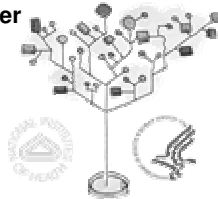


## Legislative Background for the US Government Tech Transfer Practices

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India  
February , 2006

## Technology Transfer

What Does This Mean?

- MOVEMENT OF INFORMATION, MATERIALS AND TECHNOLOGIES FROM RESEARCH LABORATORIES TO COMMERCIAL ENTERPRISES

## Why Tech Transfer Acts?

FIRST ACT IN 1980

### PURPOSE:

- ENHANCE U.S. COMPETITIVENESS IN GLOBAL ECONOMY
- SPUR ECONOMIC DEVELOPMENT
- BENEFIT THE PUBLIC – NEW INNOVATIVE PRODUCTS

## Historical Background

- 1980 THE STEVENSON WYDLER ACT. PL 96-480
- 1980 THE BAYH DOLE ACT. PL 96-517
- 1986 THE FEDERAL TECHNOLOGY TRANSFER ACT (FTTA)
- 1987 EXECUTIVE ORDER 12591.

*Subsequent amendments*

## The Bayh-Dole Act

The Bayh-Dole Act laid the foundation for Technology Transfer as we now know it

## The Bayh-Dole Act

“Possibly the most inspired piece of legislation to be enacted in America over the past half-century

*The Economist, December 2002*

*THE BAYH-DOLE ACT CELEBRATED ITS 25th ANNIVERSARY JUST 3 MONTHS AGO*

## The Bayh-Dole Act – Economic Impact

- IMPACT ON THE STIMULATION OF \$43-BILLION-A-YEAR BIOTECH INDUSTRY AND OTHER HIGH TECH INDUSTRIES
- RESPONSIBLE FOR THE CREATION OF HUNDREDS OF THOUSANDS OF JOBS. BILLIONS OF DOLLARS OF ECONOMIC IMPACT
- VITAL TO INNOVATION AND TO GETTING RESEARCH RESULTS TO THE PUBLIC. IMPACT ON SOCIETY'S WELL-BEING

## The Bayh-Dole Act

### Scope:

- *Rights and obligations of NIH grantees*
- *Patenting and Licensing of federally owned inventions*

## The Bayh-Dole Act

### 35 USC §200- §212

- §200 *Policy and objective*
- §201 *Definitions*
- §202 *Disposition of rights*
- §203 *March-in rights*
- §204 *Preference for United States Industry*
- §205 *Confidentiality*
- §206 *Uniform Clauses and regulations*
- §207 *Domestic and foreign protection of federally owned inventions*
- §208 *Regulations governing Federal licensing*
- §209 *Licensing federally owned inventions*
- §210 *Precedence of chapter*
- §211 *Relationship to antitrust law*
- §212 *Disposition of rights in educational awards*

### IMPLEMENTING REGULATIONS FOR BAYH DOLE:

#### CODE OF FEDERAL REGULATIONS – CFR

#### FOR 35USC §202- §204:

37 CFR 401 "Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts and cooperative agreements"

#### FOR 35USC §207- §209:

37 CFR 404 "Licensing of Government owned inventions"

## The Bayh-Dole Act – Policy and Objective

- TO USE THE PATENT SYSTEM TO PROMOTE THE UTILIZATION OF INVENTIONS
- TO PROMOTE COLLABORATION BETWEEN COMMERCIAL CONCERNS AND NONPROFIT ORGANIZATIONS
- TO PROMOTE THE COMMERCIALIZATION AND PUBLIC AVAILABILITY OF INVENTIONS
- TO ENSURE THAT THE GOVERNMENT OBTAINS SUFFICIENT RIGHTS IN FEDERALLY-SUPPORTED INVENTIONS

## The Bayh-Dole Act – Grantees Rights

- NIH GRANTEE MAY RETAIN TITLE TO INVENTIONS
- NIH GRANTEE MAY LICENSE THEIR INVENTIONS AND PROFIT FROM THEM

### The Bayh-Dole Act – Grantees Obligations

- FOLLOW REPORTING REQUIREMENTS
- NOTIFY FUNDING AGENCY OF A NEW INVENTION
- NOTIFY AGENCY OF INTENTION TO RETAIN TITLE
- FILING PATENT APPLICATION WHENEVER WARRANTED
- EFFORTS TO PROMOTE THE UTILIZATION (*LICENSING*)

### The Bayh-Dole Act – License Agreements by Grantees

- SHARE ROYALTIES WITH INVENTORS
- BALANCE TO SUPPORT SCIENTIFIC RESEARCH
- U.S. MANUFACTURING FOR SALES IN THE U.S.
- GOVERNMENT RIGHTS TO PRACTICE INVENTION

### The Bayh-Dole Act – Government’s Rights

- TAKE TITLE IN GRANTEE’S INVENTIONS IF GRANTEE DECLINES SUCH TITLE OR NEGLECTS FILING
- RIGHT TO REQUIRE FROM GRANTEE OR ITS LICENSEES PERIODIC REPORTING ON UTILIZATION
- MARCH-IN RIGHTS
  - *Right to require license to responsible applicant in specific field*
  - *Right of Government to grant license if grantee or its licensee decline*

### The Bayh-Dole Act – Government’s Rights

#### CIRCUMSTANCES WHEN MARCH-IN RIGHT MAY BE IMPLEMENTED:

- In extreme case of emergency (pandemic etc.)
- When licensee cannot meet public health needs

*Rights to object and appeal by licensees*

### The Bayh-Dole Act – Federally owned Inventions

- GRANT NONEXCLUSIVE, EXCLUSIVE OR PARTIALLY EXCLUSIVE LICENSES
- RIGHT OF ENFORCEMENT TO LICENSEE
- CONDITIONS FOR EXCLUSIVE OR PARTIALLY EXCLUSIVE LICENSE
  - *Investment capital required*
  - *capabilities and plans of applicant*
  - *not lessening competition*
- U.S. MANUFACTURING
- SMALL BUSINESS PREFERENCE

### The Bayh-Dole Act – Federally owned Inventions

- GOVERNMENT RIGHTS: PAID-UP LICENSE TO PRACTICE
- LICENSEE REPORTING REQUIREMENT ON PROGRESS
- CONDITIONS OF TERMINATION
- REQUIREMENT FOR PUBLIC NOTICE REGARDING INTENT TO GRANT EXCLUSIVE LICENSE
- REQUIREMENT OF DEVELOPMENT PLAN

## Bayh-Dole Act – Results

- 1980....25 Universities patent and license  
2005...350 Universities
- 1980....250 University patents  
2005...3680 University patents
- 1980....113 AUTM members (only US and Canada)  
2005...3200 AUTM members (45 countries)

## The Bayh-Dole Act- NIH Statistics

<u>Activity</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>
Invention disclosures	400	403	388
New U.S. patent applications filed	196	199	186
Total U.S. applications filed	382	396	347
Issued U.S. Patents	86	122	66
Executed licenses	209	276	313
Royalties (in millions)	53.7	56.3	98.2
Executed CRADAs (NIH only)	84	87	90
Standard	36	43	39
Material	48	44	41