



“IP Management @ Universities” Istanbul, April 14 to 15, 2011

Albert Long Hall, BOGAZICI UNIVERSITY

The U.S. Bayh- Dole Act

The Role of Legislation to the Commercialization of IP and Development of TTOs in the Universities

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The U.S. Bayh- Dole Act

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The Bayh- Dole Act 1980

- **Milestone for Technology Transfer**
- **Genesis of TTOs**
- **“Innovation’s Golden Goose”** (The Economist *December 2002*)

[...] more than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance. [...]



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What is the Bayh- Dole Act :

- **The U.S. legislation dealing with intellectual property arising from federal government-funded research**
- **Enacted by the Congress on December 12, 1980. [35 U.S.C. § 200-212]**
- **Sponsored by two senators, Birch Bayh of Indiana and Bob Dole of Kansas**
- **The most significant change:**
“The presumption of title on invention resulted from public refunded research is reversed.”



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Why the U.S. needed the Bayh- Dole Act : Pre - 1980

- **Government owned patents - only non-exclusive licenses**
- **Approximately 30,000 patents - Fewer than 5 % of these were licensed to industry**
- **The main problem: Uncertainty of Title**



- **Industry does not have the ownership or exclusive right**
- **Industry was reluctant**



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Bayh- Dole Act introduces

- **TWO MAJOR PRINCIPLES:**

1. Universities are given the right to elect title on “Subject Inventions” = “Institutional Ownership”

2. They are permitted to commercialize the inventions

AND

- **REQUIREMENTS:**

To ensure the rights of Government on “Subject Inventions”



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The requirements set forth by Bayh- Dole Act :

- **Universities should**
 - ✓ **Report the invention to the funding agency (2 months)**
 - ✓ **Elect to retain title (2 years)**
 - ✓ **File patent applications in the U.S. and abroad within specified timeframes**
 - ✓ **Grant the federal government a non-exclusive free license**
 - ✓ **Submit periodic reports**
 - ✓ **Notify the government of any decision to discontinue patent protection**



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The requirements set forth by the Bayh- Dole Act :

- **Universities should**

- ✓ **Not assign the rights to the technology, with a few exceptions**
- ✓ **Share royalties with the inventor**
- ✓ **Use any remaining income for education and research**
- ✓ **Give preference to U.S. industry and small business**



Substantially manufacture the invention in U.S.



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March – In Rights under Bayh- Dole Act :

- **March – In rights for Federal Agency**

Only in exceptional circumstance, i.e

- **No action or not effective action by the Contractor within a reasonable time**
- **Health or safety needs that have not been reasonably satisfied**
- **Requirements for public use specified by Federal regulations that have not been reasonably satisfied**
- **If the preference for U.S. industry has not been obtained**

- **To date no Federal Agency has exercised march-in rights**

4 Petitions to NIH (CellPro, NORVIR, Xalatan, Fabrazyme)



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Impacts of Bayh-Dole

- **Certainty of title**

Institutional Ownership Model \neq Professor's Privilege

- **Substantial increase in technology transfer**

- **Many new technological advances**

- **Created a three – way partnership : Government – Universities - Industry**



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Impacts of Bayh-Dole

- **The number of the TTO's increased substantially**

First formal tech transfer program: University of Wisconsin (1924)

less than 25 before 1980

200 by 1995

Association of University Technology Managers (AUTM) 1974

113 members before 1980

Today: More than 3. 000 from 30 countries

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Impacts of Bayh-Dole

Change In Core Measures of Technology Transfer Activity (AUTM Survey from 1991 to 2008)

- **The number of licenses active X 6**
- **Invention disclosures received X 4**
- **New patent applications filed X 4**
- **Licenses/Options Yielding Income X 5**



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Impacts of Bayh-Dole

- The income earned by universities from licensing has increased substantially**
from \$ 7.3 million in 1981
to \$ 3.4 billion in 2008



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Criticism of Bayh-Dole

- **Changed the nature of academia: Focus on commercial potential.**
- **Corruption in academic circles**
- **Public (tax payers) does not receive the benefits**



Despite the critics, consensus on the extreme success in technology transfer



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Worldwide Impacts of the Bayh-Dole Act

- **“Institutional Model” become the role model in many developed and developing countries**

Japan

India

South Africa

European Countries



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Worldwide Impacts of the Bayh-Dole Act

- **India**

“The Protection and Utilization of Public Funded Intellectual Property Bill, 2008”

- **South Africa**

“Intellectual Property Rights from Publicly Financed Research and Development Act” 2010

- **Japan**

“Establishment of TLOs in 1998 and corporatization of national universities in 2004”



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Worldwide Impacts of the Bayh-Dole Act

- **European Countries**



“No harmonized policy regarding “technology transfer”



At national level, countries start to adopt the institutional model



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Worldwide Impacts of the Bayh-Dole Act

- **Germany**
- **Denmark**
- **Belgium**



Institutional Model

- **Sweeden**
- **Italy**



Professor's Privilege



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Questions!

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