

SETTING THE RECORD STRAIGHT ON THE BAYH-DOLE ACT AND MARCH-IN

The National Institutes of Health (NIH) recently made the right decision to uphold the Bayh-Dole Act and not seize patent rights on an innovative medicine by exploiting part of the law known as the “march-in” provision. However, the issue of future patent right seizures remains a concern because the Biden Administration has left the door open to revising the longstanding Bayh-Dole framework. Erosion of Bayh-Dole would put the entire U.S. innovation ecosystem at risk. It's important to understand the immense success of Bayh-Dole and the potential devastating impacts of rewriting the march-in provision to allow the government to seize patent rights solely on the basis of product pricing.

What is Bayh-Dole?

Congress passed the bipartisan Bayh-Dole Act in 1980 to spur innovation and create a framework in which research institutions receiving federal funds could patent their inventions and license them to private entities to benefit the public.

Over the past 25 years, the Bayh-Dole Act has contributed



[\\$1.9 trillion to the U.S. economy](#)



[created 6.5 million jobs](#)

What was the goal of Bayh-Dole?

Prior to 1980, if an invention was created with any level of government support, the government promptly asserted ownership, which resulted in a huge number of new innovations wasting away for lack of development.



- There were [nearly 28,000](#) patented inventions gathering dust on government shelves when Bayh-Dole was originally signed into law.
- Before 1980, only 5% of patents based on federally funded research were ever used in the private sector.

Is Bayh-Dole working?

Yes. By simply allowing research institutions to own and manage patents on the technologies they invent, we have created an environment that has made the U.S. the world leader in innovation. According to the Bayh-Dole Coalition, “The Bayh-Dole Act revolutionized technology transfer as it allowed universities, small businesses and nonprofits to capitalize on their research and turn their discoveries into viable consumer products.”



- American universities, small and large businesses and individual citizens bring [approximately](#) three new products to market based on federally funded academic inventions every single day of the year.
- We have seen [200+ new medications and vaccines](#) developed through public-private partnerships since 1980.

What are march-in rights?

The march-in provision is a safeguard included in Bayh-Dole that gives the federal government the authority to require relicensing of a patent that resulted from any amount of federal support, if good-faith efforts aren't being made to commercialize the research.

There are instances where the march-in provision could be triggered, **none of which have anything to do with the price of a product**, including when the patent holder or its licensee is not taking steps to achieve practical application in a reasonable time or is unable to alleviate a health or safety need.

Why are some suggesting march-in as a way to lower drug costs?

Regardless of the facts, some policymakers want to rewrite the march-in provision to give the government broad new authority to set prices on products, such as medicines or green technologies, that resulted, in part, from federal funding.

Former Senators Bayh and Dole themselves [have said](#),

“The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.”

Why would it be bad for the government to use march-in?

In addition to not being sanctioned under the law, misusing the march-in provision would create a precedent that any product made with any level of government funding would be subject to march-in if someone made an arbitrary determination the price was not “reasonable” – stifling the same public-private innovation the Bayh-Dole Act was designed to accelerate.

Such use of march-in rights would chill innovation and undermine collaboration between the public and private sectors, returning us to the pre-Bayh-Dole era where promising new technologies sat on the shelf benefiting no one. It is not the right solution for increasing competition or improving patient affordability.

To learn more about the right way to address patient affordability at the pharmacy counter, [click here](#).