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).

- **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
- Year 3.5: Notice of Allowance
- Year 4: 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
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

• 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
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

  Claims of 3rd Party Patents vs. Proposed Technology

• 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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