

The Bayh-Dole Act's Catalytic Contributions to America's Innovation System

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ITIF

June 17, 2020

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



Today's Presentation

1 Bayh-Dole History and Impact

2 Bayh-Dole and Life-sciences Innovation

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

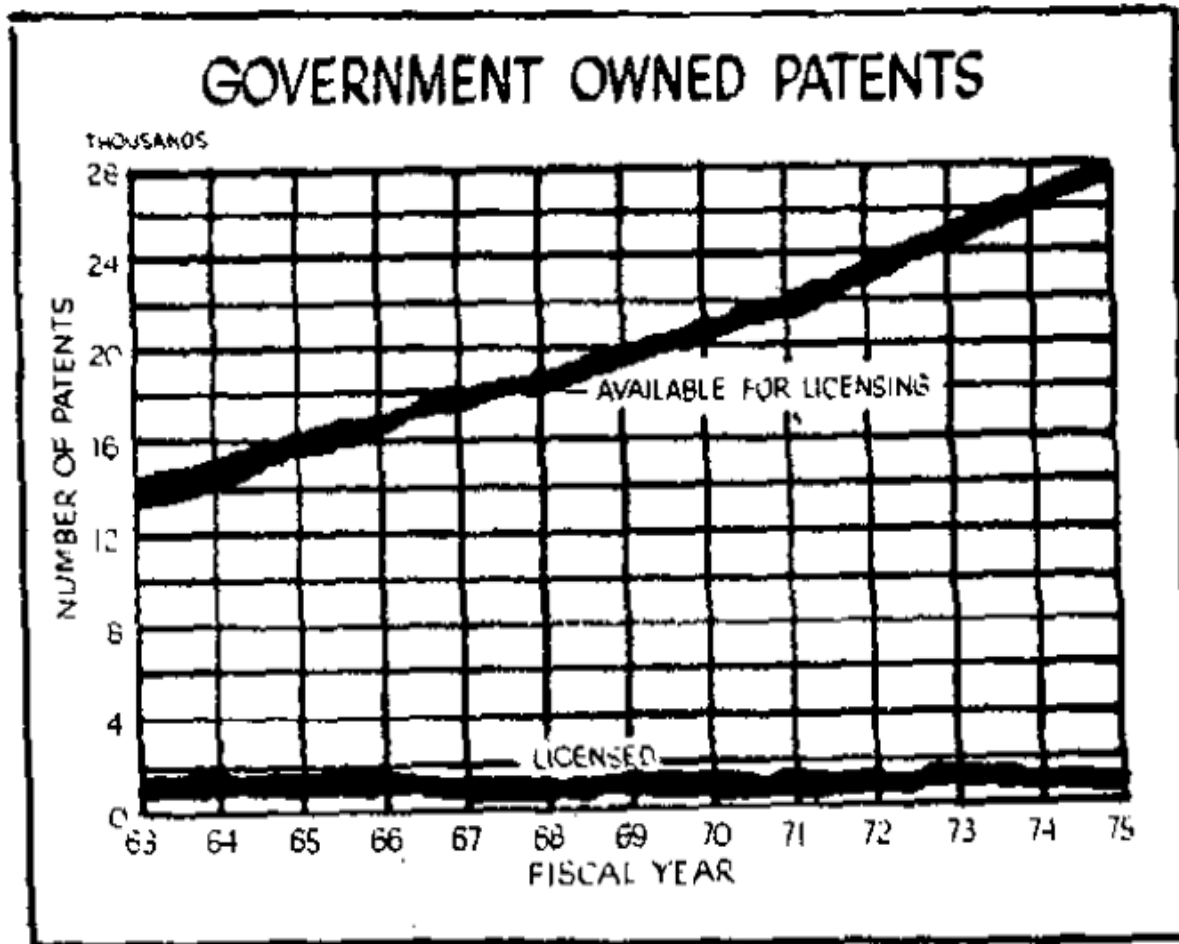
STEPHEN EZELL | MARCH 2019

Misusing the "march-in right" provision of the Bayh-Dole Act could negatively impact U.S. life-sciences innovation and result in fewer new drugs.

KEY TAKEAWAYS

- The Bayh-Dole Act, signed into law in 1980, gives universities rights to intellectual property (IP) generated from federal funding. It was never intended to be used to control drug prices.
- Using "march-in" rights to control prices could undermine the U.S. life-sciences innovation ecosystem and reduce the pace of American biopharmaceutical innovation, resulting in fewer new drugs.
- Policymakers should honor the law's original intent and reject proposals that would commandeer the Bayh-Dole Act's march-in provision for the purpose of controlling drug prices.

The Pre-Bayh Dole Era



Source: Courtesy Joe Allen

- Less than 5% of government inventions licensed non-exclusively.
- “Not one single new drug developed when patents taken from universities.”



**Elmer Staats,
Comptroller General**

The Pre-Bayh Dole Era

- Faltering U.S. competitiveness in late 1970s; decline of auto, steel, electronics, semiconductor, etc. industries.
- Leads to suite of policies to revive U.S. competitiveness.
 - Bayh-Dole Act (1980)
 - Stevenson Wydler Technology Innovation Act (1980)
 - Introduction of R&D tax credit (1981)
 - Manufacturing Extension Partnership launched (1982)
 - National Technology Transfer Act/CRADAs (1986)



The Bayh-Dole Act (35 U.S.C. 200)

- Bipartisan legislation giving universities, non-profits, and small businesses rights to intellectual property generated from federally funded research.
- The inventor retains ownership and title to subject inventions, which can be exclusively or non-exclusively licensed to third parties.
- Technology management decentralized from government to the institutions and entrepreneurs making the inventions.
- Gives preference in licensing to small companies/domestic manufacturers.
- Induce a virtuous cycle of innovation: royalties used to reward inventors, fund more R&D, cover technology transfer costs.

Government Rights Under Bayh-Dole

- Promote commercialization of government-funded inventions while ensuring the government receives sufficient rights to inventions.
- Government receives a “Government Purpose License” that is:
 - Non-exclusive
 - Non-transferrable
 - Irrevocable
 - Paid up
- Government also retains a set of “march-in” rights.

The Bayh-Dole Act: Impact

- *The Economist*: “Possibly the most inspired piece of legislation to be enacted in America over the past half-century.”
- “Unlocked all the inventions and discoveries that had been made in laboratories throughout the U.S. with the help of taxpayers' money.”
- “More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.”



The
Economist

OPINION

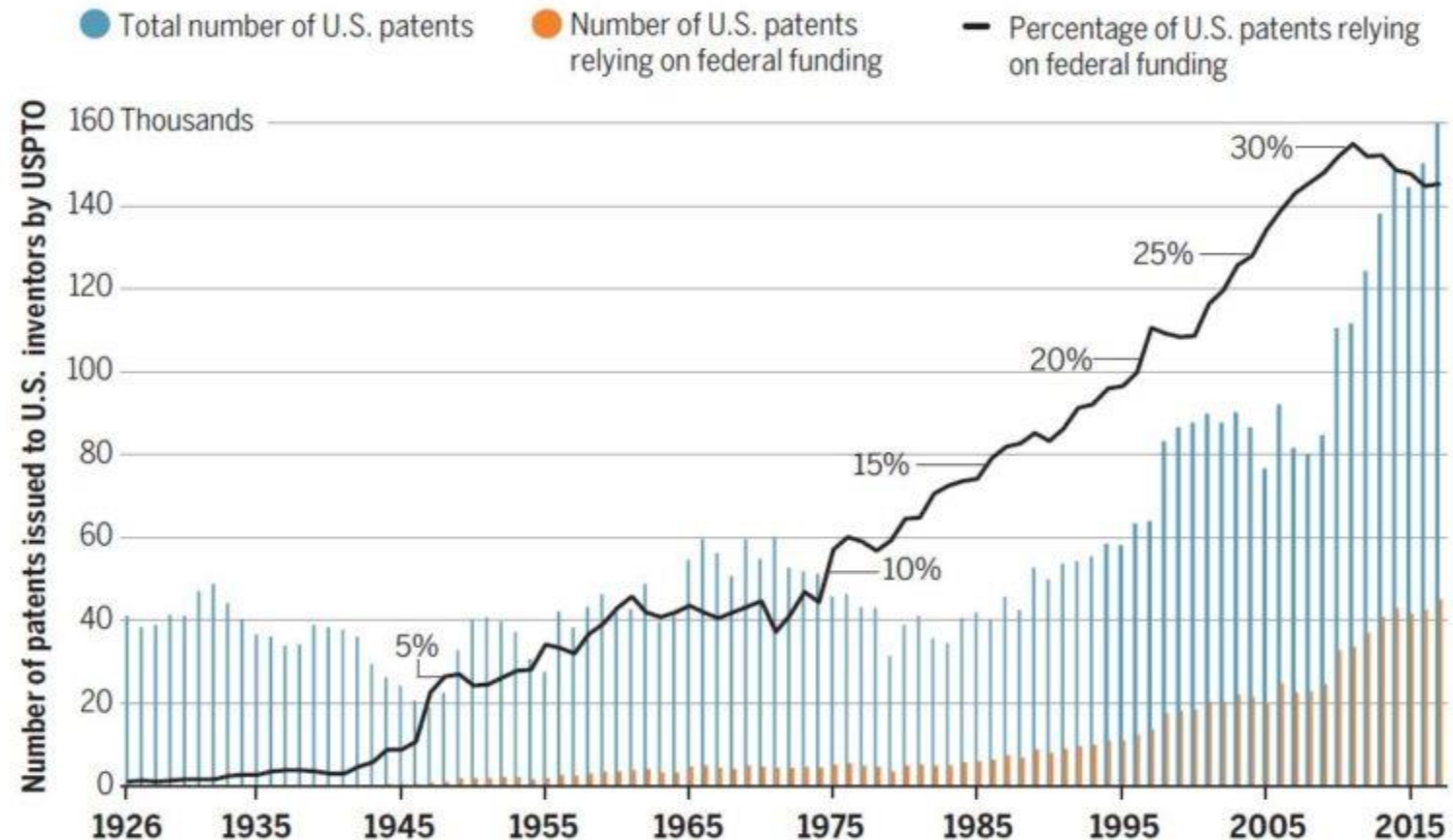
Innovation's golden goose

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

Source: *The Economist*, “Innovation’s Golden Goose,” December 14, 2002

Research Funding Linked to Inventions

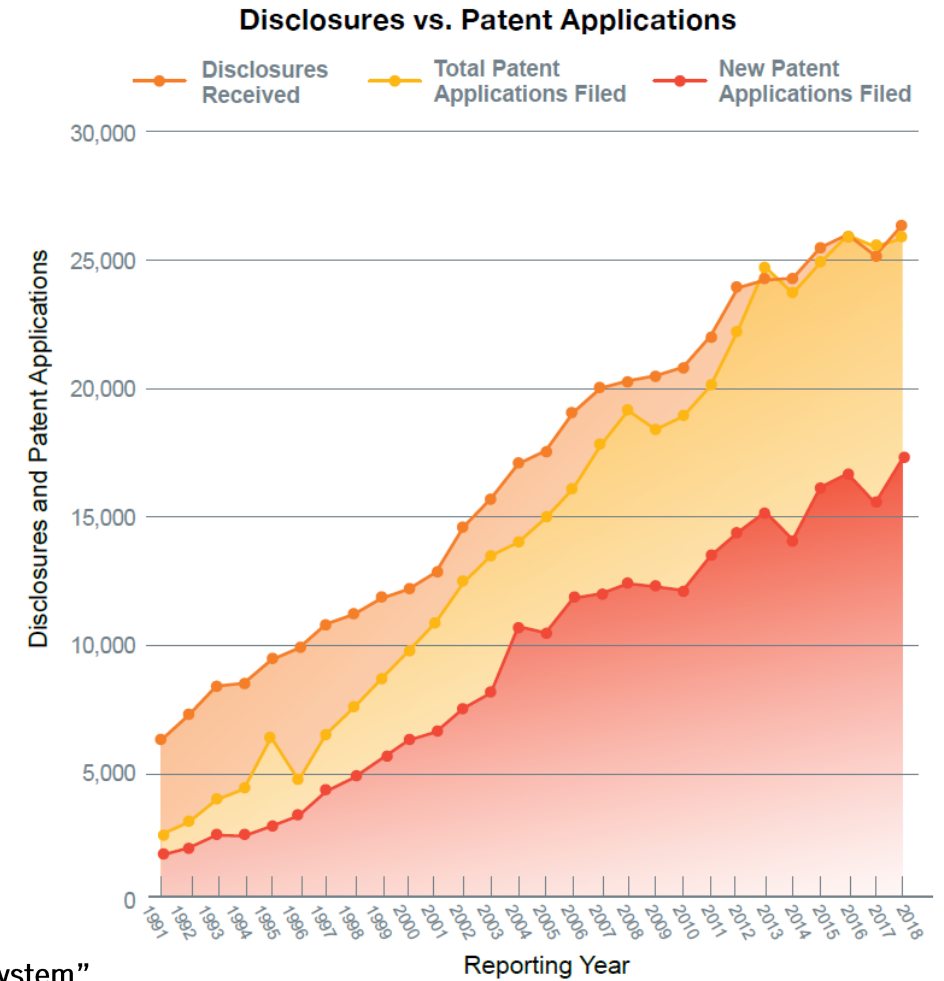
- *“The number of new U.S. patents took off after passage of the Bayh-Dole Act.”*
- Federally funded research drives nearly one-third of U.S. patents.



Sources: Flaherty, “Federally funded research drives nearly one-third of U.S. patents, report finds” *STAT*, June 20, 2019
Fleming et al., “Government-funded research increasingly fuels innovation” *Science*, June 2019

The Bayh-Dole Act: Impact

- Just 55 U.S. universities had been granted a patent in 1976; by 2006, 240.
- Led to a 10-fold increase in academic patenting in the first 20 years alone.
- Number patents awarded to universities:
 - 1980: 390
 - 2018: 7,625



Sources: AUTM, "AUTM 2018 Licensing Activity Survey"

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

The Bayh-Dole Act: Impact

- “The sort of large-scale technology transfer from universities that exists today would likely have been impossible without the strengthened property rights, standardized across agencies, set into law in 1980.”
- Long-run employment, payroll, payroll per worker, and average establishment size grew more in industries more closely related to innovations produced by a local university or hospital after BD introduced.
- “BD contributed to university faculty responding to royalty incentives by producing higher-quality innovations.”

Sources: Naomi Hausman "University Innovation, Local Economic Growth, and Entrepreneurship"
Saul Lach and Mark Schankerman, "Incentives and Invention in Universities"

UNIVERSITY INNOVATION, LOCAL ECONOMIC GROWTH,
AND ENTREPRENEURSHIP

by

Naomi Hausman *
Harvard University

CES 12-10

June, 2012

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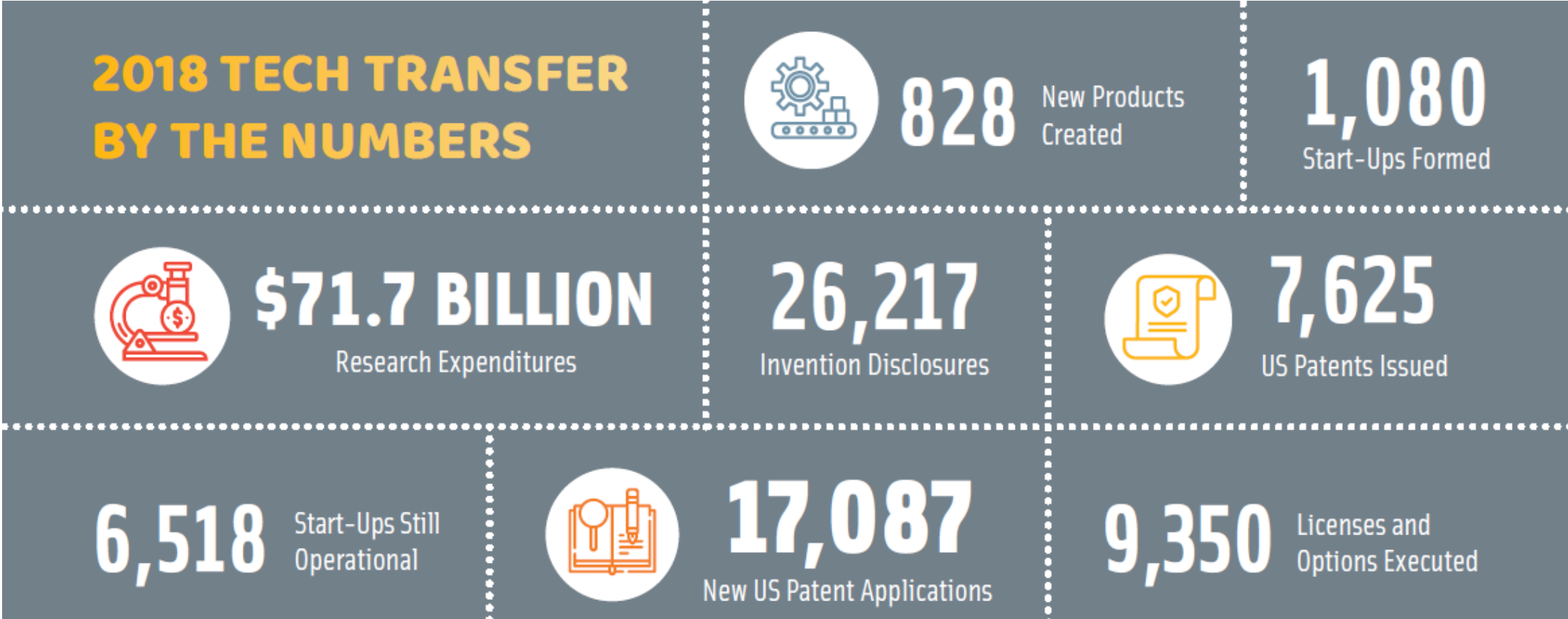
To obtain information about the series, see www.census.gov/ces or contact C.J. Krizan, Editor, Discussion Papers, U.S. Census Bureau, Center for Economic Studies 2K130F, 4600 Silver Hill Road, Washington, DC 20233, CES.Papers.List@census.gov.

Techs/Products/Companies Bayh-Dole Has Enabled

- Allegra
- FluMist
- Gleevec/Imatinib (CML)
- Yervoy/Ipilimumab (Melanoma)
- Luxturna (Inherited blindness)
- Taxol (Breast/ovarian cancer)
- Tovaxin (Multiple sclerosis)
- Ervebor/rVSV-ZEBOV (Ebola)
- Zerit/Epivir (AIDS)
- Lyrica (Epilepsy/pain)
- CAR T-cell therapy
- Cervical cancer tests
- Nicotine patch
- Magnetic resonance spectroscopy
- Organ preservation solutions
- Sustained drug delivery tech
- Advanced ultrasound imaging
- Early osteoporosis detection
- Children's rotavirus vaccine
- Blood test for brain injuries
- Honeycrisp apples
- Neoprene
- Google
- Quantum computing innovations
- Cloud computing interfaces
- High-definition television
- Autonomous vehicles
- Firefighting drones
- Lightweight wheels for cars
- Explosive-detecting scanners

Source: Courtesy AUTM, "Better World Project"

Impact of Academic Technology Transfer - 2018



Source: AUTM, "AUTM 2018 Licensing Activity Survey"

Impact of Academic Technology Transfer

From 1996 to 2017, up to...



420,000+

inventions disclosed...

100,000+

U.S. patents issued...



to research institutions since 1996

13,000+

start ups formed



67%

of university licenses are to **start-ups and small companies**



200+

drugs and vaccines developed through public-private partnerships since **Bayh-Dole Act** enacted in 1980



Source: AUTM, "Driving the Innovation Economy: Academic Technology Transfer in Numbers"

Impact of Academic Technology Transfer

From 1996 to 2017, up to...

\$1.7 trillion

contributed to
U.S. gross industrial output



\$865 billion

contributed to
U.S. gross domestic product



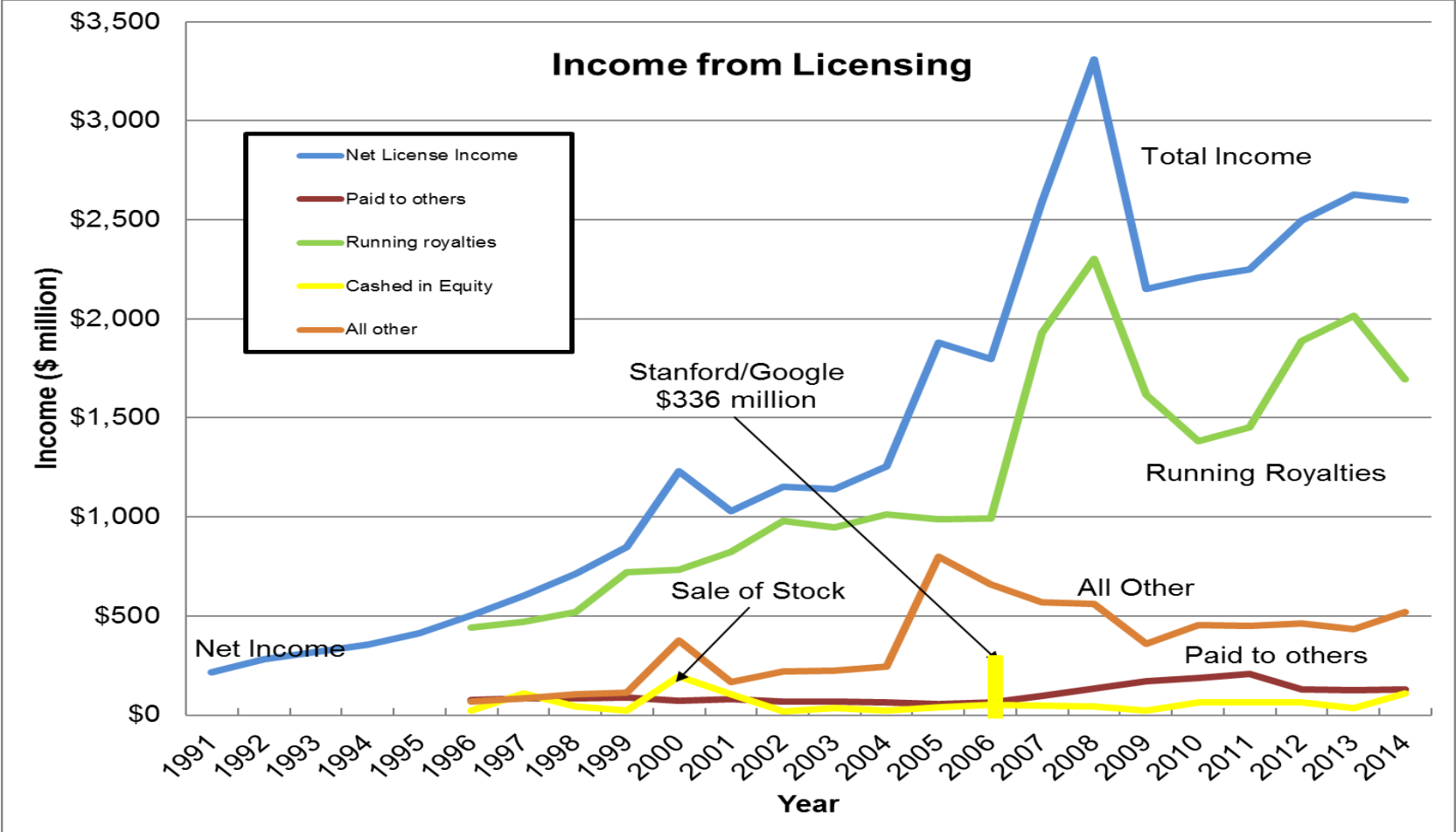
5.9 million

jobs supported



Source: AUTM, "Driving the Innovation Economy: Academic Technology Transfer in Numbers"

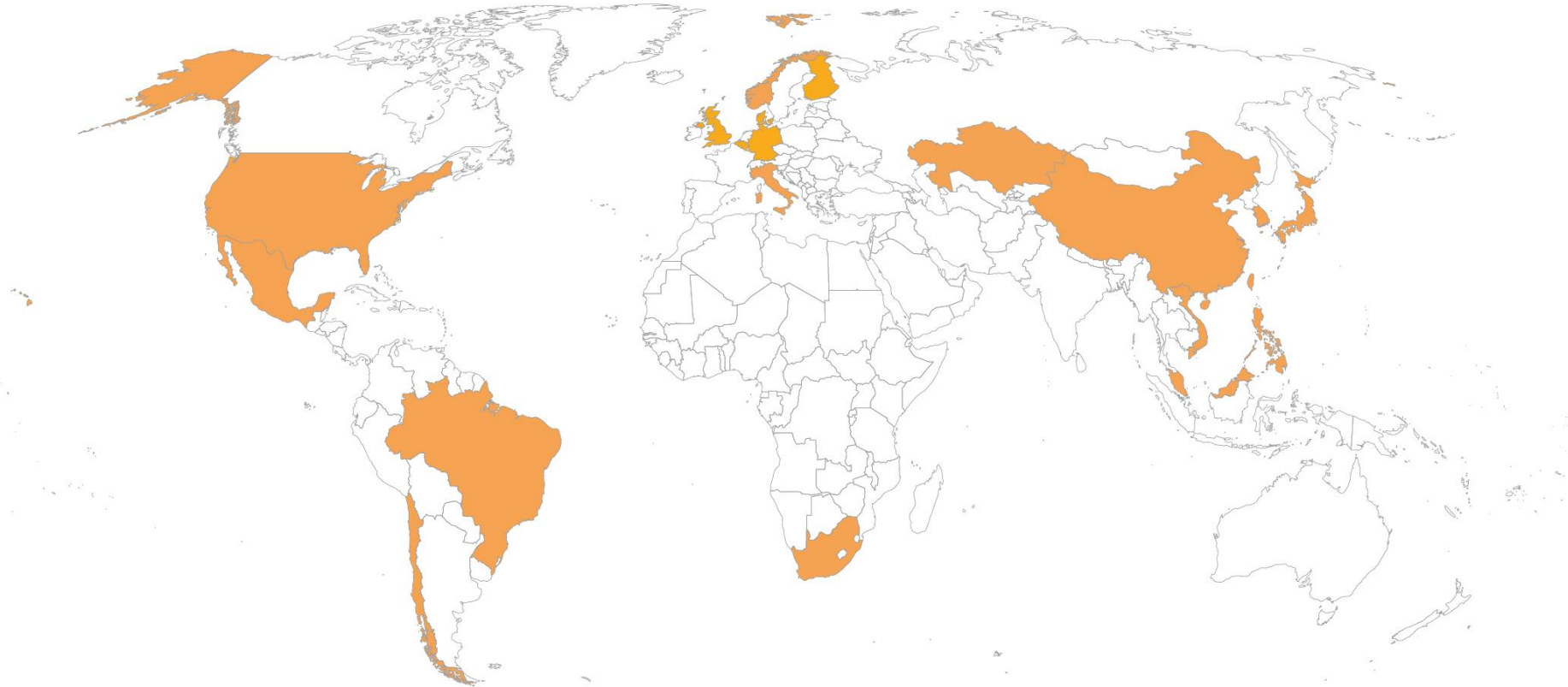
University Income From Technology Licensing



Source: Courtesy, Joe Allen

The Bayh-Dole Act: Emulated By Countries Worldwide

Sample Countries That Have Enacted Bayh-Dole-like Legislation

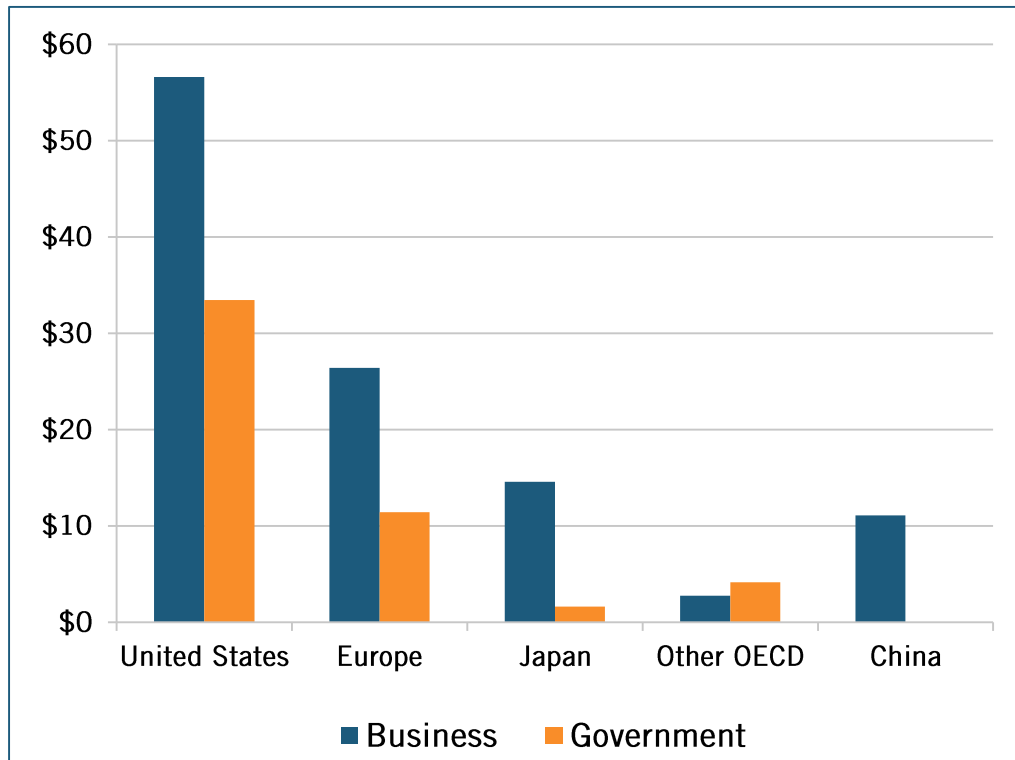


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U.S. Leads in Global Life-sciences R&D and Innovation

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

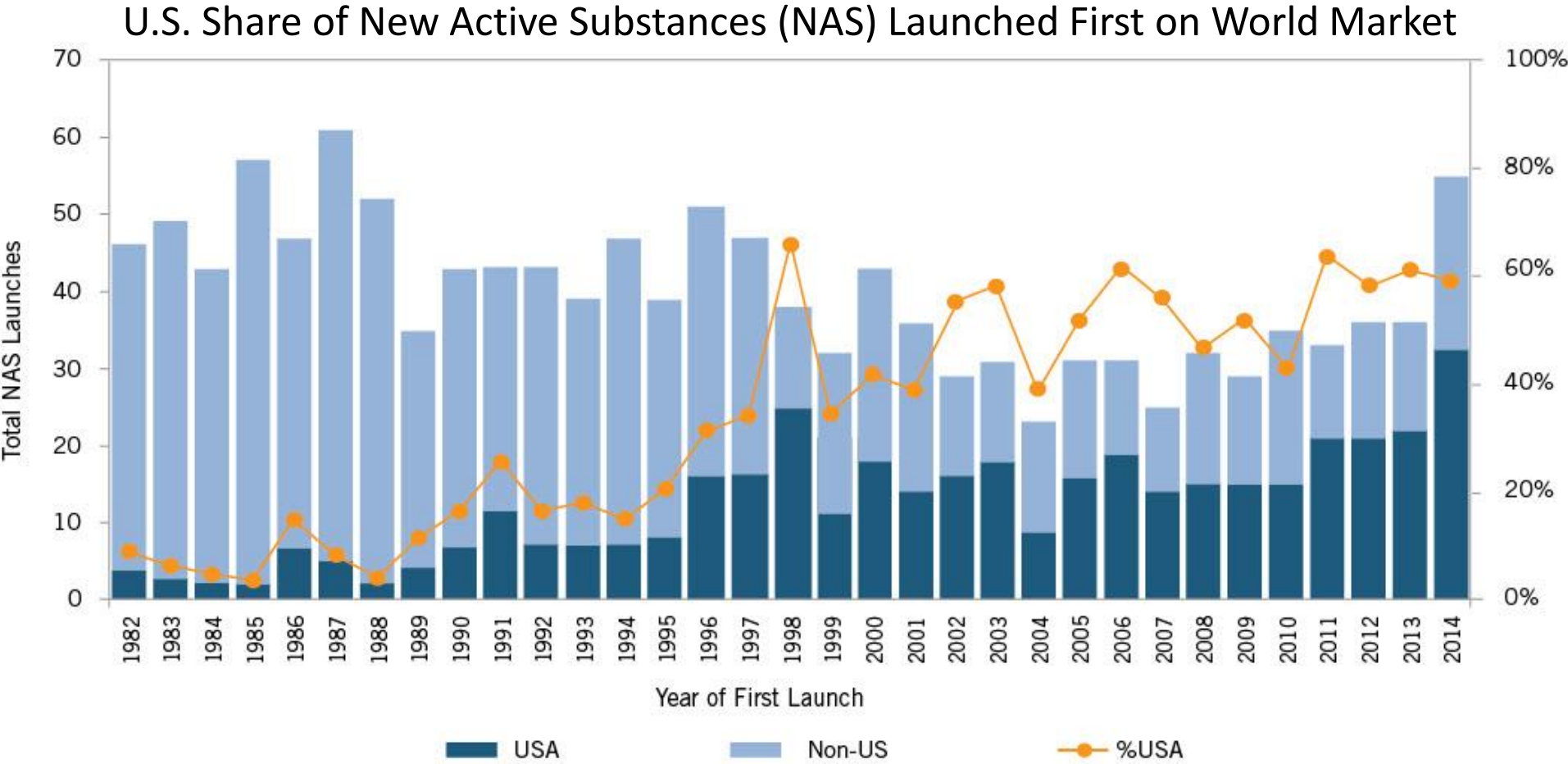


Number of New Chemical or Biological Entities Produced, 1997-2016

Region	1997-2001	2002-2006	2007-2011	2012-2016	Total
U.S.	84	67	65	88	304
Europe	79	46	52	75	252
Japan	29	21	20	32	102
Other	4	14	12	38	64

Source: ITIF, “How to Ensure That America’s Life-Sciences Sector Remains Globally Competitive”

But It Wasn't Always That Way



Source: John K. Jenkins, M.D., "CDER New Drug Review: 2015 Update"

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.

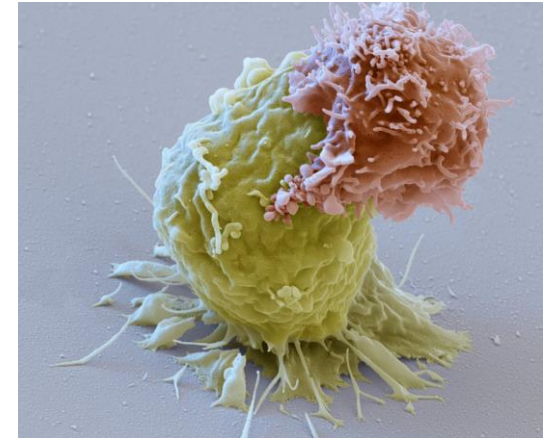


Image of a CAR-T cell (reddish) attacking a leukemia cell (green).

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

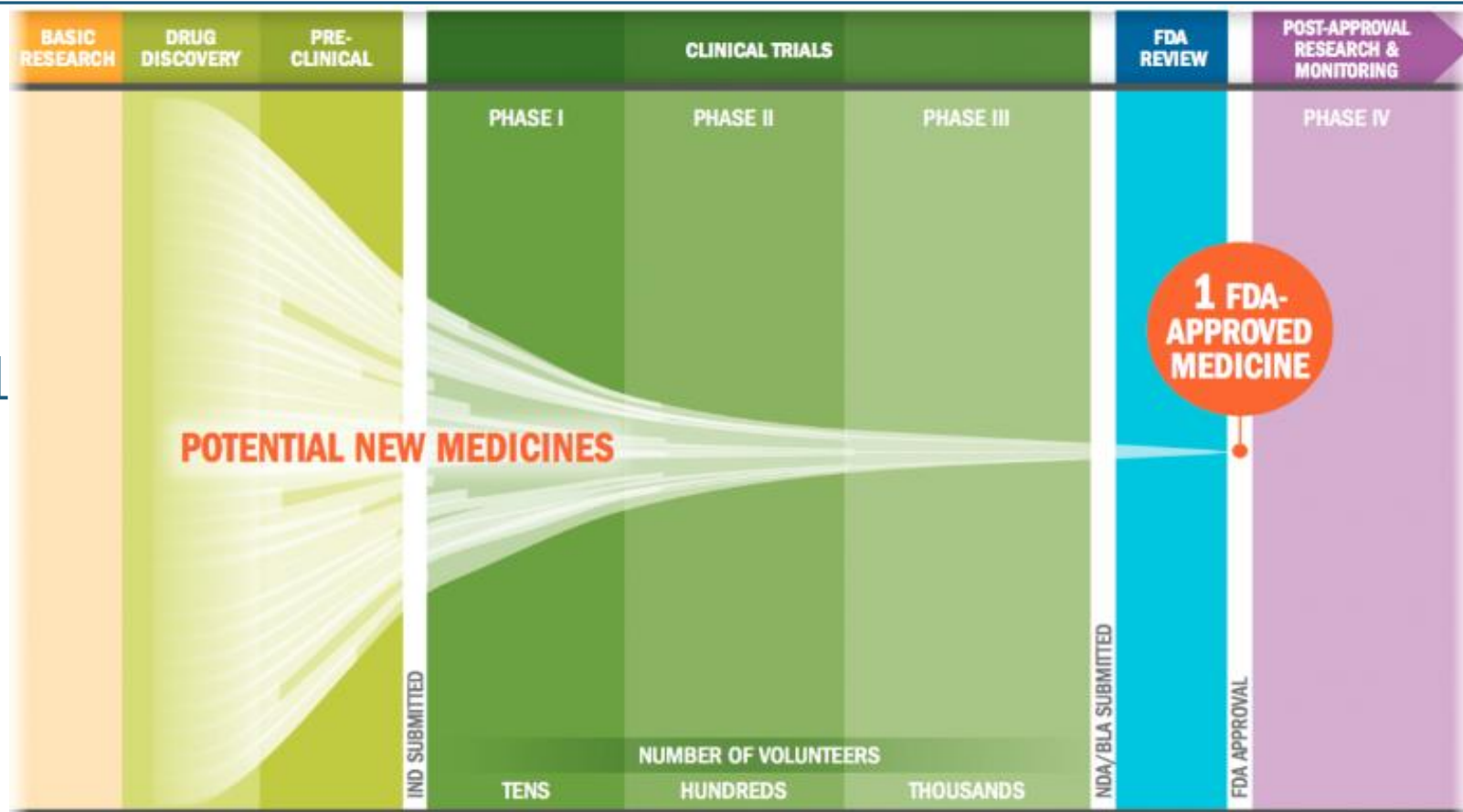
Complementary Roles of Key Actors in U.S. Life-sciences System

- **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.

Source: ITIF, “The Bayh-Dole Act’s Vital Importance to the U.S. Life-sciences Innovation System”

The Biopharmaceutical Research and Development Process

- New drugs take 12-16 years to develop, costs into the billions.
- \$100 of private investment for every \$1 of public investment into a new drug.



Sources: PhRMA, *2015 Biopharmaceutical Research & Development Report*;
Chatterjee and Rohrbaugh, "NIH Inventions Translate Into Drugs and Biologics With High Public Health Impact"

Complementary Roles of Key Actors in U.S. Life-sciences System

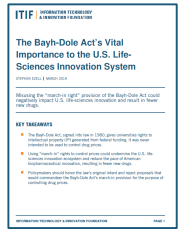
- "NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA from 2010–2016."
- ">90% of this funding represents basic research related to the biological targets for drug action rather than the drugs themselves."



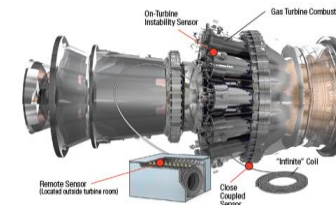
Source: Cleary et al. "Contribution of NIH funding to new drug approvals 2010–2016"

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.



United States Army
Research Laboratory

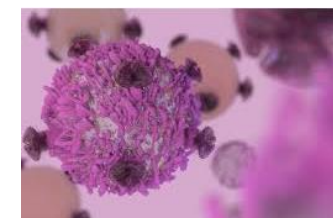


cardiomems®



Case Study: Yervoy/Ipilimumab

- Early 1990s: Dr. James Allison receives NIH grant to study operation of T-cells in human immune system.
- He theorizes cancers may work by suppressing T-cell activation; shows how cytotoxic T lymphocyte antigen-4 (CTLA-4) brakes body's T-cell responses.
- 1995: Patents a method to activate T-cells through a blockade of CTLA-4 signaling, assigns rights to UCB.
- IP rights ultimately licensed to BMS, which invests over a decade in development & clinical trial work before FDA approves Yervoy for melanoma in 2011.



Bayh-Dole and the Coronavirus Crisis



Credits patents in the field of messenger RNA and associated mRNA delivery technologies it licensed from Harvard and UPenn.



Remdesivir from NIAID CTER grant where Gilead partnered with UAB, UNC, and Vandy to study high-priority emerging infections.



Leveraged LLNL technology for rapid polymerase chain reaction thermocycling, integrating amplification, and detection for coronavirus test kits.

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: Congressional Research Service, “March-In Rights Under the Bayh-Dole Act”



March-In Rights Under the Bayh-Dole Act

John R. Thomas
Visiting Scholar

August 22, 2016

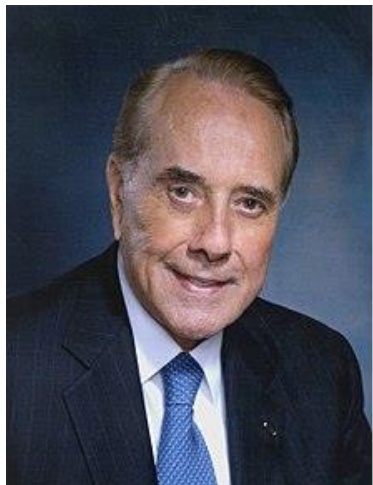
Congressional Research Service
7-5700
www.crs.gov
R44597

CRS REPORT
Prepared for Members and
Committees of Congress

March-in Rights Not Intended to Address Pricing Issues



“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 Washington Post

Our Law Helps Patients Get New Drugs Sooner

As co-authors of the Bayh-Dole Act of 1980, we must comment on the March 27 op-ed article by Peter Arno and Michael Davis about this law.

Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner.

For every \$1 spent in government research on a project, at least \$10 of industry development will be needed to bring a product to market. Moreover, the rare government-funded inventions that become products are typically five to seven years away from being commercial products when private industry gets involved. This is because almost all universities and government labs are conducting early-stage research.

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.

The article also mischaracterized the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

The law we passed is about encouraging a partnership that spurs advances to help Americans. We are proud to say it's working.

BIRCH BAYH
BOB DOLE
Washington

Bayh-Dole and March-in Rights

- March-in rights have not been applied in 40-year history of BD.
- At least six submissions made, four related to drug pricing.

“NIH agrees...that the extraordinary remedy of march-in is not an appropriate means of controlling prices.” – NIH Director Elias Zerhouni

“The use of march-in is typically regarded as a last resort.” – NIST Return on Investment Initiative



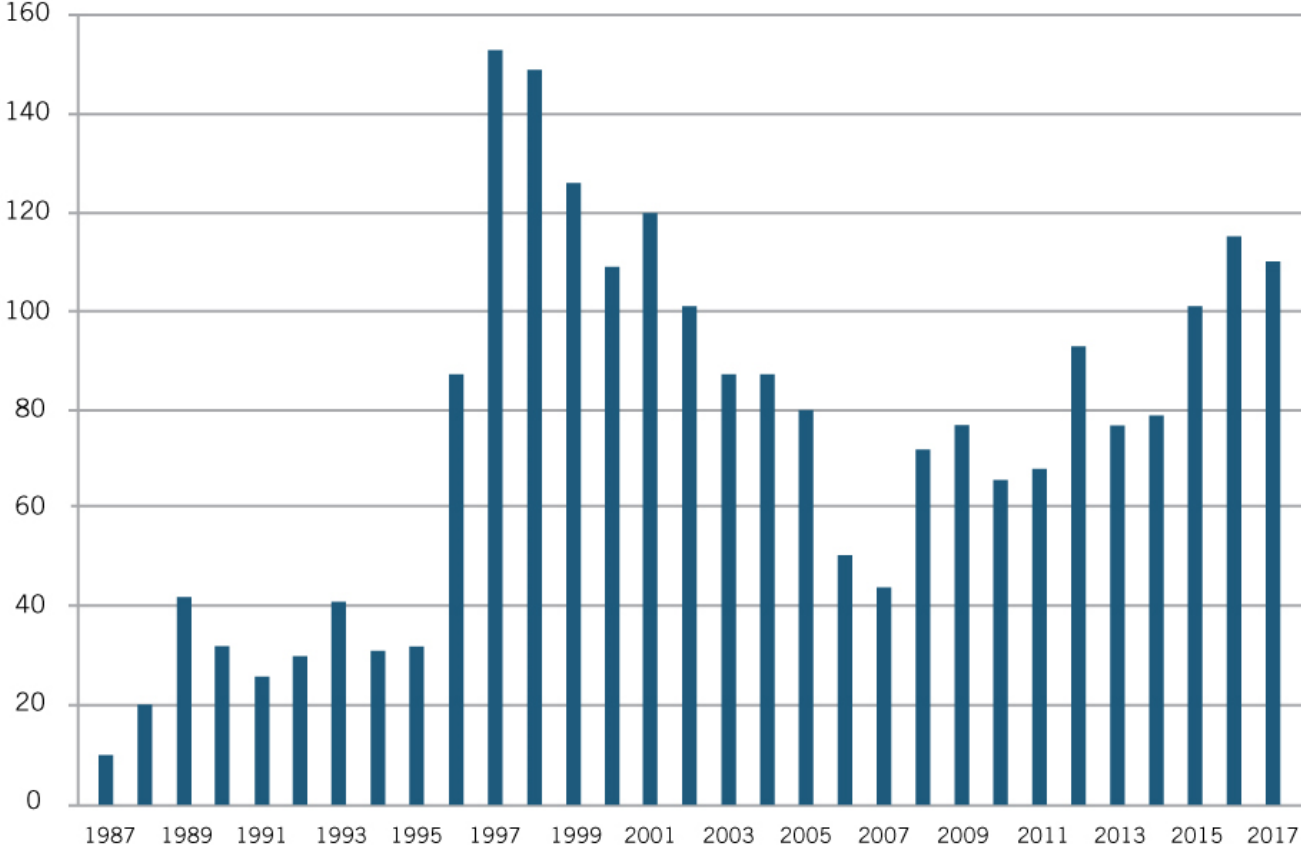
Sources: Congressional Research Service, “March-In Rights Under the Bayh-Dole Act”
NIST, “Return on Investment Initiative: Draft Green Paper” (December 2018)

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.”

NIH New CRADAs Per Fiscal Year, 1987-2017



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

Conclusions

1. The Bayh-Dole Act is working effectively, and as intended, enabling valuable financial support for America's research universities.
2. Application of march-in rights to control drug prices not intent of law and would undermine U.S. life-sciences system.

The Bayh-Dole 40 Coalition



Celebrating the past. Protecting the future.

<https://bayhdole40.org/>

Thank You!

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