

Practical Strategies for Biotechnology and Medical Device Companies to Manage Intellectual Property Rights

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Intellectual Property

- **Patents**
- **Trademarks**
- **Copyrights**
- **Trade Secrets**

Patent Basics: What is a Patent?

- **Patents provide the right to exclude others (not a right to practice) from making, using, selling, or importing the claimed invention into the United States in exchange for disclosure of the invention**
- **Patents last for 20 years from the earliest filing date (not from issue and not counting various patent and regulatory extensions)**

Patent Basics: Anatomy of a Patent

- **Specification**
 - Abstract
 - Detailed description (including examples)
 - Figures
- **Claims: Define the inventive technology owned by the patent holder**

Patent Basics: Types of Claims

- **Devices**
 - Mechanical structure
- **Compositions**
 - Drugs and compounds (including various forms)
- **Methods or Processes**
 - Making (assembly or manufacture)
 - Using (e.g., surgical procedures)
 - Treating (can include new diseases with an already-known or already-patented compound)
- **Ornamental Design?**

Patent Basics: Where to File

- **Patent rights are territorial**
- **U.S. patents provide NO rights outside the U.S.**
 - Do provide bar to imports
- **Can file directly in other jurisdictions within 1 year of priority filing**
- **A Patent Cooperation Treaty (PCT) application can be filed to provide a foundation for later filings in many other countries**
- **Individual filings in specific countries and regions ultimately required**
- **Cost \$\$\$**

Patent Basics: U.S. Application Timeline

● Year -1: Provisional application filing - “patent pending”

○ Year 0: File non-provisional – description substantively frozen
18 months after first filing – patent application publishes

○ Year 2: Claims are examined and, often, rejected

} Years 2-3.5: “Patent Prosecution” – back and forth with Patent
Office, arguing law and technology, amending
claims

○ Year 3.5: Notice of Allowance

● Year 3.9: Issued U.S. Patent

Patent Basics: Keeping Records

- **Institute an Internal Invention Disclosure and Review Process**
 - At start of project, describe the goals
 - Record research and development
 - Bound books or verifiable electronic records
 - Have a non-inventor review, understand, and witness pages of your notebook
- **Regular and Formal Review**
 - Determine how to protect particular IP developed
- **Why Are Records Important?**
 - Can be used to establish inventorship
 - Document “disclosures” for proof of “derivation” (new law)

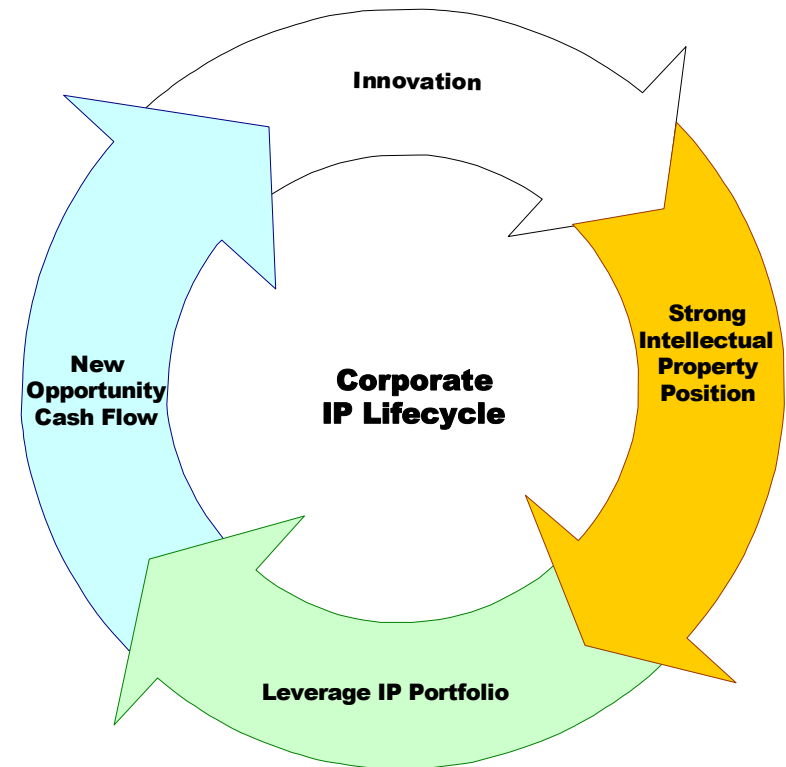
Patent Basics: A Note on Confidentiality and Trade Secrets

- **Public disclosure can destroy patentability**
 - Absolute in most foreign jurisdictions
 - One year grace period in U.S.
 - “Sale of invention” treated as disclosure in U.S.
- **Use confidentiality agreements for early third-party disclosures**
 - Avoid disclosures before filing patent applications
- **Use provisional application process**
- **Trade secrets are perpetual**
 - Require formal systems to maintain

Patent Strategy: Business Context

Goals of Portfolio Management

- **Protect current and future product developments**
- **Maintain competitively-sized portfolio with attention to patent expiration dates**
- **Evaluate competitive IP landscape and protect areas that will likely be valuable to the industry as a whole**
- **Manage COST - \$\$\$**



Patent Strategy: Market and Business Considerations

- **What is the market – present and future?**
- **Where are your competitors/the industry filing?**
- **Where do you fit in the market?**
- **What can you afford?**
- **Core technology vs. tangential or expansive**
- **Use process (e.g., PCT) to reassess scope and value**

Patent Strategy: Business Goals

- **Defensive Patenting**

- Protect present and anticipated core technologies
- Define improvements against in-licensed patents

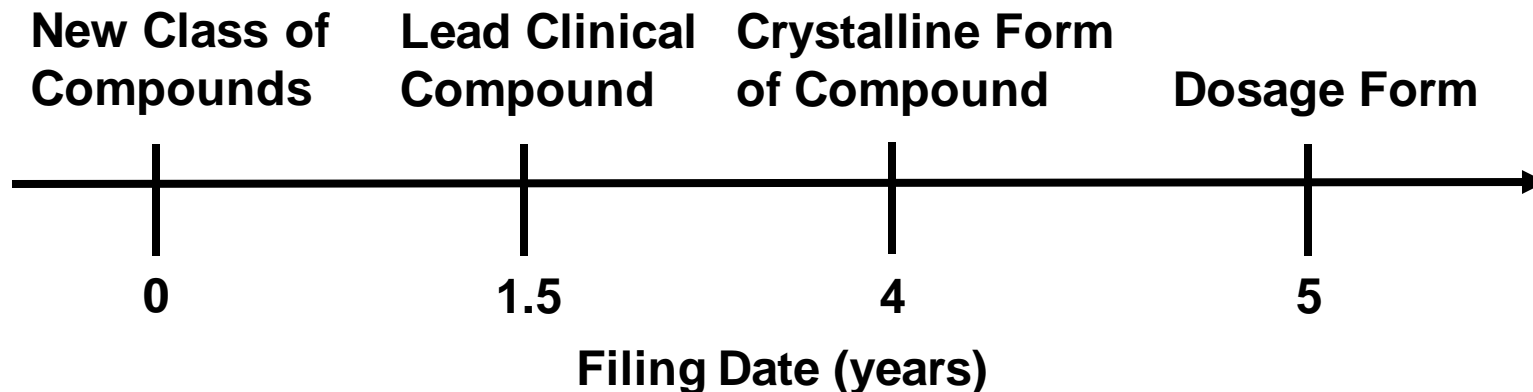
Minimum strategy

- **Offensive Patenting**

- Build larger fence to prevent competitors from designing around and avoiding core technology patents
- Publication of applications serves as prior art against others seeking broad coverage

Desirable strategy if feasible

Patent Strategy: Extend Exclusivity

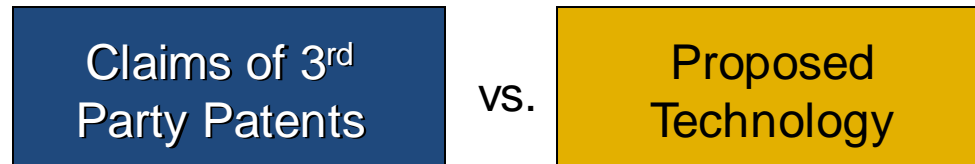


- **Length of exclusivity dramatically increases valuation**
 - 20 years from filing
- **Additional exclusivity periods**
 - Patent term adjustment (delay by the Patent Office)
 - Patent term extension (delay by the FDA)
 - Non-patent regulatory extensions (new chemical entity, orphan drug, pediatric drug)

Patent Strategy: Freedom to Operate

- If we pursue this technology, will we infringe anyone else's patents?
 - Develop an understanding of the technology
 - Conduct search for patents in the field

- Compare



- Does the technology meet all the limitations of any claim?
- Can only minimize risk – difficult to find all material patents
- May be able to find “design-around” to further minimize risk

Patent Strategy: Exit Strategy

Investors/Acquirers will ask:

- **Is technology clinically relevant?**
- **What is market/revenue potential (e.g., is reimbursement high enough)?**
- **Do you have a strong patent portfolio?**
 - Coverage (e.g., types of claims)
 - Breadth (can claims be designed around?)
 - Freedom to Operate (can you actually practice the technology?)
- **Do you actually own the technology?**
 - Assignments from employees and consultants
 - University tech transfer
 - Licenses (Assignable? Exclusive? Field of use restrictions? Other obligations?)

Other Intellectual Property Issues

- **Trademark registration and branding**
 - Need a product on the market to register
 - Clearance search for corporate name
- **Copyright registration**
 - Limited in scope and applicability
- **Deceptive trade practices**
 - Claims made must be supported
 - Cannot suggest non-approved uses

Final Thoughts

- **Consider competitive strategy early**
 - Define your market
 - Identify your competitors
- **Assess inventions early**
 - Institute an internal invention review
 - Perform patentability searches
- **File patent applications early – before public disclosure**
- **File patent applications completely – support the invention**
- **Assess IP position strategically on a continued basis**
 - Monitor competitors: technological developments; market directions; filed applications
 - Monitor portfolio: look for threats from newly identified art

Thank You

Questions?

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