Intellectual Property Primer

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The content is solely for purposes of discussion and illustration, and is not to be considered legal advice (only common sense).
What is intellectual property?

- Intellectual property (IP): intangible additions to the stockpile of human knowledge
- Dilemma of IP: Getting new IP into general use/circulation while protecting the creator’s rights
- Examples: Plagiarism, industrial espionage, patent infringement
IP in the University

- Faculty have multiple duties:
  - Teaching & mentoring
  - Governance
  - Research & publication
  - Patient care
- Research (or “discovering new things”) is part of the job description
- Publication (or “putting new things into circulation”) also part of job
IP in a company setting

- Invented on “company time”
- Invented with “company money”
- Therefore, IP from research belongs to ... the company
- But this is non-motivational
Academic Inventors Share in Fruits of IP Development

- Royalty sharing
- Research funding
- Further developments
- Protecting their IP
- Seeing their invention put into use to deliver a public health benefit
Why is intellectual property protection important?

- Commercial development considerations
- Obligations to funders
“Developing a new drug from a mere test molecule into a dose-controlled pill or injection ... requires the investment of years of work and hundreds of millions of dollars.”

(Bruce Goldstein, in Principles and Practice of Clinical Research, ed. John I. Gallin and Frederick P. Ognibene, p. 442)
What is intellectual property?

- **Patents**
  - Protects concepts & ideas
- **Copyrights**
  - Protects written expression
- **Trademarks ™ & Service marks SM**
  - Protects distinguishing mark
What is intellectual property?

- **Know-How**
  - Specialized knowledge that doesn’t necessarily rise to the level of copyright, trade secret or patent, but still has value

- **Trade secrets**
  - Protects anything proprietary (under certain conditions)
Copyrights

- Protection of authored material:
  - Texts: articles, books; Songs; Websites, software; Art etc.
  - Format itself is part of the copyright
- Copyright is automatic in some countries upon act of authorship
- Marking is a good idea:
  - “© 2015 The Administrators of the Tulane Educational Fund”
  - or
  - “© 2015 John M. Christie”
Copyright does NOT protect:

- Procedures
- Processes
- Systems
- Methods of operation
- Concepts
- Principles
- Discoveries
- Ideas
Why claim copyright to your material?

- Clearly establish authorship
- Retain control over reuse and dissemination
- Establish a base to claim infringement
- Register in order to go after larger damages
The Exclusive Rights Of Copyright

- To copy the copyrighted work
- To prepare derivative works based upon the copyrighted work
- To distribute copies of the copyrighted work to the public
- To perform the copyrighted work
- To display the copyrighted work
The Exclusive Rights Of Copyright

- One can license these rights to others
- Can pick and choose what is licensed
- Not all or nothing
Trademarks and Service Marks

- Register with the appropriate government office
- Search is performed to ensure unique mark
- Has to be actually used in commerce
- Legal assistance is required
Know-How and Trade Secrets

- Very hard to qualify or quantify
- But you know it when you see it
- Can be most valuable IP asset you have
- Requires cooperation and trust among parties to access
Trade Secrets

- Formulas, processes, and other information that derive economic value from not being generally known AND the owner has attempted to keep the information secret

- State law remedies

- Employment agreements typically include confidentiality provisions, as well as non-compete and invention/ IP assignment provisions

- Universities cannot hold trade secrets
What a Patent Is (and Isn’t)

- Gives negative rights -- prevents making, using, selling of the patented invention
- Inventors ≠ Authors
- Scope of invention is precisely defined - patent claims
What a Patent Is (and Isn’t)

- Embodiment of an agreement between an inventor and the government
- Inventor fully discloses invention in return for
  - Limited time monopoly in the invention
  - Ability to exclude others from making, using, or selling invention
What Do I Do With It?

- Treat as real property
  - Bought, sold, traded, or leased/licensed
- Includes defending it
  - Is someone practicing your patent without a license?
  - Called “infringement”
Types of Patent Applications

- Provisional patent applications
- Non-provisional (utility) patent applications
  - Structural or functional
- Design
  - Ornamental features directed to appearance rather than concept or function
- Plant
  - As in flowers, not manufacturing
- International (PCT)
A Word About Provisionals

- Can be useful as a strategy to extend patent life
- Very useful for research institutions in advance of a publication or presentation
- Not reviewed at all during its pendency
- Only available in the United States, but anyone anywhere can file
A Word About Provisionals

- These should be filed with the same care and effort as a utility patent application
- Please, please, please don’t file “quick and dirty” provisionals
- Provisionals can be reviewed during litigation or other patent validity challenges
Patent Basics

- Requirements for a patent:
  - Useful
  - Novel
  - Non-obvious

- Advantages of a patent:
  - Provides time-limited, government backed monopoly for your invention
  - Expands the base of human knowledge
Nonobviousness

- Not suggested by one prior art item or a combination of prior art items to “one skilled in the art”
- Prior art can be patents, publications, prior products, or any other publicly disclosed devices or processes
- Can introduce secondary evidence of nonobviousness
Patent Application Requirements

- Patent application includes background, summary of the invention, detailed description (including experimental examples), figures, and claims
- The claims define the legal metes and bounds of your rights
Bars to Obtaining Patents

- Enabling public disclosure
- Statutory bars
  - On sale bar (even “offers for sale”)
  - Publication—-inventor’s own articles
  - Public use/ disclosure
  - Trade show, conference, website posting, house party
- Document everything
  - Lab notebooks
  - Official invention disclosure forms
  - Napkins are tough to keep track
“Patent law has no sympathy for bruised egos.”

(Goldstein, op. cit., p. 440)
What is patentable?

- Anything that can be shown to be useful, novel and non-obvious
  - Machinery (think: iPod)
  - Compositions of matter (think: Retin-A)
  - Methods of use (think: Rogaine)
  - Medical devices (think: stents, catheters)
  - And on and on and on ...

- But it has to be a human artifact: Nothing from the realm of “Nature” can be patented
Why seek patent protection?

- Time-limited monopoly encourages commercial development
- Legal protection allows claims of infringement
- An increasing number of grants and other funding opportunities require a strategy for IP protection and commercialization of results
  - Ministries of Health & other government entities
  - Foundations & other philanthropic entities
Why seek patent protection?

- **You get**
  - Right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent

- **You don’t get**
  - A guaranteed right to practice the invention
  - Idea can be patentable but dominated by other patents

- **You give**
  - Disclosure (and fees)
Why seek patent protection?

- License
- Cross license to defend against infringement
- Force competitors to design around patent
- Build value of company/ university
- Create perception of innovation
- Create prior art against others
Patent Procedure

- Invention (conception, reduction to practice)
  - Conception alone is sufficient
- Conception
  - No prototype or working model is required (constructive RTP)
  - Best stage to initiate patent process
  - Documentation critical to establishing date of invention
Patent Procedure

- Search and opinion(s)
- Disclosure of invention to owner
- Preparation and filing of application
  - kind of application?
  - limited by prior art?
  - time constraints?
  - cooperation of inventors
Prosecution of Application

- Examination/Prosecution
  - Office Action
  - Amendment?
  - Interview?
  - Appeal?
- Allowance
- Issue; Term = 20 years from filing date
Patent Examiner

- Technically trained
- Examines in specific technology only
- Issues official action after searching and examining application
- Not necessarily a lawyer
- But patent examiners are human
  - Pay them a visit, they rarely get fed and watered
Foreign Patent Protection

- Filed most often via Patent Cooperation Treaty (PCT)
- File for PCT protection within one (1) year of the first filing date
- Costs >$250k for worldwide major-market protection
# Timeline

<table>
<thead>
<tr>
<th>Event</th>
<th>Months from Filing Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisional filing (if pursued)</td>
<td>0</td>
</tr>
<tr>
<td>Utility patent filing</td>
<td>0 / 12</td>
</tr>
<tr>
<td>PCT filing</td>
<td>12</td>
</tr>
<tr>
<td>Publication of application</td>
<td>18</td>
</tr>
<tr>
<td>First office action</td>
<td>12-36</td>
</tr>
<tr>
<td>National phase designation</td>
<td>30 or 31</td>
</tr>
<tr>
<td>Patent allowed/issued</td>
<td>24-96</td>
</tr>
<tr>
<td>Expiration of design patent</td>
<td>168 (14 years)</td>
</tr>
<tr>
<td>Expiration of utility patent</td>
<td>240 (20 years)</td>
</tr>
<tr>
<td>Competitor or next generation product discovered obviating patent</td>
<td>???</td>
</tr>
</tbody>
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Useful Resources

- [http://patents.google.com](http://patents.google.com)
- [http://uspto.gov](http://uspto.gov)
  - Public PAIR (Patent Application Information Retrieval)
  - PaFTD (Patent Full-Text Database)
  - Issued patents
  - Patent applications
  - International patent searches
“The most obvious instance [when patent protection is necessary] is where no one will invest in developing the technology without the exclusivity of a patent.”

(Goldstein, op. cit., p. 466)
When is a patent worth it?

- When the patent is
  - Marketable
  - Enforceable
  - And with Freedom to Operate
Marketable

- How many people need it?
- How much does it cost to make?
- How much will people pay for it?
Enforceable

- Who is copying?
- How do you know they’re copying?
  - The “Black Box” problem
- Would you want to, or could you sue them?
Freedom to Operate

✦ MOST IMPORTANT: IP does NOT give you the right to do something – it gives you the right to stop others from doing something

✦ Ensure that no one else can stop you, or

✦ License
“By itself, a patent is little more than a document with a pretty ribbon on it.”

(Goldstein, op. cit., p. 440)
What about IP generated outside of a university context?

- Industry-employed inventors
- Independent inventors
Written by a Lawyer:

“One of the major reasons people find patent law arcane and tedious is that patent laws (and lawyers) relay heavily on terms of art, odd jargon, stilted phrasing and other terms having meanings that are several degrees off the rest of society uses those terms.”

(Goldstein, op. cit., p. 436)
Public Disclosure

- Journals (print or electronic)
- Conference proceedings
- Speeches / seminars / defenses
- Poster presentations
- Web pages
- Social media
- Any non-confidential discussion
  - Proposals submitted to companies w/o CDA
Public Disclosure

KEY =

ACTUAL DATE FIRST AVAILABLE TO THE “PUBLIC”
How and When to Properly Disclose an Invention

❖ Before any “enabling” discussion with a third party, including:
  ❖ Paper submitted for publication
  ❖ Poster at any public event
  ❖ Speech or presentation at any public event
  ❖ Web-based disclosure
How and When to Properly Disclose an Invention

- Under the auspices of an employment agreement
- To your tech transfer office or an attorney
- Under the auspices of a confidentiality agreement
Good Laboratory and Clinical Notebooks

- Use bound notebooks
- Number all pages
- Record all data in ink
- Sign & date each entry
- Do not skip pages
Good Laboratory and Clinical Notebooks

- Have entries corroborated
- Glue in diagrams/slides/labels
- Describe inventions fully on separate page
- Print and bind computer records
- Retain in safe area
Potential Pitfalls

- Research agreements often have provisions for new IP resulting from the research.
- Government sponsored research usually asks for ongoing reporting of IP developments.
- Clinical trials agreements almost always ask that the sponsor own resulting IP.
  - Read these agreements carefully.
  - Negotiate IP provisions before signing and before initiating research.
Licensing to a large company

- **Pros:**
  - Extensive resources to develop IP and product
  - Experience and expertise in the field
  - Potentially: more $ earlier
Licensing to a large company

Cons:

- Can move and make decisions slowly
- Projects can get lost
- Often not very responsive
- Usually not in local economic area of university ($/jobs leave area/are created in a different locale)
Licensing to a small company or start-up

**Pros:**

- Know the technology very well
- Projects don’t get lost
- Usually very responsive
- Usually in local economic area of university, at least at first (bring $/jobs into local area)
Licensing to a small company or start-up

- Resource constrained
- Inexperienced
- Definitely: less $ earlier
Thank You

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What does an Office of Technology Transfer do, anyway?

- Technology transfer is the process for moving intellectual property from one setting to another.
- Involves knowledge of:
  - Science
  - Business
  - Law
“The core purpose of the technology transfer enterprise is to get technologies out of the lab and into the marketplace.”

(Goldstein, op. cit., p. 471)
Why do we engage in technology transfer?

- Make a better world
- Service to faculty and students
- Necessary part of modern research endeavor
  - Sponsored funding
  - Industry relations
- Financial return?
“Of course, patents and royalties are both useless benchmarks of how the public has benefited from research by ... scientists.”

(Goldstein, op. cit., p. 466)
What does an Office of Technology Transfer do, anyway?

- Research support
  - Industry sponsored research agreements
    - Clinical trials agreements
  - MTAs, CDAs, etc.
- Education of faculty and students
- Whatever comes along
Tech transfer Classic

- Sponsored research – preferably governmental $ to a faculty member
- Inventions or discoveries
- Patenting or otherwise protecting the IP
- Licensing the IP to an established entity
- Managing the relationship with a licensee
- Administering the $ generated by license
Tech transfer Experimental

- Research
  - Industry sponsored
  - Multi-institution collaborations
  - Foundation sponsored
  - Unfunded, perhaps? Internally funded?
Tech transfer Experimental

- Inventions or discoveries
- Patenting or otherwise protecting the intellectual property
- Licensing the IP to
  - A start-up (do you take equity?)
  - A foundation
  - A not-for-profit
Tech transfer Experimental

- Managing the relationship with the licensee
- Administering the $ generated by the license agreement
- Issues with equity, if acquired
Research support

- Industry sponsored research agreements
- MTAs
- CDAs and consulting agreements
Industry sponsored research agreements

- Major issues with
  - IP
  - Confidentiality and publication

- University requirements
  - Academic freedom
  - True research and not work for hire
  - Indirect cost recovery
Industry sponsored research agreements

- Industry requirements
  - Deliverables
  - Timeline
  - Possible IP to add value to company
  - Non-disclosure, including academic publication
“Reserving research rights is ... rooted in fundamental principles of research freedom.”

(Goldstein, op. cit., p. 469)
Material Transfer Agreements

- Unintended consequence of growth of technology transfer and its emphasis on value of research-derived IP
- IP issues
- Publication issues
Confidential Disclosure Agreements and Consulting Agreements

- Educate faculty on obligations and industry expectations
- Educate industry on academic requirements and expectations
Education

- Topic of growing interest and importance
- Complex and complicated
- Constantly changing
  - Experience
  - Court rulings etc.
- Introduces the OTT to your constituents
Odds & Ends

- Conflict of Interest resolution
- Grant support efforts, especially SBIR/STTR and similar
- Entrepreneurship topics
- Economic development
- Special topics, e.g. crowdfunding of research