

The biggest controversy surrounding the Bayh-Dole Act — which allows academic institutions and private contractors to own and manage inventions they make with federal funds — is the false claim that the law allows the government to relicense patents on these inventions to ensure that prices of resulting products are “reasonable.” While this claim has been widely bandied about, it has been rejected by every administration that has considered it for the past 20 years because that’s not how the law works. Still, attempts to undermine Bayh-Dole in this way continue.

What Are March-in Rights?

- The Bayh-Dole Act incentivizes universities, small businesses, and non-profit institutions to take ownership of inventions made with federal funding, so they can license these basic inventions for further development and broader public use.
- During Bayh-Dole’s drafting, lawmakers were concerned that a dominant company might license an invention to prevent its commercialization if it threatened one of the company’s existing products. That led Congress to include a “march-in” provision in the law, which allows the government to require the patent owner (primarily academic institutions under Bayh-Dole) to grant additional licenses if good faith efforts are not being made toward development, or if the developer cannot produce enough product to meet public health needs or requirements for public use under federal regulations. The government can also march in if the developer fails to manufacture the product in the U.S. as they had agreed to do.
- Twenty years after the law passed, critics claimed they had discovered a hidden meaning in Bayh-Dole. They said that the government could march in if a product wasn’t “reasonably priced.” Senators Birch Bayh (D-IN) and Bob Dole (R-KS) immediately responded saying that is not how their law works, as there is nothing in the legislation or its history supporting such a claim.

March-in Cases

- Nevertheless, a series of petitions were filed asking the National Institutes of Health (NIH) to use Bayh-Dole’s march-in provision to lower the price of several drugs. Each petition has been rejected by every Democratic or Republican administration that considered them.
- One particular target is the prostate cancer drug Xtandi, which had three march-in petitions filed on it during the Obama-Biden administration. Each was rejected because the drug had been successfully commercialized, thus meeting the law’s objective.

In its rejection letter to the petitioners, the U.S. Department of Defense (which helped support the original research) aptly summarized the situation:

Your letter and supporting material show that Xtandi® has achieved practical application as the DHHS (Department of Health and Human Services) and DOD (Department of Defense) understand that term. Your request does not disclose information suggesting that supplies of Xtandi® are running low or that health or safety needs are not being met by the manufacturer. In view of the above information, we decline to exercise the government's march-in authorities or utilize the government's license to the enzalutamide patents.

- Incredibly, march-in petitions on Xtandi were re-filed at NIH and DOD once President Biden took office. The petitions are now pending.

The Impact of Misusing March-in Rights

- If the government ever chose to misapply march-in rights for price control, confidence in universities or federal laboratories as reliable research partners would collapse.
- Because Bayh-Dole is a uniform policy across all agencies, anyone who wanted to undermine the system (rival companies, foreign adversaries, disgruntled relatives, etc.) could claim that the price of a product that resulted from federal funding isn't "reasonable" and that the government should relicense its patents.
- As the law was never intended to work this way, there is no statutory definition of "reasonable pricing" in Bayh-Dole, so any ruling would be completely arbitrary, made up on the whims of the bureaucracy.
- No company would agree to license a university or federal laboratory invention under these circumstances. No venture capitalist would fund a startup company with that sword hanging over its head.

Under the statute, the patent owner and the licensee can appeal adverse march-in decisions, and the courts are likely to reject attempts to misuse the statute for price controls. But the basis of our system is trust that the Bayh-Dole Act will be applied as written. Companies undertaking the risk and expense of commercializing federally-funded inventions know the long odds against success they face, but they have faith in our Bayh-Dole system as it has operated for more than 40 years. Once that trust is lost, it cannot be easily restored.