 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 outlines three overarching questions that agencies must assess in determining whether to exercise march-in rights:

- Does Bayh-Dole apply to the invention at issue (i.e., was the invention conceived or reduced to practice using federal funds)?
- Is one of the four statutory criteria (listed above) met? Notably, the draft guidance indicates that agencies may consider pricing, among other factors, in assessing whether the "practical application" and "health and safety needs" statutory criteria apply.
- Would march in support the policy and objectives of Bayh-Dole (i.e., would it incentivize U.S. 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 NIST's Draft Guidance

Groups such as the Bayh-Dole Coalition and AUTM (formerly known as the Association of University Technology Managers) have criticized the draft guidance's treatment of pricing, arguing it would discourage public-private partnerships and disincentivize critical investments required to make nascent technologies commercially viable. Pharmaceutical industry groups argued that the proposal would especially diminish U.S. competitiveness in the pharmaceutical sector and undermine R&D and investment in new treatments for patients.

Other groups expressed qualified support. The Center for American Progress applauded the proposed guidance. Some proponents of using march in questioned whether the framework goes far enough in encouraging federal agencies to exercise march-in rights. For example, 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

Whether and when pricing should be considered in march-in determinations depends on the interpretation of 35 U.S.C. § 203. Congress could consider legislation to amend Bayh-Dole to either explicitly require or prohibit the consideration of specific factors, such as pricing. 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 NIST's guidance may have on public-private partnerships. Congress might also choose to continue to engage in oversight in order to see whether and how NIST's guidance is finalized, and its practical effect, if any, on agency march-in proceedings and determinations.

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