Knowledge Transfer in the US: Tribulations and Triumphs

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One View of US Technology Transfer:
Or ...........
Outline:
- Technology Transfer: Stages of Development
- Success!
  - Whatever that is....
  - What we measure?
- Challenges....
  - Philosophical
  - Political
  - Economic
- How are we doing?
  - 2014 ALAS highlights
Success

What people think it looks like
Success

What people think it looks like

Success

What it really looks like
Technology Transfer: Stages of Development, U.S.
The Dark Ages: Pre-1980

• Federal regulations interfered
• Bureaucratic procedures
• Each agency had its own IP policy
• Long delays
• Requirement for non-exclusive licensing
• Public notice bidding
• Inefficient....
Building a Tech Transfer Infrastructure: 1980-1990

Bayh-Dole Act

• Universities set up technology transfer offices and start on a learning curve
• False starts: spending too much or too little on patent protection
• Legalistic approach
• Distrust on both sides - academia and industry
Starting to come to maturity: 1990-2000

- Universities are learning what kind of technology is easier to license
- Developing professional competencies
- Universities learn which industries are receptive
- Is the invention the actual product e.g., the drug in the bottle or diagnostic kit?
- Is the invention a small component of a complex, existing system, e.g., software to control an existing device?
Entrenched - Spreading But Changing: 2000-2010

• In economic downturns, states in the US increasingly look to universities to expand economic development
• Many see startup companies as a means to local job creation
• Other countries enact policies like Bayh-Dole and engage in technology transfer using commercialization models suited to local needs
The Future: Letting Go of Established Approaches

- Institutional goals?
  - Licensing
  - Entrepreneurship
  - Sponsored research

- New elements
  - Disease / patient advocacy groups
  - Internal technology development funds
  - Partnerships with states and federal programs set up by NSF (iCorps), NIH (SBIR/STTR) and other agencies
A New Day?

- New Paradigms
- Less transactional based
- More partnerships, collaborations
- ‘360’ relationships
  - Students
  - Philanthropy
- Old habits are hard to break....
Challenges: 2010 - Present

• Attacks on Bayh-Dole and universities are commonplace:
  – should they be taken seriously?
• Industry, journalists and economists come to the defense of academic technology transfer
• US technology transfer has become so established & successful that it can become a political target

• Claims:
  – Universities have tried to patent nature
  – University ties to industry are too close
  – There is too much emphasis on faculty entrepreneurship
  – Universities are too wealthy now
Unfunded Mandate

- Many universities do not have a budget dedicated to operating the TTO
- Offices depend heavily on licensing revenue
- Practical implications:
  - “Eat what you kill”
- Typical conversations...

- ADMINISTRATION:
  - “It’s not about revenues. Make partnerships happen.”
- TTO:
  - “I need resources to manage partnership development.”

- ADMINISTRATION:
  - “How much money can you make for me?”
High-Powered Opponents:

- New England Journal of Medicine
- Brookings Institution
- Kauffman Foundation
- Harvard Business Review
- Journal of the American Medical Association
- Then Economist...? Et tu?
The Good Old Days - Describing Bayh-Dole

“...perhaps the most inspired piece of legislation to be enacted in America over the past half-century," ...

"Innovation's Golden Goose," an opinion piece published in the Dec. 12, 2002 edition of...
University Disenchantment & Disinvestment

- Appetite for continued investment (particularly in life science intensive portfolios) is weakening; big hits are scarce
- TT is an unfunded mandate; most offices have to ‘eat what they kill’
- This limits capacity to maintain a portfolio to a maturity level that will attract licensees
- Some universities are close to abandoning traditional IP portfolio modes
  - Unrealistic expectations
  - Relying instead on business school
  - Students, at undergraduate & graduate level
  - Eliminating support for & recognition of TT as a profession
Opponents are prominently promoting their views:

- ‘It's time for Congress to recalibrate Bayh–Dole. Profits and patents can be powerful incentives for scientists, businesspeople, and universities, but new and ongoing risks — including high prices that limit access to lifesaving technologies, reduced sharing of scientific data, marked shifts of focus from basic to applied research, and conflicts of interests for doctors and academic medical centers — should be mitigated or averted through revisions of the law.

Prominently promoting their views:

• “If tax dollars fund an important part of biomedical innovation, it is not altogether unreasonable for the government to exercise some degree of control over pricing excesses. Yet, no such measures are currently in effect.”

Promoting their views....

“If universities issued more nonexclusive licenses of their products, there would be less need to rely on march-in rights. Even though non-exclusive licenses may bring lower royalty rates*, they can be successful in helping bring to market essential therapeutic technologies.”


* Or more likely, lower licensing rates......

- Proposed to amend Bayh-Dole so that inventors retain title to their inventions and be given full discretion over those titles, instead of assigning those rights to their employers, the universities.

- Claim that the university is a bottleneck in the commercialization of research and that in order to avert a slowing down of innovation, scientists should be free to choose a partner to negotiate the development of their research – to become ‘free agents’ and have their technology developed by a university of their own choosing...
  - Ignored many problematic issues:
    - Logistics
    - Multiple inventors
    - Multiple licenses
    - Industry did not favor
Defending the Freedom to Innovate: Faculty Intellectual Property Rights after Stanford v. Roche

- American Association of University Professors, AAUP
  - Strong supporter of Free Agency

- Philosophical differences
  - Faculty status???
  - Employment agreements???
  - Stanford v. Roche didn’t really change that
  - But we scrambled to change employment offer language..

  - “Hereby” and not “Shall”......may be the key?
Kauffman Foundation / Harvard Business Review on Drug Approvals....2010+

Example of rationale used:

In the years leading up to publication of the article(s), university life sciences research expenditures increased, while in the same time frame, the FDA approved fewer drugs.

Therefore.......university technology transfer is broken: we need to adopt free agency and abandon Bayh-Dole...
Brookings Institution

“University Start-Ups: Critical for Improving Technology Transfer”

• “University technology transfer has been largely dominated by a business model of licensing university patents to the highest bidder. .....”

• On nurturing startups:

• “While nurturing start-ups will not displace the standard license-to-highest-bidder model, in an environment of scarce resources the TTO may gradually redirect resources from finding licensors to finding buyers for their start-ups.”

  – Well-intentioned
  – Ill-informed
  – Never addressed with or interviewed technology transfer practitioners.....
Brookings Institution on Bayh-Dole:

• “It is less, clear, however, whether this act has always been effective in directing public research into the public interest..."

• Rather, it is quite possible that one unforeseen consequence of Bayh-Dole allows for modes of commercialization that have and (sic) inflationary effect on the whole healthcare system, not just new products.”

Building an Innovation-Based Economy, Brookings Institution (Nov. 2012)
Do We Need Patents?

“Patents are protected by governments because they are held to promote innovation. But there is plenty of evidence that they do not.”

Aug 8th 2015 | From the print edition
Do We Need Patents?

• Poorly argued, inconsistent case against patents

• Several rebuttals have appeared:
  • “What ‘The Economist’ Doesn’t Get About Patents”

“Fixing” the patent system – and more..

• Not content with “fixing” the patent system, the professors also call for reforming the pharmaceutical industry.

• One idea is having the National Institutes of Health fund Phase II and III clinical trials as “public goods,” deciding through bidding which companies are allowed to perform them.

• The winners would be required to sell resulting drugs at “economic cost” since the government is now running the show.

• Who would bother to make new drug discoveries knowing that the government would take them away?

• But not to worry, with “impartial, disinterested, wise and incorruptible” bureaucrats rather than companies in charge of drug development, what could possibly go wrong?

Joe Allen, used with permission
So much For The Golden Goose
Just One More Tribulation...

- Patent Reform
- Driven by the tech community
- Several years
- Universities

... are we....
trolls?

Some say yes:
“Patent trolls have a surprising ally: universities”

“After all, while universities don’t engage in the most egregious troll tactics, universities’ efforts to generate licensing revenue have imposed significant costs on the public that aren’t so different from problems created by patent trolls.” Nov. 30, 2013
One of the six organizations that signed the university groups' letter is the Association of University Technology Managers, which represents the "technology transfer" offices at many universities.

While the rest of a university works to promote the public interest by creating and disseminating new knowledge, technology transfer offices do just the opposite: enriching the university by obtaining patents that limit the public's access to the fruits of university research.

University administrators seem to regard the revenue generated by technology transfer offices as essentially free money. But as the above examples illustrate, the cash generated by patent licensing efforts is not free.

It represents a tax on innovation that raises prices, limits consumers' choices and slows future innovation. For licensing demands to be credible, they must be backed by the implicit threat of a patent lawsuit.

Note: “technology transfer”...
Major Media

• Well choreographed – and funded – on both sides

Washington DC National Airport advertising – September 2015:

~ 6’x4’ electronic billboards:

Major social, print, broadcast media activity
Universities Want to Stop Trolls

- The university associations are on record as wanting Congress to stop abusive patent litigation...
- But - don’t break the patent system in doing so.
- Issues with current legislation:
  - **Presumptive Fee Shifting** (‘Loser Pays”)
    - Will effectively price us – and our startup companies - out of enforcing our patents
    - Will devalue IP
  - **Joinder**
    - Universities may be dragged unwillingly into litigation
    - Investors less likely to take risk of investing
AUTM’s Response

• High level of visibility in D.C.
• Senate, Congress
• Op-Ed Piece in Financial Times
• Partnering with other associations
  – Higher education
  – Small Businesses
  – Medical Device Manufacturers
  – National Venture Capital Association
  – BIO
  – PhRMA
  – Many others....
U.S. Patent Reform Today

- Successful in slowing (stopping??) introduction in Congress
- Senate leadership leaning (slightly) our way....
- World events may dictate whether the legislation is introduced
- *Overnight activity with new amendments under discussion*
More Challenges: 2010-present

• Federal funding cutbacks have reduced the number of research outcomes and inventions

  $57.5 \text{ billion}$ reduction in federal funding if sequestration remains through 2017

• US Supreme Court rulings in *Stanford v Roche, Mayo v Prometheus and Myriad v AMP* have changed the system universities must work within

• US venture capital is investing in fewer early stage companies
Unrealistic Expectations

University Administrations, State Governments, Trustees – have seen (rare) blockbuster licensing revenues...

and set their hopes on licensing revenues to rescue them from their budget problems
Reality... revenues remain skewed:
~ 70% of revenues consistently go to only 10 universities.......

**FIGURE 2: DISTRIBUTION OF LICENSING GROSS INCOME BY UNIVERSITY**
In summary

Successful?

Maybe......
It’s always something....

• Existential
  – Philosophy of IP ownership; AAUP; Free Agency....

• Continued attacks on Bayh-Dole

• Patent Reform: split between tech & life sciences communities

• Unrealistic Expectations

• Unfunded Mandate

• How are we performing under these minor inconveniences?
Now the Triumphs....
FY2014 Licensing Activity Survey

AUTM’s survey data show impressive gains:
- Record number of U.S. Patents issued
- Continuing increase in startups launched
- Growth in new commercials products
- Overall impact on the economy
Boosting Economy with University and Nonprofit Patent Licensing

Economic impact from 1996 to 2013:

- Up to $518 billion on US gross domestic product
- Up to $1.18 trillion on US gross industrial output
- Creating as many as 3.8 million jobs
Jump in Startups

- 914 startup companies formed (up 11%)
- 4,688 startups operating by end of FY2013 (up 11.4%)
- 702 startups stayed in institution’s state (up 14.8%)
- 77% of startups operate in home state where research conducted

While only half of all new businesses formed in the United States survive more than five years, companies grounded in federally funded university research appear to do better.
Growth in New Commercial Products

- **965** new commercial products created *(up 34%)*
- **$28 billion** net product sales *(up 27.2%)*
- Nearly **10,000 patented products being sold** that originated in academic research labs

Remicade®, developed by researchers at New York University, reduces symptoms of Crohn’s disease for 1.3 million adult and teen patients worldwide.
Declining Federal Research Funding

• $62.8 billion total research expenditures (down 3.6%)
• $37.9 billion federally funded research expenditures (down 5%)
• National Institutes of Health (NIH) grants declined every year since 2004

$57.5 billion reduction in federal funding if sequestration remains through 2017.
Increased Partnership Activity Between Academia and Industry

- $4.6 billion industry-sponsored expenditures (up 1%)
- 549 executed licenses containing equity (up 17%)
- 5,435 licenses executed (up 4.5%)
- 1,461 options executed (up 7.7%)
- 42,015 active licenses and options (down 2.9%)
Record Number of U.S. Patents Issued

- **6,363** U.S. patents issued (up **11%**)
- **23,526** total US patent applications filed (up **0.10%**)
- **13,907** new patent applications filed (down **7.26%**)
- **1,107** non-US new patent applications filed (down **24.8%**)

More than 80,000 patents have been issued to research institutions over past 20 years
About the Survey

191 responded (63% response rate)

• 163 universities
• 27 hospitals and research institutions
• 1 third-party investment firm
Communicating Impact of Technology Transfer

- Infographic — Society Benefits and Economic Impact
- Postcard — Human Side of Technology Transfer
Thank you!

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