

EXECUTIVE SUMMARY

The Bayh-Dole Act's Vital Importance to the U.S. Life-sciences Innovation System

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OVERVIEW: WHAT DOES THE BAYH-DOLE ACT DO?

Congress enacted the bipartisan Bayh-Dole Act in 1980 to give universities, small businesses, and nonprofit institutions rights to the intellectual property (IP) stemming from research they have undertaken with federal funding. The legislation was part of a suite of policies Congress enacted in the early 1980s to address faltering U.S. economic competitiveness. Other measures included the research and development (R&D) tax credit and the National Cooperative Research Act.

Subsequently hailed as “possibly the most inspired piece of legislation to be enacted in America over the past half-century,” the Bayh-Dole Act has helped turn U.S. universities into engines of innovation, especially in the life-sciences, by creating a new pathway to market for discoveries and inventions made possible in part because of federal funding.

THE LAW'S PROVISION ON “MARCH-IN” RIGHTS IS IN DANGER OF BEING MISUSED

The Bayh-Dole Act includes a provision allowing the government to exercise so-called “march-in” rights to compel patent holders to issue licenses to third parties. In crafting this provision, the law's architects primarily intended it to ensure that commercialization activities ensued—for example, so government can step in if a patent holder isn't taking effective steps to produce a practical application from a federally funded invention. Yet some in Congress and civil society now are calling for Bayh-Dole march-in rights to be used to control drug prices. That runs counter to the law's intent and could compromise its effectiveness in stimulating innovations, resulting in fewer new drugs.

CASE STUDIES ILLUSTRATE HOW BAYH-DOLE WORKS IN PRACTICE

ITIF's report begins by contextualizing the Bayh-Dole Act as one of several policies that has played a catalytic role in making the United States the world's leader in life-sciences innovation. The report explains how public investment in basic life-sciences research complements private-sector investments in applied research, development, and clinical trial activities necessary to bring new drugs to market. It then provides four in-depth case studies showing the Bayh-Dole Act in action, helping to turn federally funded, university-conducted research into new knowledge subsequently licensed to private-sector actors and brought to market as an innovative drug or device. The case studies cover three drugs—Yervoy, Gleevec, and Luxturna—and the pulmonary monitoring system known as CardioMEMS.

THE HISTORICAL RECORD SHOWS HOW BAYH-DOLE SUPPORTS U.S. LEADERSHIP IN LIFE-SCIENCES INNOVATION

The report provides a history of federal policy toward IP rights stemming from federally funded research and shows how this culminated in the Bayh-Dole Act. ITIF contends that if a government ever had the authority to march in decades later and compulsorily license the intellectual property underpinning a novel biologic drug on the grounds that some of it may have been contributed by federally funded scientific research—and now the government deems the price for that drug “unreasonable”—it would seriously undermine the mechanics of America’s life-sciences innovation system, giving enterprises considerable pause about investing the additional hundreds of millions, even billions, required to bring innovative drugs to the marketplace. Further, the report shows how past efforts to include “reasonable pricing” terms as part of National Institutes of Health (NIH) Cooperative Research and Development Agreements (CRADAs) failed to lead to cheaper drugs, but did lead to less innovation.

The report emphasizes that, while the United States today is the world’s life-sciences innovation leader on a number of dimensions—from levels of public and private R&D investment, to the issuance of high-quality scientific publications and patents, to the introduction of more new-to-the-world drugs than any other country or region—that wasn’t always the case, and it cannot be taken for granted going forward. In fact, in the 1970s, the United States was an also-ran in global life-sciences innovation, with European-headquartered enterprises introducing more than twice as many new drugs to the world as American ones during the last five years of that decade and with less than 10 percent of new drugs being introduced first to the U.S. market throughout the 1980s.

That America leads the world in life-sciences innovation today is partly due to a number of intentional—and bipartisan—policy choices made over the past four decades, including:

- Significant public-sector investment in basic life-sciences research;
- Incentives such as generous R&D credits that help spur high levels of private-sector R&D investment;
- Effective regulatory systems that facilitate timely and accurate drug safety and effectiveness determinations, notably enabled by the Prescription Drug User Fee Act (PDUFA);
- Robust intellectual property rights and protections, as with the Bayh-Dole Act; and
- A drug pricing system that enables companies to earn sufficient revenues to reinvest in future generations of innovation.

These factors help explain why well more than half of the medicines under development today—4,000 out of 7,000—are being principally developed in the United States. And it’s the existence of these medicines in the first place that allows policymakers to have a debate about access and prices for them. A number of U.S. competitors—including China, the United Kingdom, Japan, Singapore, and others—have recently implemented policies to bolster their own life-sciences competitiveness, so U.S. policymakers must remain attentive to maintaining the investments and public policies that have driven U.S. life-sciences leadership.

The Bayh-Dole Act has played a catalytic role in turning American universities into engines of innovation, particularly in the life-sciences sector. Indeed, before the passage of Bayh-Dole Act, only a handful of U.S. universities even had technology transfer or patent offices, while only 55 U.S. universities had been granted a patent in 1976. But in the first 22 years after Bayh-Dole, American universities experienced a

tenfold increase in their patenting activity, such that by 2017 over 80,000 U.S. patents had been issued to academic research institutions since Bayh-Dole entered force. Moreover, academic technology transfer has supported the launch of over 12,000 start-ups since 1995, and from 1996 to 2015, academic patents and their subsequent licensing to industry bolstered U.S. GDP by up to \$591 billion, contributed to \$1.3 trillion in gross U.S. industrial output, and supported more than 4 million person years of employment.

Similarly, the Bayh-Dole Act has played a catalytic role in getting the results of federally funded scientific research off the shelf and into the marketplace where they can benefit society. In 1968, President Johnson asked the then comptroller general of the United States, Elmer Staats, to analyze how many drugs had been developed from NIH-funded research. His finding that “not a single drug had been developed when patents were taken from universities [by the federal government]” was pivotal in shaping lawmakers’ subsequent decision to craft the Bayh-Dole legislation. They recognized that market forces would do a better job of commercializing government-funded technology than federal agencies could. Today, more than 200 new drugs and vaccines have been developed through public-private partnerships facilitated in part by the Bayh-Dole Act.

CONCLUSION: CONGRESS SHOULD SUPPORT LIFE-SCIENCES INNOVATION BY HONORING THE LAW’S ORIGINAL INTENT

Tracing the history of Bayh-Dole Act march-in rights, the report explains the four specific instances in which the government is permitted to use march-in rights (ensuring “reasonable prices” is not one). The report examines the legislative history of the Act and quotes from Senators Evan Bayh (D-IN) and Bob Dole (R-KS), who have stated explicitly that the Bayh-Dole Act, “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.”

In summary, the Bayh-Dole Act is working as intended and has played a catalytic role in stimulating America’s innovation economy, especially in the life-sciences sector, since its 1980 enactment. Misusing existing march-in rights or establishing new ones to control drug prices would result in fewer new drugs. Policymakers should reject proposals that would enable the government to use Bayh-Dole Act march-in provisions for the purpose of controlling drug prices.