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Educational Institutions Could Be Impacted by a Proposed Framework to Expand the U.S. Government's Discretion to "March In" on Patent Rights

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In the Biden Administration's pursuit of increasing affordability of healthcare and prescription drugs, the National Institute of Standards and Technology (NIST) released in December 2023 its draft framework on the U.S. government's exercise of "march-in" rights, i.e., its ability to unilaterally sublicense privately owned patents if such patents cover drugs and other products that were developed using government funding. The draft framework would expand the government's discretion to "march in" under the provisions of the Patent and Trademark Law Amendments Act of 1980 (Bayh-Dole Act, or Act)—a power that it presently has never employed. The proposal may affect those who have been among the biggest beneficiaries of the Act—universities and nonprofit research institutions that make use of federal grant money to engage in patent-generating research and development—as well as their private-sector partners.

The Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Draft Framework) was released by NIST on December 7, 2023. The period for public comment on the Draft Framework closed February 6, 2024. NIST sought public input on whether the Draft Framework provides clear guidance on the factors to be considered for the exercise of march-in rights and whether the Draft Framework supports the Bayh-Dole Act's dual purpose of incentivizing American innovation and ensuring that products covered by sponsored patents are publicly available. At the close of the comment period, more than 51,000 comments on the Draft Framework had been submitted to NIST.

Bayh-Dole Act and March-In Rights

Nicknamed for its bipartisan senator sponsors Birch Bayh (D-Indiana) and Bob Dole (R-Kansas), the Bayh-Dole Act was adopted in 1980 to address the issue of commercializing or otherwise making available to the public innovations that were created using government funding. Before the Bayh-Dole Act passed, the government would own any invention that was developed while using federal funding. While the government offered to grant nonexclusive licenses to such sponsored patents, there was no standard policy in place to facilitate such licensing. As a result, the government accumulated ownership of thousands of patents with no subsequent licensees taking

rights in the resulting inventions—inventions yielded by research often carried out by universities and other nonprofit organizations. In the absence of a policy for licensing these government-owned patents to the private sector, the vast majority of the inventions embodied by these patents were not commercialized or otherwise made available for public benefit, and the universities and nonprofits that had developed the intellectual property had no ownership claim to it or ability to receive royalties based on the valuable research.

To solve this problem, Senators Bayh and Dole proposed a uniform policy enabling recipients of federal funding to fully own and license a sponsored patent. These recipients—typically universities, other nonprofits, and small businesses (contracting entities)—could then commercially exploit the sponsored patents and thereby achieve the congressional intent of the Bayh-Dole Act. Thus, the inventions in patents resulting from government-sponsored research could effectively be developed into products and services for use by the public rather than languishing under federal government ownership as uncommercialized technology.

However, the Bayh-Dole Act has two important provisos: the US government also has an irrevocable, nonexclusive, royalty-free license to use the sponsored patents and technology for its own purposes; and contracting entities assuming ownership of sponsored patents must make substantial efforts to comply with certain statutory criteria lest the government exercise its right to sublicense sponsored patents to third parties. The discretionary exercise of this right to sublicense (also referred to as "march-in" rights) is the target of the Draft Framework.

In the 43 years since the inception of the Bayh-Dole Act, the US government has received only a handful of petitions from third parties to exercise march-in rights, all of which have been denied. See March-In Rights and U.S. Global Competitiveness (last accessed Dec. 27, 2023). Thus, the US government has never exercised march-in rights, not even where petitioners complained about pricing on a drug covered by a sponsored patent. Id. Notably, the US government did not even exercise its right to march in during the height of the COVID-19 pandemic.

Original Statutory Criteria for Exercise of March-In Rights

The US government has discretion to exercise march-in rights if a contracting entity (or its licensee(s)) meets at least one of four statutory criteria; these "triggering" criteria are:

- The contracting entity (or its licensee(s)) fails to take effective steps, within a reasonable time, to make the benefits of the sponsored invention "available to the public on reasonable terms"
- The contracting entity (or its licensee(s)) fails to reasonably alleviate health and safety conditions
- The contracting entity (or its licensee(s)) fails to provide "public use specified by Federal regulations" –or–
- The contracting entity (or its licensee(s)) fails to favor US manufacture of goods or services covered by the sponsored patent

Despite petitions asserting that the above criteria have been met in certain instances, the US government has never exercised its march-in rights.

Potential Impact on Criteria for Exercise of March-In Rights

The Draft Framework proposes certain examples, clarifications, and changes to the statutory criteria that the US government must consider in determining whether to exercise march-in rights. Specifically, the Draft Framework was accompanied by a set of considerations and examples that purport to reframe the analysis.

These considerations are (1) whether the Bayh-Dole Act applies, (2) whether a statutory criterion is met, and (3) whether exercise of march-in rights would support the policy and objectives of the Bayh-Dole Act.

Consideration 1: What Is a "Subject Invention"?

The Draft Framework does not affect the substance of how a federal agency would ascertain whether a patented technology is a "subject invention" under the Bayh-Dole Act. A "subject invention" is defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a [government] funding agreement." As such, if the patented technology does not qualify as a "subject invention," then march-in rights cannot be exercised.

Consideration 2: Is a Statutory Criterion Met?

Regarding the second consideration, the Draft Framework proposes examples of when the four statutory criteria (noted above) would be met. These new examples are discussed in turn below.

Practical Application: Has the contracting entity taken steps (or will it take steps) to make the benefits of the invention "available to the public on reasonable terms"?

The Draft Framework provides guidance for three scenarios: (1) subject inventions that have not yet been licensed (and the contracting entity has no plans to do so), (2) subject inventions that are licensed or subject to development by the contracting entity for commercialization, and (3) subject inventions that have already been commercialized.

For those subject inventions that are already being commercialized, the government is explicitly authorized under the Draft Framework to assess the price at which products using the subject invention are being offered for sale in the United States to ascertain whether such price is "unreasonably limiting availability of the subject invention to consumers or customers," i.e., whether the price is too high.

Alleviation of Health and Safety Needs: Is the subject invention needed to address an identified health or safety need not being reasonably met by the contracting entity (or its licensees)?

The Draft Framework considers a number of factors in determining whether march-in rights are necessary to alleviate health or safety needs not being met by a contracting entity or its licensees. Of particular note, one factor asks whether the contracting entity or licensee is "exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of the circumstances."

The Draft Framework also clarifies that the inquiry is "not limited to reviewing price increases," as "the initial price may also be considered if it appears that the price is extreme, unjustified, and exploitative of a health or safety need."

Public Use: Does a federal regulation require that the subject invention be used, including in or with another product available commercially?

Several factors, including inquiring whether there is "evidence that the contractor(s) or licensee(s) is restricting access or imposing barriers to access," are considered for this statutory criterion.

Preference for US Manufacturing: Has the contracting entity (or its licensee(s)) failed to meet its obligations under 35 U.S.C. § 204 to make reasonable efforts to manufacture products made from or with the subject invention in the United States?

The Draft Framework sets forth inquiries for exercise of march-in rights where the contracting entity or its licensee(s) fails to meet the requirements for attempting to domestically manufacture products incorporating subject inventions.

A federal agency may ask whether licensing agreements pertaining to the subject invention include a requirement that products made with or from the subject patent be "manufactured substantially" in the United States, whether such a licensing agreement may be amended to comply with 35 U.S.C. § 204, and whether the contracting entity or its licensee(s) has sought a waiver of the domestic manufacturing requirement if suitable US manufacturing capabilities cannot be retained.

Consideration 3: Does Exercising March-In Rights Fulfill the Objectives of the Bayh-Dole Act?

Finally, after establishing that Bayh-Dole applies and that a statutory criterion is met, the Draft Framework then asks whether the exercise of march-in rights would be consistent with the objectives of the Bayh-Dole Act, as set forth under 35 U.S.C. § 200. In particular, the Draft Framework focuses on two main objectives: promoting "the development of new products in the [United States]" and promoting the availability of those new products "to end-users or consumers in the [United States]."

In order to analyze whether these two objectives would be met, the following questions are set forth in the Draft Framework:

- Would exercising march-in rights "achieve practical application, alleviate health or safety needs, meet public use requirements, or meet manufacturing requirements"?
- Do alternatives exist to "address the identified problem, and can those alternatives be pursued instead of or in parallel with any march-in proceedings"?
- What are the broad implications of exercising march-in rights?

To illustrate how the three-question framework could be used in a given situation, the Draft Framework provides eight exemplary hypothetical scenarios for considering factors under the second and third questions (with the understanding that, in the hypotheticals, the question of whether Bayh-Dole applies has already been answered in the affirmative). The authors recommend reviewing the examples set forth in the Draft Framework for specific guidance. See Would march-in support the policy & objective of Bayh-Dole, considering the specific case and broader context? Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (last accessed Dec. 21, 2023).

Potential Impact of the Draft Framework

If the Draft Framework is adopted in some form, the government will have to meet looser criteria to march in and unilaterally sublicense patents directed to subject inventions. Given the Biden Administration's goals of reducing drug prices and healthcare costs, the Draft Framework has been praised by a number of consumer and patient advocacy groups concerned about the practical ability of US citizens to afford necessary medication and healthcare. The Federal Trade Commission weighed in favorably on the Draft Framework, stating in its public comment to NIST that it was "supporting the Proposed Framework and the use of march-in rights, among other tools, to promote a competitive U.S. pharmaceuticals market and to ensure that taxpayer-funded innovations are accessible and affordable to the public." See Comment of the United States Federal Trade Commission (last accessed Feb. 29, 2024).

However, the practical effect the Draft Framework (and whether its expanded march-in rights considerations will be effective to reduce drug prices and healthcare costs) is less certain. Many drug and healthcare products are covered by a "thicket" of patents—even if one of the patents involved is directed to a subject invention, other patents covering the product often are not. Thus, there would be little benefit in the government marching in on only the subject patent when the government has no ability to march in and out-license the other patents necessary to produce the product.

Universities and non-profit research entities may also find the Draft Framework detrimental to their technology transfer programs that drive much innovation in the United States. A comment submitted to NIST by a coalition of the Association of American Universities, the Association of Public and Land-grant Universities, the Association of American Medical Colleges, the American Council on Education, the Association of University Technology Managers, and the Council on Governmental Relations set forth a number of concerns shared by research universities. See Comments in response to NIST's Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (last accessed Feb. 29, 2024).

Universities derive a substantial portion of their funding for research from federal grants and depend on the ability to file for patents from this research that can be licensed to outside companies or university-affiliated startups for commercialization, thereby fulfilling the goals of the Bayh-Dole Act. These institutions have pointed out that implementing the Draft Framework could upend these well-established technology transfer programs. Any patent covering a subject invention would be reduced in value if the government could more easily exercise march-in rights over it. Potential licensees might be hesitant to purchase licenses to patents developed with federal funds if the government decides it can sublicense the patents to a competitor. Moreover, without confidence that universities or their licensees will be able to retain control over subject patents, investors who might otherwise be interested in providing financial backing to commercialize products embodying subject inventions may refrain from doing so.

Opponents to the Draft Framework also emphasize that it is technology neutral such that industries outside just the pharmaceutical and healthcare realm could be impacted if it is adopted. Indeed, several of the hypothetical scenarios set forth in the Draft Framework illustrating the march-in rights analysis involve products entirely unrelated to healthcare or medications, indicating that the drafters of the proposal are aware that it can be applied in scenarios that have nothing to do with lowering healthcare costs.

Now that the public comment period on the Draft Framework has closed, it remains to be seen whether the Biden Administration will follow through with adding its provisions to federal regulations, or whether those opposed to the Draft Framework will succeed in narrowing the Draft Framework or preventing its adoption altogether.

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