Insights: Alerts

Government Signals Potential Sea Change Regarding its Approach to “March-in” Rights Under Bayh-Dole: What Steps Educational Institutions Should Consider Taking to Protect Their Patent Portfolio

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In Fiscal Year 2023, colleges and universities spent approximately $109 billion on research and development expenditures of which $59.6 billion, or 55%, was federally funded.[1] In Fiscal Year 2022, the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs obligated a total of $4.73 billion in funding to small business.[2] When patents result from inventions conceived or first reduced to practice in the performance of federally funded grant or contract, such patents are subject to the Bayh-Dole Act. Congress enacted the Patent and Trademark Act Amendments of 1980 (commonly known as the “Bayh-Dole Act”) to encourage the use of inventions resulting from research and development funded by the federal government.[3] Under Bayh-Dole, recipients of federal funds retain ownership of patents arising out of government-funded research, enabling them to commercialize these inventions in the private sector. This creates an incentive for private sector involvement in research and development.

The standard patent rights clause under 37 C.F.R. § 401.14 contains several key conditions requiring action by the federal funding recipient including, but not limited to:

1. Disclosing the invention to the government within two months after the inventor discloses it to the federal funding recipient responsible for patent matters.37 C.F.R. §401.14(c)(1).

2. Deciding whether to retain ownership of the invention and notify the agency of any decision to retain title within two years of the date of disclosure of the invention. 37 C.F.R. §401.14(c)(2).

3. Executing written agreements with faculty and technical staff requiring disclosure of inventions. 37 C.F.R. § 401.14(f)(2).

4. Filing for patent protection within one year of electing to retain title. 37 C.F.R. 401.14(c)(3).

5. Providing a license to the government to also practice the patent. 37 C.F.R. 401.14(b).

6. Keeping the government informed of progress in patenting or commercializing the invention. 37 C.F.R. 401.14(f); 401.14(h).

Bayh-Dole also comes with a fail-safe clause, so to speak. If the Government decides that a recipient of federal funding is not making the best use of inventions created with federal funds, it can exercise its "march-in rights." March-in rights empower a federal agency to grant compulsory licenses to third parties for patents owned privately, provided the invention was created with the agency's funding if any of the following four conditions are met:

1. 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 invention;

2. Action is necessary to address health or safety needs that are not reasonably satisfied by the contractor, assignee, or their licensees;

3. Action is required to meet public use requirements specified by federal regulations;

4. Action is warranted due to non-compliance with domestic manufacturing preferences under 35 U.S.C. § 204.[4]

Over the more than 40 years since Bayh-Dole was enacted, no federal agency has exercised these rights, but this may change now with the Trump Administration's targeting of Harvard patents. The Trump Administration announced it has launched a review of the institution's federally funded research activities and threatened to revoke its patent portfolio. In a publicly-released letter addressed to Harvard President Alan Garber, Commerce Secretary Howard Lutnick accused Harvard of breaching statutory and contractual obligations associated with federal research funding and patents.[5]

Secretary Lutnick stated that the Department of Commerce has initiated a "march-in" procedure under the Bayh-Dole Act, which could enable the government to assume control of Harvard's patents or issue licenses to third parties.[6] The Department of Commerce has given Harvard until September 5, 2025 to provide a list of all patents it has received stemming from federally funded research grants.[7]

This is not the first time President Trump has considered a policy change to make use of march-in rights.In 2018, the previous Trump Administration directed the National Institute of Standards and Technology (NIST) to consult stakeholders and identify regulatory and administrative improvements to federal technology transfer policies. The NIST publication on this subject, issued in December 2018, stated the need to clarify circumstances under which the government may exercise march-in rights consistent with the uses of march-in rights specified by Bayh-Dole.[8] The Biden Administration subsequently built on this report to propose an expanded framework for "march-in" authority, aimed primarily at reducing the price of certain pharmaceuticals.[9]

What Should Your Organization Do?

The federal government has a great deal of power in enforcing its march-in rights with regard to inventions developed with the use of federal funds, even though these rights have never been used in the 40 years since Bayh-Dole's enactment. If the Trump Administration's targeting of Harvard indicates a sea change in the Government's use of "march-in" rights, there are still things you can do to lessen your risk that your intellectual property may become subject to the Government's use of "march-in" authority for your subject inventions.

1. **Maintain Stringent Grant or Contract Compliance**
    - Adhere to all terms in federal funding agreements, including invention disclosure, reporting, and utilization requirements.
    - Ensure that inventions are commercially available to the public on reasonable terms.
2. **Document Commercialization Efforts**
    - Keep detailed records of development, marketing, licensing, and commercialization activities for each federally funded invention.
    - Demonstrate active steps to bring inventions to practical application.
3. **Address Public Health, Safety, and Use Needs**
    - Proactively respond to unmet health or safety needs linked to your inventions.
    - Monitor and comply with public use and domestic manufacturing regulations.
4. **Optimize Licensing Agreements**
    - Structure licenses to reflect genuine commercialization efforts.
    - Include provisions for domestic manufacturing when required by statute.
5. **Engage Legal and Compliance Experts**
    - Consult with legal counsel and technology transfer professionals to monitor regulatory changes and conduct periodic audits.
    - Review contracts and internal policies regularly for compliance.

To discuss strategies for navigating federal government actions impacting your intellectual property, please contact one of the authors of this Legal Alert, or a member of Kilpatrick's Government Contracting & Public Procurement Team or Intellectual Property Team.

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[1] Universities and Indirect Costs for Federally Funded Research, Congressional Research Service (May 16, 2025).

[2] Small Business Innovation Research / Small Business Technology Transfer, America's Seed Fund Powered by the SBA, Fiscal Year 2022 Annual Report.

[3] Pricing and March-In Rights Under the Bayh-Dole Act, Congressional Research Service (December 3, 2024).

[4] 35 U.S.C. § 203(a)

[5] https://x.com/howardlutnick/status/1953967726135063023

[6] *Id.*

[7] *Id.*

[8] National Institute of Standards and Technology, Return on Investment Initiative to Advance the President's Management Agenda (December 2018).

[9] Daniel G. Aaron and J. Jonas Anderson, The Biden Administration's Push to Lower Drug Prices Through March-In Rights (July 15, 2024).

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