The Vital Importance of the Bayh-Dole Act to America’s Life-sciences Innovation System

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About ITIF

- The world’s leading science and technology policy think tank.
- Supports policies driving global, innovation-based economic growth.
- Focuses on a host of issues at the intersection of technology innovation and public policy across several sectors:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy
U.S. Leads in Global Life-sciences R&D and Innovation

Business and Government Investment in Pharmaceutical R&D (in Billions), 2017

Number of New Chemical or Biological Entities Produced, 1997-2016

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Source: ITIF, “How to Ensure That America’s Life-Sciences Sector Remains Globally Competitive”
But It Wasn’t Always That Way

U.S. Share of New Active Substances (NAS) Launched First on World Market

Keys to U.S. Life-sciences Innovation Leadership

1. Robust public/private investment in biomedical research.

2. Strong incentives to encourage investment. (e.g. R&D tax credit, Orphan Drug Tax Credit)

3. Effective regulatory/drug approval system (e.g., PDUFA).

4. Pricing/reimbursement system allowing innovators to earn sufficient revenues to support research.

5. Robust IP rights/protections, including the Bayh-Dole Act.

Source: ITIF, “Why Life-Sciences Innovation is “Politically Purple”—And How Partisans Get It Wrong”
The Bayh-Dole Act

- Bipartisan legislation, passed in 1980, giving universities rights to IP generated from federal funding.

What drove Congress to enact Bayh-Dole?

- Faltering commercialization of federally funded research.
- Faltering U.S. economic competitiveness in late 1970s.
The Bayh-Dole Act: Impact

- Led to a 10-fold increase in academic patenting in first 20 years; over 80,000 patents and 12,000 start-ups resulting from academic tech transfer.

- Over 200 drugs and devices developed through public-private partnerships facilitated by the Bayh-Dole Act.

- *The Economist*: “Possibly the most inspired piece of legislation to be enacted in America over the past half-century.”

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**The Economist**

Innovation's golden goose

*The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home.*
The Bayh-Dole Act: Emulated By Countries Worldwide

Sample Countries That Have Enacted Bayh-Dole-like Legislation
Complementary Roles of Key Actors in U.S. Life-sciences System

- **Federal government:** Funds basic research (NIH: $39B) identifying underlying mechanisms of disease/promising points of intervention.

- **Universities:** Conduct $38B of life-sciences research annually, creating new knowledge/discoveries often licensed to private sector.

- **Private sector:** Invests $90B in R&D/clinical trial activities required to turn basic life-sciences discoveries into new drugs, devices, therapies.

  $100 of private investment for every $1 of public investment to a new drug.

Sources: ITIF, “The Bayh-Dole Act’s Vital Importance to the U.S. Life-sciences Innovation System”; Chatterjee and Rohrbaugh, “NIH Inventions Translate Into Drugs and Biologics With High Public Health Impact”
Bayh-Dole Case Study: CardioMEMS

- Mid-1990s: Dr. Mark Allen receives $500K ARL grant to develop sensors for jet turbines.
- Patents awarded in 1999, assigned to GATech.
- 2000: Begins working with colleagues to adapt wireless MEMS sensors for human body.
- 2001: Incorporates CardioMEMS, for remote pulmonary artery monitoring, attracts $50M VC.
- FDA approved in 2005; users have experienced a 37% reduction in heart failure hospitalizations.
Bayh-Dole March-In Rights

Under certain circumstances, the government retains the right to “march-in” and require patent holders to grant licenses:

- If the contractor fails to take effective steps to achieve practical application of the subject invention;
- If the product can’t be substantially U.S.-manufactured;
- If contractor can’t meet requirements for public use specified by federal regulations;
- If action needed to alleviate health or safety needs which aren’t “reasonably satisfied” by the patent holder.

Source: CRS, “March-In Rights Under the Bayh-Dole Act”
March-in Rights Not Intended to Address Pricing

“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.”
Inclusion of “Reasonable Pricing” Clause Stunted Innovation

NIH imposed “reasonable price” requirements on CRADAs in 1990; NIH repealed then in 1995.

Varmus: “The pricing clause has driven industry away from potentially beneficial scientific collaborations.”

Source: NIH Annual Reports; Joseph Allen, “Compulsory Licensing for Medicare Drugs– Another Bad Idea from Capitol Hill”
Conclusions

1. U.S. life-sciences leadership is the result of conscientious policy choices that need to be sustained.

2. The Bayh-Dole Act is working effectively, and as intended, enabling valuable financial support for America’s research universities.

3. Application of march-in rights to control drug prices not intent of law and would undermine U.S. life-sciences system.
Thank You!

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