

# **Innovation Promotion Through University-Industry Partnerships; Public-Private Sector Cooperation**



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**Intellectual Property Rights in Portugal:**

**The Gateway to Innovation**

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## TOPICS COVERED: IP AND U.S. GOVERNMENT FUNDED RESEARCH

- Who creates United States Government-funded IP?
- Policies followed in the past: why they didn't work
- Current policy: promoting collaboration
  - Bayh-Dole and other laws
  - Cooperative Research and Development Agreements (CRADAs)
  - National Institutes of Health (NIH)
- Keys to successful technology transfer



## Creators of Government Funded IP

- U.S. Government-owned Labs
  - e.g., National Institutes of Health (NIH)
- Universities/Non-Profits
- Private Businesses
- Individuals



## Policy in the United States Before 1980

- Federal Government retained ownership of patent rights and would not grant exclusive licenses; only non-exclusive available
- Rationale - Public tax dollars paid for the invention; it should therefore be freely available for anyone to use
- Many publications created but little conversion into products
- Companies could not obtain exclusive rights

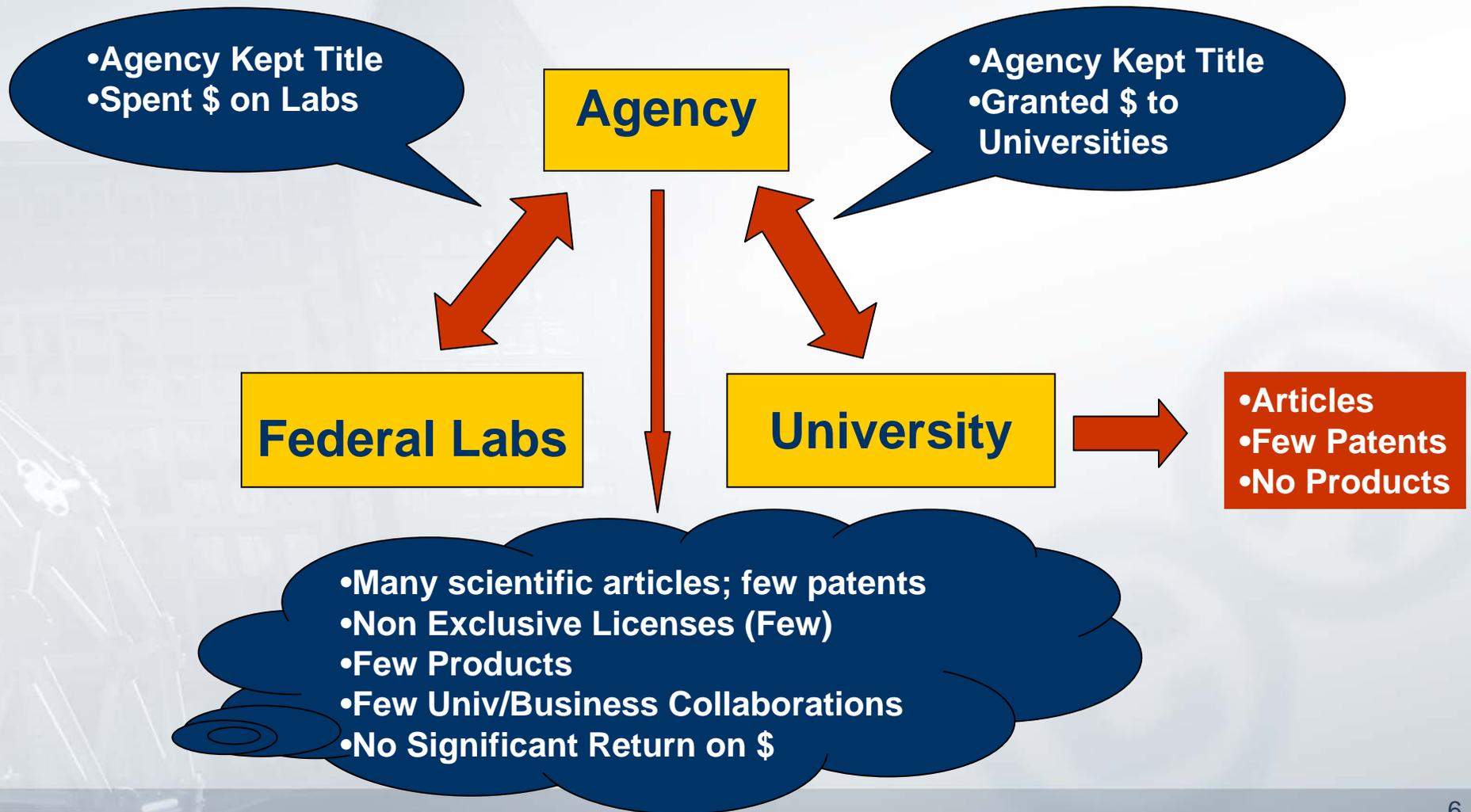


## Results of U.S. Policies Before 1980 (Continued)

- Taxpayers paid for federally funded research effort
- Taxpayers did not benefit from useful products or the economic activity (jobs) resulting from the manufacture and sale of these products.
- Congress was concerned about U.S. competitiveness in the global economy



## Pre- 1980 Policy Effects





## POLICY CHANGED IN 1980

- Policy Goals:
  - Promote economic development
  - Enhance U.S. competitiveness through innovation
  - Provide benefit to 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
- Stevenson-Wydler Technology Innovation Act of 1980
- Federal Technology Transfer Act of 1986 (FTTA)
- Executive Order 12591 “Facilitating Access to Science and Technology”, April 10, 1987
  - rights of Bayh-Dole extended to all government contractors



## HIGHLIGHTS OF BAYH-DOLE

- Universities may elect to retain title to invention; must file for patents on inventions they elect
- Encourage collaboration with industry
- Preference for small businesses
- Report patenting and use
- Government retains non-exclusive license and march-in rights (may require or grant license to a third party)
- Identify Government interest in patent text



## Bayh-Dole Results

- **Prior to 1980:** Fewer than 250 patents issued to Universities per year
- **Since 1993:** Universities have averaged more than 1,600 patents annually
- **Prior to 1980:** About 24 Universities engaged in technology transfer
- **By 2000:** About 200 Universities engaged in technology transfer based on AUTM membership



## Bayh-Dole Results (Continued)

- **By 2000:** Licensing of innovations by U.S. universities and other non-profits is estimated to have:
  - added about **\$40 billion** to the U.S. economy
  - supported about **260,000 jobs**
- **2004:** **3,680** patents issued to U.S. institutions; **4,800** new licenses or options executed; **462** new companies based on academic discovery began operations in North America; **3,114** new products introduced to the marketplace since 1998



## GOVERNMENT LABS: STEVENSON-WYDLER and FTTA

- Established basic federal technology policies applicable to inventions developed internally by federal laboratories
- Enabled federal agencies to execute license agreements with private entities that promote use, and commercialization of inventions
- Permitted royalties back to the government
- FTTA authorized federal agencies to enter into R&D Agreements (CRADA) with private parties



## Cooperative Research & Development Agreements (CRADAs)

- Created by FTTA in 1986; expanded in 1990 to include Government Operated and Owned Labs (GOGO)
- Cost-Shared collaborations between a Federal Lab and private company permitted
- Labs may accept and use funds, personnel, services, and property from collaborator



## CRADAs (Continued)

- Labs may provide personnel, services and property to collaborator; but may not provide \$\$
- Work under CRADA can occur at Federal Lab or collaborator's premises
- Decentralized decision making - Lab negotiates deal
- 5 year protection for confidential information arising from collaboration



## IP Under CRADAs

- Lab Director given authority to negotiate agreements for inventions “or other intellectual property”
- Collaborator has option to choose exclusive license for pre-negotiated field of use for any invention created under a CRADA
- Government is normally granted license in inventions made by collaborator in course of R&D under CRADA

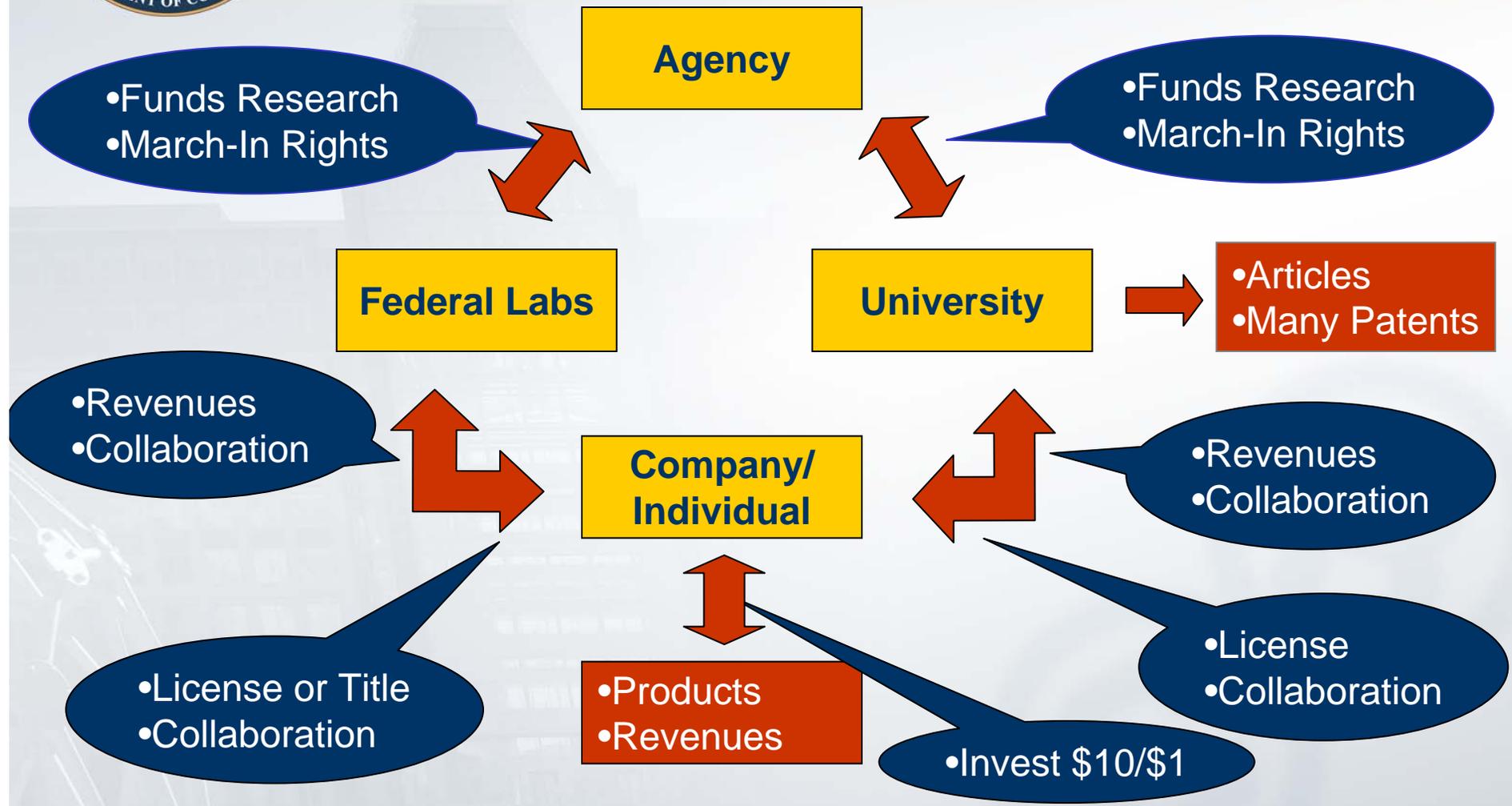


## IP Under CRADA's (Continued)

- Inventions developed at government labs by government scientists are owned by the relevant government agency



# Current U.S. Policy Effects





# Example

- U.S. National Park System Access Regime for Collection of Biological Specimens
  - Scientific Research and Collecting Permits
    - Conditions for access to research specimens
  - Cooperative Research and Development Agreements (CRADAs)
    - a benefit-sharing contractual agreement
      - Allocation of ownership of any inventions made



## A Way Forward on Genetic Resources and Traditional Knowledge

- Contract-Based System
  - May provide for benefit sharing
    - Monetary or non-monetary benefits
  - May contain regular reporting requirements
    - At regular intervals, as to uses
    - Reporting of any inventions derived from collected specimens
    - Reporting any commercial applications derived from the specimens, whether patented or not
  - May include “choice of law” provisions or dispute settlement procedures

(See IP/C/W/393 Communication from the United States in the Council for TRIPS, 28 January 2003)



## Example: NIH - An Agency With Federal Labs

- 2005 Annual Budget \$28 billion
  - \$22.9 billion supports non-Federal researchers in universities, medical centers, hospitals, and research institutes
  - \$2.7 billion is allocated to in-house research labs
- NIH has the most active and developed licensing program



## Technology Transfer Cooperation: Measures of Return on Investment

- New technologies extend life, improve quality of life
  - Bayh-Dole is credited with fostering biotechnology industry
- New technologies improve productivity
- Job creation
- Return to federal government from royalties
- Return to federal government from tax revenues



# H.Con.Res. 319

Concurrent Resolution introduced in the House of Representatives December 16, 2005

- Expresses the sense of the Congress regarding the successful and substantial contributions of the amendments to the patent and trademark laws commonly known as the **Bayh-Dole Act** on the occasion of the 25<sup>th</sup> anniversary of its enactment



# Keys to Successful Technology Transfer and Product Development

- **Laws**
- **Build infrastructure of people**
- **Cultural assumptions**
  - Encourage innovation; market access
- **Resources**
  - Funding, facilities
- **Institutions**



# USPTO /OIR Contact Info

**Thank You!**

**USPTO – [www.uspto.gov](http://www.uspto.gov)**

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