Considerations for Intellectual Property Protection & Commercialization of Research at a University

By

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Questions to be Answered

• What is a patent?
• How is patentability evaluated?
• What is Freedom-to-Operate?
• You have an idea, now what?
MUSC Navigation – Who Does What?

- **SCTR Institute**
  - Research Opportunity Core
  - Regulatory & Navigation Consults
  - Pilot Project Funding
  - Scientific Retreats

- **FRD**
  - Invention Disclosures
  - Patent Filing
  - Copyright Registration
  - IP Licensing
  - Confidentiality Agreements

- **ORSP**
  - Corporate Sponsored Research Agreements
  - MTAs

- **CIE**
  - Business Plan Assistance
  - Startup Company Formation
  - Education & Outreach

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Who Does What:

- **IP**
Goal is Translation

Improved Healthcare

SCTR Institute
FRD
ORSP
CIE

IP
FRD Manages Tech Translation at MUSC Transfer

Bench → Industry → Bedside
What Gives FRD the Right?

• Bayh-Dole Act
  – Allows the university to elect title to inventions stemming from federally funded research

• MUSC IP policy
  – Compliance with IP policy is condition of employment and/or resource utilization
    • [http://frd.musc.edu/inventors/policy](http://frd.musc.edu/inventors/policy)
Things to Know about the IP Policy

• As a condition of your employment at MUSC you must Assign ownership to MUSC.

• FRD acts as the agent for the Inventors in trying to commercialize the invention.

• Unless there is a prior agreement, all Inventors are equal in terms of ownership.

• Revenue from licensing IP is shared with Inventors.
License Income Distribution

Gross Licensing Income

- Other institutions
- Legal/Admin expenses

Inventor: 40-60% C, 25-40% P
Laboratory: 15% C, 30% P
Department: 10% C, 10% P
MUSC: 15-35% C, 15-30% P

***See MUSC IP Policy for Details
Types of Technologies Invented at MUSC

- Therapeutics
- Diagnostics
- Medical Devices
- Imaging & Algorithms
- Copyright Materials
- Research Tools
Different Forms of Protection

- Patents
  - Therapeutics
  - Diagnostics
  - Medical Devices
  - Imaging & Algorithms
- Copyright
  - Copyright Materials
- Know How
  - Research Tools
What a Corporate Partner Wants

Commercial Potential

+ 

IP Potential

$\text{$$$$$$}$
# Commercial Evaluation

<table>
<thead>
<tr>
<th>Novel technology or improvement?</th>
<th>What is the market size &amp; saturation/competition?</th>
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<tbody>
<tr>
<td>Stage of development?</td>
<td>Is a company interested already?</td>
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<tr>
<td>Potential for making a profit?</td>
<td>Novel compound or known compound?</td>
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<tr>
<td>• Cost to produce</td>
<td>• Composition of matter</td>
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<tr>
<td>• Regulatory hurdles</td>
<td>• Method of use</td>
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<td></td>
<td>• Reformulation</td>
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What is a Patent?

Power to prevent others from making, using, or selling invention in country of patent.
Patent Power

- Medtronic infringed Edwards Lifesciences’s patent on transcatheter aortic valve replacement (TAVR)
  - $245M in damages
New Drugs: High Risk Venture

- From bench to patient: 12-15 years
- Cost: $350-800M
- Past preclinical testing: 1:1000
- Failure in efficacy trials: 60%

Patent can provide freedom from competition
Patent Power-less

- Eli Lilly’s patent on a method of use for Prozac invalidated on August 9, 2000
  - $2.4B/yr sales

Immediately thereafter, shareholders dumped $36 billion in Lilly stock value
Why Not Patent Everything?

**Typical Patent Process**

- **Provisional Patent Filing**
  - $  
  - 12 months

- **PCT/U.S. Utility Stage Filing**
  - $$$  
  - 18 months

- **National Stage Filings**
  - $$$$$  

- **Issuance of patent claims**
  - $$ - $$$$$  
  - 2.5 - 4.5 years

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Money & Time
Not Everything is Patentable

**Patentable**
- Machine
- Manufacture
- New compositions of matter
- Process

*Including:*
- Method of use
- Method of detection
- Improvements
- Reformulations
- Novel delivery platforms

**Not Patentable**
- Physical phenomena
- Mechanism of action
- Naturally occurring substance
Recent Case Laws

• **Myriad**: banned patenting of gene sequences

• **Prometheus**: banned diagnosis based on observed levels of a marker
  
  – Patent subject matter:
    
    • Method of (1) administering the drug to a subject, (2) determining metabolite levels, and (3) being warned that an adjustment in dosage may be required.

  – Argument:
    
    • Metabolites detected are natural by-products

  – Decision:
    
    • Natural phenomena and not patentable
Patentability Evaluation
Patentability Evaluation

Foreign IP rights are lost upon disclosure

- Manuscripts
- Public presentations
- Thesis/Dissertation
- Published Grant Abstracts (and perhaps funded grants)
- Posters displayed in public places (e.g., halls of MUSC)

Did you publish it?

START
Academics are Notoriously Bad

Did you publish it?
Patentability Evaluation

US IP rights are lost 1 year after disclosure

- Manuscripts
- Public presentations
- Thesis/Dissertation
- Published Grant Abstracts (and perhaps funded grants)
- Posters displayed in public places (e.g., halls of MUSC)

More than 1 year ago?

START
Patentability Evaluation

Has it ever been publically disclosed or sold anywhere in the world?

Is it novel?

START
Patentability Evaluation

Could your colleague have come to the same conclusion given the same body of information?

Is it non-obvious?
Patentability Evaluation

Can you describe it in sufficient detail that your colleague could

1) generate the same data in the lab, *and/or*
2) build it per your specifications?

Is it enabled?
Patent Value Evaluation

Is it enforceable?

Now that we’ve told people how to make/do it, can we figure out:

1) Are people willing to pay for the right to use the technology?
2) Are people are infringing?
3) What would it take to stop infringement?
Off-Label Prescriptions

- Drug X is approved for treating cancer
- You find it also treats eye diseases
  
  *To patent or not to patent?*

- Bevacizumab (Avastin) is an angiogenesis inhibitor
  - FDA approved for cancer treatment
  - Prescribed off-label by ophthalmologists for proliferative eye diseases

- 20% of all drugs prescribed off-label
  - ~30% of psychiatric drugs & oncology related drugs
Patent Evaluation

Now that we’ve told people how to make/do it, can we figure out:

1) Are people are infringing?
2) What would it take to stop infringement?
3) Are people willing to pay for the right to use the technology?
Patent Evaluation

Will we be infringing?

**Patentable**
- Machine
- Manufacture
- New compositions of matter
- Process

*Including:*
- Method of use
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- Improvements
- Reformulations
- Novel delivery platforms
Patent Power

Right to prevent others from

Making
Using
Selling

invention in country of patent

It does NOT give you the right to make/use/sell it yourself.

↓

Freedom-to-Operate
The Coat Example

Innovation:

• Dr. John Doe patents a coat

  Dr. Doe can now prevent others from selling coats with a back and two front pieces.

• Dr. Jane Smith patents a coat with buttons

  Dr. Smith’s design is a patentable improvement. BUT, she can’t sell it because Dr. Doe owns the coat. She doesn’t have Freedom-to-Operate.

Claims:

• A cloak with a front opening, comprised of a back and two lapels.

• A cloak with a front opening, comprised of a back and two lapels, further comprising multiple fasteners down one lapel, and multiple holes at corresponding locations down the other lapel into which the fasteners can be inserted.
What’s Dr. Smith to Do?

Innovation:

• Dr. John Doe patents a coat

  Dr. Doe can now prevent others from selling coats with a back and two front pieces.

• Dr. Jane Smith patents a coat with buttons

  Dr. Smith’s design is a patentable improvement.
  BUT, she can’t sell it because Dr. Doe owns the coat.
  She doesn’t have Freedom-to-Operate.

1) Sell (license) her technology to Dr. Doe

2) Pay Dr. Doe for the right to sell his cloak
Coat-Science Analogies

Innovation:
• Dr. John Doe patents a coat

Science:
• Dr. Jane Smith patents a coat with buttons
Coat-Science Analogies

**Innovation:**
- Dr. John Doe patents a coat
- Dr. Jane Smith patents a coat with buttons

**Science:**
- Device
- Added features which can’t be sold separately
- Kit containing the device
Coat-Science Analogies

**Innovation:**
- Dr. John Doe patents a coat
- Dr. Jane Smith patents a coat buttons

**Science:**
- Biomarker X
- Biomarker X as part of panel
Coat-Science Analogies

Innovation:
• Dr. John Doe patents a coat
• Dr. Jane Smith patents a coat buttons

Science:
• Compound
• Method of use
• Conjugate
• Delivery system loaded with the compound
• Combination therapy
Do We Need a Patent?
First to Market

Invented in 1974 by Erno Rubik

No patent protection outside of Hungary

Rubik’s Cube is world’s high selling puzzle toy at more than 350 million cubes sold worldwide

Today, Rubik’s Cube sells for $10

That’s $3.5 BILLION in sales!
Transgenic Mice

- Knock-out mice sell for $500-$5000
- Extremely limited market
- Enforcement issue
- Hurdle to replicate is high
Transgenic Mice (& other Research Tools)

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Analysis: do not patent
Copyright Protection

• Software generally obsolete in 6 years
• Patents take 4-6 years to be enforceable
• Copyright vests immediately and is free
• Protects look and feel
• Valid for ~100 years
Wait... What?
The FRD is Here to Help

Michael Rusnak
Executive Director

Jesse Goodwin, Ph.D.
Assoc. Director

Christine Dixon Thiesing, MBA
Licensing Officer

Deanne Lucas, CPA
Chief Financial Officer

Pamela Kaufman
Patent Administrator

Mary Hedrick-Todd
Executive Admin. Assistant
How to Get Started?

- Write up your idea and supporting data in a **Record of Invention (ROI)**

  [http://academicdepartments.musc.edu/frd/inventors/inventors.forms](http://academicdepartments.musc.edu/frd/inventors/inventors.forms)
When to Report?

Before public disclosure!
Including:
- Publication of the paper
- Poster in hallway
- Student presentation
- Departmental seminar
- Discussion with colleague from other institution
- Material Transfer Agreement (MTA)
- Grants
America Invents Act

Pre-2013 First to Invent

Current Law First to File
Points to Remember about Patents

• Provide power to prevent competition
• Not everything is patentable
• Not all patentable subject matter make good patents
• Costly and lengthy process
• Patentability and Freedom-to-Operate are two different things
  – Remember this if you’re speaking to patent counsel
IP Funding Opportunities

For Fast Forward Seed Grant Pilots and High Innovation-High Reward Grant Pilots:
No pre-application process, 3 page proposal
- Applications Due: **Friday, February 14, 2014**
- Scientific Review: Wednesday March 19, 2014
- Earliest Anticipated Start Date: Tuesday April 1, 2014

SCTR Pilot Project Program RFA and more info at [https://sctr.musc.edu/index.php/programs/pilot-projects](https://sctr.musc.edu/index.php/programs/pilot-projects)
Conclusion

• FRD provides patent and commercialization services on behalf of MUSC

• Call FRD with any questions 876-1900 or visit us in Suite 101 of the Bioengineering Building

• Website
  – http://frd.musc.edu