

BAYH-DOLE “MARCH-IN” IMPACT

OVERVIEW

March-in Rights

The Bayh-Dole Act created a uniform “technology transfer” process across federal research agencies, ensuring that federally funded research could move along the R&D pipeline.

Technology Transfer refers to the licensing of patent rights. The Bayh-Dole Act created a process by which patents arising from federally funded research can be efficiently licensed to private sector companies equipped to fund the additional research and development needed to deliver medical advances to patients.

Before Bayh-Dole was signed into law in 1980, more than 95% of patented inventions arising from NIH-funded research simply “sat on the shelf.” There was no viable path to engaging private sector companies with the resources to research, develop, and secure FDA approval for final products.

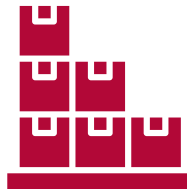
Since the enactment of Bayh-Dole, innovation has been ignited with more than 495,000 new innovations, 126,000 patents issued, and an estimated 30% of the total NASDAQ being rooted in university-based, federally funded research results.

- March-in rights allow the federal government, in specific circumstances, to require a patent holder to relicense their patent to a third party for inventions created using federal funding
- The authors crafted this law to be a catalyst to the research and development needed to translate federally funded research into medical advances for patients
- Price-based march-ins are not part of the Bayh-Dole Act
- There have been attempts to pressure NIH to march-in on patents as a means of lowering drug prices
- To date, no agency has exercised its march-in rights since the law passed in 1980
- March-in can be used toward any federally funded patents

What could happen if “march-in” rights were utilized to lower drug prices?



Potentially lower drug prices



Inventions sit unused in government stockpiles



Slower pace of medical innovation and breakthroughs



Dilute research-focused missions of federal research agencies



Decreased public-private cooperation



Difficulty attracting and retaining researchers and engineers to keep our nation competitive