Technology Transfer Explained: The Bayh-Dole Act and March-In Rights

Center Forward Basics

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Overview

The University and Small Business Procedures Act of 1980, commonly known as the “Bayh-Dole Act,'' empowers recipients of federal funding, primarily public universities and start-up businesses, to retain ownership of their inventions generated from that funding. As owners of their inventions, the university or research institution can then license the intellectual property (IP) rights of those inventions to private sector partners that can develop, produce, and commercialize a usable end product. While the licensed producer uses the IP, the patent holder maintains ownership and the ability to collect royalties that can be invested in future research. If, however, the commercialization of the invention fails to meet certain standards, the government agency that issued the grant can invoke "march-in" rights, and mandate the patent holder issue additional licenses to allow others to practice the patented invention. In the more than forty-three years since Congress passed the Bayh-Dole Act, march-in rights have never been invoked.

Recently, consumer advocates have petitioned the government to use march-in rights as a means to lower drug prices by ordering patent holders to issue licenses to other manufacturers who would be expected to provide the drug more cheaply. The White House, Department of Commerce, and Department of Health and Human Services have expressed openness to the idea, and released a draft revision of the criteria to exercise march-in rights in all fields of federally-supported technology. This Basic will explore the history of the Bayh-Dole Act, technology transfer, the criteria for march-in rights, and the potential impact of changes on consumers and industry in the United States.

Center Forward Basics

Center Forward brings together members of Congress, not-for profits, academic experts, trade associations, corporations and unions to find common ground. Our mission: to give centrist allies the information they need to craft common sense solutions, and provide those allies the support they need to turn those ideas into results.

In order to meet our challenges we need to put aside the partisan bickering that has gridlocked Washington and come together to find common sense solutions.

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Bayh-Dole Act Background

The Bayh-Dole Act permits universities and other institutions to retain patents for their inventions arising from government-funded research. The universities or small businesses receiving government research grants are referred to as “contractors” in the Bayh-Dole statute language. These contractors typically license their inventions to private sector partners for commercialization, creating an incentive for private sector development of federally funded research. The Act refers to private sector partners and producers as “licensees.” The licensee producing and distributing products from those inventions will pay royalties to the university or institution that holds the patent, allowing them to invest profits in future research.

Prior to the passage of the Bayh-Dole Act, the vast majority of such patents or inventions remained unused because universities and other grant recipients did not have the means to produce and commercialize their research themselves. Before its inception, only 5% of federally funded patents were widely commercialized in the private sector, leaving more than 28,000 inventions undeveloped or unused. Since enacted in 1980, the Bayh-Dole Act’s system for universities and research institutions to share IP with commercial producers, commonly called “**technology transfer,**” has spurred the creation of thousands of new products and remarkable economic growth. From 1996 through 2020, patented inventions from universities have generated more than $1.9 trillion in gross domestic industrial output, supported more than 6.5 million jobs, and served as the basis for over 17,000 startup businesses. In that same period, academic institutions have disclosed nearly 500,000 inventions and garnered over 126,000 patents, including patents that contributed to the creation of more than 200 pharmaceutical drugs and

vaccines. In 2022 alone, $91.8 billion in federal research funding led to 9,884 licenses executed, 850 new products, and 998 new startups formed.

Bayh-Dole has played a catalytic role in turning American universities into engines of innovation and moving the U.S. into a dominant position in a wide variety of critical industries. The success of the Bayh-Dole Act has led countries around the world to model their university technology transfer systems after ours, including India, Brazil, South Africa, Malaysia, and Jordan.

March-In Rights

To ensure the inventions from government-funded research are effectively developed and commercialized on equal footing with other, privately-funded inventions, the Bayh-Dole Act established certain safeguards to ensure private sector partners develop the licensed inventions to market-readiness. Among these safeguards are so-called "**march-in rights**." This authority allows the federal funding agency to step in and force the patent holder to share a license to their invention with a manufacturer or additional manufacturers if doing so would help rectify insufficient commercialization or resolve a limited number of other issues. Specifically, the funding agency may march-in if any one of the four criteria outlined in the Bayh-Dole statute is not met:

1. **Practical Application** - If the funding agency finds that the contractor (the recipient of government funds) has not taken, or is not expected to take effective steps to achieve the practical application of their invention in a reasonable time, the agency may exercise march-in authority. This means the contractor must show efforts to share their IP with a licensee who can commercialize and distribute a product generated from the federally funded invention.
2. **Health and Safety Needs** - Funding agencies may exercise march-in rights if doing so is needed to meet public health and safety needs and the contractor or licensed manufacturer is not taking reasonable measures to meet those requirements.
3. **Public Use** - If other federal regulations require the public use of and access to an invention generated from federally funded research, and the patent holder or licensee has not taken steps to meet those requirements, the funding agency may exercise march-in authority.
4. **Domestic Manufacturing** - Section 204 of the Bayh-Dole Act requires patented products using patented IP generated from federal research funding must be manufactured substantially in the United States if commercially feasible unless a special waiver is obtained. The funding agency may exercise march-in rights if the contractor or licensee is found to not meet those requirements.

If a funding agency exercises march-in rights, the decision can be appealed to the U.S. Court of Federal Claims. This court has jurisdiction to affirm, reverse, remand, or modify the claim by the funding agency as appropriate.

Although it is primarily a non-regulatory agency, the National Institute for Standards and Technology (NIST) has authority from the Secretary of Commerce to issue implementation guidance for the Bayh-Dole Act. This guidance can then be used by all federal agencies that issue research funding, who could then exercise march-in rights.

In the more than forty-three years since the Bayh-Dole Act passed, only eight petitions have been filed requesting the National Institutes of Health (NIH) to exercise its march-in authority on a contractor's patent, but all have been denied for failing to meet any of the four criteria outlined above. The Department of Energy has also received and rejected two petitions to exercise march-in rights, both for medical technology patents. Supporters of the Bayh-Dole Act point to this as evidence of a successful policy, that federal research funding is consistently used for commercial applications and made available to the public.

Recent Petitions and the Future of March-In Rights

Recently, consumer advocate groups Knowledge Ecology International and the Union for Affordable Cancer Treatment submitted a petition to the NIH and Department of Defense, urging the federal government to exercise march-in rights to override the existing agreement between the federally-supported university and the drug manufacturer and begin generic production of a prostate cancer drug, Xtandi®. This petition from the two groups argued that exercising march-in rights would

bring competition into the market and lower the price of the medicine. The petition cited the price of Xtandi® at $98 a pill and pointed out that the drug was developed in part by research stemming from federal grants. The drug manufacturer explained the US government's contribution amounted to approx. $500,000 in the form of initial research funding, whereas the subsequent R&D outlay by the manufacturer and its commercial partners was estimated at approx. $2.2 billion. Nonetheless, these advocates believed the price of the drug violated the clause stipulating those inventions must be made available to the public on "reasonable terms."

Supporters of the current Bayh-Dole regime and opponents of the movement to change march-in criteria noted that Xtandis, like many other pharmaceuticals being targeted for march-in petitions, was developed "in-part" by federally funded research. Under the Bayh-Dole Act, the government can only march-in on a patent from a contractor, not necessarily the full product manufactured by the licensee. Looking at the pharmaceutical industry, a single product can include more than a dozen different patents, and the IP sourced from universities may cover only a select part of the chemical formula or production process. If the government were to march-in on the subject IP, that would not force the licensee to share their full production method. Instead, the march-in authority would only force the contractor, the university holding the patent in this case, to share their specific invention with more producers and sacrifice royalty payments.

In March of 2023, the NIH declined that petition to initiate march-in proceedings. The agency explained march-in would not be a feasible means to lower the drug's price. In their denial, the NIH also found that Xtandi® was being both manufactured and widely available in the United States in a manner similar to other prescription drugs. The invention was therefore being "practically applied" within the meaning of the statute, and it also met existing health and safety needs. NIH also referred to its earlier decisions in which it had explained that agency intervention and price-setting in the market would have wider, adverse ramifications for the commercialization of federally-supported inventions in all technology areas.

The NIH decision on Xtandi® received significant pushback and criticism from progressive circles and consumer advocates. In response, the Department of Commerce and the Department of Health and Human Services announced an inter-agency working group to review and evaluate the criteria for exercising march-in authority, hinting they might be open to adding a clause that would allow price to be considered. In December of 2023, the White House announced a variety of "New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition," including steps to expressly include drug pricing in the factors agencies use in considering their use of march-in authority.

In conjunction with the White House, NIST released its *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. The draft framework adds pricing as a consideration at multiple stages in the agency's process to evaluate the application of march-in rights under the Bayh-Dole Act. The new framework directly associates price considerations with two of the four statutory criteria for exercising march-in rights: the rules for practical application and public health and safety needs. NIST accepted public comment on the draft guidance until February 6th, 2024.

The United States currently leads the world in biotechnology research and innovation, and many experts point to strong IP protections and an efficient technology transfer regime as the main drivers of industrial dominance. Ownership and control of IP and supply chains for critical medicine and technology are crucial to maintaining American economic competitiveness on the world stage and national security interests. While the current push to change march-in authority comes from an effort to reform the healthcare industry, setting a new precedent to invoke mandatory licensing as a means of price control would have far-reaching implications in other critical industries like energy, technology, and manufacturing.

In the wake of the White House initiative and NIST's draft framework, industry leaders, small business associations, venture capital groups, and higher education associations have expressed concern that removing the Bayh-Dole Act's incentives for businesses and research institutions to invest in riskier ventures could threaten American dominance in the industry. At the same time, the cost of healthcare and essential medicines is a high-priority issue for voters across the country. Going into an election year, policymakers and regulators will have to respond to conflicting political pressures and likely take visible steps to address concerns from both consumers and businesses.

Links to Other Resources

- Association of University Technology Managers (AUTM) - Academic Technology Transfer in Numbers
- Center for Strategic & International Studies - March-In Rights and U.S. Global Competitiveness
- Department of Commerce - Current Xtandi Bayh-Dole Act Debate
- Heartland Forward - Effects of the Bayh-Dole Act on Research
- Information Technology & Innovation Foundation - Ensuring U.S. Biopharmaceutical Competitiveness
- NIST - Press Release for Public Comment on Draft Guidance
- Real Clear Policy - March-In Rights Explanation
- Vital Transformation - March-In Rights and NIH Contributions to Pharmaceutical Patents