



# WIPLA meeting

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**WARF**

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# The Bayh-Dole Act

- Patent and Trademarks Amendments Act of 1980, P.L. 96-517 as amended by the TM Clarification Act of 1984, P.L. 98620
- Codified at 35 U.S.C. 200-212.  
Regulations at 37 C.F.R. Part 401.

“Trying to plan for the future without a sense of the past is like trying to plant cut flowers.”

---Daniel Boorstin

Former Librarian of Congress

# Fundamental observations

- New scientific knowledge has intrinsic value \*
- Science provides a reservoir of knowledge that can be applied to national needs.\*
- Scientific progress is essential to national welfare.\*
- Invention without innovation has little economic value and will give little impetus to economic growth.

# The University-Industry Connection in the United States

- A recognition within government circles that basic research conducted by the university sector provided a vehicle for enhancing the national economy by increasing the flow of knowledge to be used by industry;
- The establishment and success of several research-oriented agencies of the Federal government, in particular the National Institutes of Health and the National Science Foundation, the formation of which was stimulated by that recognition;
- The ultimate passage of legislation which gave the universities the first option to retain title to inventions conceived or made during the course of research conducted by university personnel with funds obtained from the Federal government through its various agencies.

# The Bayh-Dole Act

- Primary Thrust:
  - Changed the presumption of title in and to any invention made in whole or in part with Federal funds from the government to the non-profit (including universities) and small business sectors.
  - Provided for a uniform government patent policy.
  - First statutory authorization for Federal agencies to apply for, obtain and maintain patents or other forms of protection on inventions in which the Federal Government owns a right, title or interest and to grant licenses under them. (35 U.S.C. 207)

# Bayh-Dole Objectives (35 U.S.C. 200)

- To use the patent system to promote the utilization of inventions arising from federally supported research and development;
- To encourage maximum participation of small business firms in federally supported research and development efforts;
- To promote collaboration between commercial concerns and non-profit organizations;

# Bayh-Dole Objectives cont'd.

- To promote free competition and enterprise;
- To promote commercialization and public availability of inventions made in the U.S. by U.S. industry and labor;
- To ensure government's rights in federally supported inventions are adequate to protect the public against non-use or unreasonable use of such inventions.

# Bayh-Dole Opportunities

1. Permits non-profit organization (universities) and small businesses (collectively contractors) to retain title to inventions made in whole or in part with federal funds. (35 U.S.C. 202)
2. Leaves with the contractor discretion as to licensing with preference for small business and U.S. industry (35 U.S.C. 201 (c)(7)(B).
3. Provides incentives to investigator-inventors through sharing of royalty income. (35 U.S.C. 201(c)(7)(B).
4. Provides the possibility for generating income to support research and educational activities.

35 U.S.C. 201(c)(7)(c)

# Reach of the Bayh-Dole Act

- Invention (35 U.S.C. 201 (d))  
“....any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.).

## Subject invention

“....any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

## Funding agreement

“....any contract, grant or cooperative agreement entered into between any Federal agency – and any contractor for the performance of experimental, developmental or research work funded in whole or in part by the Federal government.

# Procedural obligations under the Bayh-Dole Act

- Subject invention must be disclosed to supporting Agency within two months after invention discloses it in writing to the contractor.
- Contractor has two years in which to elect to retain title.
- Contractor must file a U.S. patent application on subject invention within one year of election.
- Contractor may file patent applications in other countries.
- Contractor's rights default to government upon request.

# Procedural obligations cont'd.

- Contractor's rights default to government upon request:
  - If contractor fails to disclose invention or elects not to retain title;
  - In those countries where contractor elects not to file patent applications;
  - In any country where contractor elects not to continue prosecution or pay mandated fees, or elects not to defend in reexamination or opposition proceedings.

# Procedural obligations cont'd.

- Non-profits (universities) may not assign except to patent management organizations or with government approval including assignment to inventor(s).
- Contractors must share royalties with inventor(s).
- Balance of royalties after deduction of expenses must be used for research or education.
- Non-profits (universities) must recognize preference for small business and U.S. industry in licensing.

# Preservation of Rights in the Government

- Government reserves a non-exclusive, irrevocable, non-transferable paid-up license to practice, or have practiced for or on behalf of the government any subject invention throughout the world. (35 U.S.C. 202 (c)(4))
- Government may restrict or eliminate the right to retain title in exceptional circumstances. (35 U.S.C. 202 (a)(ii))
- Government reserves “march-in” rights under certain circumstances, primarily because of lack of effort to achieve practical application of a subject invention or for public need. (35 U.S.C. 203)

# Success of Bayh-Dole

- Contributing factors:
  - Certainty of title in contractor
  - Inventor remains in development picture
  - Uniformity in handling of intellectual property under the law

# Success of Bayh-Dole cont'd.

- The Bayh-Dole Act provided an impetus that promoted the science-innovation interface. That Act:
  - ii. Established a new university-industry relationship.
  - iii. Established a certainty of title in universities to inventions made with Federal money – essential to industry collaboration.
  - iv. Recognized that the inventor is a significant factor in the technology transfer equation.
  - v. Promoted private sector as well as government investment in university research.

# Success of Bayh-Dole cont'd.

- Institutions having technology transfer programs:

1972	30
2007	300

# Success of Bayh-Dole cont'd.

- Recognition of effect
  - “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 to reverse America’s precipitous slide into industrial irrelevance.”

# Other Observations

- Patience and persistence are key to achieving a viable technology transfer climate and endeavor.
  - Passage of the Bayh-Dole Act required almost 20 years of effort.
  - The Create Act to spur collaborations and negate an adverse judicial decision required four years.
  - Participation in the legislative and regulatory process is essential to achieving and maintaining a practical and beneficial technology transfer climate.
  - Licensing is an uncertain business with only a modicum of control over technology development residing in the licensor.

# Other Observations, cont'd.

- Technology transfer embraces a juncture of science and law.
  - Science builds on science and involves the material.
  - Law finds its basis in moral, ethical and philosophical considerations.
  - Science tells us what we can do. Law tells us if we should.
  - Both require the application of vision and at times restraint but both are essential to technology transfer if that function is to be a successful, fair and balanced endeavor domestically as well as internationally.

# Why is Bayh-Dole important?

## Research expenditures by the university sector \*

(billions of dollars)

Total R&D expenditures	42.0
Development	1.26
Research	40.74
basic research	30.55**
applied research	8.96

\*Science and Engineering Indicators 2006

\*\*54% of national total for basic research

# Why is Bayh-Dole important?

Support for university research and development:

<u>Source</u>	<u>percent</u>
Federal government	62
Academic institutions	19
Industry	5
State and local government	7
Other	7

# Anti- Bayh-Dole Initiatives

## 1. Patent reform legislation – H.R. 1908, S. 1145

- Disrupts orderly invention/innovation process established over past 25 years.
- Makes patents more difficult and expensive to obtain and more difficult to assert.
- Introduces more uncertainties as to value of patents.
- Discourages investment in developing early stage inventions – frustrating the objectives of Bayh-Dole.

## 2. Recent legislation

- H.R. 977 – prohibition against patenting any nucleotide sequence or its function or correlation.

# Initiatives cont'd.

## 3. Government programs

- ATP (Advanced Technology Program) Ignores Bayh-Dole – Congress did not mean for the Bayh-Dole Act to apply to inventions resulting from ATP funding.
- STTR (Small Business Technology Transfer) - Does not mandate use of Bayh-Dole Act directives if there is an agreement to the contrary between the parties.
- “Other transactions” – funding vehicle available to DOD and Homeland Security-not subject to Bayh-Dole Act. i.e. ARPA (Advanced Research Projects Agency)
- Anti-commons effect of patenting federally sponsored research results.

# University activities \*

Research expenditures	\$42.3 billion
Inventions disclosed	17,382
U.S. patent applications filed	15,115
U.S. patents issued	3,278
New companies formed (based on university licenses)	628
New licenses and options	4,932
New market place products	527

\* AUTM survey 2005

# basic research – public benefit

Vitamin D metabolites and derivatives – Univ. of WI

Cisplatin and carboplatin – MI State Univ.

Hepatitis B vaccine – U of CA and U of WA

Synthetic penicillin – MIT

Artificial lung surfactant for newborns – U of CA

Genetically engineered human growth hormone – City of Hope  
Medical Center

Citracal calcium supplement – U of TX SW Medical Ctr.

Metal oxide process for Taxol production – FL State U

Prostate specific antigen test – HRI/Roswell Park Cancer

rDNA technology – central to biotech industry – Stanford and U of CA

TRUSOPT -ophthalmic drop for glaucoma – U of FL

Yahoo Internet search engine – Stanford