

How to Protect Your Intellectual Property



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Founder of WALLACH – IP Management and Consulting



A little bit about me...

- B.Sc. Biochemistry, University of California Riverside
- Ph.D. Molecular Biology, University of Copenhagen, sponsored by Novo Nordisk (the “Eli Lilly” of Europe)
- Postdoctoral Fellowship in Molecular Pharmacology, Stanford University School of Medicine
- Cooley Godward, LLP (top IP firm)
- Morrison & Foerster, LLP (top IP firm)
- Sapphire Energy, Inc. (renewable biofuels)
- CONNECT – expert domain mentor re patents



A little bit about me...

- 18+ years
- Practice patent law in the fields of endocrinology, biology, molecular biology, microbiology, pharmacology, virology, immunology, biochemistry, bio-informatics, biological assays, devices, renewable biofuels, and refinery practice.
- My focus is on helping startups develop and grow their patent portfolios so that they can get funding/partnerships, and, of course, protect their most valuable asset, their IP



What is Intellectual Property?

- IP is intangible and proprietary information that you have the exclusive right to keep others from using
- The law affords different types of protection for different types of IP: Patents, Trademarks, Trade Secrets, and Copyrights



Types of IP

- Copyright: the exclusive legal right, given to an originator or an assignee to print, publish, perform, film, or record literary, artistic, or musical material, and to authorize others to do the same.
- Trademarks: a symbol, word, or words legally registered or established by use as representing a company or product.
- Proprietary Information: also known as a trade secret, is information a company wishes to keep confidential. Proprietary information can include secret formulas, processes, and methods used in production.



What is a patent?

- A right granted to the owner of the patent to stop others from making, using, or selling the invention, that is the subject of the patent
- The term of a patent is 20 years from the filing of a Utility Patent Application
- Timing: Provisional → Utility and/or PCT → outside of the US
- U.S. was a “first-to-invent” patent system in which the date of the invention could trump the date of filing a patent application in determining patent rights. The America Invents Act (AIA) patent reform bill signed into law by President Obama in September 2011 changed this
- Now, the U.S. is a “first-to-file” system (applications with a filing date of March 16, 2013 or later) meaning the first person to the Patent Office wins!
- Discuss timeline on board, including foreign filing



The importance of patents

- Ability to raise funds (e.g. venture capital)
- Able to sell or license the rights to commercialize your invention, generating revenue for your company
- Corporate valuation relies heavily on a company's IP
- Increases your company's market position and can reduce competition
- Provides freedom of movement in your field of technology
- Provides a positive image for your company in the eyes of potential business partners



Examples of assets that are patentable

- Isolated nucleic acids and polypeptides
- Cells, cell lines, and transgenic animals
- Methods of making, using, or treating
- Screening and research methods
- Articles of manufacture
- Databases and libraries
- Computer software algorithms
- Business method patents



Requirements for patentability

- The invention must be described (with the particularity required by the Patent Laws) such that a person of skill in the relevant field can understand what the invention is, and make it and use it without engaging in undue experimentation
- The invention must not have been "disclosed" to the public prior to the filing of the patent application (a few exceptions exist)



What is a disclosure?

- Manuscripts, book chapters, journal articles, proceedings, thesis, posters, proceeding abstracts, publications
- Grant Proposals *if* no active steps are made to ensure confidentiality
- Oral Disclosures *if* open to the public (meetings, seminars, a thesis defense)
- Public use or offer to sell
- Disclosure must be enabling (person reading it must be able to understand and practice it)



Patent Strategies

- Determine your company's "patent space" and compare it to your competitors' patent space
- Determine which inventions to patent, make sure that what you want to patent is aligned with the business goals of your company
- Create an offensive patent portfolio, dominate a market
- Create a defensive patent portfolio, allowing freedom to operate
- Protect your "core" or platform technologies



Patent Strategies - continued

- File broad claims in your patent application to prevent competitors from patenting the technology
- File narrower claims in your patent application to ensure that your core technology is covered by a patent
- File a Provisional application or a Utility patent application?
- Carefully plan which countries, besides the U.S. to seek patent protection in, due to the high costs involved with filing for patent protection outside of the U.S.



Provisional vs. Utility

- Provisional application
 - Not examined
 - No costs for prosecution of the patent application with the USPTO during the first year, only a small filing fee
 - Serves as a priority document (re first to file)
 - Preserves rights for 1 year, must file either a Utility patent application and/or a PCT patent application (international) after 1 year



Provisional application – cont.

- Able to file additional provisional applications and combine their contents into the Utility application or PCT that is filed at the 1 year date
- Allows time to develop technology, obtain data, get funding/partners
- File a provisional BEFORE you publicly present, publish, use, or sell your invention
- Allows a product covered by the provisional application to be labeled as “patent pending”



Provisional application – cont.

- My practice is to prepare a very solid provisional so that every aspect of the invention is described, the invention is fully enabled, there is good written support, multiple different embodiments are provided, and there are multiple layers and types of claims
- Too often a provisional is drafted that is not well prepared and then although it, in theory, provides a priority date, it only does so in regards to the subject matter that is clearly described therein. Therefore, it is CRUCIAL to write a really good provisional
- A well written provisional application will serve as a strong starting point for writing the Utility application, sometimes little additional data or description is added prior to filing of the Utility application



Utility Applications

- Examined at the USPTO
- Earlier examination, important in fast-developing technology
- Earlier issuance
- From date of filing the Utility patent application to patent grant is approximately 3-4 years
- Fast Track program with the USPTO allows a final disposition within approximately one year



Prosecution of a Utility Application before the USPTO

- Information disclosure requirement (IDS)
- Restriction Requirement, divisionals
- Non-final Office Action(s)
- Final Office Action
- Interview(s) with the Examiner
- Appeal or request to continue prosecution
- Upon grant, keep an application “alive”



Who is the inventor?

- An inventor is an individual(s) involved in the “conception” and (sometimes) “reduction to practice” of the claimed invention
- Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention
- The invention is complete only if ordinary skill is needed to reduce the invention to practice



A Joint inventor?

- A joint inventor must:
 - contribute in some significant manner to the conception or reduction to practice
 - make a contribution to the invention that is not insignificant in quality, when that contribution is measured against the dimensions of the full invention
 - do more than merely explain to co-inventor(s) well-known concepts or the current state of the art
 - contribute to the subject matter of at least one claim in the patent application



The importance of laboratory notebooks

- The practice of keeping and witnessing a laboratory notebook is still important even in light of the U.S. becoming a first-to-file system
- Laboratory notebooks are still relevant to patentability because they are often a means of proving that you are the true inventor
 - In the U.S., because you will still be able to pre-date an earlier filed applicant who obtained your invention from you, it will be important to keep a lab notebook because it can show that you invented the invention first and possibly how the other filer obtained the invention from you



Laboratory Notebooks – cont.

- Laboratory notebooks remain relevant for determining inventorship and correcting errors in inventorship
- Laboratory notebooks remain relevant during prosecution of the patent application when it may be necessary to supplement the specification with arguments and/or data from the inventors such as in a declaration



How should a notebook be set up?

- A bound hard copy with page numbers, and an electronic copy, if possible
- Signed and witnessed on a regular basis
- No loose papers, permanently affix any loose papers (including photos) into notebook
- Identify data with a specific project
- All entries consecutively dated



Notebook set up – cont.

- Each investigator should have her own notebook, no shared notebooks
- Permanent ink
- Avoid derogatory remarks
- Don't change entries, make a new entry
- Include sketches, diagrams, etc.
- Clearly identify figures, data, etc.



Our time is running out and there is still so much to cover...

- Patent law is a complex and fascinating intersection of law and science
- There are many things to consider when deciding to patent your invention
- A well written patent application (or patent portfolio) is critical in protecting your IP
- A well thought out patent strategy is critical in protecting your IP
- A ton of information can be found about patents and trademarks on the United States Patent and Trademark Office website at www.uspto.gov



USCD Office of Innovation and Commercialization

Ownership of IP at UCSD:

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“Business Strategies for Intellectual Property in the Knowledge Economy”

<https://www.youtube.com/watch?v=AR1pW4VfQyc>

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eDisclosure is a secure online method for UCSD innovators to submit, manage, track, and update their invention and copyright disclosure over the entire lifespan of their inventions.

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There is so much more...

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Thank you for your time!