Overview of Technology Transfer

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February 2016

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)

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

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:

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

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

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

Bottom Line: Results of TT at NIH
- Intramural Inventions

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)

Bottom Line: Results of TT at NIH

- Intramural Inventions

Ground-Breaking Inventions:

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

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Finding the appropriate TDC at NIH:

http://www.ott.nih.gov/nih_staff/tdc.html