Overview of Technology Transfer

Bruce Goldstein, J.D., M.S.
NIH Office of Technology Transfer

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Today's Topics

- What is "Technology Transfer?"
- Overview of IP Types
  - Patents
  - Copyrights, Trademarks, and Trade Secrets
- Transactional Tech-Transfer Agreements
- ***Bottom Line***: Results of Tech Transfer at NIH

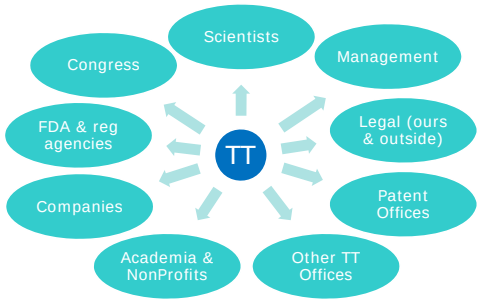
Technology Transfer "defined"

- The **authorized exchange** of ideas, confidential information, materials, and/or intellectual property rights;
- **Between (among) laboratories** in Gov't/non-profit/academic institutions and industry;
- **To facilitate** further research and to enhance development of commercial products (i.e., "adding value"), in support of the lab's underlying mission

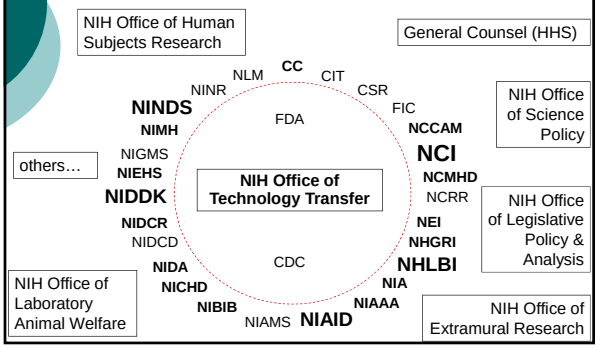
Why Engage In Technology Transfer?

- Pre-1980: The Market-Failure Problem
- 1980: First Paradigm Shift: Tap Patents and Non-Profit Research
  - Bayh-Dole Act
  - Stevenson-Wydler Act
- 1987: Second Paradigm Shift: Tap Federal Researchers
  - Federal Technology Transfer Act
- 1988-today: Updates & Adjustments

TT involves complex interactions with many different players



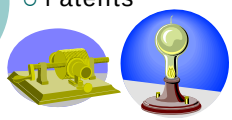
Tech-Transfer Players at NIH



Overview of IP Types

For Major Categories of IP (in US)

- Patents



- Copyrights

- Trademarks

- and Trade Secrets

For Major Categories of IP (in US) - Differences:

- **Patents**
  - Protects new embodiments of useful ideas, plants, and designs
  - Term: ~20 years from earliest filing of an application
- **Copyrights**
  - Protects original works of authorship embodied in a tangible medium of expression
  - Term (normally): life of the author plus 70 years
- **Trademarks**
  - Protects marks that identify the source of goods or services
  - Term: as long as the mark is used in commerce
- **Trade Secrets**
  - Protects commercially valuable, protected information
  - Term: as long as info remains secret and valuable in fact

For Major Categories of IP (in US) - Policy Basis:

- **Patent and Copyright**
  - Societal trade-off:
    Full disclosure for term-limited exclusivity
  - Reward to creator (over one who merely copies)
  - Economic engine
- **Trademark**
  - Marks help the marketplace distinguish goods & services offered from different sources
    - *Consumer protection*
- **Trade Secret**
  - Stop misappropriation and unfair competition
    - *Orderly commercial space*

What about "owning data?"

- To "own" a thing means you truly have the raw power to exclude others
  - Physical barrier,
  - Secret stash, or
  - Court will order others to stay away or to pay damages



- Once a datum is publicly known, no power on earth can *truly* grant exclusivity to it
- Patents, copyrights, & trade secrets are the only ways to "own" data in the US

Patents

Patents: ***Basics***

- A patent is a government-issued document granting its owner the right to exclude others from *making, using, selling, or importing* the invention for up to 20 years
  - In exchange, inventor has a "duty of disclosure"
- Limits – patents are:
  - VERY expensive
  - Country-specific
  - Neither a monopoly nor a right to profits
- US law has changed, most significantly, from "first to invent" to "first to file"
  - *Any* disclosure may jeopardize patent validity
  - Very limited "grace period" after disclosure

Patents: "***Musts***"

- Invention must be one or combination of:
  - A machine;
  - A composition of matter;
  - An article of manufacture; or
  - A method or process (e.g., making, using)
- Invention must:
  - Have a clear, substantial, and specific use;
  - Be "novel" (never disclosed); and
  - Be "non-obvious" (sufficiently different)
- Patent must contain a sufficient written description ("enabling")

Patents: ***Myths***

- Naturally occurring things, like a genome, can be patented
- Inventor must actually make the invention, and it must work as claimed
- Patenting requires social/scientific merit
- Patenting means it works better than everything else
- Patented inventions are safe to use
- Casual conversations with friends & colleagues have no impact on patent rights
- Inventor need not disclose everything to patent attorney or Patent Office

NIH's Patent Policy

- Publication is the *preferred* means of TT
- Pursue patents to create incentive for industry to develop products
  - Not for "fully developed" inventions (e.g., surgical techniques)
- *Imperative*: Share "research tools," whether or not patented
  - Characteristics: short useful life; fully developed; primary market is researchers
  - Examples: animal models, drug targets, PCR primers, methods/devices for doing research, raw DNA sequences, cell lines

NIH's Licensing Policy

(agreement not to enforce IP rights)

- Strong preference to license *nonexclusively* (~80%) and to small businesses (~50%)
- Exclusive license OK where investment is large – therapeutics, vaccines, some diagnostics, some devices
- Key license terms (NIH):
  - Appropriate scope of exclusivity
  - Benchmarks and "take-back" terms to incentivize faster development
  - Reserved rights for research (royalty-free)
  - US manufacturing requirements
  - Royalties commensurate with value added

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Copyright: ***Basics***

- A copyright applies to:
  - "Original" works of authorship
    - "Original" merely means "not copied" – contrast with "novelty" for patents
  - that are "fixed in a tangible medium"
    - Copyright exists *automatically*
    - Ink on paper, or data on a magnetic drive
- The following cannot be copyrighted:
  - Raw facts or data
  - Mere names, titles, slogans, or phrases
  - Functional aspects (domain of patents)
  - Works by government employees (if part of duties)

Copyright: ***Basics***

- A copyright provides an exclusive right ***to copy***, including in particular:
  - To **Duplicate** (including into other media)
  - To Make "**Derivative Works**" (e.g., edited works, translations, updates, remakes)
  - To **Distribute** (even for free)
  - To **Perform or Display** publicly (where applicable, e.g., dramatic, musical, or visual works)

Copyright: ***Clarifications***

- Copyright laws and treaties have changed substantially several times in the recent past
  - Which rules apply may depend on when the work was authored
  - Always check with a copyright attorney
- Registration (with the Library of Congress, not the US Patent & Trademark Office) is ***not*** required, except to sue
- Formal notice ("© 2007 Bruce Goldstein") is ***not*** required, but it is a good idea
- Term of a copyright equals the life of the author plus 70 years

Copyright: ***Enforcement***

- Filing suit requires a registration certificate; registration is simple (but weak)
- Defense: Compulsory licenses
  - Music
  - Software - RAM/backup/archive (one copy only)
- Defense: "Fair Use"
  - criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, research, or parody
  - Not a free pass: use must be bona fide and limited (i.e., *objectively* fair, not just in your perspective)
  - Highly risky to rely on doctrine

Copyright: ***and Government***

- Be aware in procurement:
  - Know before you sign what you need to do with the work the contractor will make
  - The author (contractor) owns the ©; USG has a limited license
  - While USG can make a contractor assign a © to the USG, USG cannot keep royalties (unlike patents)
- The Government can be *held liable* for copyright (and patent) infringement, but not *enjoined* (i.e., stopped)

Trademark: ***Basics***

Definition: A trademark (or "mark") is any word, phrase, logo, symbol, shape, number, letter(s), color, sound, scent, or other device (or a combination of these) that serves to identify the source of specific products in commerce, and to distinguish them from similar products sold by others.

Functional and purely descriptive elements cannot be used as a mark

Trademark: ***Basics***

There are four types of marks:

- ✓ Trade marks, for goods
- ✓ Service marks, for services
- ✓ Collective marks
- ✓ And certification marks

What's with the "®" and "™"?

"®" = successfully registered at the USPTO

"™" = simple claim that you own (but not registered) a mark

NOTE: You get rights by *actual use*, not by registration

Why get a mark?

(1) To protect the consumer's ability to identify the source of particular products

"Easily identified trademarks reduce the costs consumers incur in searching for what they desire. … [T]he lower the costs of search, the more competitive the market."

– *Scandia Down v. Euroquilt* (7th Cir, 1985)

(2) Quality assurance/proxy for goodwill

(3) To protect the reputation of a famous Mark long in use, even in the absence of confusion as to source (the "dilution doctrine")

- **NOTE**: Each policy protects the *market*, not the mark-owner

Trade Secrets: ***Basics***

- Each US state & territory has its own definition
- Generic concept: a trade secret is any information –
  - that is secret in fact,
  - that has economic value, **and**
  - where the owner has taken reasonable steps to keep it secret
- *Disfavored* form of IP; requires "bad act"
- ***TRAPS***:
  - Insider trading by collaborators
    - WSJ 3June2011 – SEC probe into FDA scientists & family
  - USG: Federal Trade Secrets Act & FOIA

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Transactional Agreements - Overview

Why Bother?

- ○ To share information, materials
- ○ To authorize collaboration
- ○ To avoid damaging patent rights
- ○ Clarify expectations; avoid misunderstandings
- ○ Encouraged in NIH policy statements
  - NIH intramural: http://www.nih.gov/news/irnews/guidelines.htm
  - NIH grantees: http://ott.od.nih.gov/policy/rt_guide_final.html

Transactional Agreements - Overview

Major Types:

- ○ Confidential Disclosure Agreement (CDA)
- ○ Material Transfer Agreement (MTA)
- ○ Clinical Trial Agreement (CTA)
- ○ Cooperative Research And Development Agreement (CRADA)
  - For universities, "Sponsored Research Agreement" (SRA)

Transactional Agreements - Overview

Major Traps:

- Signature Authority
- "Indemnification"
- Undue or sneaky confidentiality restrictions
- "Reach-through" rights in inventions
- "Shelving" exclusive rights

Confidential Disclosure Agreements

- When you want to share:
  - pre-publication manuscripts, raw data, ideas that might become inventions, pending patent applications
  - with someone *outside* your institution
- Key terms in a typical CDA –
  - What will be disclosed
  - Duty to mark "CONFIDENTIAL"
  - Exclusions (e.g., data already public)
  - Duration of the secrecy; right/freedom to publish

Material Transfer Agreements

- Used to authorize *non-sale* transfers of research materials for basic research
  - Not appropriate for clinical research
  - No re-transfers, no commercial uses
  - Technically, MTA is a loan – *just because you possess it doesn't mean you own it!*
- For Gov't labs, MTA cannot be used to avoid procurement or gift/ethics rules
- Recent NIH policies on sharing:
  - 1999, research tools; 2003, data; 2004, model organisms; 2005, licensing genomic inventions; 2006, GWAS

Material Transfer Agreements

- Major types of MTAs:
  - Simple Letter Agreement (SLA)
  - MTA for Transgenic Organisms (MTA-TO)
  - Uniform Biological Material Transfer Agreement (UBMTA)

  Note: Some institutions have given signature authority to senior lab staff – but don't assume they do!
- Special Types (specific forms, extra signatures):
  - Human embryonic stem cells
  - Materials of human origin (outbound)

Clinical Trial Agreements

- Authorizes transfer and use of materials in human-subjects research
- Assigns/clarifies regulatory and clinical duties
- Grants rights to use data for regulatory filings
  - Limited exclusivity
- Coordinates publication
- Otherwise like an MTA

Cooperative Research And Development Agreement ("CRADA")

- US Government only
- Power of a CRADA:
  - Each party gets *present* rights in *future* (CRADA) inventions
  - Authorizes exchange of
    - Significant material, equipment
    - FTE-ceiling-exempt personnel
  - Collaborator can give government lab funds
  - Clinical research *enabled*
- Cornerstone of any NIH CRADA: *actual collaboration*
- Agreement is complex: 3-8 months average negotiation/processing time

Other Agency-Specific TT Arrangements

Title	Agency
"Biological Materials License"	NIH, FDA, CDC
"Work for Others"	DoE, DoI
"Technology Investment Agreement"	DoD, DoE
"Education Partnership Agreement"	NSA, DoD
"Space Act Agreements"	NASA
"Facility Usage"	DoD, NIST, DoI, DoE
"Other Transactions Agreements"	DoD, DHS, NSA
"Gov't Owned, Contractor-Operated"	DoE, NIH
...and many more	

http://www.federallabs.org/flc/education/t2-mechanisms/matrix-mechanism/

The Bottom Line

Technology Transfer
makes a difference

Bottom Line: Results of TT at NIH - Agreements

- MTAs and CDAs
  - Estimated 3,000-4,000/year across all of NIH
- CRADAs
  - ~80 new per year; >200 active at any given time
- Clinical trials enabled under CTAs and CRADAs
  - Estimated 40-50 new per year; >50 active
  - $Millions (mainly drugs or in-kind) received by NIH
- Other arrangements
  - Formalized collaboration agreements
  - Memoranda of understandings (MOUs) and Letters of Intent (LOIs)

Bottom Line: Results of TT at NIH - Products from Selected CRADAs

Product	Company	Use
FluMist	MedImmune	Intranasal Influenza vaccine*
Havrix	GlaxoSmithKline	Vaccine against hepatitis A
Taxol	Bristol-Myers Squibb	Treatment of solid tumor cancers and Kaposi's sarcoma
Taxus Express	Angiotech (sublicensed to Boston Scientific)	Treatment of coronary artery disease (drug-eluting stent)
Thyrogen	Genzyme Therapeutics	Adjunct to thyroid cancer treatment
Velcade	Millennium Pharmaceuticals	Treatment of multiple myeloma

*Note: original technology from University of Michigan

Bottom Line: Results of TT at NIH - Intramural Inventions

New Invention Disclosures	~400/year
Newly issued US patents	~100/year
Invention licenses executed	~250/year
Royalties	~$100M/year (on >$5B sales)

- **Some of the top royalty-earning inventions:**
  - TAXUS Express2 (paclitaxel stents);
  - Synagis (mAb to RSV);
  - Videx (ddI);
  - Thyrogen (rTSH);
  - HIV Ab (diagnostic kits);
  - Twinrix (joint vaccine for hepatitis A & B);
  - Velcade (proteasome inhibitor for multiple myeloma);
  - Ocuvite (dietary supplement for macular degeneration);
  - Zevalin (radio-mAb/chelator combo for NH lymphoma)

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- **Ground-Breaking Inventions:**

Gardasil	1st HPV vaccine
Velcade	1st proteasome inhibitor
Synagis	1st mAb for any infectious disease
Zenepax	1st mAb for organ transplant
Vitravene	1st antisense therapeutic
Zevalin	1st radioimmuno-therapeutic
RotaShield	1st rotavirus vaccine
MenAfriVac	1st vaccine designed for Sub-Saharan Africa (*N. meningitidis A*)
Taxol	1st natural-product therapeutic against cancer

Bottom Line: Economic Impact of Tech Transfer (all sources)

- ~5,000 US companies formed from TT are active today; average 1.6 new companies per day; nearly 300,000 jobs directly created
- US Tech Transfer conservatively accounts for >$200B in US GDP; technologies containing inventions from NIH *alone* resulted in $6B sales
- ROI: Federal funding of R&D has equivalent of ~30% annualized "return" in value to taxpayer

Bottom Line: Economic Impact of Tech Transfer (NIH-funded)

- Public perception of low gov't productivity vs companies is *upside down* here
  - Efficient: 32 issued US patents/$100M (US biomed private sector, mean = 2.5 patents/$100M
  - High quality: Forward citations/patent = 7.9 (2x rate for US biomed private sector, 6x rate for EU biomed private sector)
  - High impact: Every $1 spent on intramural research produces $2.21 in economic growth
  - NIH-funded universities similarly beat private sector (AUTM data, subscription required)

See, e.g., Kalutkiewicz MJ & Ehman RL, "Patents as proxies: NIH hubs of innovation." *Nat. Biotech.* 32:536-537 (2014)

Tech Transfer – Moving Technologies Forward

- Stevens, A., et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *NEJM* 364:535-541 (2011)
  - Public-sector research ("PSR"), largely supported by NIH, has had a disproportionate role in drug development
    - 9% of all NDAs resulted directly from PSR
    - 13% of all "NCE" NDAs started in a PSR Institution
    - ~20% of all priority-review NDAs resulted from PSR
    - 90% of all NDAs for new indications originated with PSR
    - NIH is the most prolific (co-)discoverer of all PSR Institutions
  - Patent licenses, CRADAs, and other tools of Tech Transfer played an essential role in moving each of these ideas from the bench to the clinic

Thank you for your attention

Speaker Contact:
Bruce Goldstein
NIH Office of Technology Transfer
6011 Executive Blvd., Suite 325
Rockville, MD 20852
Phone: +1(301)-435-5470
Fax: +1(301)-402-0220
email: goldsteb@mail.nih.gov
web: http://www.ott.nih.gov

Finding the appropriate TDC at NIH:
http://www.ott.nih.gov/nih_staff/tdc.html