Introduction to Medicine for Innovators: Patents and Licensing at Stanford
May 20, 2008

Overview
- Bayh-Dole, OTL Background, and SU Patent Policies
- OTL Facts and Figures
- What is a Patent
- Inventorship
- OTL Process - Invention to License
- Start-ups
- Summary

Bayh-Dole Law
- First right to title to universities
- Royalty free license to government
- Substantial manufacture in US
- Preference for small business
- Share royalties with inventors

OTL's Mission
To promote the transfer of Stanford technology for society's use and benefit while generating unrestricted income to support research and education.

Types of Technology
- Patents
- Copyrightable Material
- Software
- Biological Material (unpatented tech)
- Semiconductor Maskworks

Stanford's Intellectual Property Policy
- Patentable Technology - University takes title to all inventions created with more than incidental use of University resources
- Copyrighted Works - University takes title to copyrightable works created with significant University resources.
Stanford Internal Royalty Sharing Policy

- Cash Royalties: Issue, Minimums, Earned Royalties
- Deduct: 15% for administrative expenses, then out of pocket expenses
- Net Royalties:
  - 1/3 to Inventor(s)
  - 1/3 to Department(s)
  - 1/3 to School(s)

OTL Facts and Figures

- Established in 1970
- Staff of 29
  - 376.5 cumulative years of experience
- 7 full-time Licensing Associates
  - Technical degrees / Industry Experience
  - Licensing Liaisons-Marketing, Patent, Admin function

Conversion Numbers

- Receive ~8 disclosures per week
- File patents on ~50%
- License 20-25%

Disclosure and Licensing History

- ~6900 cumulative disclosures
  - ~2,580 currently active cases
- Executed over 2,780 cumulative licenses
  - ~940 currently active licenses

Licenses

- Executed 77 new licenses in FY07
  - 42 non-exclusive licenses
  - 24 exclusive licenses
  - 11 option agreements

OTL Expenses

- Operating budget of $4.1 million/year
- Patent expenses of ~$6.8 million/year
**Patent Expenses**

~$6.8 million/year

- US only patent usually costs $25K to $35K over the life of the patent
- Broad foreign coverage usually $200K

**What is a Patent**

- Patent owner has right to exclude others from making, using, or selling claimed invention
- A License from the owner (licensor) gives the recipient (licensee) the right to make, use, and sell the invention.

**What is a Patent**

Utility patent protects:
- Processes (methods), machines, articles of manufacture, and compositions of matter
- That are useful, novel, and non-obvious inventions.

**More on Utility Patents**

- To secure patent protection:
  - File patent application USPTO
  - 2 to 5 years from filing to issuance

- Length of right to exclude others:
  - Starts upon patent issuance
  - Expires 20 years from date of utility patent filing
  - Maintenance fees at 3.5 years, 7.5 years, and 11.5 years

**Invention to License**

- Disclosure
- Evaluation
- Licensing Strategy
  - File patent?
  - Market to potential licensees
- The License
- Maintaining the Relationship

**Disclosure Form**

- Legal document recognized by the Patent & Trademark Office (PTO)
- Establishes a date of invention under US patent law
- Disclosure must outline the invention sufficiently
- Must be signed, witnessed and dated
- Provides some marketing and uses info to OTL
Naming Inventors on Disclosure Form
- Authorship and inventorship have different criteria and are not equivalent.
- An inventor is someone who conceives or reduces to practice an essential element of the invention.
- The correct inventors must be named on the patent.
- Inventorship determined by a patent attorney.

The Main Question
Does it have the potential to create meaningful income for the University and at the same time have a commercial path to benefit society?

Evaluation
- Discuss with inventors
- Discuss with others at OTL
- Contact industry experts
- Patentability Assessment

Inventor's Role in the Process
- Disclose inventions
- Identify potential licensing prospects
- Participate in patent preparation and prosecution
- Host visits and/or provide technical information to potential licensees
- Provide input into the licensing strategy
- Sometimes consultant to licensee(s)

Marketing Strategy
- OTL Markets all Tech
- When do we start?
  - Waiting for publication
  - Waiting for data
- Shotgun vs. Rifle?
- Portfolios?

The Patenting Decision
- Can we license as Biological Material/Tangible Research Property (TRP)?
- Can we license it as copyright?
- Is it patentable and enforceable?
- Has it been publicly disclosed?
Licensing Strategy

- Exclusive vs. non-exclusive
  - Selecting exclusive licensee(s)
  - Prefer to license more than one company, if practical
  - Large company vs. Small/Start-up company
- Field of use
  - Applications
  - Diagnostics vs. Therapeutics
- Geographies - limited vs. worldwide

The Parameters of a License

- Royalties
  - License Issue Royalty
  - Annual Minimum Royalty
  - Earned Royalty
  - Equity
- Development Milestone payments
- Diligence provisions
- Reimbursement of Patent Costs

Royalties

- 1970 - $50,000 in royalties
- FY2007 - $50.4M in royalties
- ~$1.14B cumulative

Royalties - Looking Closely

- In FY06-07, $50.4 million from 494 disclosures
- 30 out of 494 disclosures generated over $100,000 each
- 3 out of 30 generated over $1 million each
- From 1970 through 2007
  - 55 inventions generated $1 million or more
  - 3 out of 7000 is BIG WINNER

Start-ups

- Universities want to share in the upside and help with economic development
- Cash Sparing license structure
- Conflict of interest issues are primary concern
- No negotiating with inventors/founders due to their conflicted positions
- Many start-ups first take option agreements for 6-12 months
- Most work with local VC firms

OTL Interactions with Start-ups

- Typical situation:
  - Researcher discloses invention and states s/he would like to found a company around the technology
  - OTL markets technology
  - Often start-up is the only interested party
  - Start-up submits business plan
  - Negotiate financial terms with business person/attorney
  - OTL initiates conflict of interest review if inventor-faculty member involved
Equity at Stanford - Philosophy
- Equity is only one component of a whole financial package.
- Historically, most income is generated from earned royalties (~$777.7M vs. ~$362.3M).
- Equity is liquidated soon after IPO.
- We can’t hold equity if licensee conducts clinical trials here.

Equity at Stanford - History
- Equity in ~172 companies (OTL lifetime)
- Equity in about 92 companies currently
- 10 licenses with equity in FY07

Equity Cash-Out*
- ~$362.3 million equity liquidated to date
  - 1998 - Amati (Texas Instruments) $8.0 million
  - 2000 - Abrizio (PMC-Sierra) $9.7 million
  - 2005 - Google™ $336 million

*Graph does not include liquidation of Google™ equity in FY04-05

Equity at Stanford - Facts for 2007
- 7 Schools
  - Business, Earth Sciences, Education, Engineering, Humanities and Sciences, Law, and Medicine
- Students
  - 7,167 undergraduates
  - 3,082 graduate
- Faculty - 2,877 members
- $3.28 billion budget (FY 06-07)
- 53% supported by state government
- $336.6M endowment

Differences with other TLOs
- OTL does not have the goal of stimulating the local economy
- Stanford does not have an incubator
- Stanford never assigns patent rights to another party in a license
- OTL does not help write business plans
- OTL can provide introductions to Venture Capitalists, but the start-ups rarely require them

Notable Stanford Inventions
- 1970 - OTL Established
- 1971 - FM Sound Synthesis ($22.9M)
- 1974 - Recombinant DNA ($255M)
- 1981 - Phycobiliproteins ($46.4M), Fiber Optic Amplifier ($33.8M), MINOS ($3.5M)
- 1982 - Amplification of Genes ($32.9M)
- 1984 - Functional Antibodies ($158.2M)
- 1986 - CHEF Electrophoresis ($2.1M)
- 1990-1992 - DSL ($29.4M)
- 1996 - Improved Hypertext Searching (Google™) ($336.6M)

2008 - the next big thing???
Summary
- Bayh-Dole gave Univ ownership rights
- Patents give a right to exclude
- Disclosure key step to begin process
- Inventorship, patent application prep, and marketing are key duties for inventors
- Active marketing/start ups by inventors lead to licenses
- Gage your expectations - most inventions do not make money

U.S. Statutory Bar: Printed Publication
- What is considered a printed publication?
  (a) journal article
  (b) abstract in advance proceedings
  (c) thesis
  (d) grant or contract proposal
  (e) slides used during oral presentations
  (f) description posted on the internet
- Criteria for a printed publication
  - publicly available and accessible
  - enabling disclosure

Marketing Steps
- Create marketing content
- Create list of potential licensees
- Contact potential licensees
- Follow-up

Web Page
otl.stanford.edu

Typical Invention → U.S. Patent Timeline
- Conception
- Reduction to practice
- Provisional application
- Filing
- 3.5 years
- Maintenance fee
- 7.5 years
- Maintenance fee
- 11.5 years
- Maintenance fee
- 20 years
- Patent prosecution
- Issuance
- Publication @ 18 months
- Expiration