Technology Transfer & Commercialization

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Technology Transfer

- Process by which new innovations flow from the basic research bench to commercial entities and then to public use.
- Property of the academic institution rather than the individual inventor.
- Technology transfer offices are tasked with seeing to it that such intellectual property rights are properly managed and commercialized.
- Intellectual property (IP) rights are secured through patents, trademarks, copyrights, and trade secrets.


Academic Center Innovation...


Before World War II, almost all R&D in the United States was conducted in federal facilities by federal employees. Government policy generally made all patents from such work available to the general public in order to encourage product development.

Following the war, use of government facilities for R&D declined, but the government nevertheless remained a huge contributor to R&D through federal research grants, salaries, and other contributions.

The Bayh–Dole Act of 1980

Until the latter half of the 20th century, the government had few policies to encourage the public use of its huge reservoir of R&D.

The Bayh–Dole Act allowed the funded entity to retain title to any invention created as a result of government contracts and grants.

U.S. government no longer takes title to inventions created by government contractors and grantees, although it continues to be the single largest sponsor of all R&D in the nation.

The Bayh–Dole Act gave research institutes ownership of patents resulting from federally funded research.

They generally commercialize such IP assets by granting access rights to (mostly) for-profit commercial entities by way of a license—while in most cases retaining ownership of the underlying IP.

They must attract private manufacturers or investment bodies such as venture capital enterprises.

Strength of the IP and the quality of research are foremost attractors.
**Academic Institutions**

- **Technology Transfer Office’s (TTO, OTC) role:**
  - Determine whether an invention can likely be patented or copyrighted. In so doing, determine if the university will claim title to it.
  - To source innovations.
  - To manage IP protection,
  - Provide commercialization promoting resources (such as gap funding programs, access to business savvy mentors and entrepreneurs as well as regulatory consultants, connections to industry and investment bodies, etc.).
  - Negotiate and execute licensing deals.

- **Methods for Transfer of Technology:**
  - Through publication of innovations to the general public without taking further measures of a commercial nature.
  - Through sponsored research agreements with private industry.
  - Through the formation of startup companies.

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**Exceptions to Automatic Patent Assignment...**

- If the inventor is a student at the university, but not employed by the university, and did not receive any direct support from the university regarding the invention.
- If the inventor is an employee, but the invention was developed entirely on the employee’s own time, did not involve the use of any university resources, and the invention is not related to university business, or to any actual or demonstrably anticipated research or development.
Technology Transfer

Technology transfer begins when the inventor discloses an invention to the University.

Is there commercial value or social impact?

Find a licensee/partner (many may be considered),

- Type, risk, current stage, cost, market size, profit margin, patent status, cost of research, scope of license and comparable royalties.

Patent process can take 2 to 4 years.

Research for new drugs may take up to 12 years.
Commercialization – Comparison

- In private industry, TT often occurs through the sale of IP, products, or services.
- In universities, the majority of TT typically occurs through the licensing of IP. This includes partnership relationships.
  - Opportunities for new research collaborations and funding, and for the exchange of materials, information, and personnel with private industry.
  - Brookings Institution indicates that 84% to 87% of universities will not realize enough income to cover the costs of a TTO.*


TABLE 3: Top 10 U.S. Universities by Patents Issued From 1995 to 2012

<table>
<thead>
<tr>
<th>University</th>
<th>Number of Patents 1995-2012</th>
<th>Number of Patents 1993-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, San Diego</td>
<td>301</td>
<td>7,500</td>
</tr>
<tr>
<td>Massachusetts Institute of Technology</td>
<td>218</td>
<td>4,417</td>
</tr>
<tr>
<td>Stanford University</td>
<td>181</td>
<td>2,602</td>
</tr>
<tr>
<td>California Institute of Technology</td>
<td>106</td>
<td>2,187</td>
</tr>
<tr>
<td>University of Texas at Austin</td>
<td>141</td>
<td>2,077</td>
</tr>
<tr>
<td>University of Wisconsin-Madison</td>
<td>161</td>
<td>2,194</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>79</td>
<td>1,567</td>
</tr>
<tr>
<td>Cornell University</td>
<td>55</td>
<td>1,366</td>
</tr>
<tr>
<td>University of Michigan</td>
<td>50</td>
<td>1,259</td>
</tr>
<tr>
<td>University of Florida</td>
<td>20</td>
<td>1,236</td>
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</tbody>
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Sponsored Research Agreements (SRA) – Issues

- Academic freedom.
- Shift away from research.
- Personal and institutional conflicts of interest.
- Misappropriate use of public funds for commercial and for-profit pursuits.
- Delayed publication for purpose of “academic lead.”
- Knoll case* – University of California San Francisco prevented from publishing results of equivalent levothyroxine by Flint Laboratories as it was detrimental to their commercial interest.
- SRAs bias research conclusions.

Venture Capitalists

- Promoting and developing promising university inventions that are in an intermediate stage of development and not yet ready to attract a larger commercial sponsor.
- Approach inventors to form companies around inventions.
- Relationship between the researcher and investing firm is critical.
- Inquire as to prior companies the VC has supported.
- “Faculty startups.”
  - University supportive?
  - Requisite skills?
  - Conflicts of interest?

Sharing with the Inventor

- Sharing with the inventor is a requirement under federal law.
- Fewer than 1/3 of university patents are licensed. Few of these earn significant revenue.
- The share commonly paid to inventor is 30% of revenues earned by the institution after deducting patent and marketing costs.

Summary

- Technology Transfer,
  - Academic institutions.
  - Role of the Technology Transfer Office.
  - TTO patent process.
- Commercialization
  - SRA – Sponsored Research Agreements.
  - Venture capitalists.
  - Sharing with the inventor.
- Addendum –
  - Transfer process when the TTO takes to title.
  - Material transfer agreements.
  - Obligations in accepting federal funding & US Government rights.
  - Common elements in a license contract.
  - Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.
Materials that do not have significant commercial value but may be useful in noncommercial research are sometimes nonexclusively transferred to other parties via materials transfer agreements (MTAs).

Department of Health and Human Services, National Institutes of Health. Principles and guidelines for recipients of NIH research grants and contracts on obtaining and disseminating biomedical research resources: final notice. Federal Register, Vol. 64 No. 246. Thursday, December 23, 1999.

COGR: Council on Government Relations, an association of research universities and independent research institutes. A tutorial on technology transfer in the U.S. colleges and universities. August 1, 2011.
TABLE 2. U.S. Government Rights Regarding Inventions That Result From Federally Funded Work and Research

- Rights to a nonexclusive, nontransferable, nonroyalty, pass-up license to the invention, to practice it, or have it practiced on its behalf throughout the world.
- Can require the university to assign title to the government if the university fails to report the invention, files an invalid title, or does not file for patent within the required period of time.
- Can require the university to license the invention to third parties (including the right to require the university to assign exclusive licenses), or the right of the government (not to grant those licenses) as related "manufacturing rights", provided that the following circumstances apply: (1) the invention has not been brought into public use or into a commercial sale; (2) where health or safety considerations require license; or (3) if the licensing regulations have not been met and were not waived by the funding agency.
- Can make a determination of exceptional circumstances that there are compelling reasons why the right of the university to retain title should be restricted or eliminated.


TABLE 3. A Partial List of Common Elements in a License Contract:

- Exclusive or nonexclusive license
- Field of use
- Geographic restrictions
- Term of license
- diligence requirements - performance milestones
- Accounting for milestones and fees
- Royalties and sublicensing provisions
- Protection of (inventor) costs (e.g., costs of obtaining a patent)
- Interference and nuisance
- Research and development funding
- Payment and facilities
- Consulting agreements
- Access to proprietary and technical information about the invention
- Whether equity shares (or the case of startups) may serve as payment
- Other terms

Adapted from Roy, R. (2011).


SBIR and STTRs

- The federal government Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs represent the largest seed stage funding sources for companies in the world.

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td>Principle investigator must be ~50% employed by the small business.</td>
<td>Principle investigator may be primarily employed by either the small business or the research institution.</td>
</tr>
<tr>
<td>Small business majority owned by wealthy individuals or private equity firms are eligible to apply.</td>
<td>Formal cooperative R&amp;D effort is between the small business and a U.S. research institution.</td>
</tr>
<tr>
<td>The small business must do a minimum of 40% of the work, research institution must do a minimum of 30% of the work.</td>
<td>The small business must do a minimum of 40% of the work, research institution must do a minimum of 30% of the work.</td>
</tr>
</tbody>
</table>

Both programs are designed for small business concerns, not-for-profit, U.S.-based businesses with fewer than 500 employees.

SBIR = Small Business Innovation Research; STTR = Small Business Technology Transfer. — where applicable.