Overview of NIH Technology Transfer: All You Ever Wanted to Know But Were Afraid to Ask

OFFICE OF STRATEGIC ALLIANCES
NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

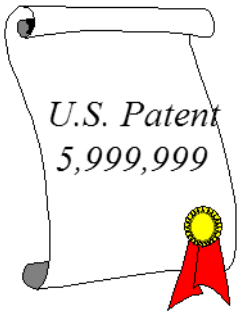
NCATS

Topics to Cover Today

- What Is Technology Transfer?
- Bayh–Dole Act
- Technology Transfer Agreements
- Examples of Technology Transfer Assistance

What Is Technology Transfer (T2)?

- T2 = the transfer of tangible or intellectual property (IP) between parties to advance research, development or commercialization for mutual benefit
- IP = know-how, ideas, patents, trademarks and copyrights



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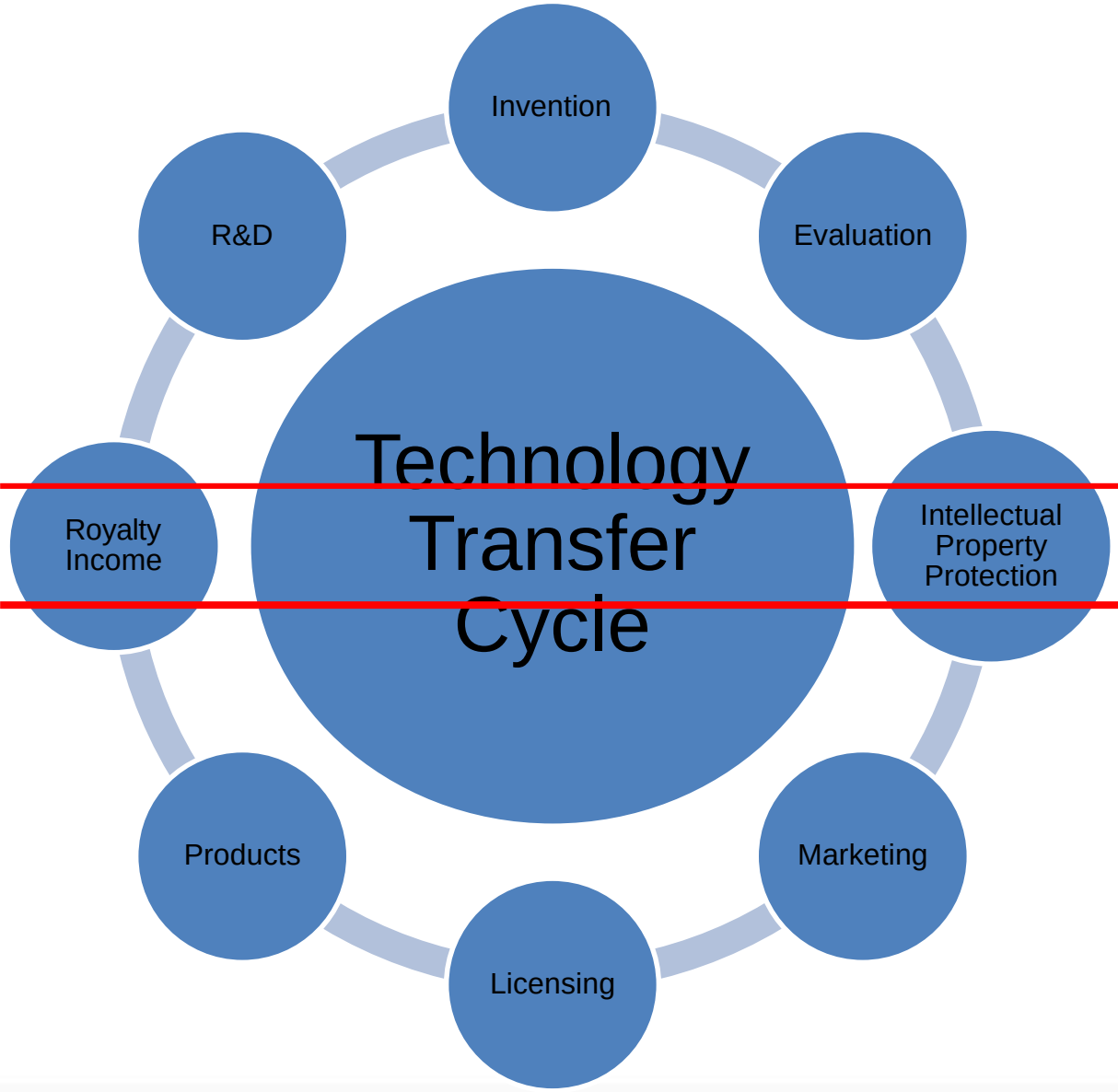


Government Labs/Academia

Industry

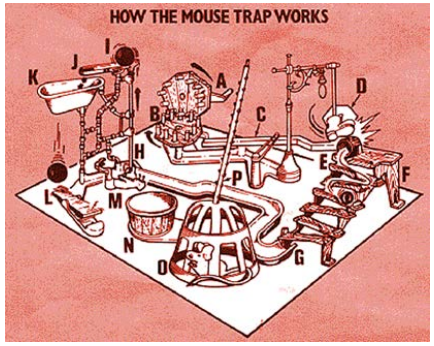
The Founding Fathers recognized that stimulating inventions and their commercialization was essential to the country.

History of the U.S. Patent System

- The idea of a patent system came to the New World from England. Many of the 13 colonies had their own patent systems.
- Article I, Section 8 of U.S. Constitution states that Congress will have the right *"to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."*
- The Patent Act of 1790 (H.R. 41, introduced February 16, 1790, and passed March 10, 1790) was drafted in part by Thomas Jefferson, who incorporated many of his beliefs, including that *"ideas should not be patentable, rather patents should be issued only for physical inventions that have been reduced to practice."*
- Abraham Lincoln (the only U.S. President to own a patent) said the U.S. patent system *"added the fuel of interest to the fires of genius."*

Four Major Categories of IP

Patents



Copyrights

Trademarks

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Trade Secrets

Four Major Categories of IP

- **Patent**
  - Protects new embodiments of useful ideas, plans and designs
  - Term: ≤ 20 years from earliest filing of an application
- **Copyright**
  - Protects original works of authorship embodied in a tangible medium of expression
  - Term (normally): life of the author + 70 years
- **Trademark**
  - Protects marks that identify the source of goods or services
  - Term: as long as the mark is used in commerce
- **Trade Secret**
  - Protects commercially valuable, protected information
  - Term: as long as information remains secret and valuable in fact

Bayh-Dole Act (Patent and Trademark Law Amendments Act of 1980

"Fathers of Technology Transfer"

What Was Happening to Our Federal R&D Dollars?

- At the end of WWII, the Marshall Plan for technology said “all Government funded technology would be made freely available to the public.”
- Late 1960s: U.S. had about 28,000 government-owned inventions; < 4% were licensed.
- Hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry, because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of the product.

1968 General Accounting Office study of Department of Health, Education and Welfare for President Lyndon B. Johnson

Technology Transfer Before 1980

- Centralized technology management
- 35 different federal patent and license policies across federal agencies
- No incentives for universities/federal labs to commercialize R&D

The Bayh-Dole Act (Public Law 96-517) 35 U.S.C. § 200-212

- Universities and contractors given title to patentable inventions produced using federal government support through:
  - Contracts and/or grants to include small business (SBIR/STTR)
- Instructed grantees and contractors to give companies proposing substantial manufacturing in the U.S. preference to licenses
- The federal government reserves the right to use the invention royalty-free for its own purposes.
  - Including for treaty obligations and national emergencies.
- Universities are not required to share royalties with their inventors.

The Impact of Bayh-Dole

- The amount of industry funds invested in university R&D and patents increased.
- It led to the creation of the U.S. biotech industry, which is still clustered around major universities.

"Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980….More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

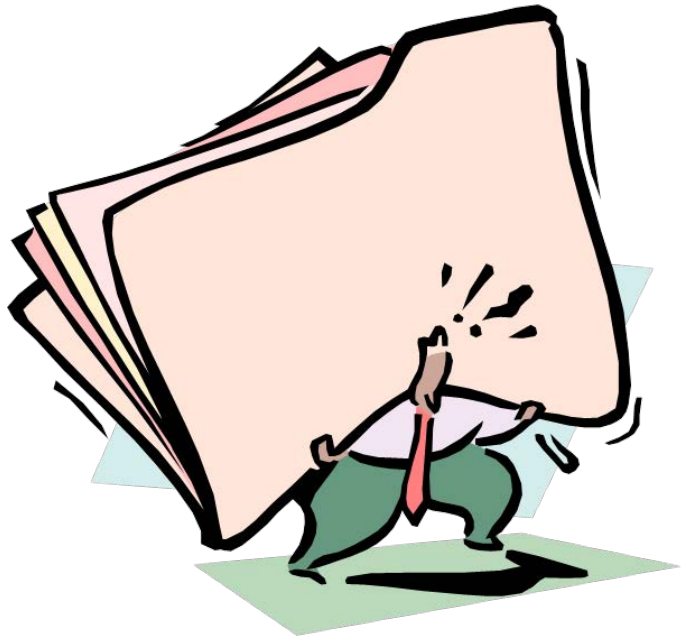
Economist Technology Quarterly, December 14, 2002

NIH Tech Transfer: Shared Responsibilities

- **Institute Technology Development Coordinator (TDC)**
  - Manages Institute/Center IP issues (patent, copyright) and patent prosecution
  - Negotiates and executes all transactional agreements (CDAs, MTAs, CTAs, CRADAs) and patent licenses)
  - General technology transfer and strategic alliance advice
- **NIH Office of Technology Transfer**
  - Monitors all NIH Licenses
  - Docketing management system
- **NIH Office of Extramural Inventions**
  - All grantees/contractors must report their inventions to the funding agency through iEdison

Types of Technology Transfer Agreements

- Confidential Disclosure Agreement
- Material Transfer Agreement
- Clinical Trials Agreement



Confidential Disclosure Agreement (CDA)

- Specifies treatment of proprietary information
- Often the first step in collaboration
- Limited term of confidentiality obligation
- Scope clearly defined
- No promises regarding rights in inventions

Material Transfer Agreement (MTA)

- Transfer of research material (and data)
- Specifies recipient's permitted use
  - Academic research; no human use
- Limits transfer to third parties
- Publications
- No promises regarding rights in inventions

Clinical Trial Agreements: Primary Purpose

- Establishes drug or device supply in exchange for data (without charge and in sufficient quantity)
  - How much?
  - To where will collaborator send study drug? Who will distribute it? Labeling requirements?
  - Will re-supply be needed and on what basis?
  - Will placebo be needed?
- What happens if industry collaborator terminates for reasons other than safety?

Clinical Trial Agreements: Primary Purpose

- Establishes data rights and data flow
  - What data can/will be provided to industry collaborator?
    - Publication review or preprint of publication
    - Data for regulatory filings
    - Summary data
    - Raw data
  - What data does NIH require of industry collaborator?
    - Cross-referencing letter for Drug Master File (DMF)
    - Investigator brochure
    - Who will hold the IND?

Federal Technology Transfer Act (Public Law 99-502)

- Laboratories may contribute their resources to a CRADA, excluding funding.
- Laboratory employees may assist in any subsequent commercialization efforts.
- Federally owned and operated laboratories will manage their inventions much like universities under the Bayh-Dole Act do.

Federal Technology Transfer Act (Public Law 99-502)

- Agencies must share the royalties (at least 15%) with the inventor.

NIH Patent and License Policy

- Selective tool to facilitate availability of technology to public
  - Therapeutic, preventive, diagnostic products
- Research tools not patented
  - Transfer to academic via MTA
  - Transfer to industry via biological materials license
- Royalty bearing licenses
- Nonexclusive licensing when practical

Invention Reports

- Inventor submits to NIEHS TDC (John Penta)
- NIEHS TEAC reviews and recommends approval to patent
- Transfer to NIH Office of Technology Transfer
- OTT contracts with patent attorney
- Application prepared, filed, prosecuted
- OTT advertises
- OTT negotiates licenses

Invention Reports: Keys for Lab

- Submit to IC TDC (John Penta) at least 3 months prior to public disclosure
- Signed by each inventor and witnessed
- Complete with attachments

CRADA Policies

- **Law**
  - Consistent with missions of the federal laboratory
  - Provide option to exclusive license in specified field of use
- **NIH CRADA policies**
  - Intellectual contribution by NIH and collaborator
  - CRADA PI tenure/tenure track
  - Dissemination of research results
  - Conflict-of-interest (COI) review
  - Focused CRADA research plan
  - License option balanced with research tools policy

CRADA Clearance

- Ethics (COI review)
- PI
- Lab/Branch Chief
- Division Director
- Technology Development Coordinator
- Office of the General Counsel
- CRADA Subcommittee
- NIH Office of the Director (DDIR)
- Executed by Institute Director

IP in Unexpected Areas

- **Acquisition (purchased materials)**
  - Promises about ownership of inventions made using materials or providing a portion of future royalties
- **Grants from foundations to intramural**
  - Requirement that inventions be owned or controlled by foundation
- **Check with OTTAD for guidance**

Any Questions

Office of Strategic Alliances
NCATSPartnerships@mail.nih.gov