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**Introduction to  
Intellectual Property Diligence:  
Somewhere Between Prosecution and Litigation**

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# Typical Contexts for Conducting Intellectual Property Diligence

- Company A is interested in buying Company B
- Company C wants to perform an internal audit of its patent portfolio
  - Assess own strengths and vulnerabilities
  - In anticipation of sale of assets to a third party or litigation

# Things We Wish Every Client Would Do as Part of Their Diligence

- Diligent Diligence:
  - Patent strategy development, competitive landscape assessment.
  - Involve counsel in IP agreement negotiations – from the “Get Go”

# Minimum Components of Patent Due Diligence

- Chain of Title / Ownership
- Scope of Intellectual Property Protection
- Freedom to Operate

# Chain of Title Review – Sounds Simple, But...

- Keep In Mind the Quirky Ownership Rules: Inventor owns invention unless it is assigned or there is an obligation to assign
  - Employment contracts
  - Consultant's Agreements
  - “hereby assigns” vs. “agrees to assign”
- Persons named as inventors must have contributed to claimed subject matter

# Chain of Title: What to Look For

- Are patents/technology assigned to the company?
- Are patents properly assigned?
- Do all key inventors/employees/consultants have duties to assign?
- Can an inventor assign to third party?
- Has company licensed technology to any third party?

# Real World Examples

- Unsigned, but recorded, assignments
  - Take home message: always look at the actual assignment document – do not rely on abstracts of title from PTO.
- Secret Inventor of 1 claim of a patent (there could be hundreds of claims...)
- Beware University Involvement Issues (i.e., “Not Invented Here”)
  - Unlikely to get exclusive rights
  - “Off label” uses / Exhaustion problem
  - Consultant is also employee of University (next slide example)

# Real World Examples

- Company Q enlists Consultant Company to develop a modified drug compound for certain indication
- No agreement in place, “100K +” given by Q
- Consultant Company succeeds - problems start
- Consultant plans to publish, so Q files a patent application (not naming inventors, yet). Q learns of it and also files own, less comprehensive application.
- One of Consultant “inventors” is employed by University X
- University X exercised its rights under employment agreement, claimed ownership and granted non exclusive license to patent pending technology to a third party for a different indication (how nice of them...)

# Scope of Intellectual Property Protection

- Do the patents cover, at a minimum, the thing that is to be sold?
  - Oftentimes, the patents do not
- Can an entity prevent others from making, using and selling competing products or services? How broad are the claims?

# Real World Examples

- Thin film developer uses a polymer that is listed in the specification, but is not recited in the claims and the claims only recite other very specific polymers. Developer changed polymers to one that is recited in the claim, but already showed feasibility of other polymer.
- Drug formulation and method of administration not within scope of claims due to water content limitations. Third party company bought product line for 200 + million. Client may spend 10 million to enter market with identical competitive product.

# Freedom to Operate

- Can an entity sell a product or service without infringing another party's intellectual property?
- Problematic during deals because most other issues between the parties can typically be solved by negotiations (i.e., “show me the money”). This issue cannot be cured so easily because if there is a problem, you don't want to stick your head up (request a license) and become a target and risk an injunction.
  - We are usually asked to check FTO right before the deal closes
- Can also include trademark, copyright and trade secret analysis
  - Typically, analysis ends with patents and trademarks

# Non-infringement/Validity Analysis Of Third Party Patents

- Requires a very detailed description of the product upon which we can rely – a patent application will not suffice.
- Freedom to Operate Searches (focus on third party patents and patent applications)
  - Prior Art Search (focus on patents, applications, articles, speeches, sale of goods, etc.)
    - Typically only done if there is a problem that extends beyond non-infringement
  - Legal Research
  - Analysis and Written Opinion
  - Avoiding Willful Infringement - Recent developments in case law diminish need for opinions
  - Jurisdictions for Typical Freedom to Operate Study
    - U.S.
    - Ex U.S. (e.g., Europe International)

# Real World Examples

- Major healthcare company to produce a product having multiple facets – device as a whole, components of device, peripheral components of device, software to run device.
- Each facet needed to be searched
- Resulted in 5 patents of primary interest
- References found to invalidate relevant claims of 5 patents of interest.

# IP Agreements Review

- Are necessary rights granted?
- What are costs of license?
- Can rights be terminated by licensor?
- What obligations/milestones does target company have?
- Has target company met its obligations/milestones?
- Are there change of control provisions?

# Starting Materials To Help Us Out

- Detailed Description of the Technologies and/or products that are key to the valuation
- Copies of the patents and patent applications that are owned by or licensed to the target company
- Copies of patentability searches and opinions relevant to the target company's patents and patent applications
- Copies of 'Freedom to Operate' searches and opinions, if any
- Copies of material IP agreements (e.g., licenses) or other technology transfer agreements
- Access to technical and legal personnel involved with the target company

# Benefits of Freedom to Operate and Patent Due Diligence

- Facilitate development of and/or confirm patent strategy
- Competitive landscape assessment
- Freedom to operate adds tremendous value to an entity
- Identify possible vulnerabilities and possible solutions to solidify patent position
- Use intelligence gathered during due diligence to add value to target company post closing of funding or other transaction

# Real World Examples – A Company That Did It Right

- Pharmaceutical Company develops product #1. Patentability and FTO Search performed identifying literally dozens of patents and pending applications. Strategy developed to address all – Company had a good story to tell about all the known art.
- Multiple patent applications filed by Company
- Ongoing monitoring discovers new publication. Company considers abandoning patent applications and product in favor of new technology, product #2.
- Search performed again, identifying dozens of patent and patent applications. Strategies developed to address all. (to date, high success rate – 100%)
- Company files second family of applications (all new inventors)

# Real World Examples

- Following advice of counsel, Pharmaceutical Company redrafts claims in first family in attempt to encompass new proposed product
- Patent issues in first family, covering new proposed product.
- Results of searches and strategies are summarized in three, 3-ring binders. The binders were provided to prospective licensees in advance of meetings, significantly reducing third party diligence counsel burden.
- Total legal fees (including BF, FDA, Trademark and Patent) over 5 years = 1 million dollars.
- Negotiations lead to licensing arrangement valued in excess of 180 million dollars.

# Conclusion

- For Discussion