

February 9, 2021

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden:

On behalf of the Bayh-Dole Coalition, congratulations on your historic victory. Our diverse group of research and scientific organizations looks forward to working with you to grow America's economy, create new jobs, and advance innovation.

As our name suggests, the Bayh-Dole Coalition believes the best way to accomplish these goals is by defending the University and Small Business Patent Procedures Act, a visionary piece of bipartisan legislation commonly known as the Bayh-Dole Act. Spearheaded by U.S. Senators Birch Bayh (D-IN) and Bob Dole (R-KS), the bipartisan legislation gave U.S. universities, small businesses, and nonprofit research centers the right to own patents on inventions arising from federal grants.

You supported this landmark piece of legislation as a member of the Judiciary Committee in 1980. Since then, the Bayh-Dole Act has spurred decades of public-private sector collaboration that has bolstered U.S. economic output by up to \$1.7 trillion, supported 5.9 million jobs, and helped lead to more than 13,000 start-up companies.

The following white paper details the long-lasting impact of the Bayh-Dole Act and recommends ways your administration can ensure that it continues to support public-private sector collaboration, particularly as our nation recovers from Covid-19 and the 2020 recession.

Congratulations again. We look forward to working with your administration to build our economy back better.

Sincerely,

Joseph P. Allen
Executive Director



*Bayh
Dole*
COALITION

*To Foster Innovation,
Biden Administration
Must Protect Bayh-Dole*

To Foster Innovation, Biden Administration Must Protect Bayh-Dole

The Bayh-Dole Coalition congratulates President Joe Biden and Vice President Kamala Harris on their historic victory. As we look forward to working together to grow America's economy, create new jobs, and advance innovation, we urge the new administration to defend the University and Small Business Patent Procedures Act, a visionary piece of bipartisan legislation commonly known as the Bayh-Dole Act.

Spearheaded by U.S. Senators Birch Bayh (D-IN) and Bob Dole (R-KS), the bipartisan legislation gave certain institutions, like universities and nonprofit research centers, the right to own patents on inventions arising from federal grants. This seemingly simple policy had a transformative effect. By incentivizing inventors to commercialize their findings, it moved numerous breakthroughs from laboratories and drawing boards to the real world.

Supported by then-Senator Biden when he served as a member of the Judiciary Committee, the 1980 law has since been emulated by countries around the world eager to spur innovation.¹ *The Economist* hailed it as “possibly the most inspired piece of legislation to be enacted in America over the past half-century.”² Without question, Bayh-Dole helped the United States regain its position as a leader in science and discovery.

But the law is not without critics. Over the years, many have questioned the value in allowing the private sector to commercialize — and profit from — federally funded research. Some have even urged regulators to override the intellectual property rights associated with products that, at some point, benefited from federal grants when these products are deemed too costly.

Such efforts are misguided — and willingly misinterpret the text and spirit of the law. The Bayh-Dole Act is a crowning achievement that has helped make our nation the world's leading innovator.

The new administration takes office facing two great challenges. We are fighting Covid-19, the pandemic that has killed more than 400,000 Americans. At the same time, we are still struggling to emerge from the 2020 recession.

Bayh-Dole will play a central role in our recovery from both crises. The legislation gave way to a research and development infrastructure that is supporting the creation of several coronavirus-fighting medical technologies.^{3,4,5} And it established a legal framework that fosters innovation, which is an essential ingredient in the thriving economy we all want.

By facilitating collaboration between academia, government, and business, Bayh-Dole will ensure that the United States remains in the technological and economic vanguard.

1 <https://autm.net/about-tech-transfer/advocacy/legislation/bayh-dole-act>

2 <https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose>

3 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/coventor>

4 https://madison.com/wsj/news/local/health-med-fit/uw-madison-develops-saliva-test-for-covid-19/article_bde92123-71ce-5cbd-91fcc37b6c52b950.html

5 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/unmc-shield-to-protect-from-covid-during-intubatio>

The Bayh-Dole Act's Importance to U.S. Innovation

Prior to the enactment of Bayh-Dole, the government was reluctant to grant exclusive patent rights. It was evident that without exclusive patent rights, companies rarely invested in taking discoveries further. And even once a discovery is made, there is a lot further to go: Research accounts for only about a quarter of the cost of bringing a new invention to market.⁶ The remaining investment required to manufacture, distribute, and ultimately bring a new product to market can be enormous. Without exclusive rights, companies had little incentive to translate early research findings into useful products.

By 1980, the federal government possessed nearly 30,000 patents — and less than 5 percent had been licensed for commercial development.⁷ U.S. competitiveness in critical sectors, like the life sciences, lagged behind Europe and Japan, while U.S. taxpayers were seeing almost no return on the billions of dollars invested in scientific research. As a 2012 Congressional Research Service report found, “the earlier lack of exclusivity appeared to interfere with the further development and commercialization of federally funded R&D.”⁸

The old system, in short, hindered rather than accelerated innovation.

Sens. Bayh and Dole had the insight to realize that if the universities and other nonprofits conducting federally funded research had patent rights, it would motivate them to license the rights to companies capable of commercialization — in return for the possibility of royalty payments on successful products.

So began the heyday of public-private partnerships.

The bill gave the institutions conducting the research the ability to own any invention made in whole or in part with federal funds. It had an immediate impact:

- University patents skyrocketed from fewer than 250 in 1979 to more than 7,500 in 2018.^{9,10}
- Technology partnerships led to the founding of more than 13,000 start-up companies.¹¹
- One study found that, on average, three new companies are formed, and two new products are brought to market every day, thanks to public-private partnerships.¹²

While most licenses are for relatively modest improvements to existing products, some of the discoveries enabled by Bayh-Dole have transformed society. Examples of technologies and products emanating from federal funding during the past four decades are truly impressive. They include quantum computing,¹³ firefighting drones,¹⁴ the once-a-day pill for HIV,¹⁵ high-definition televisions,¹⁶ and Google's original search algorithm.¹⁷

6 https://www.everycrsreport.com/files/20121203_RL32076_836129be0e45a4049a32a64c143ec94df38236be.pdf, Summary.

7 <https://www.gao.gov/assets/230/225671.pdf>

8 https://www.everycrsreport.com/files/20121203_RL32076_836129be0e45a4049a32a64c143ec94df38236be.pdf

9 <http://people.ku.edu/~sumac/coursetl731/clientproject/alttp2/about/whatistt.html>

10 https://autm.net/AUTM/media/SurveyReportsPDF/AUTM_FY2018_US_Licensing_Survey.pdf, 11.

11 https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

12 https://www.autm.net/AUTMMain/media/SurveyReportsPDF/AUTM_FY2015_Highlights_US_no_appendix_FINAL.pdf, 8

13 <https://news.yale.edu/2017/11/14/quantum-computing-startup-inspired-yale-expertise-announces-new-funding>, <https://bit.ly/3cGhu1k>, <https://bit.ly/3cBo09J>, <https://bit.ly/36DMiw6>

14 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/firefighting-drones>, <https://bit.ly/3oMOpnn>, <https://bit.ly/3pJDxYE>, <https://bit.ly/3avevpR>, <https://bit.ly/3czi7d7>

15 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/emtriva>, <https://bit.ly/3tqqNIT>, <https://bit.ly/3tnBo7h>, <https://bit.ly/3tnqGgV>

16 http://innovation.columbia.edu/technologies/MS92-2F01-2F25_jpeg-mpeg-decoder-compatible, shorturl.at/hipl5, <https://bit.ly/3rmF0Ey>

17 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/google>, <https://bit.ly/3pJEvnK>, <https://stanford.io/3oF8wUs>

Without Bayh-Dole, these technologies might have been relegated to researchers' filing cabinets, never changing the world.

These innovations have made public-private partnerships a major economic driver in the United States. Experts estimate that academic technology transfers to the private sector have generated up to \$1.7 trillion in economic output and support nearly 6 million jobs.¹⁸

Understanding “March-In” Rights

Bayh-Dole's great success has attracted the spotlight, which in turn has led some to suggest changes in how the law is interpreted. Some of these proposals — particularly as they pertain to “march-in” rights — appear to be founded on misunderstandings.

Sens. Bayh and Dole included a provision in their bill to make sure companies didn't simply sit on valuable technology. The aim was to forestall the danger that a company might license a technology, then freeze its development in favor of a rival technology, depriving the public of the benefit of the invention.¹⁹

The march-in provision allows federal agencies to require universities to license their intellectual property under certain very limited circumstances — for instance, if a company is not making an effort to bring an invention to the market or if a developer is not able to meet the needs of a national emergency.

The march-in provision says nothing about how companies that license patent rights should price, distribute, or market the resulting products. Indeed, nothing in the law suggests that products benefiting from federal funding should somehow be subjected to different market rules than any other products. Nevertheless, over the years, activists have tried to use march-in as a means to intervene in the marketplace. In their view, companies that don't conform to their expectations of how products should be priced should lose their intellectual property rights.

Sens. Bayh and Dole were clear that the march-in provision was never intended as a government price-setting mechanism. As they explained in a 2002 letter to *The Washington Post*:

*Bayh-Dole did not intend that government set prices on resulting products. 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.*²⁰

In keeping with the lawmakers' intent, no Administration — Democratic or Republican — has ever employed march-in rights for price setting. The National Institutes of Health (NIH) has rejected every one of ten petitions to use the provision to control price.²¹ Indeed, as NIH Director Francis Collins explained in 2012, “the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients.”²²

18 https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

19 <https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/>

20 <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>

21 <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>, 29.

22 <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf#page=7>

Dr. Anthony Fauci, who directs the National Institute of Allergy and Infectious Diseases, has said that the federal government, “[doesn’t] really have the mechanisms to influence pricing of a product, even products in which we make a major investment for the development of.”²³

Legal scholars have also rejected claims that Bayh-Dole’s march-in provision can be used as a price-setting mechanism. The American Intellectual Property Law Association said, “march-in rights are not to be used as a mechanism to control or regulate the market price of goods or services in the US or to control or regulate competition in the US,” when providing comment to the National Institute of Standards and Technology (NIST) in 2019.²⁴ NIST, an agency within the U.S. Department of Commerce, later concluded that the federal government should, “Reserve march-in for use when other remedies have failed and not solely to regulate the market for price controls.”²⁵

Beyond staying true to the law’s intent, though, there is a bigger reason to resist the call to turn march-in rights into a pricing mechanism. Doing so could poison the system that supports U.S. innovation.

Bayh-Dole recognizes that discovery is only the beginning of commercialization. For ideas to reach the public, they must undergo lengthy development cycles. While the government funds most basic research, late-stage development is funded mainly by private industry.²⁶ This period between discovery and proof of concept is extremely risky. Most would-be products wither along the way. In biotechnology, only a handful of the thousands of compounds that enter laboratory testing ever make it to human testing, and an even smaller fraction of those make it to market.²⁷

Without the ability to retain patent rights, private industry would have little incentive to make the enormous investments needed to translate early-stage research into useful products. Consider that, on average, pharmaceutical companies spend \$2.6 billion to bring a single drug to market.²⁸ The average NIH grant in 2019 covered just over \$553,000 of those costs.²⁹ Companies cannot bear this kind of financial risk if they lack patent protections — and without these protections, may simply choose not to make investments.

This is exactly what happened when the NIH instituted a “reasonable pricing” clause for certain licensing agreements in 1989.³⁰ Companies shied away from partnering with the NIH, and use of these agreements dwindled until 1995, when the NIH eliminated the clause to “promote research that can enhance the health of the American people.”³¹ Reinterpreting Bayh-Dole’s march-in provision would have a similar impact, gutting public-private partnerships.

As a 2019 Information Technology & Innovation Foundation report notes, “Weakening the certainty of access to IP rights provided under Bayh-Dole by employing march-in to address drug pricing issues... would significantly diminish private businesses’ incentives to commercialize products supported by federally funded research.”³²

23 <https://www.govinfo.gov/content/pkg/CHRG-115hhrg26480/html/CHRG-115hhrg26480.htm>

24 https://www.aipla.org/docs/default-source/advocacy/documents/aipla-letter-to-nist-draft-green-on-paper-2019feb08.pdf?sfvrsn=a040cdca_0,7.

25 <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf>, 121.

26 <https://nces.nsf.gov/pubs/nsb20201/u-s-r-d-performance-and-funding>

27 <https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>, 8.

28 <http://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66adc758d46b001a996d6/1522952924498/pr-coststudy.pdf>

29 <https://report.nih.gov/nihdatabook/report/155>

30 https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system#_Ref536611880

31 <https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf>

32 <https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system>

That certainty is most important to small companies. Indeed, 70 percent of academic inventions are licensed by small firms, many of which depend on venture capital.³³ These companies would struggle to attract investment dollars if the government could arbitrarily march-in and seize a patent if a government official or political leader decides that a product is too costly.

America's "Most Inspired Piece of Legislation"

Imagine what the world would be like today without advanced diagnostic imaging,³⁴ the nicotine patch,³⁵ or the page-rank algorithm that powers internet search.³⁶

All of these technologies benefited, in some way, from federal research funding — and were brought to the market thanks to public-private partnerships and large, private-sector investments of time, money, and know-how.

We don't want to dismantle the system that brought these innovations to market. Yet a misguided reinterpretation of Bayh-Dole will shut down a great deal of invention — and with it, an important swathe of our economy.

The Bayh-Dole Act is a national success story, and is the foundation of productive interaction among government, universities, and industry. As the new Administration begins its work, it will have an opportunity to protect and uphold this groundbreaking law, to the benefit of all Americans.

33 https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

34 <https://mag.uchicago.edu/science-medicine/image-health>, <https://bit.ly/3oO7yoS>

35 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/habitrol%C2%AE-nicotine-patch>, <https://bit.ly/2MON1DB>, <https://pubmed.ncbi.nlm.nih.gov/6734425/>

36 <https://autm.net/about-tech-transfer/better-world-project/bwp-stories/google>, <https://bit.ly/3pJEvnK>, <https://stanford.io/3oF8wUs>