

## **Background**

Congress enacted the Patent and Trademark Act Amendments of 1980 (commonly called “Bayh-Dole” or the “Bayh-Dole Act”) to ensure that basic innovations discovered through federal research are developed into real-life products. Before Bayh-Dole, federally funded research often remained within government agencies, and any innovative breakthroughs sat in the lab rather than going to market.

Bayh-Dole revolutionized technology transfer from academia to industry by allowing universities, small businesses and nonprofits to capitalize on their research and turn the discoveries into viable consumer products. By ensuring that academic institutions and companies retain ownership of any inventions created as a result of federal funding, the Bayh-Dole Act spurred the transformation of laboratory discoveries into new products benefitting the American taxpayer and consumers worldwide.

It is widely considered the cornerstone for public-private R&D partnerships which have long fueled America’s innovation engine. Without the Act’s long-standing and consistent framework to enforce and exclusively license patent rights, industry is discouraged from investing in the risky process of creating new products that utilize federally backed research.

## **Key Provisions**

- The University is entitled to retain ownership of any inventions created as a result of federal funding.
- The University must patent all inventions it elects to own and commercialize.
- The University must attempt to develop and commercialize the invention. If an attempt is not made, the federal government retains the right to take control of the invention. The government also may take control of the invention for other reasons, such as a need to alleviate health or safety concerns. This provision is referred to in the law as the government's "march-in" rights.
- The University must provide the U.S. government with a nontransferable, nonexclusive license to use the invention.
- In granting licenses to use the invention, the University also generally must give priority to small businesses, while maintaining the fair-market value of the invention.
- When granting an exclusive license, the University must ensure that the invention will be "manufactured substantially" in the United States.
- Excess revenue must support research and education, and the University must share a portion of the royalties with the inventor(s).

## **Bayh-Dole Under Attack**

In December 2023, the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) issued a request for information seeking public comments on its [Draft Guidance](#), which NIST envisions as a tool to help federal agencies evaluate when it is appropriate to exercise "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 federal funding and the agency finds that certain statutory criteria apply.

***TECNA strongly opposes NIST's proposed framework and is deeply concerned that it would significantly distort the criteria for compulsory licensing of patented technology and thereby upend the law that has been the basis for public-private R&D partnership for over 40 years. Below is a summary of TECNA's opposition. To view TECNA's full comments, please click [here](#).***

- **The Current System is Working**  
The march-in rights system is essentially a policing mechanism to curb abuses of the Act. It is important to note that march-in rights have existed for more than forty years, but no federal agency has ever exercised its power to march-in and license patent rights to others. This indicates that the innovation sector understands and is complying with the requirements of the Act, and that the intent of the Act is being effectuated.
- **March-in Rights Should Not Include "Reasonable Pricing"**  
The proposed framework inappropriately considers pricing in determining whether the government can exercise its march-in authority. Furthermore, the proposed framework does not define what would constitute "reasonable pricing". The Bayh-Dole act did not intend that government set prices on resulting products. In fact, the law makes no reference to a reasonable price and the omission was intentional. Simply put, it introduces subjective and ambiguous language that could cause confusion and inconsistency in the adjudication process and will certainly create uncertainty and instability for the innovation community.
- **Negative Impact on Small Business**  
Bayh-Dole has served as the cornerstone for the Small Business Administration's (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The proposed framework puts these successful programs in jeopardy and creates a predatory environment whereby large corporations can file march-in petitions against smaller companies who have already assumed all of the risk and development costs for innovative products. It enables large corporations, copycat companies, or foreign adversaries to unfairly piggy-back off of their smaller competitors' efforts or, in some cases, to kill future competition.
- **Negative Impact on Innovation**  
The proposed framework calls into question the patent system's reliability and stability. Simply put, misusing the Act to control after-market pricing will result in a severe distrust in federally funded partnerships and a massive decline in innovation. It sends a clear signal to private investors, often key in bringing early-stage technologies to the marketplace, that future U.S. patent management cannot be trusted and will steer industry away from leveraging federal funding.