Case Competition

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Great! What is a Patent?

- A patent is a PROPERTY right.
- A patent is a right of EXCLUSION.
- A patentee can prevent others from
  - MAKING,
  - USING
  - OFFERING FOR SALE
  - SELLING
  - OR IMPORTING
- A Patented Invention.
What is a Patent?

A patent is NOT a right to USE an Invention.

Example:

- Company A owns patent on antibiotic Compound and method of treating bacterial infection with Compound.
- Company B discovers that that Compound also can be used to treat male pattern baldness.
  - B files a patent on using Compound to so treat such male pattern baldness
What is a Patent?

- Company A markets and sells Compound as an antibiotic.
- Company B cannot market and sell Compound for treating male pattern baldness because it does not have the right to make or sell Compound for ANY purpose/use.
- Company A cannot sell Compound as method to treat male pattern baldness because Company B owns that method of use!
- Stalemate on male pattern baldness treatments?
- Probably not – this leads to a license! A may license its rights to the Compound for the specific use to treat male pattern baldness to Company B
Your Invention

- An Invention qualifies for a patent if you can convince the federal government (a patent examiner at the United States Patent and Trademark Office) that your invention is
  - Useful
    - For Chemical inventions straightforward
    - Less straightforward for methods of diagnosis, computer-based processes, financial methods, etc.
  - Novel
    - Is it new?
  - Non-obvious
    - Even if new, is it obvious given the prior art?
An eager junior scientist comes into your office and screams “Eureka” I have found the following compound! I just characterized it by Mass Spec, NMR, IR, and Elemental Analysis!

The scientist says, I shall call it “Aspirin”
Novelty – More complicated

• Suppose Article I teaches Compound and teaches that Compound has been dosed into rats with great results against Disease in Yr. 1
• Further suppose that Scientist hypothesizes that Compound might metabolize *in vivo* and thus investigates metabolites of Compound
• After years of painstaking research, Scientist identifies a critical metabolite, determines its activity against Disease, and develops a unique way to synthesize it
• Scientist files a patent application in Yr. 5 claiming:
  – Metabolite
  – A method of treating Disease with Metabolite
  – A process for preparing Metabolite (the unique synthesis)
  – Novel?
• Let’s Vote!
Democracy in Action

- Is the Metabolite Novel?
  - Nope
  - It existed in the prior art because the rats metabolized Compound
  - But, you say, nobody recognized that at the time or prepared it?
  - Does not matter, it existed
- Is the method of treating Disease with Metabolite novel?
  - Nope, see above
- What about the process?
  - Yes! If the process is different than the natural way of metabolizing compound.
- What also might be patentable?
  - Metabolite in a pure form
  - A pharmaceutical formulation comprising Metabolite and one or more pharmaceutically acceptable excipients
  - A solid form of the metabolite (e.g., crystalline or amorphous salt, cocrystal, polymorph etc.)
Qualities of the Invention
Cannot be Obvious

Q: Would aspirin be obvious over Methyl Salicylate?
Obviousness

• Establishing a “prima facie case”
  – By using known organic texts, one could convert the closest prior art (methyl salicylate) to aspirin with a reasonable expectation of success

• Perhaps, but what about “secondary considerations”
  – Suppose methyl salicylate is a poison, but aspirin is a wonder drug, that is an unexpected result which rebuts the prima facie case!
  – Which is why patent attorneys will hound you (inventors) for data such as evidence of “synergy” or other unexpected results
Patents and the FDA

• NDA = New Drug Application
  – Typically filed at the conclusion of a successful Phase III trial
    • Success = Safe + Effective
  – If directed to a new chemical entity ("NCE"), then the applicant will be granted four years of data exclusivity and five years of market exclusivity that run concurrently
    • Orphan indications get seven years, but only to that indication
  – Data Exclusivity = Data Protection
Patents and the FDA

• **ANDA =** Abbreviated New Drug Application
  – Does not need to show safety or efficacy, can reference the NDA for its data after data exclusivity expiration
  – Needs to have “same” NCE and show bioequivalence
  – Against an NCE, can only be filed not earlier than **four** years after NDA approval (data exclusivity)
  – Can only be approved not earlier than **five** years after NDA approval (market exclusivity)
Patents and Exclusivity

• Exclusivity
  – Prevents a generic drug from referencing NDA or getting onto market for a limited period of time and is independent of patent status; will not prevent a third party from submitting its own NDA

• Patents
  – Have potential to prevent any and all third parties from putting the same drug on the market (or even a class of drugs depending on the claims) for a term that is not typically shorter than 20 years after the filing date of the patent application
Patents and Exclusivity

• For return on investment, five years of exclusivity is usually insufficient
  – Which makes a 10 year proposal intriguing!
• Patents are relied upon to try delay generic entry for as long as possible
• There is a highly complex mechanism for adjudicating patents in regulated pharmaceutical products and is unlike any other sector
• Called “Hatch Waxman”
Roche v. Bolar, 733 F.2d 858 (Fed. Cir. 1984)

- Roche owns patent to drug Dalmane
- Bolar wishes to do R&D for premarket work to get FDA approval for generic launch to submit for approval to FDA
- Roche sues for patent infringement based on research by Bolar
- Court states nothing in the law immunizes Bolar for infringement simply because this was pre-commercial research
- Hatch-Waxman passed in wake of ruling (US)
Key Elements of Hatch - Waxman

- Generics need not submit clinical efficacy/safety data and can rely on data submitted by the NDA applicant; (this talk)
- Safe Harbor - no suit for infringement until the filing of an ANDA; (this talk, sort of)
- 180-day exclusivity period for first generic to file; (not this talk, but really interesting)
- Patent Term Extension for Regulatory Delays (5/14 rule); and (not this talk, but really important to innovators)
- The 30-month stay (definitely not this talk)
Factors in Clinical Development

- **Cost**
  - Clinical trials are expensive
  - Patient medical costs
  - Cost of medical team

- **Intellectual Property**
  - Preference for EU and US where IP rights are protected
Patent Rights in Pharma

• Composition of Matter Patents most valuable
  – Covers the API
  – Recall patents are rights of exclusion

• Process patents less valuable
  – Harder to prove infringement
  – Design-around issues
  – However, may be easier to get in some third world markets
    • E.g., India where composition of matter patents have traditionally been frowned upon even after GATT
Pharma Patent Challenges

- Patents can be found invalid
- So, expiration of monopoly unknown
- Not all patents of equivalent value or enforceability
- Different standards of obtaining and enforcing patents worldwide
- Expensive to obtain and very expensive to enforce
Exclusivity Challenges

- Only protects against a third-party from referencing your data
- Does not protect against someone developing their own data
- The longer the exclusivity, the more economically viable it becomes to make another innovator product by a third party if the costs can be controlled and can learn from the initial innovator