Program Agenda

Opening - Why are we covering IP?  Hank Foley
The Faculty Perspective  Steve Wyatt
The Success Perspective  Luis Jimenez - EternoGen, LLC
The Legal Perspective  Gary Myers, Dennis Crouch, Erika Lietzan
The Business Perspective  Joan Gabel
University Policies on Patents, Plant Varieties, and Copyrights  Scott Uhlmann
Identifying IP and Navigating the Contract Process  Craig David
University Technology Transfer  Chris Fender and Lana Knedlik
The Industry Perspective - There and Back  Bill Turpin
Summary and Closing  Hank Foley
Question and Answer Session  --
H.C. Foley
Executive Vice President for Academic Affairs, Research and Economic Development -- University of Missouri System
Senior Vice Chancellor for Research and Graduate Studies – University of Missouri
"It is essential to document with solid evidence the returns our Nation is obtaining from its investment in research and development. STAR METRICS is an important element of doing just that."

- John P. Holdren
  Assistant to the President for Science and Technology and Director of the White House Office of Science and Technology Policy
  June 1, 2010.

Which is to say universities will now be expected to provide the seed corn, the innovations and inventions for the future…

“Universities as Engines of Innovation”
Steve Wyatt
Associate Vice Chancellor and Vice Provost for Economic Development

Intellectual Property: A Faculty Perspective

economicdevelopment.missouri.edu
Luis Jimenez
President and Chief Operations Officer
EternoGen, LLC

Intellectual Property:
A Success Perspective

http://www.ternogen.com/
Gary Myers
Dean, University of Missouri
School of Law

Intellectual Property:
A Legal Perspective
Patent
A New and Useful Invention

Trademark
A Brand or Identifier Meaningful to Consumers

Copyright
An Original Work of Authorship

Trade Secret
Private Valuable Information
Intellectual Property and New Medicine

ERIKA LIETZAN, MA, JD
ASSOCIATE PROFESSOR, SCHOOL OF LAW
Innovation Imperative

The government uses a variety of overlapping intellectual property and IP-like incentives to stimulate research into and development of new medicines and medical interventions.
Broader Regulatory Context

Intellectual property policy for new medicines is intertwined with federal regulatory policy for new medicines, including the rules and policies governing research, development, and access to the market.
Public Health Policy

With respect to medicine, federal intellectual property policy reflects a careful balancing of the need to incentivize new research with the need to ensure timely access to affordable versions of already developed medicines.
Conclusion

WATCH THIS SPACE!
Joan Gabel
Dean, Robert J. Trulaske, Sr. College of Business

Intellectual Property:
A Business Perspective
University of Missouri Intellectual Property Policies

November 12, 2014

Scott Uhlmann
Asst. Vice President, Innovation and Economic Development
Office of Academic Affairs
University of Missouri System
Disclaimer:

- This presentation contains an overview of certain policies within the University’s Collected Rules & Regulations (CRRs).
- The information is provided for informational purposes and is not a substitute for the CRRs.
- The CRRs supersede any interpretation given herein.
Introduction:

UM Collected Rules and Regulations

Business Management

Chapter 100: Patent and Copyright Law

• 100.020 Patent and Plant Variety Regulations
• 100.030 Copyright Regulations
100.020 Patent and Plant Variety Regulations

Application of the Regulations:

• Form a part of the employment contract;

• Constitute a condition of employment;

• Apply to all Inventions and Plant Varieties made during any period of employment with the University.
Who is considered an “Employee” under the University’s Patent Policy?

CR&R 100.020.C.2 – “Employee” shall mean:

• any person receiving compensation from the University for services rendered, regardless of whether the Employee be full-time or part-time, or

• any person receiving compensation paid through the University from any funds placed in its hands for distribution, or

• any person that has voluntarily elected to enter into a written agreement with the University in exchange for the University's agreement to treat such person as an Employee for purposes of this policy.
Rights of the University and its Employees

A. The University owns any Invention or Plant Variety developed in the course of the Employee's service to the University.

• Each Employee is required to assign to the University any Invention or Plant Variety made within the general scope of his/her duties as an Employee of the University (unless such requirement is waived in writing by the University).

• Each Employee has the right to share in revenues received by the university for such Invention or Plant Variety.

B. The Employee owns Inventions or Plant Varieties made outside the general scope of the Employees University duties.

C. The University may elect to waive or assign rights back to the inventors.
What is Considered “Within the Scope of Duties”?

1. Whenever the Employee's duties include research or investigation, and
   a. the Invention or Plant Variety arose in the course of such research or investigation and
   b. is relevant to the general field of an inquiry to which the Employee was assigned;

   **OR**

2. Whenever the Invention or Plant Variety was in a substantial degree made or developed
   a. through the use of University facilities or financing,
   b. on University time, or
   c. through the aid of University information not available to the public.
How are Patent License Revenues Distributed?

1. Payment to Inventors (33.33% of Gross Revenues)
2. Deduction of Unreimbursed Patent Expenses
3. Net Revenue
   - Originating Campus (33.3% of Net Revenues)
   - Originating Department (33.3% of Net Revenues)
   - UM System (33.3% of Net Revenues)
How are Plant Variety License Revenues Distributed?

- Payment to Inventors (10% of Gross Revenues)
- Deduction of Unreimbursed Plant Variety Protection Expenses
- Net Revenue
  - Breeding Program (95% of Net Revenues)
  - University (5% of Net Revenues)
Coverage of Policy

• Governs the rights and responsibilities of University employees, students, and of any other persons using University facilities or resources in the creation of original works of authorship subject to protection by copyright law.

• Faculty own copyright for works developed in their roles as teachers and scholars. (e.g. books, workbooks, study guides, articles, etc.)
University will own copyrights in materials that are:

1. Commissioned for its use by the University, or
2. Created by employees if the production of the materials is a specific responsibility of the position for which the employee is hired; or
3. Sponsored works (internal or external grants).
   - Does not apply to grants to perform research where the production of copyrightable materials is ancillary to the purpose of the grant.
   - Employees continue to own the copyright to scholarly and other publications that present the findings of research; or
University will own copyrights in materials that are:

4. Created with the use of substantial University resources which are specifically provided to support the production of copyrightable materials.

- If substantial University resources will be used in the development of copyrightable materials, a written agreement between the author and University shall precede the use of such resources.
Software created by non-academic employees:

Software and associated works created by a non-academic employee within his/her scope of employment constitutes a “work for hire”.

- Ownership and other rights belong to the University.
- Employee is not deemed the author or have any ownership or rights in the software under the policy (e.g. won’t share in revenue, etc.)
- Doesn’t apply to an employee whose primary appointment is academic.
How are Copyright Revenues Distributed?

Subject to a written agreement between the author and University.

- General principles of the agreement:
  - 50% of the net income shall go to the department, areas, or units responsible for production of the materials, and
  - 50% shall go to the authors or producers.
- University may enter into agreements for dividing the net income on some other basis under special circumstances.
Where to go for more information:

**Patent Policy**

http://www.umsystem.edu/ums/rules/collected_rules/business/ch100/100.020_patent_and_plantVariety_regulations

**Copyright Policy**

http://www.umsystem.edu/ums/rules/collected_rules/business/ch100/100.030_copyright_regulations

**Campus Technology Transfer Office**

Office of Technology Management and Industry Relations
University of Missouri
1601 S. Providence Road, Suite 124, Columbia, MO 65211
Director: Chris Fender (fenderc@missouri.edu)
Thank you.

Scott Uhlmann
Asst. Vice President, Innovation and Economic Development
Office of Academic Affairs
University of Missouri System
(573) 882-9287
uhlmanns@umsystem.edu
FACILITATING PRODUCTIVE PARTNERSHIPS: CONTRACTING WITH INDUSTRY

Craig David, Director
MU Office of Sponsored Programs
Facilitate the goals and objectives of MU Investigators

Delegated authority to enter into contracts on behalf of The Curators of the University of Missouri

Negotiate on behalf of The Curators of the University of Missouri

Ensure that contracts executed comply with institutional policies and procedures:

- Intellectual Property Language
- Legal language
  - Jurisdiction
  - Indemnification
  - Sovereign immunity
- Export Controls
- Conflict of Interest
- Restrictions on Publication
- Proper authorizations (PSRS)
Industry funding vs Federal Funding
- Bayh-Dole Act

Empower the Investigator to make informed decisions
- Ensure protection of background IP
  - Existing IP that does not result from the project
- Our first position will not default to owning all IP
- MU is not encouraging waiver of IP
Intellectual Property

Policy on IP

https://research.missouri.edu/ospa/files/OSPA_SPPG_Intellectual_Property.pdf

Standard simplified contract

- Industry-Sponsored Project Agreement:
  http://research.missouri.edu/forms/by_department#ospa
- Retains Publication Rights
- Additional 5% F&A
Collected Rules allow President or designee to waive IP
- If IP is waived a form must be completed
  - Simplified form for Industry-Sponsored Projects
  - [http://research.missouri.edu/forms/by_department#ospa](http://research.missouri.edu/forms/by_department#ospa)
- Faculty may work with their department research administrator, or OSPA preaward contact to complete the IP waiver form.
If the industry partner (sponsor) accepts MU’s standard agreement without modification, then the agreement can be executed quickly.

Delays can occur if either party has a rigid position on IP rights, publication rights or other key contract terms.

OSPA recognizes that projects with industry are often time-sensitive, and works to facilitate industry agreements as quickly as possible while ensuring compliance with University policies.
OSPA’s primary goal is to facilitate the goals and objectives of MU Investigators
Empower investigators to make informed decisions concerning IP
Simplifying procedures, standard agreements and communication to facilitate industry partnerships
Contact

Office of Sponsored Programs Administration  
882-7560  
http://research.missouri.edu/ospa/  
Craig David, Director  
davidcr@missouri.edu  
Jill Ferguson, Preaward Compliance Team Lead  
fergusonjs@missouri.edu  
Karen Geren, Preaward Lead  
gerenk@missouri.edu  
Jamie Szabo, Postaward Compliance Team Lead  
szaboj@missouri.edu
TECHNOLOGY TRANSFER

• Identify-assess-protect-market-license

Chris Fender MS, Director
Technology Management & Industry Relations
University of Missouri

Lana Knedlik, Counsel
University of Missouri System
WHAT IS AN INVENTION?

Conception of Idea
- The complete performance of the mental part of the inventive act. All that remains is to convert the idea into reality by reducing it to practice. Both what is to be accomplished and how it is to be accomplished are necessary. Knowledge of a desirable result alone is not enough; nor is a means for an unknown result.

Reduction to Practice
- Creating either actual or constructive proof that the idea actually works, can exist, or the like.

Enablement & Best Mode
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
• What is the invention?
  • Title, summary, supporting data, draft manuscripts

• Was the invention publicly disclosed?
  • Verbal? Abstracts? On the web?
  • Statutory bars? (AIA – US; foreign)

• How was the invention supported?
  • Federal funding? Industry sponsored? Research consortium? MTAs?

• What is the commercial potential?
  • Potential licensees?
  • What is the closest “prior art”?

• Who are the contributors (possible inventors)?
  • Students? Non-University inventors?
INVENTION DISCLOSURE REVIEW
Critical for informed decision making

- Invention Disclosure
  - Fully Signed and Completed Invention Disclosure Form Received in OTMIR Administrative Office

- Disclosure Triage
  - Review for funding source and possible deadlines resulting in patent bar
  - Bayh-Dole Compliance for federal funding

- Patentability Analysis
  - Analyze Technology for:
    - Utility
    - Novelty
    - Non-obviousness
    - Reduction to Practice
    - Enablement

- Marketability Analysis
  - Analyze Market for:
    - Market Size
    - Barriers to Entry
    - Competitive Advantage of Technology
    - Patent Strategy
    - Licensing Strategy
    - Marketing Strategy

- Strategy for Commercialization
FILING A PATENT APPLICATION

- **Provisional patent applications often filed “in-house”**
  - 1 year to convert to non-provisional
- **Non-provisional patent applications handled by outside patent counsel**
- **Contents of a patent application**
  - **Claims - Metes & Bounds of the Invention**
    - What is claimed is:
      - A composition of matter that comprises:
      - A method of producing, or treating that comprises:
  - **Specification - Establish Utility, Novelty, Non-obviousness**
  - **Supporting Data, Enablement, Best Mode**
  - **Drawings & Figures**
COMMERCIALIZATION STRATEGY
Factors that drive the decision making process

**Patent Strategy**
- Pending publications that would create a patent bar
- Provisional vs. Non-Provisional
- Foreign Patent Rights
- Shaped by IP Analysis

**Licensing Strategy**
- Exclusive vs. Non-Exclusive
- Established Company vs. Start-Up Company
- Shaped by Market Analysis

**Marketing Strategy**
- Driven by both Patent and License Strategy
- If licensing to Start-up then marketing strategy is driven by necessity to attract financing
PATHWAY TO COMMERCIALIZATION

Commercialization Strategy

Marketing
- Hold for additional research
- Waive Rights

Licensing
- Waive Rights
- Continue Marketing
- Re-evaluate for commercialization
- Post Transaction Monitor and Maintenance
SIZE & SCOPE OF OTMIR

- 200+ Active technology license and option agreements
  - 30 New licenses and options executed in FY2014
  - $10.2 Million in licensing revenue in FY2014

- 85 New invention disclosures in FY2014
- 59 New provisional patent applications filed in FY2014
- 36 New patent issuances received in FY2014

- Over the last 10 years, sales of products with MU technologies have exceeded $1.0 billion
- Nearly $78 million in royalties have been received by MU
OGC SUPPORT

- Agreements / Amendments
  - With third parties
    - E.g. Licenses, options, IIAs, NDAs, MTAs
  - Within the University
    - E.g. Assignment, authors’ agreements, non-assertion of rights agreements, waivers to inventors
- Patent Prosecution advice
  - Commercially important cases
  - Significant legal research
- IP ownership advice
Incubating Startups

Presentation for R&D Advisory Board
Bill Turpin
October 17, 2014
The Entrepreneur is provided what he or she needs to get started
All in one place
Typical Engagement

1. University Research Project
2. University Patents Technology or Process
3. Principals form Startup
4. Company Develops Business Plan
5. Company Negotiates Patent License(s)
6. Company Obtains Funding (Grants or Angels)
7. Company Develops Initial Product
8. Company Starts Regulatory Process
9. Company Demonstrates Success
10. Company Graduates
    Sells License
    More Funding for Regulatory Process

At Incubator
## Areas of Expertise

<table>
<thead>
<tr>
<th>Existing Areas</th>
<th>Additional Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutics</td>
<td>New Media &amp; Advertising</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>Medical Informatics</td>
</tr>
<tr>
<td>Animal Health</td>
<td>Online Education</td>
</tr>
<tr>
<td>Plant Science</td>
<td>Online Marketplaces</td>
</tr>
<tr>
<td>Alternative Energy</td>
<td>Social Networking</td>
</tr>
<tr>
<td>Nano Engineering</td>
<td>Cloud Services</td>
</tr>
</tbody>
</table>
Startup skills are best learned via apprenticeship
Similar to renaissance artists, film directors & doctors
Domain experience is invaluable
Applies to Founders, Venture Partners, and Suppliers
Accelerators should incorporate this teaching mode

Unfortunately, apprenticeship is difficult to accelerate
It’s done on a 1:1 basis
It’s lead by an accomplished Master
It’s done “on the job”
It’s done over a significant period of time
Matching a company with a mentor is the single biggest contributor to future success

Example: Steve Trampe - Elemental Enzymes

Prior **startup experience**
Relevant **industry experience**
Relevant **industry contacts**
Intro for **funding and acquisitions**

Hank Foley helping to evaluate MIT’s mentoring program
Support from local mentors (CarFax, Veterans United)
Need support from MU Alumni
Thank you for coming!

Please be sure to join us for all of the “Let’s Talk...” Seminars!

Industry-Funded Research
11/20/2014

Entrepreneurship
12/18/2014

Please join us for a series of discussions about

**Intellectual Property**
Wednesday, November 12, 2014

**Industry-Funded Research**
Thursday, November 20, 2014

**Entrepreneurship**
Thursday, December 18, 2014

Time and Location for all three seminars
8:30 a.m. - 11:30 a.m.
Monsanto Auditorium, Christopher S. Bond Life Sciences Center
Continental breakfast will be served

Broad Scope of Topics
- Patent, Trademark, and Trade Secret Law
- Copyright and Licensing
- Business Plans and Product Licensing
- Technology Transfer
- Funding Opportunities

Faculty who have achieved success!
- How they turned their passion into production
- Tips and tricks for getting started

Hosted by:
Hank Foley, Ph. D.
UM System Executive Vice President for Academic Affairs, Research and Economic Development and MU Senior Vice Chancellor for Research and Graduate Studies
MU School of Law
Robert S. Tulasie, Sr. College of Business
Missouri Innovation Center
MU Department of Economic Development

Mizzou
University of Missouri