Patents before 1980: Pre Bayh-Dole Act

• Federally funded research:
  • ~28,000 patents owned by Government
  • Provided non-exclusive licenses to any interested party

• Resulting Societal Impact:
  • 0 drugs developed by research institutes
  • Low pharmaceutical company priority
  • Technology Transfer: low impact
Bayh-Dole Act - 1980

What did it do?

• Uniform patent policy - federally funded recipients retain ownership of inventions
• University responsibility for commercialization – how would they do it?
Bayh-Dole Act - 1980

Impact:

• 2013: 153 new drugs/vaccines developed via federal funding

• Examples include:
  • Synthetic penicillin, Hepatitis B vaccine, Citracal calcium supplement, Cancer therapeutics, Human growth hormones, Treatments for Crohn's disease, Avian Flu vaccine, Clean water technologies
Tech Transfer offices – Translational Resource

Goal: Get new Products on Market

- Establish innovative climate
  - Champion current faculty
  - Attract/retain world-class faculty

- Public Benefits
  - Convert discoveries into products/services

- Strategic partnerships
  - Private sector engagement

- Economic development
  - Think globally act locally
A Common Arrangement: Know your Rights

• Ownership of ideas
  • Condition of employment, studentship, and/or resource usage

• Requirements:
  • Employees and Students must disclose Intellectual property
  • Ownership is then determined
  • Traditional academic copyrights owned by author(s)

• Revenue from licensing IP shared with Inventors
What interests Tech Transfer?

Technologies

- Therapeutics
- Diagnostics
- Medical Devices
- Imaging & Algorithms
- Copyright Materials
- Research Tools, data
When to engage Tech Transfer: shepherding innovation
When would one want Copyright Protection

• Creator granted legal rights for:
  • Exclusive copying
  • Preparing derivative works
  • Distributing, performing
  • Displaying and transmitting copyrighted work

• Author granted legal right for exclusive use on expression of an idea
  • Specific expression of words, design or other form
  • Allows for multiple expressions to be available for same idea
Copyright Protection Length

• Vests immediately © upon fixation

• Lasts the lifetime of author plus 70 years
  • 120 years for a work made for hire

• Copyright infringement: when exclusive right granted to creator is carried out by someone else without permission
Copyright Benefits/Detractors

**Pros**
- Automatic rights
- Easy and relatively cheap registration and fees
- Provides right to control exclusive rights, such as reproduction, distribution, and derivation

**Cons**
- Copyright protects expressions of idea, not idea per se
- Expensive to enforce
Example: Duck, Duck, Punch

- © protection
- Stroke rehabilitation game
- Dissertation project
- FDA approved
Know How

Distinct and unique body of knowledge

• Capitalizing on know-how “is still a bit of black magic,” says Dipanjan “DJ” Nag, a director at intellectual capital equity firm Ocean Tomo. “It’s very hard to define exactly what know-how is.” Nag defines it as trade secrets and unfiled patents. Other technology transfer experts believe source code and research notes on software also would fall under the “know-how” umbrella.

• https://techtransfercentral.com/reprints/ttt/1207-licensing-your-know-how/

• Usually a high hurdle for replication
Know-How: Benefits and Detractors

• Pros
  • Unlimited duration
  • Worldwide protection
  • No application required and no registration costs
  • Effective immediately

• Cons
  • Not easily enforceable
  • Not effective when reverse engineering possible
Do Research Tools Qualify as Know-How?

- Knock-out mice
- Cell lines
- Reagents
Power to prevent others from:
- Making
- Using
- Selling

the invention in country of patent

Patents reward risk & fosters innovation

Invention description crucial - know how to make & use it

Community gains knowledge in trade for inventor to have a limited period of exclusivity

Last 20 years

Can be designed around

Does NOT give you the right to make/use/sell yourself (Freedom-to-operate)
# Cost and Time Associated with Patents

<table>
<thead>
<tr>
<th>Typical Patent Process Activity</th>
<th>Money</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisional Patent Filing</td>
<td>$1k to $5k</td>
<td>12 months</td>
</tr>
<tr>
<td>U.S. Utility Filing</td>
<td>~$20k</td>
<td>30 months</td>
</tr>
<tr>
<td>International Filings</td>
<td>&gt;$100k</td>
<td>N/A</td>
</tr>
<tr>
<td>Issuance of patent claims and Maintaining applications</td>
<td>$$ to $$$</td>
<td>2.5 to 4.5 + years</td>
</tr>
<tr>
<td>Defending patents and stopping infringers</td>
<td>$$$ to $$$$$</td>
<td>N/A</td>
</tr>
</tbody>
</table>
USPTO Patent Analysis

• PRIOR ART.—A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, present in a patent application, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention;

• In other words, any public disclosure from the inventor or otherwise before the patent is filed!
Prior Art: Public Disclosures - Publish or Perish Problem in Academia

- Manuscripts, public presentations (internal or external), dissertations, posters in public places
- Grant abstracts for awarded federal grants are public disclosures
- Public uses and sales
Patent: Benefits and Detractors

Pros

• Effective Tool against infringers
• Product credibility
• Helps gather investments
  • Critical for high risk ventures, e.g., medical device and drug development
• 20 years of protection
• Others must be granted permission to use through licensing

Cons

• High cost, lengthy patent process
• Invention must be fully disclosed
• Litigation cost high
Tech. Transfer helps you, help people

- Bayh-Dole Act: Modernized Patent Policy
- Tech Transfer - Enabling innovation
  - Culture
  - Climate
  - Think globally, act locally
- Provide mechanism to commercialize your ideas to help people
Now, it’s your turn

• Gratitude and Appreciations
  • Scott Davis, Ph.D., Patent Agent
  • Christine Dixon-Thiesing
  • Daniel, S. Johnston, Ph.D.