



DR. JOHN HAMRE

Former U.S. Deputy Secretary of Defense and President and CEO at the Center for Strategic and International Studies



PAUL KIM

Capitol Hill veteran and Health Policy Expert

The Bridge that Bipartisanship Built: Challenges to Our Nation's Technology Transfer System



ON MONDAY,
JANUARY 22



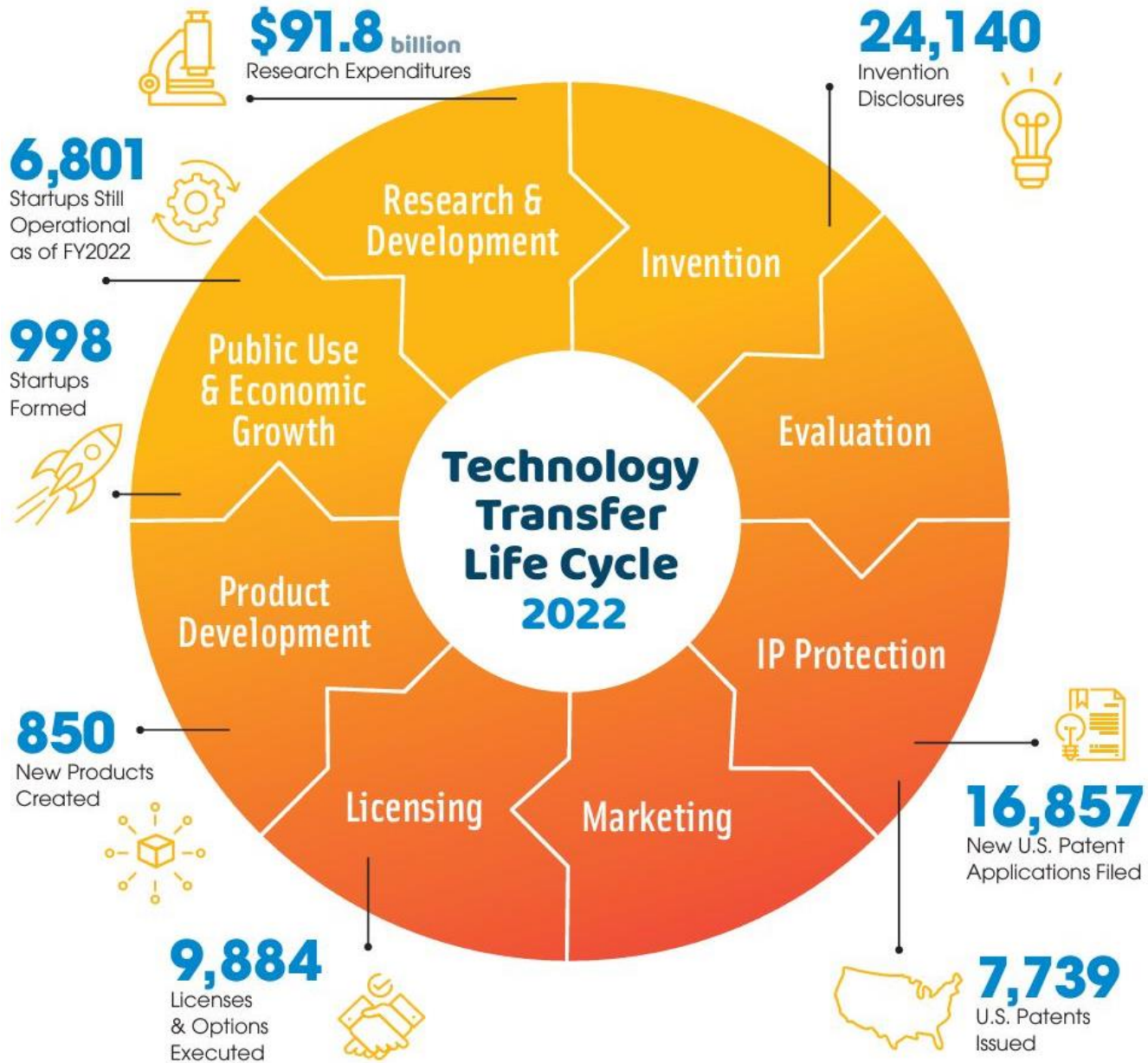
AT 12:30 PM ET

What is “technology transfer”?

“**Technology transfer**, or the process of getting knowledge and discoveries from the laboratory to the general public, is important so that laboratory research can lead to benefits to people’s lives and society.

Often this is done by private sector involvement to transform these discoveries into products and services for the market.”

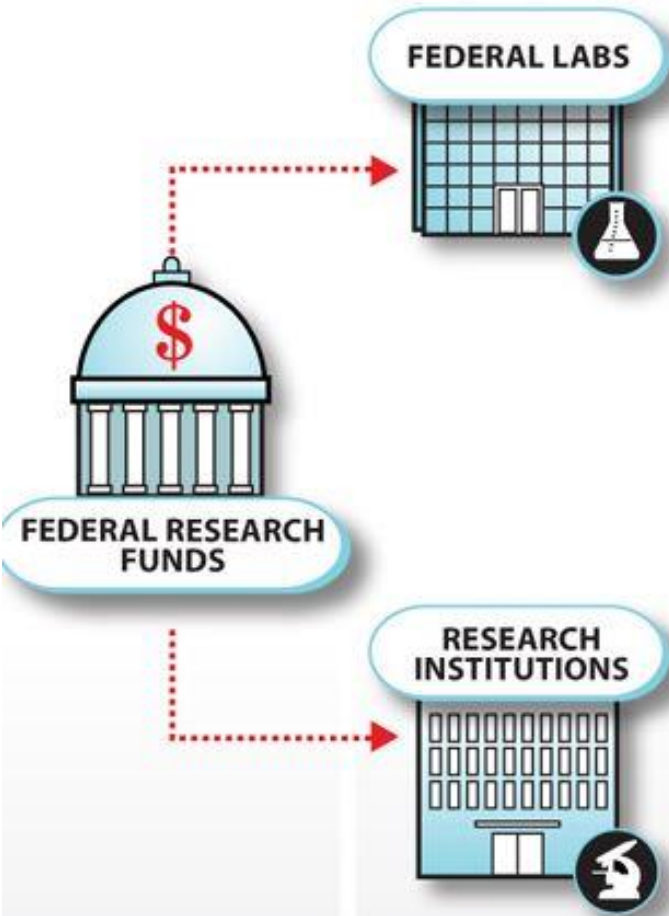
- National Institute of Standards and Technology (NIST), Department of Commerce



Source: AUTM

Before Bayh-Dole

“The GAO believes that... **an agency** operating under the Presidential policy **can move in almost any direction when determining rights to inventions.**”



NO CLEAR POLICY FOR GRANTING TITLE:
The federal government or research institution held title.

NO CLEAR POLICY FOR EXCLUSIVE LICENSING:
Patents were not licensed and instead languished in the public domain.

AS A RESULT,
very little federally funded research was commercialized. Only 250 patents were issued to US Universities prior to 1980.



Source: *The Bayh-Dole Act at 25 (BayhDole25)*

“Of the 30,000 patents that the Government presently holds, less than 4% are ever successfully licensed. **That is very little return on the billions of dollars that we spend every year on research and development.**”

- Sen. Birch Bayh, Hearing on S.414, the University and Small Business Patent Procedures Act, Senate Judiciary Committee, May 16, 1979

What is the Bayh-Dole Act of 1980?

“Bayh-Dole gave **ownership of inventions back to the universities** that created them and gave universities the **freedom to negotiate whatever license** terms would **best encourage development** of the technology.”*

- **Universities** and other nonprofits, and **small businesses retain title to “subject inventions”** made through federally-funded R&D.
 - All contractors, including **private sector**, eligible since 1983 presidential memorandum
 - They commit to **commercialization** within agreed upon timeframe
- The **Federal government** -
 - **retains** “a nonexclusive, nontransferable, irrevocable, paid-up **license to practice** or have practiced for or on behalf of the United States...throughout the world....”
 - may **keep title** under “**exceptional circumstances**”
 - retains “**march-in rights**” which enable an agency to require licensure of a third party to use the invention under narrow circumstances

35 USC §200. “Policy and objective”

It is the policy and objective of the Congress to use the patent system—

- to promote the utilization of inventions arising from federally supported research or development;
- to encourage maximum participation of small business firms in federally supported research and development efforts;
- to promote collaboration between commercial concerns and nonprofit organizations, including universities;
- to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;
- to promote the commercialization and public availability of inventions made in the United States by United States industry and labor;
- to ensure that the Government obtains sufficient rights in federally supported inventions;
- to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and
- to minimize the costs of administering policies in this area.

(Enacted under Pub. L. 96–517, §6(a), Dec. 12, 1980, 94 Stat. 3018; amended Pub. L. 106–404, §5, Nov. 1, 2000, 114 Stat. 1745.)

Why is Bayh-Dole significant?



Sens. Birch Bayh (D-IN) and Bob Dole (R-KS) in 1985
(Dole Photograph Collection, University of Kansas)

“Before Bayh-Dole, intellectual property belonged to the federal government. After Bayh-Dole, it was vested with the institution receiving the federal grant. Bayh-Dole opened the floodgates for universities to commercialize inventions and created the world of tech transfer we know today.”

- [Richard Atkinson](#), NSF Director (1975-1980) and University of California president *emeritus* (1995-2003)

“Possibly the **most inspired piece of legislation** to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... [I]t **unlocked all the inventions and discoveries** that had been made in laboratories throughout the United States with the help of taxpayers' money. **More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.**”

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

Bayh-Dole Outcomes

From 1996 to 2020, up to...

\$1.9 trillion

contributed to
U.S. gross industrial output



\$1 trillion

contributed to
U.S. gross domestic product



6.5 million

jobs supported



495,000+

inventions disclosed...

126,000+

U.S. patents issued...



to research institutions since 1996

17,000+

startups formed



73%

of university licenses are to
startups and small companies



200+

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



35 USC §203. “March-in rights”

(a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title ... the **Federal agency ... shall have the right ... to require the contractor... to grant a nonexclusive, partially exclusive, or exclusive license [or] grant such a license itself, if the Federal agency determines...—**

(1) action is necessary because **the contractor... has not taken, or is not expected to take... effective steps to achieve practical application of the subject invention...;**

(2) action is necessary to **alleviate health or safety needs which are not reasonably satisfied by the contractor ...;**

(3) action is necessary to meet requirements for public use... and such requirements are not reasonably satisfied by the contractor...; or

(4) action is necessary because... a licensee... is in breach of its agreement obtained pursuant to section 204.

“March-in” rights have never been exercised by any Federal agency since 1980

Recent Developments



2019 NIST white paper on Federal technology transfer concluded “march-in authority should not be broadened, and that doing so would create uncertainties in the U.S. innovation system.”

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

37 CFR Parts 401 and 404

[Docket No.: 230315–0076]

RIN 0693–AB66

Rights to Federally Funded Inventions and Licensing of Government Owned Inventions

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Final rule.

2021-2023 NIST rulemaking for final Bayh-Dole regulations, effective April 24, 2023, proposed – then retreated from – provision that “[m]arch-in rights shall not be exercised exclusively based on... the pricing of commercial goods and services”

Recent Developments

THE WHITE HOUSE



Executive Order
on Promoting Competition
in the American Economy

JULY 09, 2021

July 2021 Executive Order (“Promoting Competition”) directed NIST to “consider **not finalizing any provisions on march-in rights and product pricing** in the [2021] proposed rule”

THE WHITE HOUSE



Executive Order on Federal Research
and Development in Support of
Domestic Manufacturing and
United States Jobs

JULY 28, 2023

July 2023 Executive Order (“invent it here, make it here”) gave DOD, HHS, NASA and NSF 90 days to **reconsider Bayh-Dole “exceptional circumstances”** to restrict private sector companies from receiving title to inventions.

Also expanded Bayh-Dole domestic manufacturing requirement beyond exclusive to non-exclusive licenses and funding awardees.

NIST Releases for Public Comment Draft Guidance on March-In Rights

December 07, 2023

GAITHERSBURG, Md. — The U.S. Department of Commerce’s National Institute of Standards and Technology (NIST) released for public comment its *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, a tool to help agencies evaluate when it might be appropriate to require licensing of a patent developed with federal funding. The draft guidance will help agencies work through a range of policy considerations relevant to a potential march-in decision, including price. The proposed guidance is [now available in the Federal Register](#).

Under the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh-Dole Act, the government allows recipients of federal research funding to retain rights to inventions conceived or developed with that funding. The act gives federal agencies the right to “march in” under specific circumstances related to accessibility of the invention, as well as national health and safety (35 U.S.C. 203). There have been calls for greater clarity on when it is appropriate or warranted for a federal agency to exercise such rights.

“The Bayh-Dole Act is an important tool for fostering U.S. innovation and the commercialization of inventions that come from federally funded research and development,” said U.S. Secretary of Commerce Gina Raimondo. “With this draft guidance and request for comment, we are seeking continued stakeholder input to ultimately provide greater clarity on march-in rights and maintain a balance between incentivizing companies to innovate and making sure those innovations serve the American people.”

Draft Framework

1. Does the Bayh-Dole Act apply?
2. Is a statutory criterion (35 USC 203(a)) met?
3. Would march-in support the policy and objectives of the Bayh-Dole Act?

“Product is commercialized, but the **price** or other terms at which the product is currently offered to the public are **not reasonable**”

32 USC 203(a)(1)

Has **not taken... effective steps to achieve practical application**

“At **what price and on what terms** has the product... been sold... in the U.S.?”

“Has the contractor... made the product **available only to a narrow set of consumers ...because of high pricing**..?”

Has the contractor...provided any **justification for the product’s price** or... any extenuating factors **which might be unreasonably limiting availability**?”

32 USC 203(a)(2)

Action necessary to...
alleviate health or safety needs

“Is the contractor...**exploiting a health or safety need**... to set a product price that is **extreme and unjustified**?”

“...a **sudden, steep price increase** in response to a disaster... **putting people’s health at risk**?”

“[T]he initial price may also be considered if it appears that the price is **extreme, unjustified, and exploitative of a health or safety need**.”

- “**Agencies may need to further assess** whether march-in is warranted” and ask “**Would march-in have an impact on U.S. competitiveness and innovation**?”
- “If **only one of several patents** necessary to produce a product is subject to march-in, that likely **weighs against march-in**.”

Is Pricing Grounds for March-In?

- In 1979, **GAO reported**: “DOE said that march-in rights... were developed to... address... contractor windfall profits... **[S]uch problems are illusionary and not actual.**” and “NASA has **not enforced** its “march-in“ rights...”
- In 1995, **NIH** struck a controversial “**reasonable pricing**” CRADA clause as “a **restraint on the new product development** that [is] an important return on [public] research investment” - unacceptably “at **the expense of a more open research environment and more vigorous scientific collaborations.**”
- In 2002, **Senators Bayh and Dole** publicly affirmed in the *Washington Post* that “**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.”
- **NIST itself** in its 2021 proposed rule that “**[m]arch-in rights shall not be exercised exclusively based on... the pricing** of commercial goods and services”
- **NIH historically** - most recently in **March 2023** - has **refused to “march-in”** on grounds that marketing a prescription drug constitutes “practical application” under Bayh-Dole, and that pricing is addressed by other Federal laws and policies (1997, 2004, 2004, 2013, 2023).

Is Pricing Grounds for March-In?

- **AAU, APLU, AAMC, ACE, AUTM, and COGR:** “[The proposed framework] represents a **significant departure** from [how] federal agencies...assess whether to exercise march-in rights...The current criterion has existed for **more than 40 years** ...and these proposed changes will have **significant impact** on...the technology transfer process.”
- **AUTM:** “This policy will create **significant uncertainty** in licensing federally funded inventions.”
- **Bayh-Dole Coalition:** “[The proposed framework] **casts a shadow of uncertainty over America’s innovation system.**”
- **BIO:** “Using the Bayh-Dole Act’s march-in process as a mechanism to control prices is a **dangerous precedent to set.** The move would create **yet another element of uncertainty** within the biotech industry.”
- **CSIS Renewing American Innovation project’s** Sujai Shivakumar and Thomas Howell: “[T]he **harm** that this policy will inflict on a pillar of the nation’s innovation system **will be substantial.**
- **PhRMA:** “Misuse of march-in rights would **chill innovation** and **undermine collaboration** between the public and private sectors, which could return us to the pre-Bayh-Dole era...”