Tech Transfer and Intellectual Property

ILO/SPI Mentoring Program

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Intellectual Property Primer



What is Intellectual Property?

Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce

-- World Intellectual Property Organization (WIPO)



U.S. Constitution

Article I, Section 8, Clause 8 – Patent/Copyright Clause

"[Congress Has The Power To] Promote the progress of science and useful arts, by securing for limited times to authors and inventors the <u>exclusive right</u> to their respective writings and discoveries."

- Exclusive rights incentivize public disclosure, and progress
- Comparison w/ Trade Secrets



Patent Rights

What a patent <u>DOES NOT</u> provide its owner...

 The right to make, use, offer for sale, sell or import the invention

What a patent **DOES** provide its owner...

 Right to EXCLUDE OTHERS from making, using, offering for sale, selling or importing the invention

Negative Rights, Not Positive Privileges (perhaps Freedom to Operate)



Completed Invention – Two Steps...

• **Conception** – performance of the mental part of inventive act

- "...formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)
- "Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994)

• Reduction to Practice – actual vs. "constructive"

- Those who reduce an invention to practice based on the suggestion or instructions of others are <u>not inventors</u>
- Inventorship established via <u>CONCEPTION</u>



Bayh-Dole Act of 1980

Universities can <u>take title to</u> and <u>license</u> inventions developed from federally-funded research

- Inventions must be reported to funding agency
- US gov't is granted a non-exclusive, non-transferable, irrevocable, paid-up license
- Preference for US industry and small businesses
- Royalties must be shared with inventor(s)



Copyright

- Protects original works of authorship (ex.: software, music, literature)
- Provides exclusive right to:
 - Reproduce
 - o Distribute
 - o Create derivative works
 - o Publicly perform
 - o Display
- Rights attach to work upon fixing in a tangible medium of expression (i.e. fixed in a tangible form that is perceived either directly or with a device)
- Copyright registration with U.S. Copyright Office is not required
- Copyright term for published works
 - o 70 years after death of author
 - For corporate authorship, the shorter of 95 years from publication, or 120 years from creation



- Patents
 - Provides rights of exclusion
 - Protects utility inventions (process, machine, article of manufacture, composition of matter); designs; asexually reproduced plants
 - Utility patent term is 20 years from the date of filing
 - For Utility Patents, USPTO Examines Whether Invention Is:
 - o Statutory
 - o Useful
 - o Novel
 - o Non-obvious
 - Key Parts of Utility Patent
 - Front Page w/ Abstract, Misc. Info.
 - Drawings
 - Background
 - Summary of Invention
 - Detailed Description
 - Claims



- **Patents** (cont' d)
 - Prosecution
 - Application preparation
 - Filing w/ assignment, declaration and power of attorney forms
 - USPTO "office actions"
 - o Inventor response
 - o Allowance
 - o **Issuance**
 - Timeline can take (several) years
 - 2013 Patent Law Changes (America Invents Act)
 - Prior to AIA *First to Invent* system
 - After AIA *First Inventor to File* system
 - New system aligns with other major jurisdictions
 - Interesting Patent Areas
 - o Biotech
 - o Software



Software

- S/W source code is copyrighted and is protectable by trade secrets
 - Does this provide sufficient protection?
- Patents Not Available For:
 - Abstract ideas potential barrier for inventions embodied in S/W
 - o Laws of nature
 - Natural phenomena
- Alice Corp. v. CLS Bank (2014) → computer-implemented process for reducing two-party financial transaction risk.
 - o Decision: Not Patentable
 - Lead Counsel for CLS Bank. "The Supreme Court correctly rejected the attempt of Alice Corp., a nonpracticing entity or 'troll,' to foreclose productive companies like banks from practicing the ancient economic method of intermediated settlement. As the court explained, <u>patent law does not allow</u> <u>someone to monopolize a fundamental abstract idea</u>, and implementing the idea on any generic computer does not change this result."
- Some S/W enabled inventions are patentable law still evolving
 - Method for protecting computer from malicious code; removal of distortion from an electronic signal, etc.
- Not Patentable, Too Abstract
 - fundamental economic practices, methods of organizing human activity, an idea itself (standing alone), or a mathematical relationship
- Open source S/W may be licensed



- Marks (Trade and Service)
 - Protects words, phrases, symbols and designs that distinguish the source of goods and services
 - Mark registration with USPTO not required
 - If in use, use TM; if registered, use $\ensuremath{\mathbb{R}}$
 - Misuse of marks
 - \circ Confusion
 - \circ Dilution



BioTech Challenges

- One of the most research intensive industries.
- Generally high costs for development of new products/processes, but relatively low cost of imitation.
- Basic and applied research are often interlinked.

• Academic research often basis for spin-offs.

- For some Biotech companies IP rights are actually the final product.
- High costs and long cycle of development and regulatory approvals.



BioTech Challenges



"YOU'RE DOING FINE. THE ONLY SIDE EFFECT IS THAT PART OF YOU IS NOW MY INTELLECTUAL PROPERTY."



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BioTech Challenges

- Patentability considerations may vary by country.
- Not considered inventions:
 - Natural living beings.
 - Biological materials found in nature.
 - Natural biological processes or methods
- Could be patentable:
 - Synthetic biological materials
 - Biological processes or methods such as those for obtaining, modifying, manufacturing or using biological materials or living beings.
 - Compositions found in nature and at least one additional component that could be a patentable subject matter.
- Composition of matter patent is king.



Typical Timeline



Obtaining a Patent

- Submit invention disclosure
- Legal assessment of patentability (prior art search/patentability opinion)
 - $_{\circ}~$ Pay your lawyer
- File Utility application (may be 12 months after filing a provisional application)
 - $_{\circ}~$ Pay your lawyer a lot
- Wait
 - Range of 12-36 months to first Office Action



Obtaining a Patent

- Prosecution
 - Initial office action could have restriction requirement
 - Pay your lawyer
 - Response
 - $_{\circ}\,$ Pay your lawyer
 - Second office action
 - $_{\circ}\,$ Pay your lawyer
 - Response
 - $_{\circ}\,$ Pay your lawyer
 - (Interview with examiner)
 - $_{\circ}\,$ Pay your lawyer a lot
 - Final office action
 - $_{\circ}\,$ Pay your lawyer



Obtaining a Patent

- Notice of allowance
 - Pay USPTO
- File divisional application
 - Pay your lawyer
- Parent patent issues
- Foreign prosecution in parallel, 2-3 years delayed
 - $_{\circ}~$ Pay your lawyer and his/her foreign buddies an awful lot



Developing IP Assets

- Develop IP Plan that:
 - Supports your ERC's story.
 - Puts your ERC to be in a position to be a leader in field.
- What are you Intending to Address:
 - Is it 6 mos?, 2 yrs?, 5yrs?
 - o Are there multiple markets with short and long term views?
- Which is most valuable:
 - Core
 - Fence IP
- IP is an Asset:
 - $_{\odot}~$ Value for potential rather than \$\$\$ today
 - Consider brainstorming sessions to build a fence
- Protecting IP is a Business decision; Do not let NSF metrics drive process.



Confidentiality

- You are working on research with potential commercial applications.
- Promptly report inventions to your tech transfer office so they can file a wellprepared patent application BEFORE you publicly disclose the invention
- Treat non-public information as confidential.
 - Password protect computer; smartphone
 - Don't lose device
 - Use university-provided email providers
 - Use university-provided document storage/sharing
 - Be careful with social media
- Members: Cell-Met Membership Agreement requires confidentiality from Members (Visitors sign NDA)
 - Information must be marked as "Confidential"
 - Oral disclosures of non-public information must be followed-up with written communication identifying information as "Confidential"
 - There is a formal mechanism for sharing IP with members



Tech Transfer Function

- Evaluate commercial potential of technologies
- Assess IP protection alternatives:
 - Patent
 - Copyright
 - Trademark
 - Other (Trade Secret, etc.)
- Manage IP application filings and prosecution; maintenance of issued IP
- IP valuation
 - NPV & cashflow analysis, <u>equity analysis</u> (startups)
 - 25/33% Rules
 - Industry standards for deal terms (royalty, etc.)
- License & sponsored research negotiations
- Startup development & interface to entrepreneurs, VCs
- Dispute resolution, litigation
- Technology marketing



Challenges of Univ. Tech Transfer

- Managing early stage technologies lower TRL, higher risk
- Academic publication requirements
- U.S. vs. foreign IP protection; level of investment
- Institutional strategy, clarity re: IP
- Management of expectations
 - Royalty revenue
 - Filing decisions
 - Deal terms
- Bayh-Dole compliance
- Dispute resolution
- Developing knowledge base
 - Contract & IP law
 - Multiple technology sectors
 - Negotiation, licensing & business development
 - University policy
- Surviving on less-than-perfect information



Identifying Routes to Commercialization

- o Large Company?
- o Small/Medium Company?
- Startup?
- Value Chain Considerations
- Platform Technology vs. Incr. Improvement
- Free Access (via SW Open Source, Publication, Student Hiring, etc.)

University Licensing



Anatomy of a License

- Parties, Whereas Clauses
- License Term
- Territory
- Field(s) of Use
- License Grant (Exclusive vs. Non-Exclusive)
- Financial Terms
 - Upfront fee (cash, equity, etc.)
 - royalty (running, minimum)
 - patent cost reimbursement
 - milestone payments
- Sublicensing Rights
- IP Management, Including Infringement Mgmt.
- o Warranty, Indemnity, Insurance



Center IP policy



Members

- Academic Members
 - Core Academic Members (BU, UM, FIU)
 - Multiple researchers, contribute cost share, significant contribution to education and outreach.
 - Member Council of Deans.
 - New core academic members by invitation of Deans.
 - Non-Core Academic Members
 - Provide crucial technology expertise, may offer educational programs and industry networks.
 - New non-core academic members by invitation of Director.
- Industry Members
 - Open to all for-profit or non-profit corporations, foundations, government agencies, federally funded research & development corporations (FFRDC) and government owned contractor-operated laboratories.
 - Four classes of membership (Varies by Center):
 - o Sustaining, Full, Associate, Affiliate



Types of IP







IPAB Structure

	SUSTAINING	FULL	ASSOCIATE	AFFILIATE
Member IP Rights:				
Review Research Make Rcmd.	Yes	Yes	Yes	Yes
Advise on IP protection	Yes	Yes	Yes	Yes
NERF for non- commercial internal research use only	Yes	Yes	Yes	Yes
Royalty bearing commercial license	1 st Option	2 nd Option	2 nd Option	Open Option Period



Commercial License Flowchart



IP Policy Elements

- All patentable inventions conceived or first reduced to practice in the conduct of University research by faculty, postdoctoral researchers, staff and/or students of University *shall belong to University.*
 - If jointly invented by two or more Academic Partners or with Industry Members, then the invention will be jointly owned.
- All potentially patentable inventions conceived or first reduced to practice by University researchers in the course of their University responsibilities *must be disclosed* in a timely manner to the University.
- Royalty sharing w/ inventors is per the respective Academic Partner's policies
 - Define upfront the royalty sharing with the ERC



Not Addressed in Policy Document

- No Center IP fund to support patent application/prosecution costs.
- Identification of Background IP.
- How to handle IP that needs to be taken as portfolio to be fully exploited.
 - Especially involving multiple institutions.
- Terms of any licensing deal.
- General ERC technical information being further developed and patented by members.
- Licensing revenue designated for ERC is held by inventor's institution for ERC related research.
- Implicitly addressing NSF desire to prioritize small businesses in licensing technology.
- Detailed Bayh-Dole requirements.
- High risk and costs associated with market introduction.



Challenges

- Existing Sponsored Research Agreements that create conflicts for the ERC.
- Prior commitments on Background IP.
- Varied IP Policies among the ERC Academic Members.
- Enabling university/faculty spin-outs while satisfying IPAB member benefits and licensing priorities.
- Dual appointments of PI's may mean that the established Invention reporting is different than the sub-contracted Academic Partner.
- Goal is Technology Transfer, but:
 - Large companies may license for defensive reasons only.
 - SBE may not have resources to exploit license.
 - Most companies will not license unless they absolutely need to.
 - Avoid licensing to make metrics to NSF look good.



Expectations, Competencies for ILOs



Expectations, Competencies for ILOs

- Should have familiarity on IP matters equivalent to a Corporate Business Development executive.
- Should have ability to assess the market potential of inventions.
- Organizational skills to coordinate the necessary reporting requirements.
 - Establish expectations from each of the Tech Transfer Offices of the Center's Academic Members
 - Communicate disclosure of inventions to IPAB members and track member intentions on licensing.
- Follow-up with respective Tech Transfer Offices to track progress of licensing discussions.
- Management skills to work with TTOs.
- Train students/faculty on obligations of Center IP Policy.



Center Documentation

- Member Agreement written as a "continuous contract"
- Bylaws
 - Includes IP policy and confidentiality obligations
 - Can be modified with simple majority of SLT.
 - Attachment to Membership Agreement
- Non-disclosure Agreement
 - Generally for non-Members/visitors
- Signature Process



Thank You! Questions?

