

University of Trento School of Law
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*University Tech-Transfer and Patenting
Strategies: The American Experience*

Craig A. Nard
Galen J. Roush Professor of Law
Director, Spangenberg Center for Law, Technology & the Arts
Case Western Reserve University
Cleveland, Ohio U.S.A



UNIVERSITÀ DEGLI STUDI DI TRENTO
Facoltà di Giurisprudenza



SCHOOL OF LAW
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University Technology Transfer

What is Technology Transfer?

- Technology transfer is the process by which technology or knowledge developed in one place or for one purpose is applied and exploited in another place for some other purpose.
- Translational research** involves moving knowledge and discovery gained from the basic sciences to its application in clinical and community settings - “bench-to-bedside”
- But also, **economic development**, start-ups, local investment, job creation, etc.

Some History - Prior to 1980

- The title (ownership) to any invention created using federal funding was owned by the U.S. Government
- No uniform policy among federal agencies for the transfer of the invention into private sector commercialization
- Government controlled the patents
 - Would only grant non-exclusive licenses
 - Only **5%** of patents were used by industry

The Bayh-Dole Act – 12 Dec 1980



Keystone/Getty Images



MPI/Getty Images

US Senators Birch Bayh, left, and Bob Dole, who sponsored a small amendment (P.L.96-517) to the Patent and Trademark Act in January 1980. Little did they know how important their act would be for the growth of the fledgling biotech industry.

What did the Act do?

- Created uniform federal intellectual property policy
- Universities and small business could elect title to inventions that were created in whole or in part with federal funding
- Prompted universities to set up “technology-transfer” departments

THE TOP 10 WORLDWIDE UNIVERSITIES GRANTED US UTILITIES PATENTS 2014

Rank	University	Patents
1	University of California, The Regents Of	453
2	Massachusetts Institute of Technology	275
3	Tsinghua University	230

In 1980, a **total** of 394 patents issued to universities..... In 2014, nearly 4,900 patents issued to universities

8	John Hopkins University	140
9	Columbia University	119
10	University of Michigan	118

Source: Top 100 Worldwide Universities Granted US Utility Patents in 2014

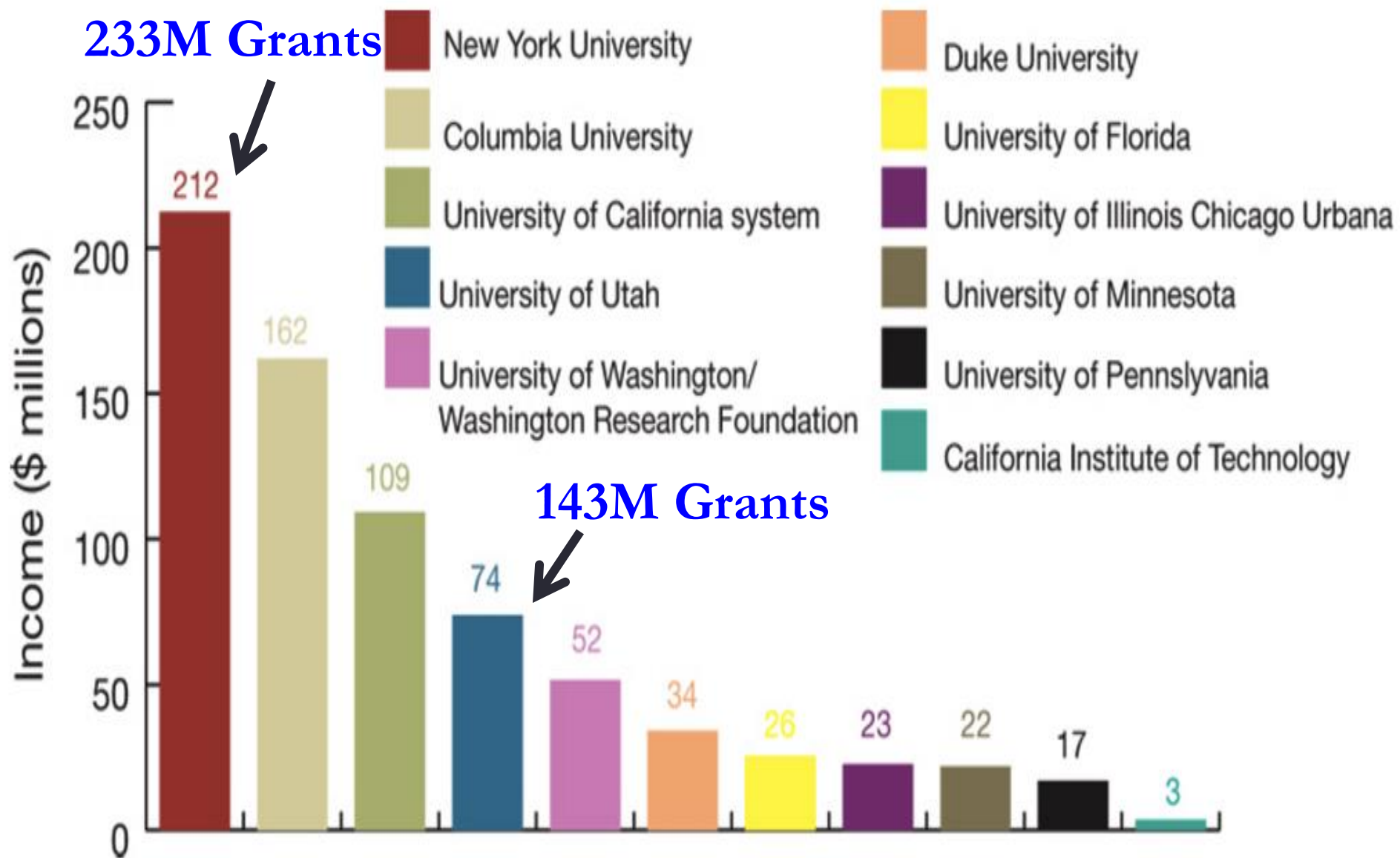
Top Grantee Research Universities

1. Univ of California System = 1.8B/4209 awards
2. Johns Hopkins Univ = 604M/1255
3. Univ. of Texas System = 600M/1558
4. Univ. of Pennsylvania = 458M/1095
5. Univ. of Michigan = 457M/1061
6. Univ. of Washington = 447M/901
7. Univ. of Pittsburgh = 437M/957
8. Univ. of North Carolina = 423M/1005
9. Stanford Univ. = 423M/928
10. Duke Univ. = 392M/759

13. Harvard Univ. = 362M/690
21. Case Western Reserve University = 255M/576
45. MIT = 100M/256

283. Univ. of Maine System = \$9,062/1

Life Science University Licensing Income - 2014



Obligations of Bayh-Dole

1. Establish and implement an employee invention reporting policy.
2. Report all subject inventions to the federal funding agency within 60 days after the inventor discloses the invention to the university.
3. Elect title (or waive title) within two years.
4. File for a patent within one year of electing title, or public disclosure, whichever comes first.
5. Provide a confirmatory license to the government.
6. Acknowledge federal government support in the patent application.
7. Notify the federal agency of any decision not to pursue patent rights (or licensing).
8. Submit an annual utilization report for all patented and licensed inventions.

Rise of University Technology-Transfer Offices

Welcome Case Western Reserve University Faculty and Students!

The mission of the Technology Transfer Office (TTO) is to assist and lead the successful commercialization of innovations created at CWRU. As steward of the intellectual property assets of CWRU, the TTO has resources to protect the rights of both the inventor and the university, and to assess the commercial potential of new discoveries. The TTO also seeks to educate the university faculty, staff and students and the regional community on issues such as intellectual property, standard licensing practices, and the formation of new ventures.

Our professional staff possesses a mix of business, technical, scientific, legal, and venture capital experience so that we can effectively and efficiently handle the wide variety of tasks for which our office is responsible. We take the job of protecting your discoveries very seriously, and to that end, we are always available to discuss your research with you and to offer advice or guidance on intellectual property issues or university policies. For a list of our policies please visit our policies section.

Disclosure of Invention to Federal Government

- Within 2 months after an inventor discloses an invention to the Tech Transfer Office, the institution is required to disclose the invention to the Federal Government
- Must include:
 - Grant # or Contract #
 - Invention detail
 - Inventor(s) names
 - Any publication, on sale or public use of invention

Election of Title

- Institutions must elect title in writing within 2 years of disclosure to the federal agency
 - Can be made at the time of disclosure
 - Sometimes done during preparation to file patent application
- Patent application must be filed within one year after election of title
- Failure to elect title or disclose the invention will result in university conveying title to government agency

Confirmatory License

- Gives the Federal Government royalty-free rights to the license for government use
- Confirmatory license must be submitted to the federal agency and is recorded in the Patent & Trademark Office (PTO)
- Not necessary for provisional applications

March-In Rights

- Federal Agency can exercise march-in rights if action is necessary:
 - Assignee has not taken, or is not expected to take within a reasonable time, steps to achieve practical application of the invention
 - To alleviate health or safety needs that have not been reasonably satisfied
 - To meet requirements for public use specified by Federal regulations that have not been reasonably satisfied
- To date no Federal Agency has exercised march-in rights
 - 4 Petitions to NIH all denied

Sharing of Royalties with Inventors

CWRU Intellectual Property Policy

When successful, university inventions create value through economic and societal utility and additionally provide economic return to CWRU, including its faculty inventors, schools and departments. In fact, CWRU shares 50% of the first \$100,000 of net income, and 42.5 % of all net income thereafter, to its creators - representing one of the most generous distribution policies in the United States; for further information, please review the CWRU Intellectual Property Policy.

- Case Western Reserve Univ. has a sliding scale for royalty distribution

Positive Effects of Bayh-Dole

The *Economist* claimed: “Possibly the most inspired piece of legislation to be enacted in America over the past half-century... More than anything, this single policy measure helped reverse America’s precipitous slide into industrial irrelevance.” *Economist Technology Quarterly*, Dec. 14, 2002.

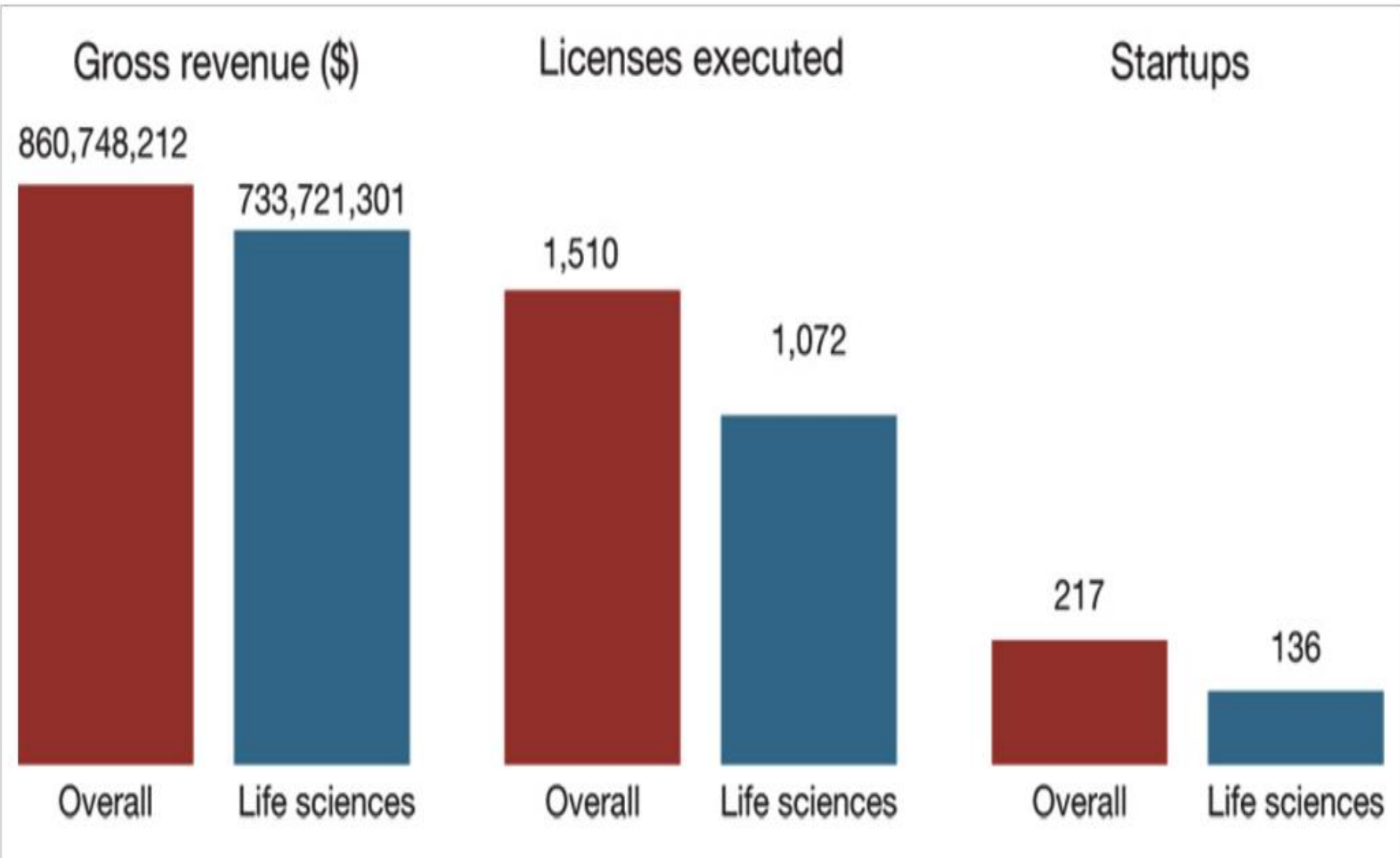
academic institution

Life Science 2014 Univ. Revenue, Licenses Executed & Start-Ups

University	Licenses and/or options executed	Gross licensing revenue received (\$)	Startups	NIH awards	NIH funding (\$)
Univ. of California System	223	109,253,453	52	4,134	1,780,390,316
Univ. of Washington/Wash. Res. Fdn.	222	51,547,500	13	933	427,465,936
Duke Univ.	124	34,117,861	4	730	350,742,239
Univ. of Minnesota	119	21,900,000	9	550	248,295,819
Univ. of Pennsylvania	103	17,000,000	11	1,106	484,421,830
Univ. of Utah	71	73,770,453	12	381	145,539,936
Columbia Univ.	68	162,000,000	12	874	351,353,417
Univ. of Illinois Chicago Urbana	49	22,630,000	5	314	114,689,235
New York Univ.	42	212,317,461	5	593	301,329,508
Univ. of Florida	31	25,699,314	6	313	129,743,178
California Inst. of Technology	20	3,485,259	7	138	63,082,330

*MIT, Stanford, University of Wisconsin-Madison, and the University of Texas system also ranked highly in gross licensing revenue, but could not provide information specific to life sciences. Source: AUTM, University tech transfer offices, NIH.

Life Science 2014 Accounted for a Majority of Revenue

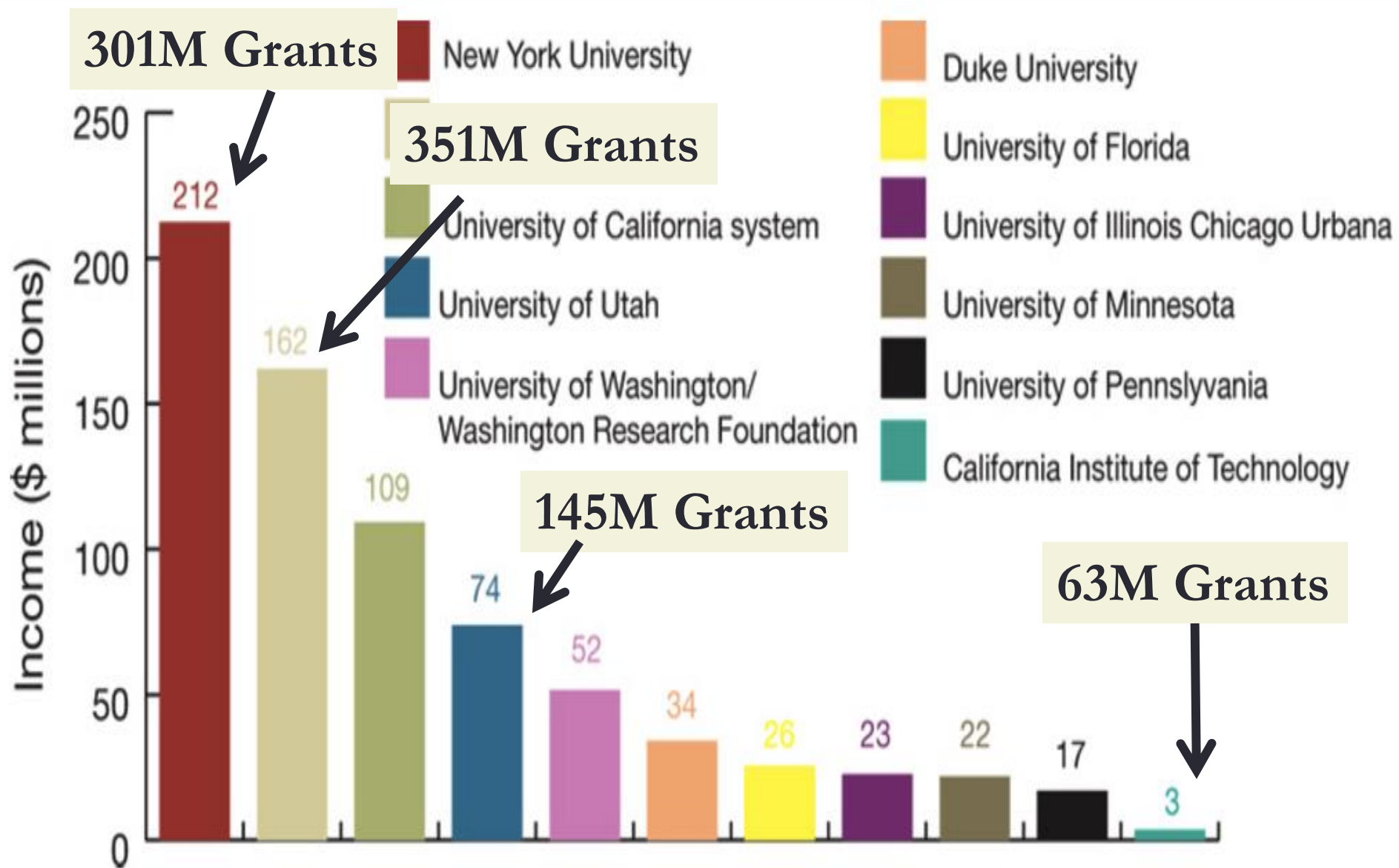


Reservation Clause: “Nothing in this Agreement will be deemed to limit the right of The Regents (the University)...to make and use the Invention ... and associated technology and allow other

The NIH addressed this issue with guidelines for preserving access to research tools. These guidelines suggest that research tools developed under NIH funding be licensed nonexclusively and made widely available.

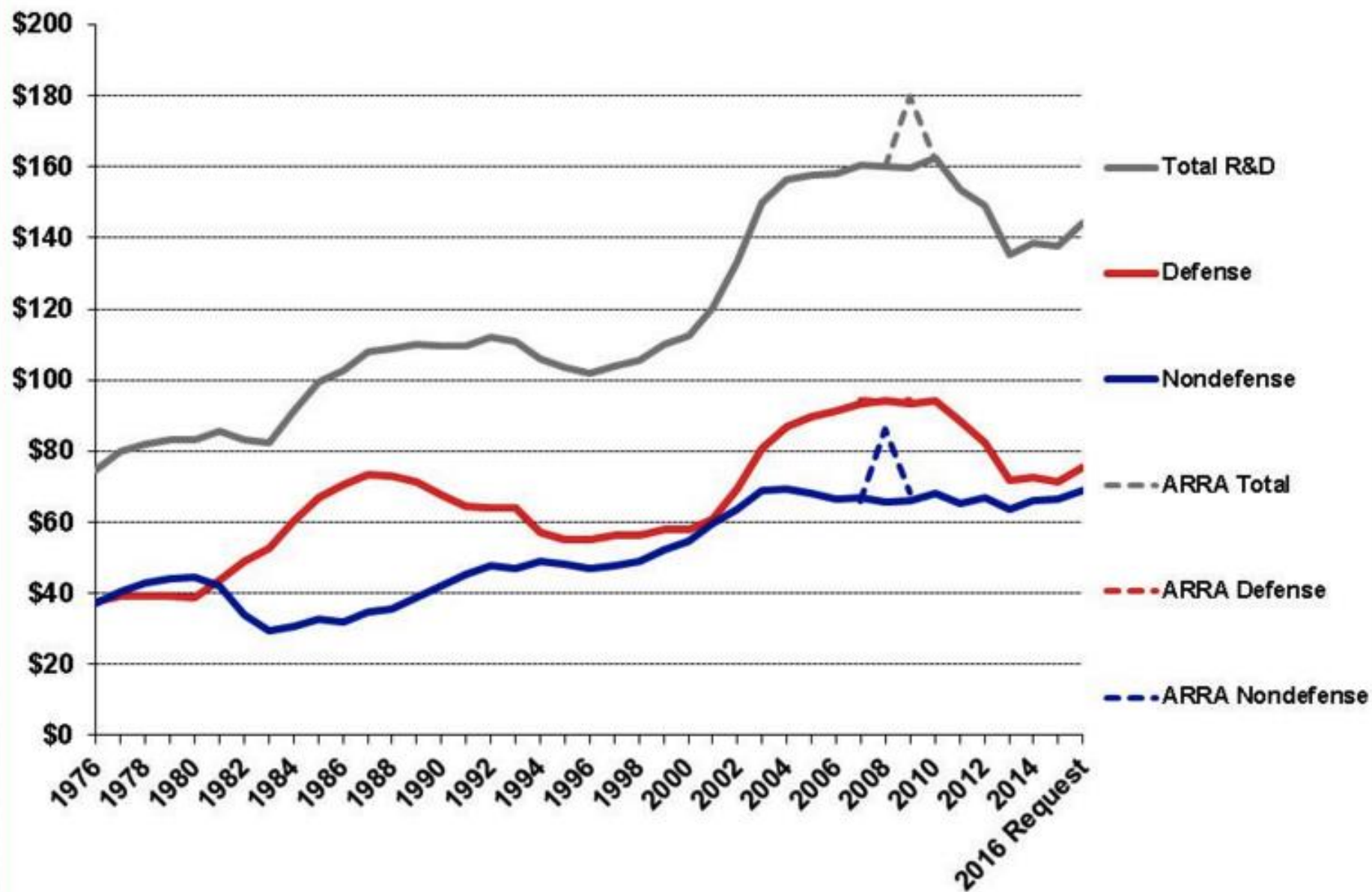
- Not worth the investment

Life Science University Licensing Income - 2014



Trends in Federal R&D, FY 1976-2016

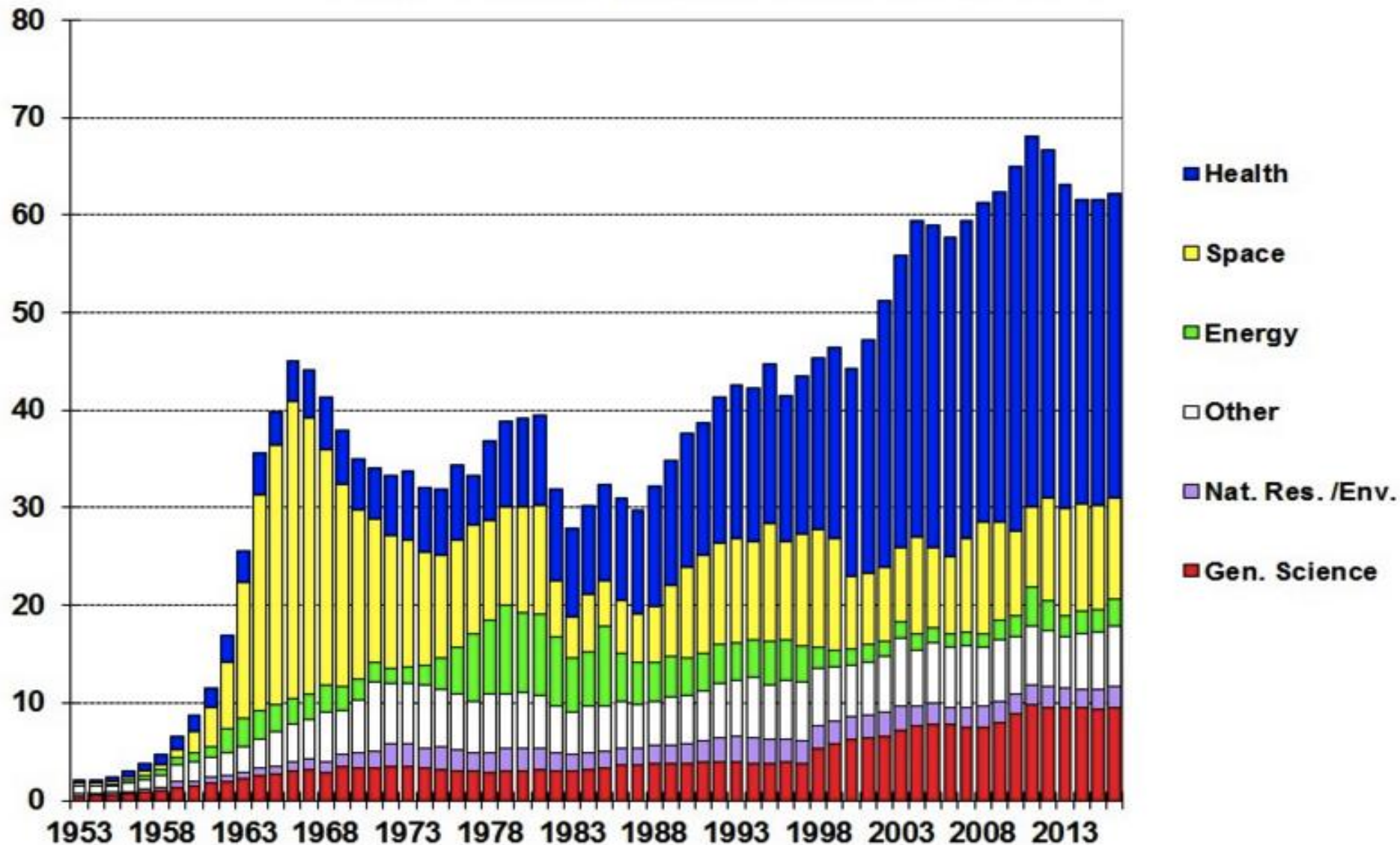
in billions of constant FY 2015 dollars



Source: AAAS analyses of historical budget and agency data. FY 2016 is the President's request. R&D includes conduct and facilities. © 2015 AAAS

Trends in Nondefense R&D by Function

outlays for the conduct of R&D, billions of constant FY 2015 dollars

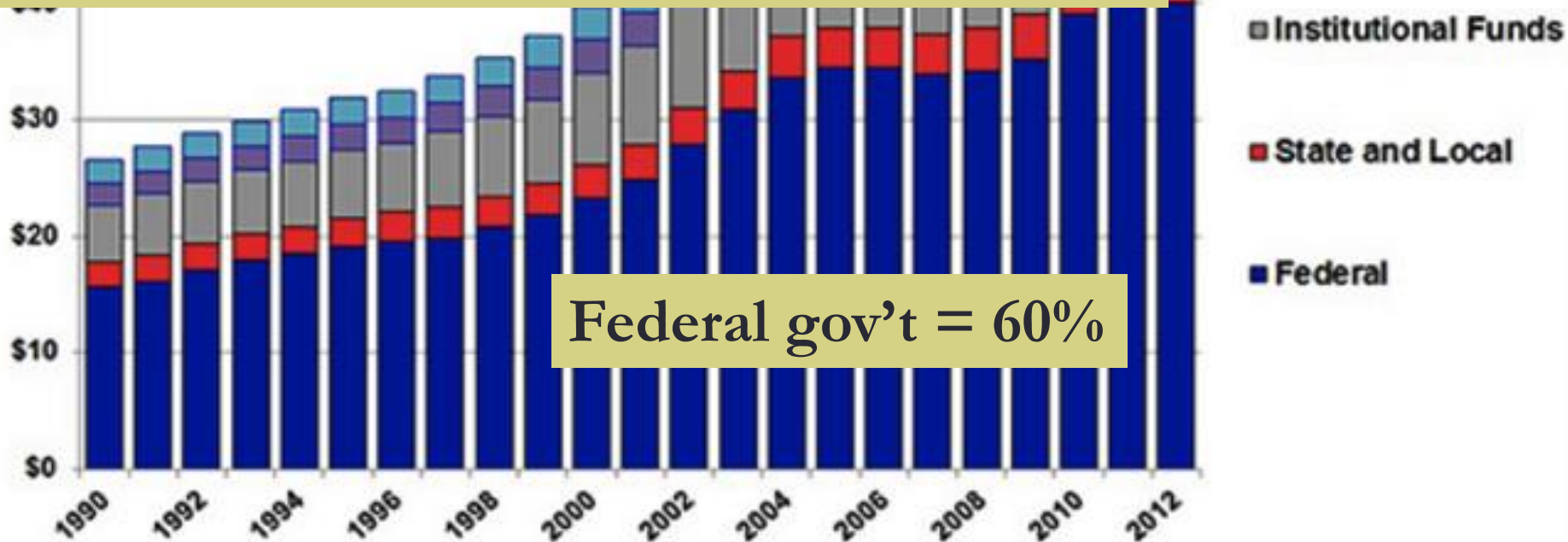


Source: AAAS, based on OMB Historical Tables in *Budget of the United States Government FY 2016*. Some Energy program shifted to General Science beginning in FY 1998. © 2015 AAAS

University R&D Funding by Source

expenditures in billions, FY 2014 dollars

1. Life Sciences (medical/bio/agri) = 57%
2. Engineering (EE, ME, Civil) = 15%
3. Physical Sciences (physics/chem) = 7.2%
4. Environmental Science = 4.6%
5. Social Sciences = 3.1%



Federal gov't = 60%

-3,200 members represent managers of intellectual property from more than 300 universities, research institutions and teaching hospitals around the world as well as numerous businesses and government organizations

Association of University Technology Managers®
Advancing Discoveries for a Better World®

Patenting Strategies in the U.S.

Understanding the New Novelty Provisions

Novelty - Section 102(a)(1)

(a) NOVELTY; PRIOR ART.--A person shall be entitled to a patent unless--

(1) the claimed invention was **patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date** of the claimed invention...

Prior Art Events: “Disclosures”

Critical Date

Prior Art Activity that is Patent Defeating

Your invention was:

1. Patented;
2. Described in a printed publication;
3. In public use;
4. On sale;
5. Otherwise available to the public

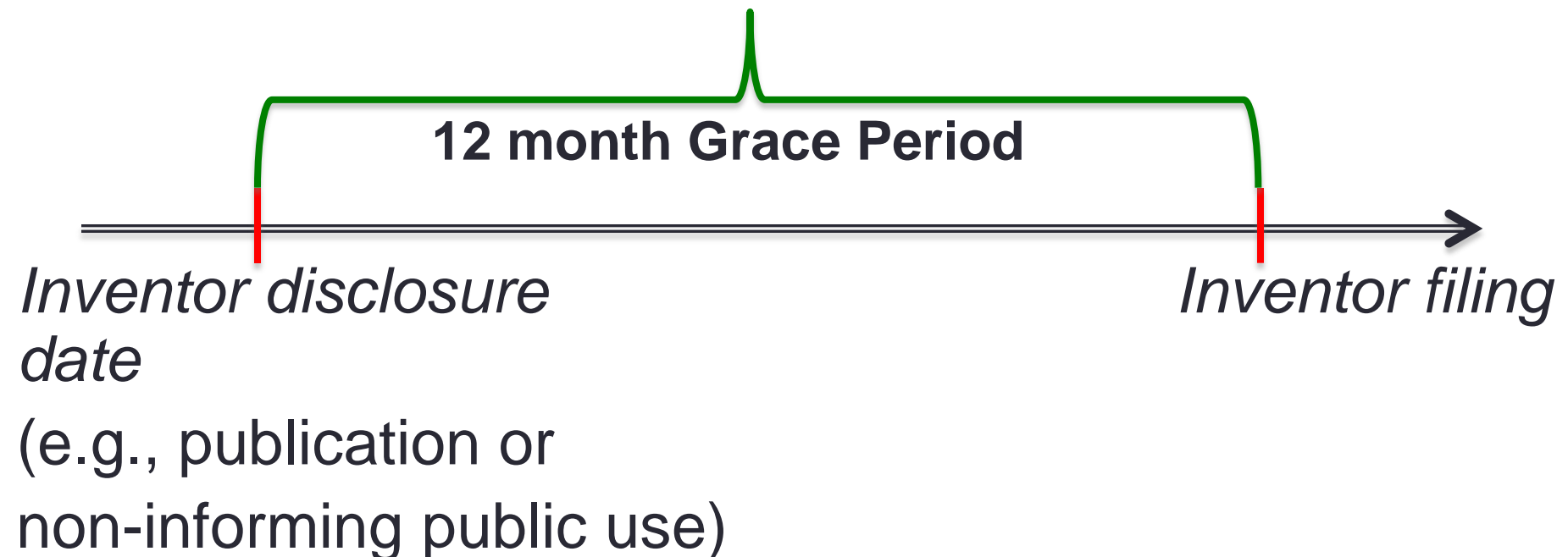
When? Before the effective filing date of
your patent application

Section 102(b) - Exceptions

(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.--A **disclosure** made **1 year or less before the effective filing date** of a claimed invention shall **not** be prior art to the claimed invention under subsection (a)(1) if—

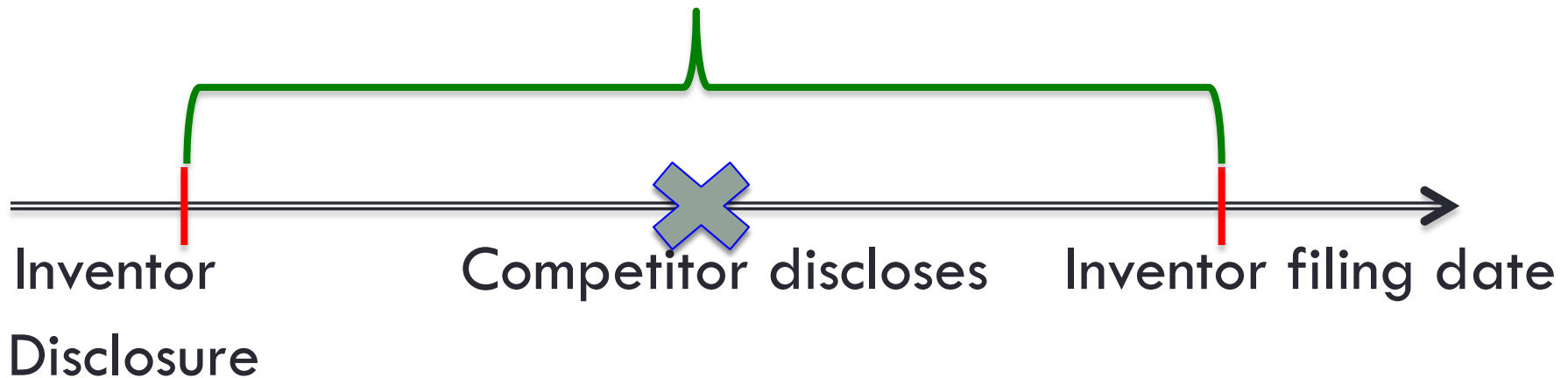
- (A) the **disclosure** was made by the **inventor** or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- (B) the subject matter disclosed had, **before such disclosure**, been **publicly disclosed by the inventor** or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

1. Exception One: Inventor files within 12 months of his own disclosure; no intervening competitor disclosure



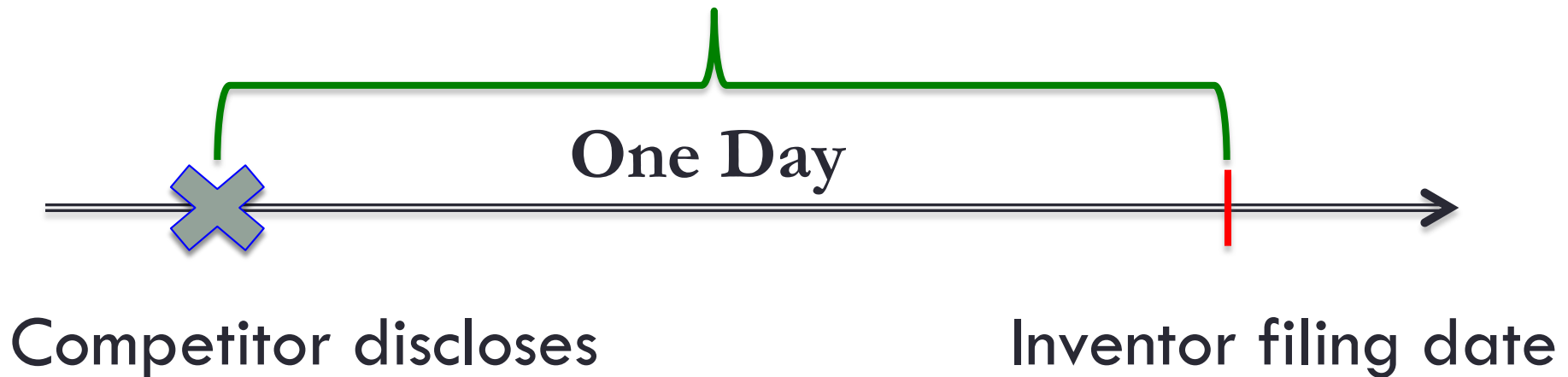
2. **Exception Two:** Inventor **publicly** discloses prior to a third-party disclosure and files within 12 months of Inventor's public disclosure

12 Month Grace Period



Absolute Novelty Scenario

Inventor discloses or files **after** a third-party disclosure



102(b) - Important Points

- 1. Absolute novelty attaches if third party publicly discloses claimed invention **prior** to inventor disclosing or filing patent application. Compare Art. 54 EPC. This is new to U.S.
- 2. But grace period triggered if:
 - A. Inventor discloses and files application within one year from his disclosure (same as old 1952 grace period in sec. 102(b)); OR
 - B. Inventor discloses **prior** to third-party public disclosure or filing of patent app AND Inventor files patent app within one year from Inventor disclosure

Response: File a provisional patent application to buy time, and perhaps a non-provisional within 12 months of provisional to buy more time and preserve trade secrecy

A provisional patent application allows you to file without a formal patent claim, oath or declaration, or any information disclosure (prior art) statement.

Questions