

A Condensed Timeline of the Bayh-Dole Act

The story of the Bayh-Dole Act began long before its passage in 1980 and its legacy will endure well into the future.

1945-1971: Patent Policy Beginnings

1945
Office of Scientific R&D Director Vannevar Bush recommends a degree of individual patent rights for federally-funded inventions

1947
Attorney General Tom C. Clark provides President Harry S. Truman with patent policy recommendations that laid the basis for Bayh-Dole's march-in provision

December 1, 1968

The NIH and WARF sign the first Institutional Patent Agreement, allowing UW-Madison to retain patent rights on federally-backed inventions

May 26, 1977

NIH Patent Counsel Norman Latker advocates for exclusive patent licenses for federally-backed inventions before the U.S. House of Representatives

May 16th, 1979

Senators Birch Bayh (D-IN) and Bob Dole (R-KS) introduce the Bayh-Dole Act to the Senate Judiciary Committee

December 12, 1980

President Jimmy Carter signs the Bayh-Dole Act into law, allowing small businesses and nonprofits to retain patent rights for federally-funded inventions

1989-2004: The Bayh-Dole Act's Impact and Pricing Arguments

April 11, 1995

Citing dwindling private-sector partnerships, NIH Director Harold Varmus removes the agency's "reasonable pricing" clause in CRADAs to develop novel medicines

December 14, 2002

The Economist calls the Bayh-Dole Act "Possibly the most inspired piece of legislation to be enacted over the past half-century"

July 2, 2004

The NIH denies a march-in petition filed on the basis of price for the HIV/AIDS drug Norvir

December 1, 2010

The NIH denies a march-in petition filed on the basis of health and safety for the Fabry disease drug Fabrazyme

June 20, 2016

The NIH and DOD both deny march-in petitions filed on the basis of price for the prostate cancer drug Xtandi

July, 1945

Office of Scientific R&D Director Vannevar Bush recommends a degree of individual patent rights for federally-funded inventions

August 12, 1968

Comptroller General Elmer B. Staats informs President Lyndon B. Johnson that zero NIH-funded, experimental drug candidates were successfully commercialized

August 23, 1971

President Richard Nixon expands the circumstances when government contractors can own an invention made with federal funding

1977-1980: Bayh-Dole's Drafting

January 18, 1978

Stanford Tech Transfer Director Niels Reimers recommends exclusive licensing agreements for federally-backed inventions to Attorney General Griffin Bell

April 23, 1980

The Senate passes the Bayh-Dole Act, despite nearly derailing it by introducing a rival patent bill

1989

The NIH establishes a "reasonable pricing clause" in Cooperative R&D Agreements with private companies due to Congressional pressure about drug prices

March 3, 1997

CellPro files the first march-in petition to gain a license to a Johns Hopkins invention they are accused of infringing

May 25, 2004

Fmr. Sen. Bayh testifies before the NIH clarifying that Bayh-Dole's march-in rights were never intended as a price control

2004-Present: Attempts to Misuse the Bayh-Dole Act

September 4, 2004

The NIH denies a march-in petition filed on the basis of price for the glaucoma treatment Xalatan

November 1, 2013

The NIH denies a second march-in petition filed on the basis of price for the HIV/AIDS drug Norvir

March 21, 2023

The NIH denies another march-in petition filed on the basis of price for the prostate cancer drug Xtandi