

PRESERVE THE BAYH-DOLE ACT AND UNIVERSITY TECHNOLOGY TRANSFER

It is critical that Congress protect and preserve the original legislative intent of the Bayh-Dole Act by preventing “march-in” from being used to control prices.

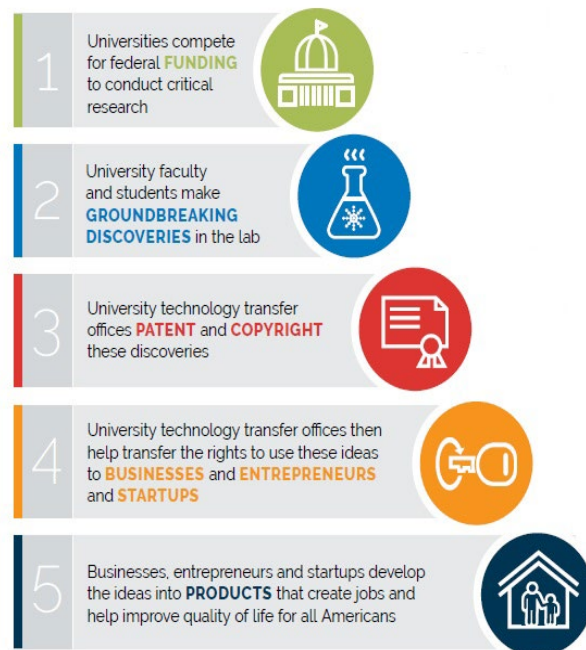
Prior to 1980, discoveries which were based upon federally funded research were retained by the federal government and very few were licensed (less than 5% of patents). The Bayh-Dole Act of 1980 revolutionized technology transfer by allowing universities, small businesses, and nonprofits to retain intellectual property and to license discoveries –that were based on federal research funding-- to private sector partners. This provided a significant incentive for universities and their researchers to turn discoveries into viable consumer products.

The Bayh-Dole Act continues to have a significant and lasting impact on U.S. innovation and industry. Since it was enacted in 1980, the Act has led to over \$1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country, and contributed to the success of over 11,000 new startup companies throughout America. Bayh-Dole continues to encourage American entrepreneurship today, helping to strengthen the nation’s innovative capacity.

University technology transfer has resulted in innovative new medicines and technologies that have saved lives, grown the U.S. economy, and greatly improved quality of life in the United States and throughout the entire world. University technology transfer occurs in every single industrial sector including agriculture, advanced weaponry and surveillance technologies, quantum computing, telecommunications, life sciences, medical diagnostics and therapeutics, and green energy technologies.

In recent years, however, there have been an increasing number of calls for federal funding agencies to exercise their Bayh-Dole Act “march-in” rights to control the prices of drugs based on patented federally funded research. Allowing march-in to be used to control drug prices will impede the creation of new drugs by discouraging companies from making the substantial additional research and development investments necessary to take federally funded university-based research from the laboratory to the bedside.

What’s at stake: By enabling universities to patent and license groundbreaking discoveries, the Bayh-Dole Act of 1980 significantly improved the U.S. system of technology transfer. Now proposals to reinterpret when Bayh-Dole “march-in rights” can be used are threatening the future of university technology transfer.

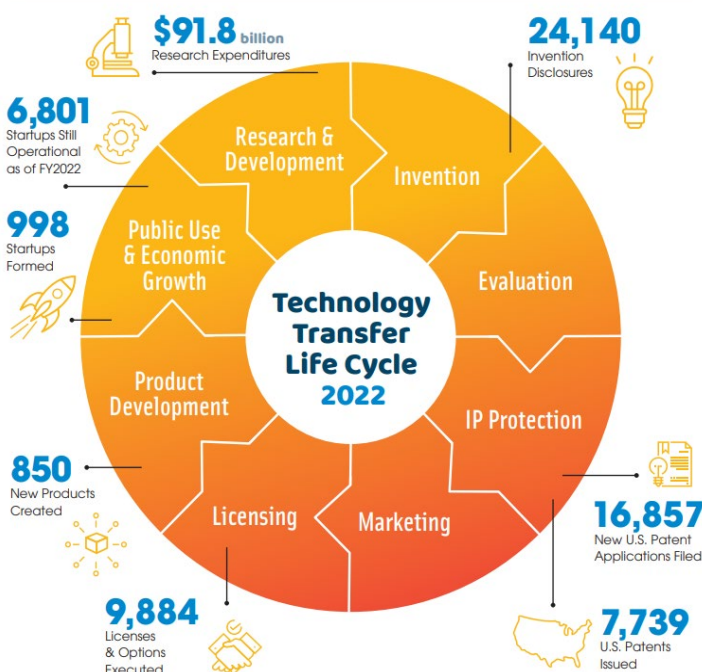


Key Facts:

- **Congress built safeguards into Bayh-Dole that enable the government to protect the public against nonuse or unreasonable use of federally supported inventions.** The law grants the federal agency that funds the research a limited right to “march in” and require the owner of a patent that was developed through federal funding to grant additional licenses to the invention to ensure that the invention is made available to the public. Congress approved the march-in provision to address concerns that dominant companies would pay to license competitive university inventions solely to prevent their development and entry into the marketplace.
- **The legislative record and subsequent statements by Senators Bayh and Dole make clear that Congress intended this march-in provision to apply only in narrow circumstances,** such as when a licensee fails to make a good-faith effort to bring the invention to market or if health or other emergencies arise and the licensee is unable to make enough of a product to meet public needs.
- **The march-in provision was never intended to serve as a vehicle for controlling drug pricing.** Rather, the statute refers to “practical application,” which is defined as providing availability to the public on terms that are “reasonable under the circumstances.” The statute deliberately does not address or define what may constitute a “reasonable price.”
- **Over the years, the National Institutes of Health (NIH) has considered and rejected several petitions asking it to exercise its march-in authority to address drug pricing concerns.** In each review to date, NIH has concluded that the “practical application” requirement was satisfied if the patented drug was on the market and available to the public.
- **For universities and their patent licensees, the exercise of march-in rights for reasons other than exigent health or safety needs would create substantial market uncertainty that would chill university technology transfer.** If the scope of applicability of march-in rights is broadened beyond Congress’ original intent, the private sector will be hesitant or unwilling to license federally funded inventions from universities, potentially impeding progress against some of our costliest and most challenging diseases to the detriment of public health and safety.

Benefiting Society and the Economy

Academic Technology Transfer for 2022



Source: AUTM Infographic; <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf>

Intellectual property rights make the existence of, and access to, critical medicines and medical technologies more likely, not less. Undermining Bayh-Dole and the important patent protections this landmark legislation provides will impede the development of innovative new medicines and medical technologies resulting in fewer – not cheaper – new drugs.