BayhDole25, Inc.

The "Bayh-Dole" Model & Lessons for India

Publicly Funded Patents & Technology Transfer: A Review of the Indian "Bayh Dole" Bill

September 12, 2009
NUJS, Calcutta

Susan Kling Finston,
Finston Consulting, LLC

BayhDole25, Inc.

Introducing BayhDole25

BayhDole25, is a non-profit, non-government organization, dedicated to providing educational resources on the Bayh-Dole Act of 1980 and related legislation that revolutionized technology transfer through licensing of government owned patent rights and other intellectual property.

The Bayh-Dole Framework for Technological Transfer

FEDERAL LABS

RESEARCH INSTITUTIONS

COMMERCIALIZATION OF RESEARCH AT FEDERAL LABS FORMALLY ENCOURAGED.

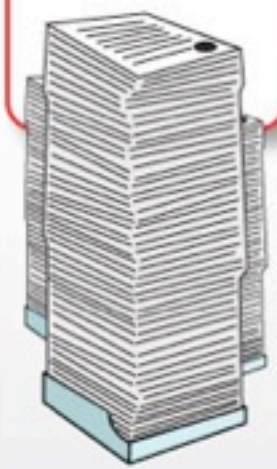
TITLE IN CONTRACTOR POLICY ADOPTED FOR FEDERALLY FUNDED RESEARCH.

RESEARCH INSTITUTIONS became responsible for filing patents and were able to grant exclusive licenses.

SMALL BUSINESSES were to be given preferences in licensing

THE FEDERAL GOVERNMENT Retained "march-in rights" to pull back title to inventions to ensure development, address health and safety concerns, or address abusively favorable deals.

THE BAYH DOLE FRAMEWORK RESULTED IN DRAMATIC GROWTH IN COMMERCIALIZATION OF FEDERALLY FUNDED RESEARCH. From 1991 to 2003, more than 25,000 patents were issued. 4,081 companies have been created from universities since 1980.



In the 1970s, policymakers and universities began creating a U.S. technology transfer policy that would promote successful commercialization of research, and would gain meaningful benefit from the then-$8 billion annual investment in federal research.

The new policy applied to research conducted in universities and other research institutions, and later was extended to research conducted in federal laboratories.

The Bayh Dole Act produced great benefits for the American economy and society. It relied on three key mechanisms: promoting intellectual property protection for innovators; relying on market forces to guide commercialization of innovation; and maintaining a consistent level of support for higher education and scientific research.

BayhDole25, Inc.

Why is this Important?

Despite 25 years of documented success, there is a profound lack of awareness of the importance of technology transfer to commercialization of science. In part because there has been no sustained educational campaign, the building-blocks or pillars of Tech Transfer are under not well-understood, threatening the architecture supporting continued science innovation.

Tech Transfer:
What are we trying to measure?

What counts:

- ⋆ Commercialized scientific innovation
- ⋆ Improved project management
- ⋆ Expanded R&D, CRO capacity
- ⋆ Related commercialization skills (Quality assurance, Production, Supply Chain Management)

The Three Pillars: Building-blocks for Commercialization of Science

The documented success of the Bayh-Dole Act and related technology transfer legislation in the United States and internationally rests on three inter-related traditions:

- reliance on market forces for R&D
- strong rule of law protections, including IPP, and,
- a durable government commitment to science education and financing of scientific research.

Success of Bayh-Dole Act (1980)

"[O]ne of the most successful pieces of economic development and job-creation legislation in recent history."

Lita Nelson, Director, MIT Tech Transfer Office

- Launch of global biotech revolution
- Preeminence in life sciences science & technology
- Employment of more than 3 million in bio-pharmaceutical, agro-biotech, and other enabled technologies

National Institute of Health

"It is impossible to overstate the achievements of the global macroeconomic impact of taxpayer-supported biomedical research. Federal funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have improved and extended, have been the beneficiaries of the remarkable medical advances that comes from this enterprise."

NIH Report to Congress: A Plan to Protect Taxpayer Interests (August 2001)

Role of Patents

- Tech Transfer requires certainty provided by patents.
  - ★ Fundamental Right of ownership and control
  - ★ Intellectual Property is Property
    - ✓ Provides incentive for long-term investment
    - ✓ Provides incentive for (Indian) technology importers

> "Without patents the return from investment in pharmaceutical research and development would fall to zero, and private companies would no longer engage in research and development."

Schwartzman, David. Innovation in the Pharmaceutical Industry. Baltimore: Johns Hopkins Press, 1976.

Building an Intellectual Infrastructure for Tech Transfer

"From my experience in Bangladesh, well-qualified local scientists generally prefer to remain in their home country if they can find meaningful employment in institutions where they can be productive. Well-functioning institutions contribute to 'brain-gain,' thus increasing the scientific and economic resources of a country as a whole."

David A. Sack, Executive Director, ICDDRB, Center for Health and Population Research, Dhaka 1000, Bangladesh, Editor in Chief, Journal of Health Population and Nutrition

Tech Transfer Markers

- India's FDI/Clinical Research growth:
  - ⋆ Record growth in knowledge-intensive sectors, e.g. biotech:

2005	1billion
2006	1.5billion
2007-08	2.5billion

  - ⋆ Top-5 countries as R&D destination (Ernst and Young European Attractiveness Survey 2006); Nearly all major bio-pharmaceuticals now active in pre-clinical, clinical R&D; Indian companies strengthening R&D

India's Tech Transfer Assets

- High-quality human capital, 'brain gain'
- Strengthening intellectual property protection (IPP) & administration
- High-level political leadership to promote commercialization of basic science research, e.g.: "The Protection and Utilisation of Public Funded Intellectual Property Bill, 2008"

IPP: India's Patents MindShift

- Product Patent Protection: Wonderful, Incomplete (product patents grafted onto Patents Act of 1970)
  - ⋆ Political process limited reforms, & added or left intact controversial provisions (e.g. mailbox limits, local working requirements, broad compulsory licensing, genetic invention disclosure) that all apply EQUALLY to government funded inventions
  - ⋆ Mandatory Disclosure of Source/Origin: Need to eliminate negative incentives for AYUSH/Other Traditional Medicine research to create livelihoods for Megadiverse States beyond the "Biotech Bubbles"

India's Human Capital

- India: The Land of Ideas* - 300,000 biotech, bio-informatics and biological science grads annually (more than all of Europe!)
- India's Reverse Brain Drain
  - ★ Non-Resident Indians (NRIs) lead in biotech research; 20% of scientists in U.S., European labs,
  - ★ now many returned home, e.g. leadership of Bangalore-based Aurigene (400+ scientists)

*Dr. R.A. Mashelkar

Key Questions for India

- Does the Bill balance carrots and sticks?
  (substantial penalties, fines, recovery of grants, see §21- 23)

  ★ Will this approach create an enabling environment to encourage technology transfer?

  ★ Could it potentially chill research?

  ★ May require patent filing where there is little commercial opportunity or where invention should be placed in the public domain.

Key Questions for India (2)

- Should the Bill assume Technology Transfer Offices (TTOs) can be self-supporting based on royalties?
  - ★ This is NOT true for MOST U.S. and other developing country TTOs
  - ★ Related Issues: Where is Capacity Building for TTOs, Academic Researchers? Why is there no funding for patent filings? (See §7(b))

Key Questions for India (3)

- Are (NEW) "local working" requirements in the interest of India? (See §12)
  - ★ Will they discourage international R&D partnerships?
  - ★ What about NRIs with foreign affiliations and India's generally growing international research linkages?
- Related Issues: Patents Act of 1970 contains other elements including famously 3(d), local working requirements, broad-scale compulsory licensing, all of which will have unknown impact on potential for patenting/licensing of university inventions.

Thank you!

BayhDole25 Board

Dr. Ananda Chakrabarty, University of Illinois Medical School, Chicago

Mr. Dan Woods, BayhDole25 Executive Director, New York, NY

Mr. José Miguel Flores Acuña, LL.M., Flores & Asociados, Concepcion, Chile

Mrs. Susan K. Finston, Finston, J.D./M.P.P. Consulting, LLC, Washington, DC

Contact Us

BayhDole25, Inc.
242 West 30th, Suite 801
New York, New York 10001
phone: (646) 827-2196
web: www.bayhdole25.org
e-mail: info@bayhdole25.org

BayhDole25, Inc.