Patent Prosecution and Protection

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Protecting your IP

- Different forms of IP protection
  - patent
  - trademark
  - trade secret
  - copyright
- Needs/Goals determine the forms used
- Life Sciences generally use patents and trademarks
What is a Patent?

- Bargain between an inventor and the U.S. government – a property right

- In return for a period of exclusivity (20 years from the filing date + any extension), the patentee agrees to make public sufficient information so that others can make and use the invention (after the patent has expired)
Why Patent?

- "Offensive" reasons
  - Injunctions
  - Royalty income
- "Defensive" reasons
  - Cross-licenses
  - Settlement value
- "Market" reasons
  - Increase company value
  - Intimidate competitors
What Protection Does a Patent Provide?

• Right to exclude others from:
  – Making
  – Using
  – Selling, offering to sell
  – Importing
    ... the claimed invention

• Not a right to practice the invention
  - e.g. a patent owner might not be able to practice their invention without licensing another patent
Barriers to Obtaining a Patent

You cannot obtain a patent if, more than 1 year before filing your patent, there was a:

• **Public** disclosure or **use** of invention; or
• Product incorporating invention **sold** or **offered for sale**
Filing for a Patent

• Prepare the Application
  - type of application (provisional vs. utility)
  - drawings?
  - additional experimental data?
  - claims

• File the Application with Patent Office
  - provisional application allows one year to optimize
  - consider filing internationally (PCT)
  - 18 months to publication
Provisional vs. Utility Appl’n

- **Pros of Provisional Applications:**
  - Fast and less formal (grant; journal article)
  - Cost ($125 to file; $2-5K for preparation)
  - Priority date set with one year to decide whether to spend $$$ for utility application

- **Cons of Provisional Applications:**
  - Must still file utility application ($190 to file; $8-10K for preparation)
  - Needs to completely enable claims in order to rely on filing date for priority purposes
Exemplary Patent Claims in the Life Sciences

- **product claims**
  - a new machine,
  - a new “composition of matter” / a new compound
  - a new device

- **process claims**
  - how a compound is made; how the invention is carried out

- **formulation/composition claims** (tablet, capsule)

- **methods of use claims**
  - only available in some countries
  - use of compound X to treat disease Y
Before the PTO (“Prosecution”)  

- The Patent Office conducts a search and substantive review of the prior art (12+ months)
- The Examiner issues an Office Action citing references, applying patentability tests and raising procedural issues
- 1-6 months for Applicant to respond, by making scientific or legal arguments or by amending the application, or both
- Inventor(s) involved in preparing the response
- Possible additional Office Actions and subsequent arguments and amendments (6-24 months)
- Patent is granted
International Filing Options

- MUST OCCUR WITHIN 1 YEAR OF FIRST FILING
- (to maintain priority date)

- Direct country filings
  - Canadian patent office
  - European Patent Office (followed by National Entry)
  - Japan
  - China, etc.

OR

- Patent Cooperation Treaty (PCT) application
PCT Applications

• No such thing as a world patent

• International treaty allows one filing to be treated as a filing in elected countries

• Search at 16 months

• Publication at 18 months

• 1st examination in 22-26 months

• Then “nationalize” country by country
Advantages of a PCT Appl’n

- A single filing has the same effect as filing in all elected countries

- Allows you to “park” the application (delaying nationalization for 30 months from priority date)

- Delays major cost outlay (which delays individual filing fees or translation costs)

- Examination report gives some idea of issues going forward
Patent Costs

- Application: $8-15k
- Prosecution: $8-12k over 3-5 yrs
- Issuance: $870 (small entity)
- Maintenance: $4400 over 11 years
- Foreign: $ for PCT Appl’n
  $20-30k per country
America Invents Act (AIA)

- Enacted Sept. 16, 2011; rolling implementation
- Micro-Entity Status Established
  - Small Entity + Less than 4 Applications + Gross Income Limitations
  - 25% of many PTO fees
  - “Effective” Sept. 16, 2011
- First to File
  - March 16, 2013
Thank You

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