

PATENT BASICS

FOR LIFE SCIENCE COMPANIES

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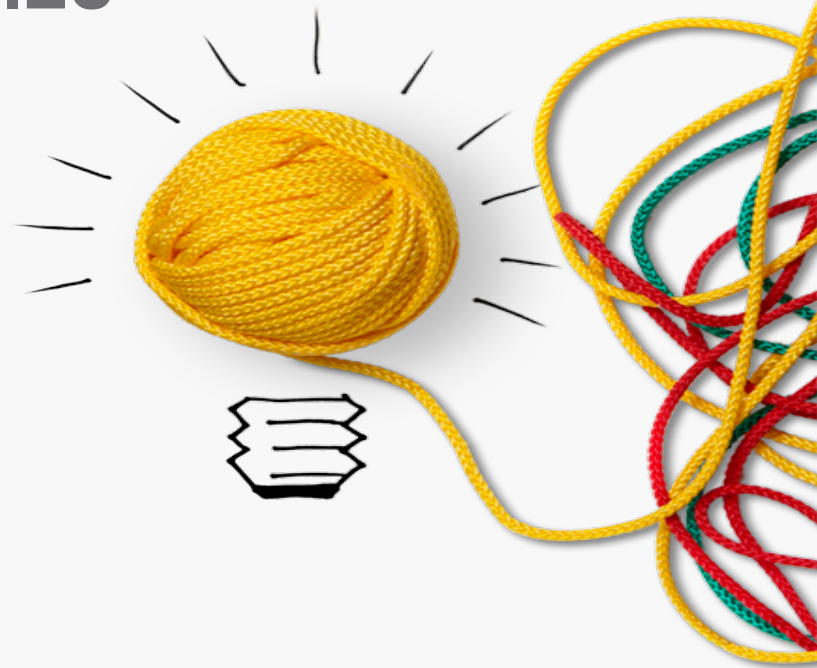
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NEXT CHALLENGE. NEXT LEVEL.

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INTELLECTUAL PROPERTY BASICS

- Types of IP:
 - ▶ Patents/Patent Applications
 - ▶ Trade Secrets
 - ▶ Trademark/Service Marks/Applications
 - ▶ Copyrights

PRE-FILING STRATEGY

- Define the invention.
- Consider other ways the invention might be applied.
- Redefine the invention.
- Determine patentability.
- Consider potential infringement/enforcement issues.

SEARCHES/OPINION LETTERS

- Obtain patentability and/or FTO searches/opinions.
- Identify patentable and commercially valuable subject matter
- Identify potential infringement issues.
- Consider ways to address these issues.

TYPES OF PATENT OPINIONS

Patentability

Non-Infringement

Invalidity

Freedom to Operate

Design-Around

SEARCHES

- Other than a non-infringement opinion, all opinions require a search.
- The type of search depends on the type of opinion.
- Understanding the differences between opinions helps to determine what type of search is required.

WHAT IS PRIOR ART?

- Prior Art - information publicly available before the effective priority date.
- Printed publications published before, and U.S./PCT applications filed before, the priority date.
- Prior public use or sale.
- Exceptions - Confidential disclosures/Self-disclosure.

PATENTABILITY OPINIONS

- A patentability opinion considers whether prior art exists that could invalidate claims to the invention.



WHY OBTAIN PATENTABILITY OPINIONS?

- A patent application is one part of a multi-year program to develop a product/process.
- It is best to determine up-front whether the invention is potentially patentable. If not, the company focus can shift to more patentable ideas.



DRAFTING A PATENT APPLICATION BASED ON THE OPINION

- A patentability search can help when drafting claims.
- Where a search identifies prior art, the claims can be drafted to distinguish over the art.
- It is important to draft patent applications with “fallback” positions.

WHY OBTAIN AN INVALIDITY OPINION

- Company receives a cease and desist letter.
- Freedom to operate search identifies one or more potentially relevant patents.
- ANDA-filers may need to show that Orange Book-listed patents are invalid or not infringed.

NON-INFRINGEMENT OPINIONS

- A non-infringement opinion considers whether a specific product infringes a given patent.
- Non-infringement opinions are similar to clearance opinions (Freedom-to-Operate Opinions), but provide a detailed assessment of a single patent.

FREEDOM TO OPERATE

- Freedom to operate (FTO) - the freedom to make, use, sell, offer for sale, or import.
- This assessment considers each element of a product or each step of a process.
- Depending on the technology, this assessment can be extremely complicated.

BIOTECHNOLOGY EXAMPLE

- Company wishes to sell a protein.
- FTO must consider whether one or more patent claims cover the DNA, RNA, vector, and transfected cell used to make the protein.
- FTO must also consider whether the protein itself is covered by one or more claims, and whether the intended use of the protein is covered by one or more claims.

DESIGN-AROUND OPINION

- What if a proposed product/method infringes one or more valid patent claims?
- One answer is to obtain a license.
- Another answer is to suggest non-infringing alternative designs.

BIOTECHNOLOGY SUBJECT MATTER

- Genetic Material
- Small Molecules
- Proteins/Peptides
- Antibodies
- High Throughput Syntheses/Bioassays
- Purification Methods
- Bioinformatics
- Theranostics
- Targeted Drug Delivery

CHEM/PHARMA SUBJECT MATTER

- Compounds/Pharmaceutical Compositions
- Methods of Making/Screening/Treating
- “Evergreening”
- Potential Orange Book Listings

WAYS TO BROADEN THE DISCLOSURE

- Potential modifications to the lead compound.
- Ways the compounds can be delivered, including targeted delivery.
- Prophetic syntheses, based on the actual syntheses, to cover broader formulae.
- Actual/prophetic assays for activity/selectivity/binding affinity and cytotoxicity.

IMPORTANT SUBJECT MATTER TO INCLUDE

- Compound Formulae – Broad and Narrow
- Compositions Including the Compounds
- Methods of Making and Using the Compounds
- Fallback Positions
- Assays for Binding Affinity, Activity, and Selectivity
- Data on at Least Three Compounds (Preferably More)

EVERGREENING

- Optimal dosages
- Prodrugs, active metabolites, salt forms, pseudomorphs/polymorphs
- New formulations/drug combinations
- New syntheses
- Sub-populations of patients that benefit more than others
- Theranostic screening/treatment methods

MEDICAL DEVICES

- Medical Devices
- Diagnostic Methods
- Therapeutic Methods
- Theranostic Methods
- Combinations of Devices and Active Agents
- Kits

ISSUES UNIQUE TO LIFE SCIENCE CASES

- Broad Claims May be Anticipated/Obvious.
- Narrow Claims May Cover Commercial Embodiments.
- Are Narrow Claims Sufficient?
- Are Likely Competitors Big Pharma or Generics?

A REPRESENTATIVE INVALID CLAIM

A compound of the formula: $C(R^1)(R^2)(R^3)-O-C(R^1)(R^2)(R^3)$

- Where $R^1 = H$, alkyl, aryl, arylalkyl, amine, thiol, ether
- R^2 and $R^3 = H$, quinuclidinyl, thienyl
- When $R^1-R^3 = H$, the compound is dimethyl ether, so the claim is invalid.

UTILITY GUIDELINES

- Specific, Substantial, and Credible Utility
- Patent-Eligible Subject Matter
 - ▶ Process, machine, manufacture, or composition of matter; and
 - ▶ Patent-eligible subject matter, not a judicial exception (unless claims include additional limitations amounting to significantly more than the exception). See MPEP §§ 2105 and 2106.
- **This Area is One of the Most Difficult in U.S. Patent Practice Today (Case law includes Myriad/Alice).**

WRITTEN DESCRIPTION

- **35 U.S.C. 112(a)/pre-AIA 35 U.S.C. 112** – “the specification shall contain a written description of the invention”
- This requirement is separate and distinct from the enablement requirement.
- Must adequately describe the technology, and disclose “the technologic knowledge upon which the patent is based.”

ENABLEMENT

- Disclosure must contain sufficient information to enable one skilled in the art to make and use the claimed invention.
- Examiners consider “Wands Factors” to determine whether the breadth of the claims would require “undue experimentation.”

THE “WANDS FACTORS”

- The breadth of the claims and the nature of the invention;
- The state of the prior art and level of one of ordinary skill;
- The level of predictability in the art and the amount of direction provided by the inventor;
- The existence of working examples; and
- The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

PROVISIONAL APPLICATIONS – A TRAP FOR THE UNWARY

- A provisional application **must** be thorough, and is ideally as thorough as a non-provisional or PCT application.
- Subject matter inadequately disclosed in a provisional, but later disclosed in the non-provisional/PCT, **ONLY** gets the priority date of the later-filed application.
- If there is a publication between the provisional and non-provisional filing, it can invalidate certain patent claims.

INTERNATIONAL PROSECUTION

- PCT Applications preserve rights to file in multiple countries for 30/31 months from priority.
- Determine whether the invention is commercially viable; if not, save money by not entering the national stage.
- International Search/Written Opinion can help determine what subject matter is patentable.

NATIONAL STAGE ENTRY

- Common Countries– U.S., Canada, Europe, and the “BRIC” countries (Brazil, Russia, India and China).
- Regional applications can cover multiple countries.
- For particularly valuable inventions, consider adding other countries.

NEED FOR CONSISTENT PATENT STRATEGY

- Develop a consistent, worldwide patent strategy. Inconsistent statements can lead to invalidity/unenforceability.
- Patent laws vary across the globe, making consistency difficult, and different countries often cite different prior art.
- Method of treatment claims are not always patentable. Some countries allow Swiss-type claims, and others do not.

HIRE COMPETENT COUNSEL

- An experienced patent attorney can:
 - ▶ Draft Thorough and Enabling Patent Applications.
 - ▶ Develop a Cohesive Worldwide Patent Strategy and Adapt the Strategy to Match Product Development.
 - ▶ Conduct Periodic IP Audits and Add New IP When Necessary.
 - ▶ Draft Opinions as Needed, and Assist with Licensing/Litigation/IPRs.

QUESTIONS?



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If your questions would extend beyond the scope of this discussion, or the applicable time limits, feel free to reach us by email.