

Technology Transfer: United States Policy and Laws



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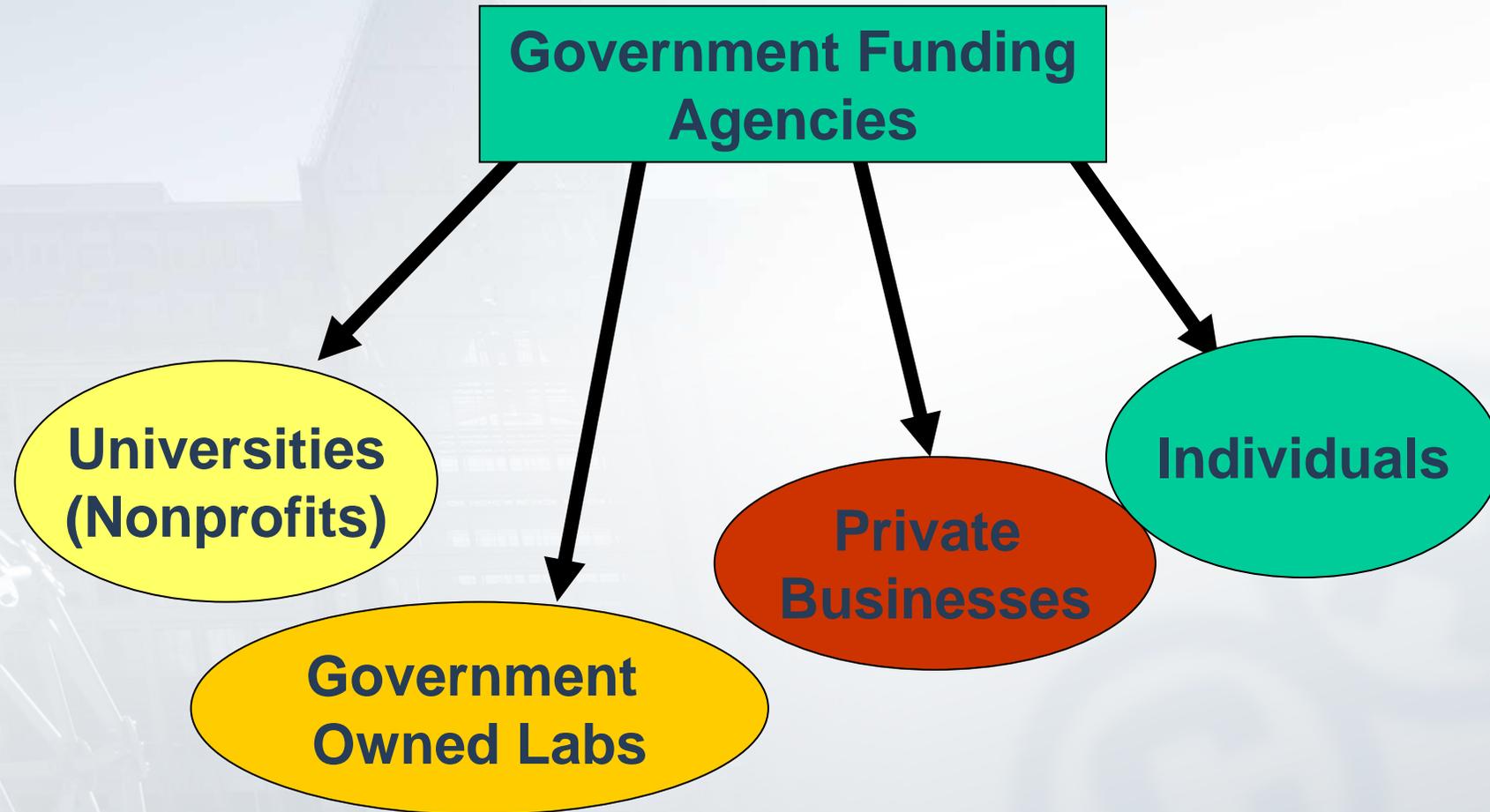


TOPICS:

- Policy Before and After 1980
- Technology Transfer Laws in the US
- Technology Transfer in Universities
- Federal Technology Transfer
- Keys to Successful Technology Transfer



Government Research Funding



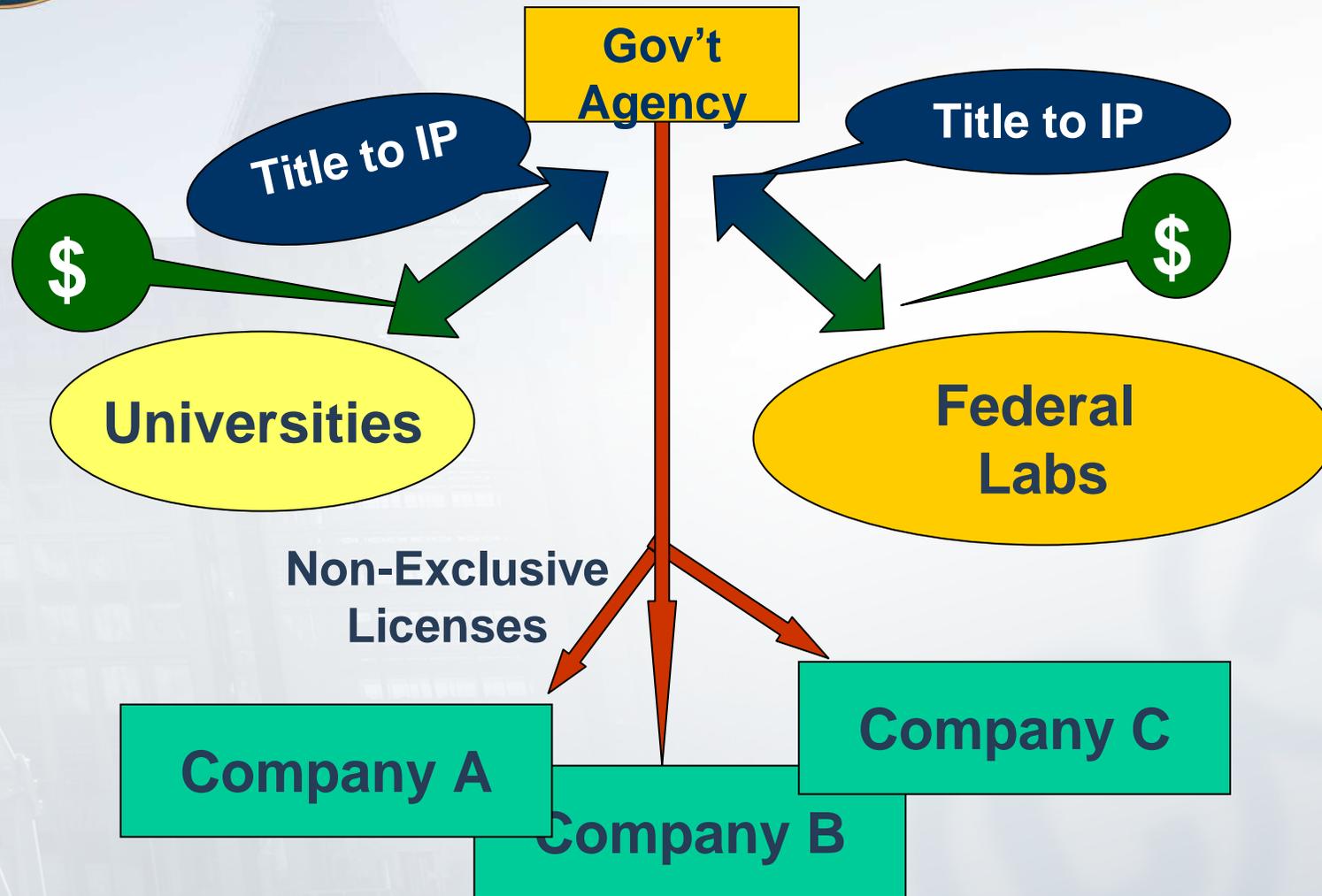


Policy in the United States Before 1980

- Federal Government retained ownership of patent rights in gov't funded projects
- Only non-exclusive license available
- Rationale:
 - Public tax dollars paid for the invention; it should therefore be available for anyone to use



Policy in the United States Before 1980





Results of U.S. Policy Before 1980

- Many printed publications
- Little conversion into products
 - In 1980, the government held title to approximately 28,000 patents
 - Fewer than 5% had been licensed
 - Few of those licenses related to commercial products



Results of U.S. Policy Before 1980

- Companies could not obtain exclusive rights
 - Companies were reluctant to invest in developing new products and markets; competitors could later acquire licenses and then manufacture and sell the same products
- Taxpayers did not benefit from
 - commercialization through creation of new, useful products or
 - the economic activity (jobs) resulting from the manufacture and sale of these products.
- Congress was concerned about competitiveness in the global economy



TT POLICY CHANGED IN 1980

- Policy Goals:
 - Promote economic development
 - Enhance U.S. competitiveness through innovation
 - Benefit public by encouraging commercialization of technologies that would otherwise not be developed into products due to lack of incentives



Laws Enacted to Achieve Policy Goals

- **Bayh-Dole Act of 1980**
 - University and Small Business Patent Procedures Act
 - sponsored by two senators, Birch Bayh of Indiana and Bob Dole of Kansas
 - Codified in 35 U.S.C. § 200-212
- **Stevenson-Wydler Technology Innovation Act of 1980**
 - Requires federal laboratories to have a formal technology transfer program and actively seek opportunities to transfer technology to industry, universities, and state and local governments
 - Federal Technology Transfer Act of 1986 (FTTA)
 - Makes tech transfer a responsibility of every federal laboratory scientist and engineer
 - The National Competitiveness Technology Transfer Act of 1989
- **Executive Order 12591 “Facilitating Access to Science and Technology”, April 10, 1987**
 - Implements royalty-sharing programs with inventors who were employees of the agency, and cash award programs
 - Provides incentive to gov’t employees to innovate



Technology Transfer in Universities



CHARACTERISTICS OF INVENTIONS by Universities

- Commercial potential usually unknown
- Licensed inventions are far from being products that generate revenue (in conceptual stage)
 - 12% of licensed technologies were ready for commercial use at time of license
 - over 75% of inventions licensed were no more than proof of concepts (no prototype available or only lab scale prototype at the time of license)



CHARACTERISTICS OF INVENTIONS by Universities

- To develop University Innovations into Products:
 - Significant additional expenditures required for product development
 - Successful commercialization often requires cooperation and involvement by inventor and licensee



U.S. University Technology Transfer in General

- Technology transfer by U.S. universities has long history
- Morrill Act of 1862 created “land grant” colleges, that were directed to apply technological developments to enhance U.S. agriculture
- Tech transfer also occurs through other means i.e. employment of students by companies, conferences and publications by researchers, **which remain primary means for academic institutions and investigators**
- Term “technology transfer” today usually refers to licensing of discoveries by a university to a for-profit company for further development into commercial products



University Tech Transfer Goals

- Disseminate new and useful knowledge resulting from university research where further development is required (usually through use of the patent system)
- Promote practical application of university inventions (with milestones included in licensing terms to ensure due diligence)
- Assist states and geographic regions in economic development
- Provide revenue to support further research and education



US Laws: Bayh-Dole Act

- Enacted in 1980
- Universities own new discoveries (patentable matter) with certain conditions
- Prior to enactment, had to petition to the funding agency for ownership
 - Many important new discoveries passed into the public domain and consequently had no commercial value



US Laws: Bayh-Dole Critical Elements

- Non-profits, including universities, and small businesses may elect to retain title to innovations developed under federally-funded research programs
- Universities are encouraged to collaborate with commercial entities to promote the utilization of inventions arising from federal funding
- University must share commercialization revenues with inventors
- Universities are expected to file patents on inventions they elect to own
- Universities are expected to give licensing preference to small businesses
- The government retains a non-exclusive license to practice the patent throughout the world
- The government retains march-in rights (the funding agency may demand full rights back)
- University must report back on progress to the funding agency



Bayh-Dole Results

Prior to 1980	FY2005
<ul style="list-style-type: none">• Universities received ~250 patents per year	<ul style="list-style-type: none">• Universities received > 3000 patents
<ul style="list-style-type: none">• ~24 Universities engaged in technology transfer	<ul style="list-style-type: none">• ~ 200 Universities engaged in technology transfer



Bayh-Dole Results (Continued)

licensing of innovations by U.S. universities and other non-profits

- **By 2000:**
 - added about \$40 billion to the U.S. economy
 - supported about 260,000 jobs
- **2005:**
 - 527 new products introduced into the market (3,641 introduced from 1998 through 2005)
 - 628 new spin-offs created (5,171 since 1980)
 - 28,349 current, active licenses (each single license represents a one-on-one relationship between a company and a university)
 - 4,932 new licenses signed in 2005

Source: <http://www.autm.net>



Highlights from the *AUTM U.S. Licensing Activity Survey Summary*

FY2008

- 648 new commercial products introduced
- 5,039 total license and options executed
- 595 new companies formed
- about 72 percent of new companies formed with the primary place of business in the institution's home state
- 3,381 startup companies still operating as of the end of FY2008
- \$51.47 billion total sponsored research expenditures

<http://www.autm.net>



Example

- In year 2008, Purdue Research Foundation reported 227 invention disclosures, 24 issued patents, and royalty income at \$3.4 million. The foundation also reported the creation of ten startup companies 2008.



Example

MIT has over 1,500 issued U.S. patents in its portfolio, and has signed between 60 and 100 option and license agreements in each of the past five years. This success can be attributed to factors including:

- the wealth of technology generated by MIT researchers
- application of clear licensing policies and streamlined procedures
- enthusiastic support from MIT administrators committed to technology transfer
- a technically trained, industrially-experienced licensing staff



Bayh-Dole Results (Continued)

- **Technologies developed under the Bayh-Dole Act:**
 - Synthetic penicillin
 - Hepatitis B vaccine
 - Citracal calcium supplement
 - Cisplatin and carboplatin (cancer therapeutics)
 - Human growth hormones
 - Treatment for Crohn's disease
 - Avian Flu vaccine
 - Clean water technologies



Federal Technology Transfer in the US



Stevenson-Wydler Technology Innovation Act of 1980

Technology Transfer is a mission of the Federal Government

- Inventions by Federal laboratories
- Federal laboratories must actively seek opportunities to transfer technology to industry, universities, and state and local governments
- Preference be given to industrial partners that agreed to manufacture in the United States.



Federal Technology Transfer Act (FTTA) of 1986

Technology transfer is a priority for Government Owned Government Operated (GOGO) Laboratories employees.

Technology Transfer Activities:

<ul style="list-style-type: none">• Technical assistance	<ul style="list-style-type: none">• Educational partnerships
<ul style="list-style-type: none">• Grants	<ul style="list-style-type: none">• Cooperative agreements
<ul style="list-style-type: none">• Patent licenses	<ul style="list-style-type: none">• Cooperative Research and Development Agreements (CRADAs)



EXECUTIVE ORDER 12591, 1987

“Facilitating Access to Science and Technology

- promote the commercialization
- grant to all contractors, the title to patents, in exchange for royalty-free use by or on behalf of the government
- implement royalty-sharing programs and cash award programs with inventors who were government employees



The National Competitiveness Technology Transfer Act , 1989

- Technology transfer a mission of government-owned, contractor-operated (GOCO) laboratories and their employees.



Federal Technology Transfer

- Federal Laboratories continuously partner with non-Fed entities:
 - Industry organizations
 - Academia
 - Non-profit sector
 - State and local gov'ts
- Transform results of research into viable products, medical treatments, services
- Fed Agencies utilize a variety of authorities and agreements to evaluate, protect, transfer, and monitor the utilizations and commercialization of technologies developed by Fed Laboratories



Federal TT: benefits

- **Benefits of partnerships between Federal Laboratories and non-Fed entities:**
 - Economic growth thru development of new products and other innovations that reach the market
 - Domestic and Regional
 - Creating jobs
 - Manufacture and Marketing of new goods
 - Creating new businesses, especially small
 - Attracting and retaining talented scientists within the Fed Labs
 - Supporting further research by generating licensing revenue
 - Rewarding innovations by Fed inventors thru royalty sharing



Federal Agencies with Significant Fed Laboratory Operations and Technology Transfer Offices

- Department of Agriculture (USDA)
- Department of Commerce (DOC)
- Department of Defense (DoD)
- Department of Energy (DOE)
- Department of Health and Human Services (HHS)
- Department of Homeland Security (DHS)
- Department of the Interior (DOI)
- Department of Transportation (DOT)
- Department of Veterans Affairs (VA)
- Environmental Protection Agency (EPA)
- National Aeronautics and Space Administration (NASA)



TT Principles and Approach

- Fed OTTs rely on the following principle mechanisms to facilitate the transfer of federally-developed technologies:
 - **Cooperative Research and Development**
 - **IP Management**



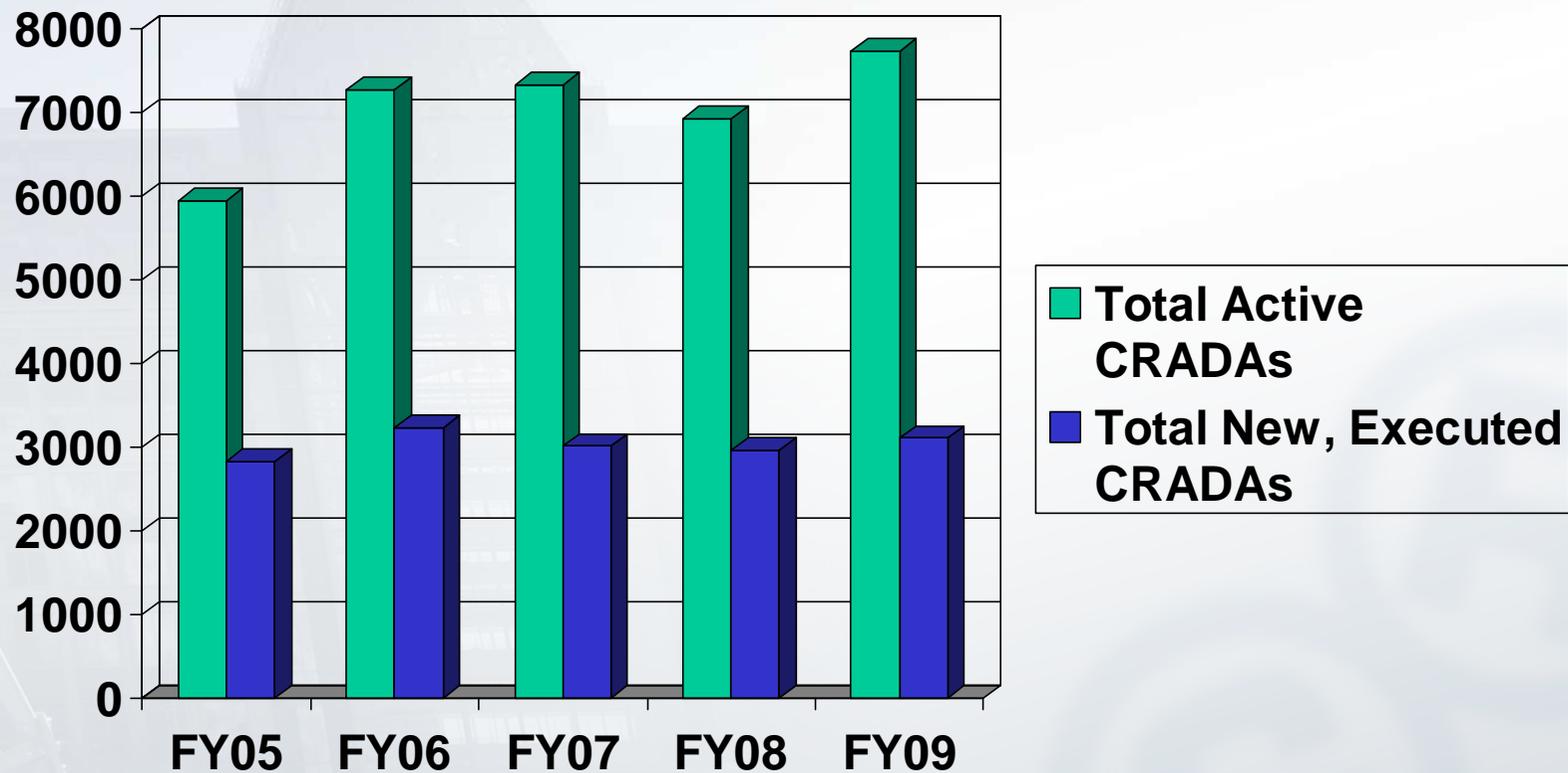
TT Principles and Approach: Cooperative R&D

– Cooperative Research and Development

- Fed labs + non-Fed collaborators
- Effective and economical means of TT and joint research
- Mutually advantageous leveraging of resources and technical capabilities; development of new skills
- Cooperative Research and Development Agreements (CRADAs) - one mechanism for establishing these joint relationships
 - Agreements between Fed Lab and one or more collaborators
 - To work together on a R&D project
 - Define scope of work



Total CRADAs: 2005-2009





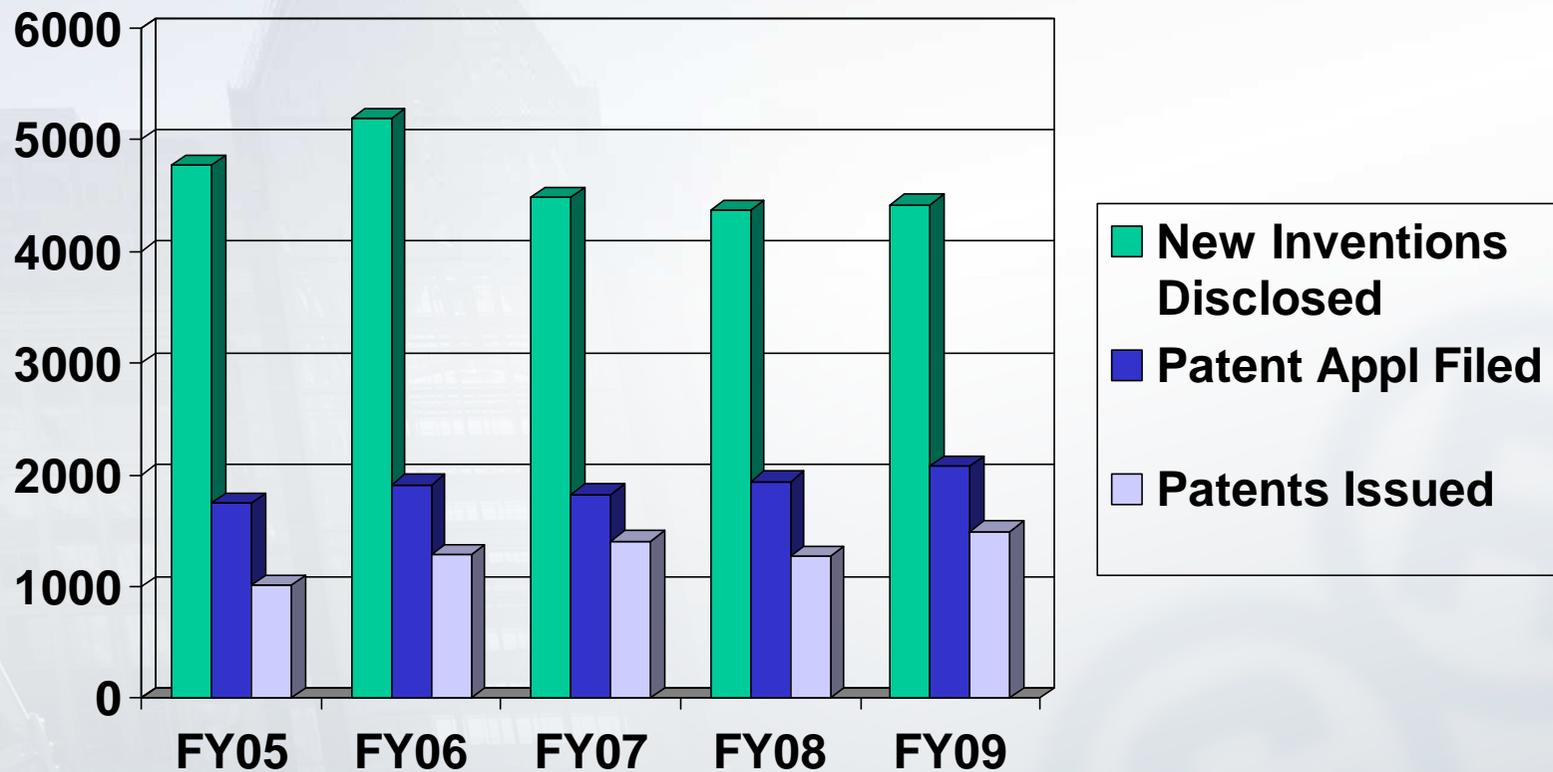
TT Principles and Approach: IP Management

– Intellectual Property Management

- Invention Disclosure and Patenting
 - IP protection is vital for attracting add'l investment and products development resources
- Licensing
 - One of the primary mechanisms to create incentives for industry to further develop and commercialize technologies
- Other Technology Transfer Mechanisms
 - Presentations at conferences, workshops
 - Utilization of guest researchers and facilities users
 - Outreach to trade and technical media
 - Technical publications and other reports
 - Development of Standard Reference Materials
 - Development of Standard Reference Data
 - Development of documentary standards
 - Material transfer licenses
 - Calibration services
 - Collaborative research agreements (e.g. MOU, Clinical Trial Agreements)



Invention Disclosure and Patenting





Performance Metrics

- Each Fed R&D Agency is required by statute to prepare and submit an annual report of its TT activities*
 - Details on TT program
 - Specific data to measure level of basic TT
 - Number of patents filed
 - Number of patents granted
 - Number of licenses
 - Earned royalty income
 - Number of licenses terminated for cause
 - Other relevant parameters unique to the agency

* 15 USC 3710(f)

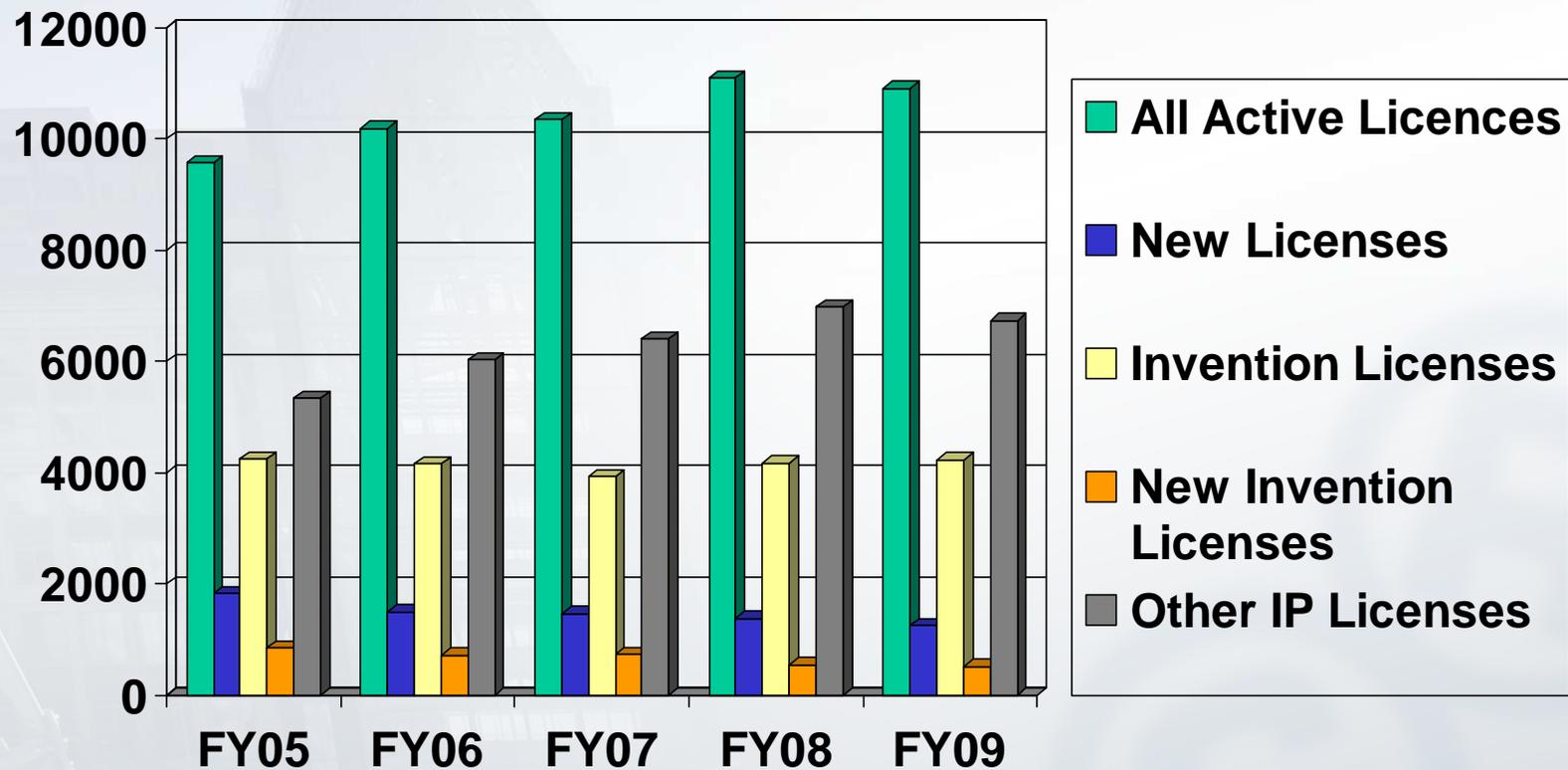


Performance Metrics (cont'd)

- How to measure effectiveness of TT and actual downstream benefits??
 - Federal Interagency Working Group on TT (IWGTT)
 - Regular meetings of TT experts from across the Fed Gov't
 - Forum to identify and discuss best practices, concerns and trends
 - New means to improve measurements of TT activities

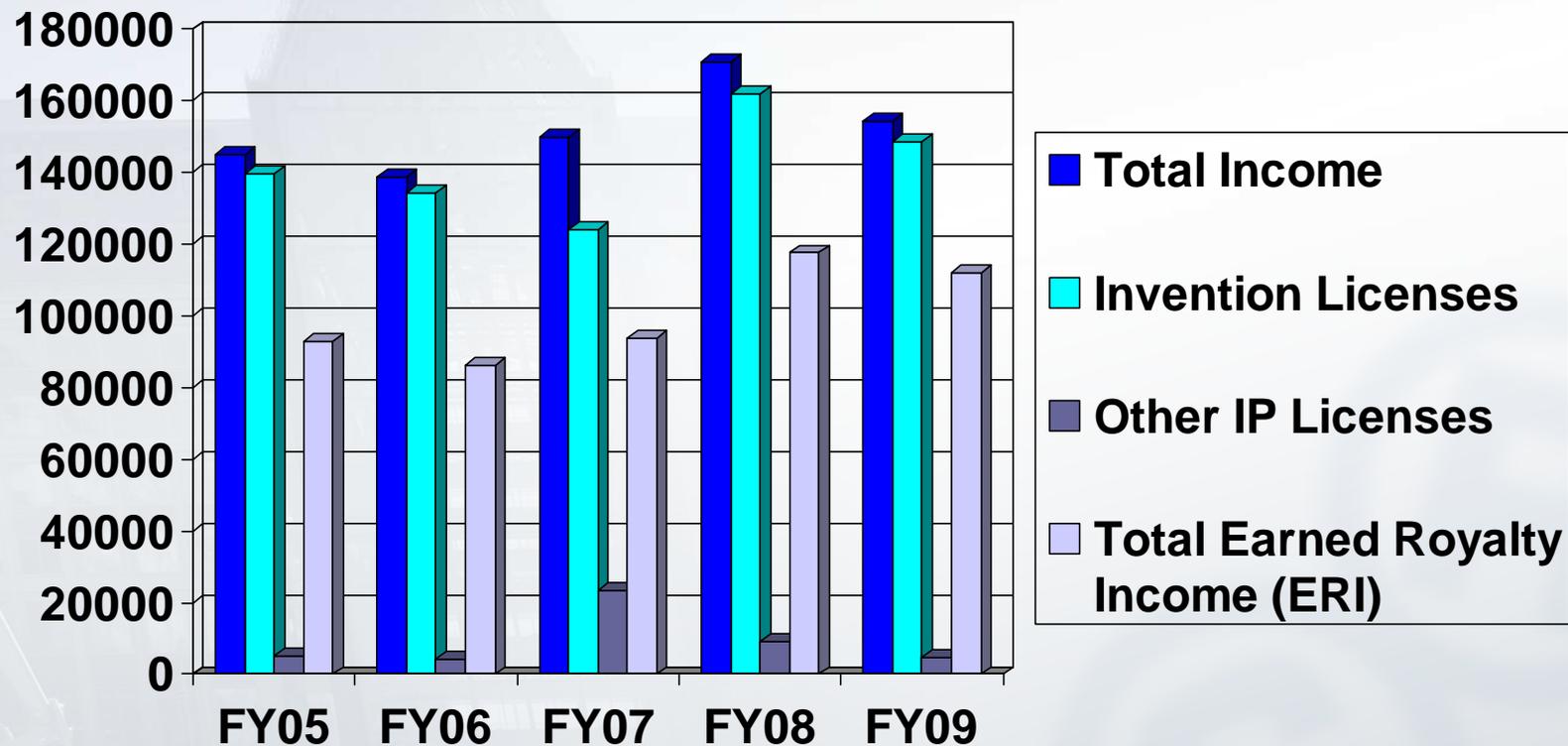


Profile of Active Licenses: 2005-2009





Total Income from Licensing (in thousands \$)





PATENTS

(11 agencies)*

	2005	2006	2007	2008	2009
New inventions disclosed	4,771	5,193	4,486	4,365	4,422
Patent applications filed	1,745	1,912	1,825	1,938	2,080
Patents issued	1,012	1,284	1,405	1,272	1,494

*DHS data only since FY 2008



Licenses

(11 agencies)*

	2005	2006	2007	2008
All active licenses	9,577	10,186	10,352	11,098
▫ New, executed	1,824	1,495	1,463	1,377
Active Invention licenses	4,236	4,163	3,935	4,172
▫ New, executed	838	711	728	544
Other Active IP licenses	5,341	6,023	6,405	6,972

*DHS data only since FY 2008



Income from Licensing

(11 agencies)*

Dollars reported in thousands

	2004	2005	2006	2007	2008
Total income	\$99,515	\$144,862	\$138,689	\$149,928	\$170,901
▪ Invention licenses	\$95,182	\$139,621	\$134,280	\$123,999	\$161,785
▪ Other IP licenses	\$4,334	\$5,241	\$4,409	\$23,367	\$9,116
Total Earned Royalty Income, (ERI)	\$53,114	\$92,823	\$86,348	\$93,951	\$117,644

*DHS data only since FY 2008

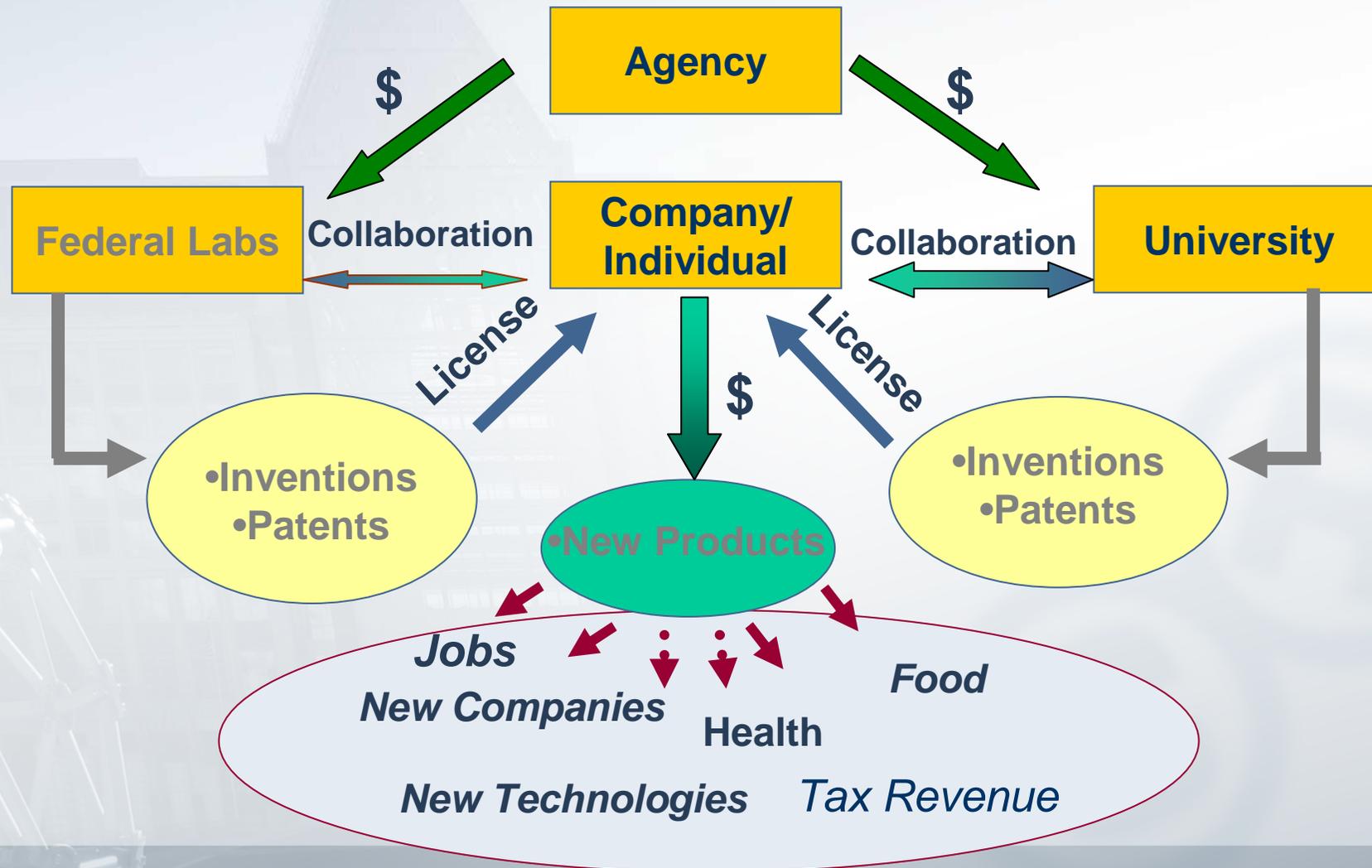


How are the royalty payments calculated (NIH)

- Inventors receive the first \$2,000 received from a licensee.
- Next, they receive 15 percent of royalties received above \$2,000 up to \$50,000.
- Finally, they receive 25 percent of royalties in excess of the first \$50,000 received each year.
- Each inventor cannot receive more than \$150,000 in royalty payments for a calendar year.



CURRENT U.S. POLICY EFFECTS





KEYS TO SUCCESSFUL IP ASSET MANAGEMENT AND TECHNOLOGY TRANSFER

- **Laws**
 - Promote public-private cooperation; provide incentive for innovation
- **Build infrastructure of people**
 - Research and development; business development; IP
- **Cultural assumptions**
 - Encourage innovation; market access
- **Resources**
 - Public and private funding
- **Institutions**
 - Universities; Government Labs; Business organizations

Questions?



Thank You!