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Marching Forward: How NIH's Proposed Framework Could Reshape the Bayh-Dole Act's Use of March-in Rights

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Introduction

In connection with the Biden-Harris Administration's recent announcement of various actions to lower health care and prescription drug costs, the National Institute of Standards and Technology ("NIST") released for public comment a 'Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights' (the "Draft Framework"), on December 7, 2023. Central to this Draft Framework is the inclusion of "price" as a factor for enforcing "march-in" rights under the Bayh-Dole Act. If implemented, the Draft Framework marks a significant policy shift, making it clear that the government can effectively recapture the exclusive rights of technology derived from federally funded research if the price of a product is deemed too high – in effect, fixing prices on certain consumer products.

This article examines the implications of these proposed changes, especially within the pharmaceutical and agricultural industries where patent protection is essential to commercialize products.

Summary

The proposed use of "march-in" rights in the Draft Framework for federally funded patents will likely have little impact on lowering prices for consumers. With respect to the pharmaceutical industry, only about 8 percent of FDA-approved drugs from 2011-2020 received any level of federal funding, with less than 2 percent being fully federally funded.[1] Similarly, in the agriculture industry, it is estimated that less than 15 percent of agriculture technologies are federally funded.[2]

Although the implementation of "march-in" rights might not be widely felt, their potential use could negatively affect public-private relations. With the vast majority of research in each industry being privately funded, using "march-in" rights could disincentivize collaboration between federally funded institutions like universities and private institutions without effectively lowering prices for consumers.[3]

Background of the Bayh-Dole Act

The Bayh-Dole Act of 1980 (the "Act") empowers universities, businesses, and nonprofits to patent inventions developed with federal funding. These are termed "subject inventions." The Act motivates these entities to license patents to private companies for further development, aiming to translate government-funded research into commercial products.

The Act allows a federal agency to exercise control over an invention if the contractor, such as a college or university, has not actively developed or commercialized it. "March-in rights" thereby permit an agency to compel a contractor to license an invention to a third party, or to issue the license directly in case of non-compliance. These rights are subject to four specific conditions set by the Act.[4]

As it stands, the Draft Framework would function as a guidance document and, as such, would not carry the force of law.[5] The Draft Framework provides a discretionary three-step framework to aid the assessment of whether one of the four conditions[6] for "march-in" rights have been met:

1) As a threshold matter, the agency must determine whether the invention was conceived or reduced to practice using federal funds;

2) The agency must determine whether one of the four statutory conditions applies to the invention at issue; and

3) The agency must analyze whether the exercise of "march-in" rights would support the policy objectives of the Act (would it incentivize innovation and promote public access).[7]

The Draft Framework primarily concentrates on the second step, which outlines a variety of factors an agency can evaluate to determine if a particular scenario meets one of the statutory march-in criteria. Most notably, the Draft Framework introduces "price" as a key factor for consideration. Generally, it assesses "the reasonableness of the price and other terms" to determine if they might "unreasonably limit availability of the invention to the public." [8] Again, if implemented, this framework would simply act as a guidance document, meaning that agencies are not legally bound to follow it.

Historically, "march-in" rights have never been used, often due to preference for negotiation over forceful intervention. However, the Draft Framework "price" consideration could change this dynamic.

Reaction to the Draft Framework

The goal of the Draft Framework is to ensure that subject inventions are utilized in a way that benefits the public. Proponents contend that the mere possibility of an agency "marching-in" alone encourages contractors to set fair and reasonable prices, making them accountable to taxpayers whose money supported the research they profit from.

Unsurprisingly, the pharmaceutical industry is strongly against the Draft Framework for price control. Fearing their expected profits would be effectively reduced through government intervention, advocates of the pharmaceutical industry argue that "march-rights" would discourage private investment in federally funded research. Even if this policy was implemented, opponents state it would not fulfill its intended purpose. A 2023 study by Vital Transformation (consultancy company specializing in the healthcare and pharmaceutical industries) supports this concern, showing that 92 percent of FDA-approved drugs from 2011-2020 were industry-developed without federal funding.[9] They also found that less than 2 percent of therapies were fully funded by the federal government, and another 8 percent having some federal contribution to their development, indicating the Draft Framework might not have its intended impact on price control.[10]

The Potential Effects of the Draft Framework on the Agriculture Industry

On its face, the Draft Framework advertises the use of "march-in" rights in order to lower health care and drug costs; however, if passed, these "march-in" rights could also be exercised in other industries, specifically agriculture.

Private and public sectors have distinct goals in agriculture. The private sector aims for profit, focusing on producing high-yields of commercially viable crops.[11] On the other hand, the public sector prioritizes societal welfare,[12] utilizing government funded programs such as public breeding programs which focus on developing crops that have high social but low private returns.[13] For example, cover crops, though not highly lucrative, improve soil health and combat erosion, thus increasing potential agricultural yield.[14] These programs have also aided in enhancing crop resilience in addressing climate change, and have increased certain plant nutritional profiles to address pervasive malnutrition.[15]

Public plant breeders also strive to keep seed varieties in the public domain for wider access.[16] However, decreased public funding and the Bayh-Dole Act's emphasis on intellectual property rights have changed the landscape.[17]

Bayh-Dole aimed to drive innovation by financially rewarding inventors for patenting their creations. Yet, in the plant/seed industry, the reality has been quite the opposite. The USDA found that as markets for corn, soybean, and cotton grew more concentrated, private research efforts diminished or slowed compared to scenarios without market

concentration.[18] This had led economists to caution that companies may innovate less when they can maintain high prices with lower production levels.[19]

Despite these concerns in the plant/seed industry, implementing the Draft Framework's "price" based "march-in" rights is unlikely to resolve these issues. Similar to the pharmaceutical sector, such price controls would impact only a small fraction of patents. According to a study by the Center for Security and Emerging Technology, only 15 percent of biotechnology patents, including many agricultural technologies, are federally funded.[20] It is important to note that this 15 percent encompasses a broad range of technologies, not just those specific to agriculture. Therefore, the actual percentage of agriculture-specific patents within this federally funded group is even smaller. This indicates that most agricultural patents are privately funded, suggesting that the Draft Framework, which targets only federally funded research, would have a minimal impact on the broader plant/seed industry.

Conclusion

The Draft Framework's proposal to employ Bayh-Dole Act mechanisms for price control appears to be met with significant concern, particularly within the pharmaceutical and agricultural sectors. However, upon closer examination, the reactions to this proposal may be overblown, considering the limited practical impact it is likely to have.

In both the pharmaceutical and agricultural industries, the vast majority of research and innovation are privately funded, with only a small fraction attributed to federal funding.[21] Given this reality, the implementation of "march-in" rights based on price considerations is unlikely to significantly affect commercialization within these industries. The fear of stifling private investment due to government intervention appears largely unfounded, considering the minimal impact such actions would have on the majority of products.[22]

Moreover, the historical non-use of "march-in" rights, along with the discretionary enforcement nature of the Draft Framework, suggests that the proposed framework may not drastically alter the current landscape. Instead, it is more likely to serve as a symbolic gesture rather than a substantial policy shift.

While concerns regarding fair pricing and public access to inventions are valid, it is crucial to recognize that the proposed framework may not effectively address these issues within the context of industries primarily driven by private investment. Ultimately, the Draft Framework's potential impact on commercialization and pricing in pharmaceuticals and agriculture is likely to be minimal, suggesting that the alarmist reactions may be disproportionate to the actual consequences.

1. Information Technology & Innovation Foundation, *Comments Letter regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Feb. 6, 2024), **https://www2.itif.org/2023-interagency-framework-march-in-rights.pdf** .

2. Jack Corrigan and Sara Abdulla, *Bayh-Dole Patent Trends*, Center for Security and Emerging Technology (Aug. 2023), **https://doi.org/10.51593/20230012**.

3. *Id*.

4. *See* 35 U.S.C. § 203(a).

5. Congressional Research Service Report IF12582, *March-In Rights Under the Bayh-Dole Act: Draft Guidance* 2, by Kevin J. Hickey & Emily G. Blevins.

6. Specifically, the four conditions under the statute arise, when:

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 in such field of use;
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 and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
4. action is necessary because the agreement required by section 204 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 its agreement obtained pursuant to section 204. (35 U.S.C.A. § 203 (West)).

7. Congressional Research Service Report IF12582, *March-In Rights Under the Bayh-Dole Act: Draft Guidance* 2, by Kevin J. Hickey & Emily G. Blevins.

8. *Id.*

9. Information Technology & Innovation Foundation, *supra* note 1.

10. *Id*.

11. Mathew Abraham & Sage Grasso-Monroe, *Improving Public Sector Plant Breeding for the Future of Food Security* (Aug. 25, 2022), **https://cals.cornell.edu/news/2022/08/improving-public-sector-plant-bree...**.

12. *Id*.

13. University of Wisconsin-Madison Department of Plant and Agroecosystem Sciences, *Intellectual Property Rights And Public Plant Breeding*, **https://pasdept.wisc.edu/research/ipr-summit/#:~:text=Public%20breeding%...** (last visited March 18, 2024).

14. American Society of Agronomy, *Plant Breeders Balance Shared Innovation, Revenue: Researchers Advocate for Support*

of Public Plant Breeding Programs, ScienceDaily (May 2, 2018), **https://www.sciencedaily.com/releases/2018/05/180502075847.htm**.

15. Abraham, *supra* note 10.

16. Shea Swenson, *We're Losing Our Seed Breeders*, Ambrook Research (May 19, 2023), **https://ambrook.com/research/crops/public-seed-breeders-land-grant-unive...**.

17. Bayh-Dole made it easier for universities to patent and license their research, and it largely eliminated their reluctance to do so. *See* Kristina Hubbard, *Seed Privatization and the Path Toward Equitable Exchange*, National Sustainable Agriculture Coalition, 5-6 **https://sustainableagriculture.net/wp-content/uploads/2021/03/Hubbard-Se...** (last visited March 18, 2024).

18. *Id*. at 4 (citations omitted).

19. Dr. Neil Harl of Iowa State University warns that firms become complacent and less likely to innovate when they can produce less and obtain a higher price for their input. *Id*. (citations omitted).

20. Jack Corrigan and Sara Abdulla, *Bayh-Dole Patent Trends*, Center for Security and Emerging Technology (Aug. 2023), **https://doi.org/10.51593/20230012**.

21. See Information Technology & Innovation Foundation, *supra* note 1; *see also* Corrigan and Abdulla, *supra* note 2.

22. See *id.*