

Patent Prosecution and Protection

Rachel M. Slade, Ph.D.



UTC Life Science Workshop

June 5, 2012

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?

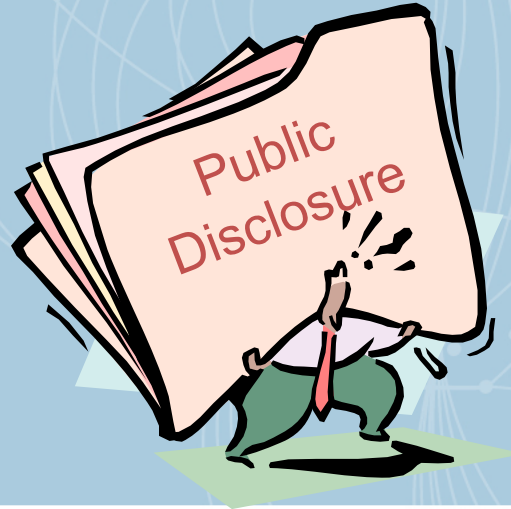
- Right to exclude others from:
 - Making
 - Using
 - Selling, offering to sell
 - Importing... the claimed invention
- Not a right to practice the invention
 - e.g. a patent owner might not be able to practice their invention without licensing another patent



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

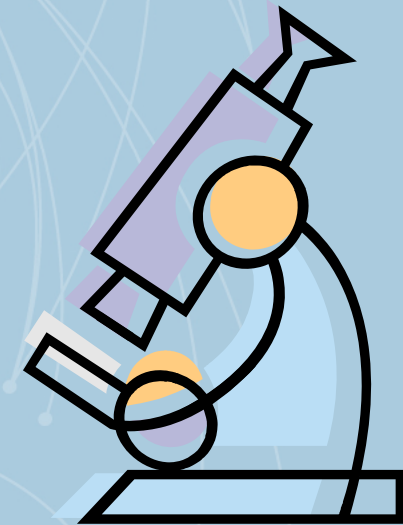
Patent Costs

- **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



Rachel M. Slade, Ph.D.
(801) 428-6344
rmslade@stoel.com



Bart W. Giddings, Ph.D.
(801) 578-6920
bwgiddings@stoel.com