An Introduction to Licensing in Commercializing Biomedical Technology

October 5, 2016
Tracy Roberson
Director for Technology Commercialization
Notable Intellectual Property Licensed from Universities

- Gatorade®
- BRCA1/BRCA2 Test
- Nicotine Patch
- PSA Test
- Google
- Pepcid®
- Taxol®
- Remicade®
- QUIKCLOT®
- Lyrica®
- Sun-Crisp Apple®
- Berkeley-Darfur Stove
- University of Florida
- University of Utah
- UCLA
- Roswell Park Cancer Institute
- Stanford
- Brigham & Women’s Hospital
- Florida State
- New York University
- UC Santa Barbara
- Northwestern
- Rutgers University
- UC Berkley
Our Mission

- The Office for Technology Development ("OTD") promotes the research enterprise at UT Southwestern Medical Center by commercializing research results in order to bring medicine to many.

- Inventions made by UTSW employees and students are the property of the Board of Regents of the University of Texas System (with a few exceptions) and OTD is charged with managing and commercializing these inventions.
Why Do We License Technologies?

- To initiate and sustain cooperation between UTSW and industry to advance new technologies and therapies.
- To provide our faculty with strategic guidance to effectively manage intellectual property developed on campus.
- To generate revenue for UTSW, our inventors, and to support our research enterprise.
- To facilitate the maturation of the North Texas biotechnology industry and other healthcare related economic development.
- To benefit society.
Why Should You Be Interested In Commercialization?

- When we grant a company the right to commercialize a UTSW invention, we expect to receive value (consideration) in exchange from that company, typically in the form of cash and/or securities.

  Promotes advancement of research (SRA)
  Unrestricted laboratory funds (Licensing)
  Personal income (Licensing)
  Personal satisfaction & recognition
License Proceeds

- Any gross license revenues received are first used to reimburse patent and licensing expenses.
- After reimbursement of these expenses, net cash license revenues are distributed as follows:
  
  50% Inventor(s)
  
  25% Inventor(s)' Laboratory
  
  25% President's Office
UT Southwestern Products

- TEV Protease
- Tenecteplase®
- Citracal®
- UroCit-K ®
- ORBIT GALAXY COIL®
- CELLSEARCH®
- HKL-2000 Software
- 3D Motion/Perfusion Map Software
- MoleMeter®
What is a License Agreement?

- A license agreement is permission in the form of a written agreement enabling patent rights owned by one party to be used by another party, typically involving the exchange of consideration between the licensor (the owner of the rights) and the licensee (the party seeking permission to use the rights).

- Use of such issued patent rights without a license is infringement.
The Role of The Office for Technology Development (OTD)

- Licensing at UTSW is governed by statutes of the state of Texas and the *Rules and Regulations* of the UT Board of Regents.

- All licensing is handled exclusively by OTD.

- Inventors are kept informed throughout the process, unless they want no further role.

- Although OTD negotiates all financial and legal terms, inventors can add value to the process through their scientific and medical advice.
Typical Agreements for Technology Commercialization

Industry Need

- Need to exchange information?
- Need to test materials?
- Need to develop the technology?
- Need time to evaluate the technology?
- Need to acquire the technology?

Agreement

- Confidential Disclosure & Limited Use Agreement
- Material Transfer Agreement
- Collaborative or Sponsored Research Agreement
- Option Agreement
- License Agreement
# Primary License Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant of Rights</td>
<td>Rights licensee obtains</td>
</tr>
<tr>
<td>Retained Rights</td>
<td>Rights the university keeps</td>
</tr>
<tr>
<td>Consideration</td>
<td>$$$</td>
</tr>
<tr>
<td>Indemnification</td>
<td>Protection for university and its investigators</td>
</tr>
</tbody>
</table>
Grant of Rights

- Patent rights and/or technology rights
- Exclusive vs. Non-exclusive
- Field of use
- Territory
- Term
Retained Rights

- When we grant licenses, we always must retain the right to:
  - Publish the general scientific findings from research related to the licensed technology;
  - Use the licensed technology for non-commercial research, teaching, patient care, and other educationally-related purposes; and
  - Transfer the licensed technology to academic or research institutions free-of-charge.
Consideration

- The consideration received in exchange for the license granted can include any of the following:
  
  - Reimbursement of sunk-in patent expenses
  - Up-front fee
  - License re-issue fees
  - Minimum annual royalties
  - Milestone payments and/or success fees
  - Royalties
  - Sublicense income sharing
  - Equity
Key Licensing Factors

- Attract licensees to early stage technologies
- Identify a quality licensee ("Licenses are like marriages. They are easier to get into that to get out of.")
- Develop an effective licensing strategy (type of grant, field of use, etc.)
- Identify acceptable non-monetary terms
- Develop a reasonable value proposition
Determining Value

- Scientific value ≠ Commercial value!
- Patent rights only vs. technology rights only
- Up-front revenues vs. downstream revenues
- Royalty rates
- Cash vs. Equity
Most Common Dealbreakers

- Warranties & Representations
- Restrictions on retained rights (including publication, though we work out timelines to file patent applications prior to publication)
- Indemnification
- Unrestricted or unwarranted demand for access to improvements
- Ownership of IP

Financial terms are rarely dealbreakers!
Basic Metrics For Our Office

Several years ago, we analyzed UTSW historic data and determined the following:

For any initial disclosure arriving in our office,

US patent filing rate = 41.8%

License/option rate by disclosure = 39.1%

License/option rate, no patent = 36.8%

License/option rate, patent filed = 56.6%

The license/option rate for ALL US patent applications filed is 68.2%.

Currently, 57.2% of our active US portfolio has been licensed.

This doesn’t mean all licenses/options make money!

Somebody has to end up selling a product!
Licensing Performance

- Over 700 license and option agreements executed.
- Over 575 active license and option agreements.
- Over $173 million in license revenues ($14.9 million from equity and over $3 million from software).
Time from Disclosure to First License

Median Time, Technology License = 8 months
Median Time, Patent License = 30 months

% of License Transactions

Years

# of License Transactions
UT Southwestern
Cumulative License Revenue and Disclosures

Fiscal Year

Cumulative Income
Cumulative Disclosures

Disclosures

$0

$20,000,000

$40,000,000

$60,000,000

$80,000,000

$100,000,000

$120,000,000

$140,000,000

$160,000,000

$180,000,000

$200,000,000

$220,000,000

$240,000,000

$260,000,000

$280,000,000

$300,000,000

Textbook Performance for Net License Revenue

- Disclosure
- Decision to File Patent
- License Granted & Fees Received
- Milestone Payments
- First Sale
- Royalties
- Maturity
- Patent Expiration

Breakeven

$ Gain

$ Loss

Time
Big Winners are Rare: Stanford

- Since 1970, approximately 9,400 disclosures received
- 3,183 licenses completed (1,100 currently active)
- Over $1.5 billion in gross license revenues
- 75 technologies generated >$1 million over their life (0.8%)
- 3 technologies generated >$100 million over their life (0.03%), accounting for 66% of their total gross license revenues (1 of these generated $336 million, approximately 22% of their income)
## Contact Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frank Grassler, J.D.</td>
<td>Vice President for Technology Development 214-648-1902 <a href="mailto:Frank.Grassler@utsouthwestern.edu">Frank.Grassler@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>Tracy Roberson</td>
<td>Director for Technology Commercialization 214-648-1888 <a href="mailto:Tracy.Roberson@utsouthwestern.edu">Tracy.Roberson@utsouthwestern.edu</a></td>
</tr>
<tr>
<td>Kathy Schutt, CLP®</td>
<td>Director, Cooperative and Sponsored Research 214-648-1881 <a href="mailto:Kathy.Schutt@utsouthwestern.edu">Kathy.Schutt@utsouthwestern.edu</a></td>
</tr>
</tbody>
</table>