Intellectual Property Basics

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Top 10 Things Every Startup Should Keep in Mind

- 1. Know What Intellectual Property You Have
 - Will discuss the types today, each can play a role in protecting your assets
- 2. File Early for Patents and Trademarks
 - Want to maximize exclusivity
- 3. Do not be afraid to use Non-Disclosure Agreements (NDAs)/Confidentiality Disclosure Agreements (CDAs)
 - Protect your sensitive information
- 4. Ensure Ownership of IP Created by Employees and Contractors belongs to Company
 - Employee/Contactor Agreements are essential
- 5. Protect Trade Secrets
 - Requires active steps to implement NDAs, limit access to sensitive information, and have internal policies

- 6. Avoid Infringing on Existing IP
 - Do your due diligence
- 7. Establish a Strong Brand Identity
 - Use trademarks to protect company name, logo
- 8. Be Mindful of IP When Raising Capital
 - Investors will want to see you are protecting your IP and own it, be sure there are no red flags
- 9. Monitor and Enforce Your IP Rights, Monitor competitors' IP
- If necessary, send cease-and-desist letter or take legal action
- 10. Plan for IP Licensing and Partnerships
 - Think about how you can monetize your IP? Should you enter into an agreement with a third party to license their IP?
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Types of Company IP



Goals of IP:

- Adds Value
- Protects Your Investment
- Provides the Right to exclude
- Maintains Freedom to operate
- Hinders competitors
- Preserves market share
- Improves bargaining position
- Avoids litigation or allows ability to effectively counter-sue
- Corporate image / prestige
- Entry into new markets
- Profit center royalties
- Collateral for investments



Who Owns Company IP?

Pre-Company Formation

- University-owned
- Inventor- requirement to assign

Once Formed

- Licensing
- Acquisition
- Company owned, In-house research

Type of IP	Initial Ownership
Patent	The inventor(s)
Trade Secret	The person who developed it
Copyrights	 Copyright belongs to the "author." However, under the "Work for Hire" doctrine: An employer is deemed to be the author of works created by an employee within the scope of his or her employment, <u>but</u> Different rule for consultants -must be "specially ordered or commissioned" and fall into 1 of 9 limited categories – contributions to collective work, AV/motion picture, translation, supplementary work, compilation, atlas, instructional text or test/answer material for test
Trademarks	Whoever first uses the mark in commerce in connection with the relevant goods and services.





What are Patents?

- Patents provides the patent owner with the <u>right to exclude others</u> from making, using, offering to sell, selling, or importing an invention in the country it has been granted for a limited time (*i.e.*, 20 years from filing)
- Property Right Granted By Government In Exchange For Full Disclosure Of The Invention To The Public.
- A Patent Does NOT Mean You Can Practice Your Invention
 - A Third Party Can Have a Dominating Patent
- Need Freedom to Operate to practice your invention
- Patents are territorial and must be sought *in each jurisdiction, i.e. a* U.S. patent provides the right to exclude others from making, using, offering to sell, selling, or importing an invention in the United States only
- Process for examination and enforcement of patents differs jurisdiction to jurisdiction.



Types of Patent Applications

Provisional – place holder, will not publish or be examined

Non-Provisional

- Utility (most common)
- Plant (new asexually reproduced variety)
- Design (new, original, and ornamental design for an article of manufacture)

Patent Cooperation Treaty (PCT) – place holder, will publish and be examined but will not result in a patent

National Stage – US or any other country





Contents of a Patent Application

Specification

- Describes the invention and teaches others how to make and use it
- Explains why the invention is needed and its advantages
- Includes experimental evidence and rationale for expanding coverage beyond specific examples
- Identifies any federal funding that supported the underlying research

Claims

- Define the scope of protection, the "Metes And Bounds" Of The Invention

Abstract

- Briefly summarizes what is disclosed in the patent/application

Drawing(s)

- Figures, illustrations, diagrams, spectra, etc.



Patent Prosecution Process

Formal application that is examined by the USPTO

- Step 1: File application
- Step 2: Examined by USPTO, my be objected to or rejected, modifications will be made in response including claims
- Step 3: Allowed and issued as a patent -or- abandoned

Published by the USPTO

Must satisfy formal requirements

Specification, claims, abstract, drawing(s)



U.S. Requirements for Utility Patents

- Patent-Eligible Subject Matter
- Utility (an invention must be "useful")
- Novelty
- Non-obviousness
- Disclosure Requirements
 - Written description of the invention
 - Enable person of ordinary skill in the art to make/use the invention
 - Definiteness (claims must be clear)



Patentable Subject Matter

Includes anything under the sun that is made by man.

Process

Machine

Article of manufacture

Composition of matter

or improvement thereof



Three Exceptions to Patentable Subject Matter

Laws of Nature

- Naturally Occurring Relationships (e.g., a correlation between a biomarker and a disease)

Natural Phenomena // Products of Nature

- Metals, Minerals, Nucleic Acids, Proteins, Peptides, Antibiotics, Toxins, Fats/Lipids, Carbohydrates, etc.
- Organisms (e.g., bacteria, multicellular animals)

Abstract Ideas – composed of only mentals steps

- Fundamental Economic Practices
- Methods of Organizing Human Activities
- Mathematical Relationships and Formulas



Novelty

> A Single Reference Must Not Disclose the Invention

- This is Referred to as "Anticipation"
- Prior art must be identical, disclosed in: Patent, publication, any public document, or public use
- U.S. offers a 1 year grace period

Inherent Anticipation

 A reference can inherently disclose a feature of an invention if that characteristic is a necessary feature or result of the prior-art embodiment



Obviousness

- A patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art
- > Burden on Patent Office to Show that Claimed Invention is Prima Facie Obvious
 - Combination of References Yield Invention
 - Must Be Some Reason to Combine and/or Modify the References, which can be:
 - Economic Motivation
 - Teaching in the Prior Art
 - Suggestion in the Prior Art
 - Common Sense



Inventorship

Who is an Inventor?

The person or persons who conceive of a definite and permanent idea of a complete and operative invention

- Inventorship of a patent is determined on a claimby-claim basis
- Only need to contribute to the conception of one claim to be an inventor
- Inventorship can change during patent prosecution as claims are amended

Who is not an Inventor?

- "A pair of hands"
- Someone whose only contribution is writing text of manuscript or patent application
- Someone who only provided reagents
- Someone who only did confirmatory analytical work
- Someone who posed a problem, but did not contribute to the solution
- Someone who supervises the inventors but does not contribute to the invention
- Authorship does not necessarily equate to inventorship



Exclusivity – Keeping others out

- Patent expires 20 years from the earliest non-provisional filing date, potential to extend Expiration dates through Patent Term Adjustment (PTA), calculated based on Patent Office and Applicant delays during prosecution
- Life Sciences
 - Patent Term Extension (PTE)- up to 5 years to recover time spent in clinical development and regulatory approval, can extend one patent
 - Regulatory exclusivity (exits in many countries), US:
 - New Chemical Entity 5 years
 - New Clinical Investigation 3 years
 - Biologic 12 years
 - Orphan Drug 7 years
 - Added to other exclusivities: Pediatric 6 months, Antibiotics 5 years



Freedom-to-Operate

- A third party owns a dominant patent that prevents you from practicing your invention
- FTO is the ability make, use and sell products without legal liabilities to a third party based upon infringement of a valid and enforceable third party patent.
- Freedom to operate can also be extended to the ability make, use and sell products without legal liabilities to a third party based upon trademark rights, copyright rights and trade secret rights



Challenges to a Patent

Federal Court

- Patent owner alleges infringement
- Third party alleges patent is invalid and unenforceable

Post-grant Proceedings at USPTO

- Post-Grant Review (PGR)
 - initiated by 3rd parties; within first 9 months after the grant of a patent (any invalidity ground except best mode)
- Inter Partes Review (IPR)
 - initiated by 3rd parties; based on publications (anticipation and obviousness)
- Covered Business Method (CBM)
 - initiated by 3rd parties; applies to patents related to "business methods"- data processing or other operations used in the practice, administration, or management of a financial product or service but excludes patents related to "technological innovations" (any invalidity ground except best mode)
- Ex Parte Re-Examination
 - initiated by patentee or by 3rd parties; based on publications (anticipation and obviousness)
- Derivation Proceedings: applies only to "first-to-file" patents, intended to determine true inventor



Preserve FTO or Commercialization of Patent Rights

Patent License

- > Grant of patent rights from owner (licensor) to another party (licensee), with licensor retaining ownership
- Conveyance of Patent Right can include:
 - Exclusive vs. non-exclusive rights
 - Rights specific to a particular field of use (*e.g.*, diagnostic vs. treatment)
 - Right specific to a particular territory (*e.g.*, U.S. vs. world-wide)
- Other rights that may be conveyed
 - Right to sublicense
 - Right to material necessary for commercial development
 - Right to certain know-how necessary for commercial development



License Agreements

- Grant of rights
- Development and commercialization plan
- Fees and payments: Upfront fees and maintenance fees, Royalties, Milestone payments, Sublicensing fees
- Retention of rights for the University Use of technology for research, right to publish, future improvements, etc.
- Responsibilities for Patent prosecution

In addition to the license, there can be collaboration agreements, sponsored research, consulting agreements with inventors, and arrangement of scientific advisory boards



Building Your Patent Estate – Life Science Space





Variants of and modifications to the Molecule

Methods of Making – may be kept as a trade secret





Methods of Treating Indication of Interest – new filings as identify additional indications that can benefit from the Molecule





Development Timeline

Building Your Patent Estate – Tech Space

<u>Method</u> Software description (not the code itself)





Storing the software code



<u>Network</u> Incorporating the software code





Trade Secrets

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What are Trade Secrets?

- Unlike patents or copyrights, trade secret protection extends to a broad array of information that has competitive value and is treated by the owner as confidential.
- Must Be A Secret and maintained as such, Can't Be Public Knowledge
- Competitive Advantage: The information must confer an economic advantage over competitors
- Examples: Manufacturing Processes, Screening Assay, Validation Assay
- Protects against misappropriation of information that derives value from being secret and is subject to reasonable efforts to maintain secrecy
 - NDAs
 - IT / Network Protections
 - Avoid publication



Copyrights / Software



What are Copyrights?

- Works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be
 perceived, reproduced, or otherwise communicated, either directly or with aid of a machine or device.
- Protection for original creative expression in a tangible medium
- Copyright gives you particular exclusive rights in the work (reproduce, modify, display, etc.)
- Rights begin immediately do not need to register
 - 70 years after the death of the author
 - "works made for hire"- the shorter of 95 years from first publication or 120 years from creation.
- Examples of copyrightable works
 - Software code
 - Video content
 - Creative text and artistic designs on labelling or packaging
- The work must be creative
 - Most software code will qualify
 - Not just a list of ingredients but cookbook OK



Avoiding Copyright Problems

- Make sure that you own or have the right to use any software, text, images, etc.
 - If you have someone else write or design something for you (including software), get an agreement in writing that you own it or have permission to use it
 - If you use images of real people, get their permission first
 - Don't just use clip-art, movies, songs or copy images that you find online
 - Other parties do not need a copyright notice on work in order to have copyright protection
- Consider placing a © mark next to your copyrighted content. You do not need a registered copyright to do this.
- Open source software



Software Copyright Issues

- Graphical User Interfaces (GUIs) virtual identity between the look and feel of a screen display is required to infringe
- **Open source –** use restrictions, notice requirements, reciprocal licenses
- Reverse engineering fair use when it is the only way to gain access to functional elements and there is a legitimate reason for seeking access (e.g., making compatible products)
- Territoriality first sale abroad exhausts copyright and copyright infringement is limited to US borders
- Artificial Intelligence (AI) the Copyright Office has declared that it will "register an original work of authorship, provided that the work was created by a human being."
 - AI-based technologies are patent-eligible subject matter (e.g., using machine learning to analyze images for detection of pathological conditions)
- Application Programming Interfaces (APIs) fair use



Open Source Software

- Open source software is software whose source code can be freely used, modified, and shared, by anyone
- Can't restrict how others use the software
- Commercial use allowed
- Includes permissive ("non-copyleft") and "copyleft" licenses
- Many different OSS licenses
- Breach of an OSS license is copyright infringement



Trademarks



What are Trademarks?

- Any word, name, phrase, slogan, symbol or device, or combination of these, that identifies and distinguishes
 one's own goods or services from other's goods or services
- You become a trademark owner as soon as you start using your trademark in commerce with your goods or services. You establish common law rights in your trademark by using it, but those rights are limited, and they only apply to the geographic area in which you're providing your goods or services. If you want stronger, nationwide rights, you'll need to apply to register your trademark
- Words, designs, and logos are the most common trademarks
 - Example: Coca-Cola®
 - Example: Coca Cola
- Trademarks are limited to certain classes of goods and services
 - Apple Computer / Apple Records
 - Delta Faucets / Delta Airlines



What Makes a Good Trademark?

- Before choosing a mark make sure it is available!
 - Anyone else using this mark for your goods/services?
 - Google search is helpful
- Spectrum of Marks
 - Generic, Descriptive, Suggestive, Arbitrary, and Fanciful
- Marks that are more distinctive get stronger protection
 - Fanciful = made up words like XEROX, KLEENEX, KODAK
 - Arbitrary = word use unrelated to dictionary meaning, like APPLE computers
 - Suggestive = word tells you something about the product indirectly, like COPPERTONE sunscreen
 - Descriptive = word describes product directly, like APPLE for apple sauce
 - Generic = mark is the product, like APPLE for apples
- You want to have a fanciful, arbitrary, or suggestive trademark
 - Otherwise you probably won't be able to register or legally protect your trademark



Process for Trademark Registration

- Register the "®"
 - Federal Registration
 - For trademarks used in business across states
 - Lets you use and protect the trademark anywhere in the country
 - State Registration
 - For smaller, regional companies
 - Usually fast and inexpensive
 - Registration prevents others from using or registering the same or a similar trademark
- Use the "TM"
 - Provides common law rights



Q+A

Thank You

Goodwin Starter Packages for Startups

Early-Stage Company Package

\$2,500	5 hours/month
\$5,000	15 hours/month
\$7,500	25 hours/month

Hourly rates for time over monthly allowance are **50% off** Goodwin rates (approx. \$650-700/ hour for partners, \$350-600/hour for science advisors/associates).

THIS INCLUDES

- Access to any of our practice areas you may need assistance with, including corporate, licensing, employment, tax, etc.
- Our attendance at board meetings free of charge.
- Discussions of graduating from the program once you receive a significant infusion of capital.

IP Package

\$2,500/month

With one-year subscription

GOODWIN

THIS INCLUDES

- Monthly 1-hour IP strategy meeting with the partner and science expert (science advisor or associate) best suited for your technology. Discussions during these calls may lead to other opportunities requiring the input of other disciplines, which will be included when relevant.
- Competitive landscape review with monthly monitoring and analysis when necessary.
- Freedom-to-operate search, which will include review of the results and a summary of the analysis.
- Drafting and filing a provisional application. Any additional provisional filings, beyond the one included in the yearly package, would be at a fixed fee of \$10,000 per application.