An Introduction to Licensing in Commercializing Biomedical Technology
Notable Intellectual Property Licensed from Universities

- **Gatorade®**
  University of Florida

- **BRCA1/BRCA2 Test**
  University of Utah

- **Nicotine Patch**
  UCLA

- **PSA Test**
  Roswell Park Cancer Institute

- **Google**
  Stanford

- **Pepcid®**
  Brigham & Women’s Hospital

- **Taxol®**
  Florida State

- **Remicade®**
  New York University

- **QUIKCLOT®**
  UC Santa Barbara

- **Lyrica®**
  Northwestern

- **Tenectaplasce brand of TPA**
  UTSW

- **Berkeley-Darfur Stove**
  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.
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?

- Promotes advancement of research (Sponsored Research)
- Unrestricted laboratory funds (Licensing)
- Personal satisfaction & recognition
- Personal income (Licensing)

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.
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:

**Net Cash License Revenues Distribution**

- Inventor(s): 50%
- President's Office: 25%
- Inventor(s)' Laboratory: 25%
UT Southwestern Products

- **TEV Protease**
  - Life Technologies™

- **Tenecteplase®**
  - Genentech
  - A Member of the Roche Group

- **Citracal®**
  - originally Mission®
  - Pharmacal

- **UroCit-K®**
  - Mission® Pharmacal

- **ORBIT GALAXY COIL®**
  - Codman
  - a Johnson-Johnson company

- **CELLSEARCH®**
  - formerly Veridex

- **HKL-2000 Software**
  - HKL Research, Inc

- **3D Motion/Perfusion Map Software**
  - formerly Picker International

- **MoleMeter®**
  - Mary Kay®
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 Office for Technology Development (OTD)

All licensing is handled exclusively by OTD.

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

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

Agreement Used

- License Agreement
- Material Transfer Agreement
- Collaborative or Sponsored Research Agreement
- Option Agreement
- Confidentiality Agreements
Primary License Terms

Grant of Rights
- Rights Licensee Obtains

Retained Rights
- Rights the university keeps

Consideration
- $$$

Indemnification
- Protection for university and its investigators
Grant of Rights

*Rights Licensee Obtains*

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

Rights Licensee Obtains

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.
The consideration received in exchange for the license granted can include any of the following:

<table>
<thead>
<tr>
<th>Consideration</th>
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<tbody>
<tr>
<td>Reimbursement of sunk-in patent expenses</td>
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<tr>
<td>Up-front fee</td>
</tr>
<tr>
<td>License re-issue fees</td>
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<tr>
<td>Minimum annual royalties</td>
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<tr>
<td>Milestone payments and/or success fees</td>
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<tr>
<td>Royalties</td>
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<tr>
<td>Sublicense income sharing</td>
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<tr>
<td>Equity</td>
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Key Licensing Factors

Attract licensees to promising technologies

Identify a quality licensee

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 Deal Breakers

<table>
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<tr>
<th>Warranties &amp; Representations</th>
<th>Restrictions on retained rights (including publication, though we work out timelines to file patent applications prior to publication)</th>
<th>Indemnification</th>
<th>Unrestricted or unwarranted demand for access to improvements</th>
<th>Ownership of IP</th>
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Financial terms are rarely deal breakers
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%
- License/option rate for ALL US patent applications filed = 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 950 license and option agreements executed.
- Over 575 active license and option agreements.
- Over $199 million in license revenues ($17.7 million from equity and over $3 million from software).
Median Time, Technology License = 8 months
Median Time, Patent License = 30 months
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

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