

# Surviving and Thriving in IP Due Diligence

Presented to Vancouver Island Life Sciences

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# What is Due Diligence?

- Per Meriam Webster: Due Diligence is the careful, thorough evaluation of a potential investment, whether on a corporate or individual level
- AKA kicking the tires on the car before you buy it
- Prospective Buyer does a look at what the Prospective Seller is selling in order to (a) help determine the price and (b) decide whether to enter into a transaction at all
- Special considerations when IP is at issue and even more particular in a life science transaction

# Why it Matters?

- Between 2014 and June 30, 2019 there were nearly 2,900 deals in gene therapy, immuno-oncology, microbiome and orphan drug space
- Deals totaled more than \$1 trillion
- 270 deals in immuno-oncology in 2018 alone (63% growth over 2014)
- 133 Gene therapy deals 2018 and 82 in 2014
  - Source – GlobalData 2019
- All deals require some level of due diligence and usually involves IP due diligence

# Elements of Due Diligence

- Financials
  - What is the asset worth (not this talk)
- HR (not this talk)
- Regulatory (a little this talk)
- Contracts and Obligations (more this talk)
- Intellectual Property (a lot this talk)

# IP Due Diligence

- Rationale
- Scope
- Process
- Title/Inventorship
- Patentability
- Primary and Secondary Patents and Loss of Rights Dates
- Infringement Issues
- Reps and Warranties

# Rationale for IP Due Diligence



# Scope of IP Due Diligence

- Patents and patent applications
- Unpatented Inventions
- Know-How
- Trade secrets
- Trademarks
- Copyrights



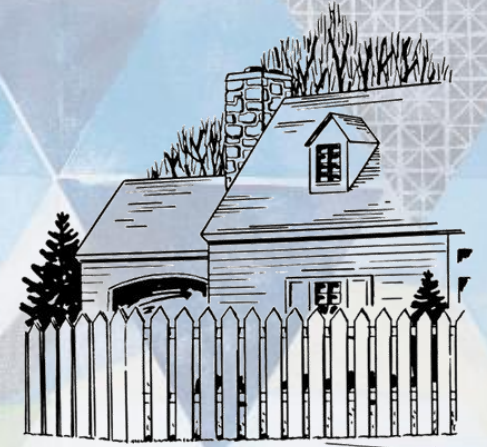


# Process for IP Due Diligence

- Initial general discussions at high-levels
- Non-Disclosure Agreement
- Exchange of information
  - Data Room
  - Interviews
  - Iterative
- Works into Deal financial terms and reps/warranties

# Title

- Just like a house, one can check title of a patent
- Title documents (called “Assignments”)
  - In U.S., they are provided at the USPTO
  - They establish “chain of custody” from the inventors to the current owners of a patent
- Under U.S. law (and many other jurisdictions), the default rule is that inventors own the patent, but they can transfer ownership by contract
- This is why both title and inventorship are important IP due diligence items



# Ownership and Multiple Inventors – US Case

- 35 U.S.C. § 262

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.



# Inventorship

- “Conception is the touchstone of invention”. In re Verhoef, 888 F.3d 1362, 1366 (Fed Cir. 2018), quoting [Burroughs Wellcome Co. v. Barr Labs., Inc.](#), 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).
- Inventors conceive of the invention, but do not necessarily physically “reduce it to practice”
- Determined as a matter of law
- More than 1 inventor = joint inventors
  - Claim by claim basis
  - Need not work together physical but need some nexus – “We require that ‘inventors have some open line of communication during or in temporal proximity to their inventive efforts.’” [Eli Lilly & Co. v. Aradigm Corp.](#), 376 F.3d 1352, 1359 (Fed.Cir. 2004).

# Typical Title/Inventorship Questions

- Was an inventorship analysis performed? How was it performed?
- Are there any inventors outside the United States/Canada?
  - Tax implications?
- Did a government agency fund any of the research?
- Was any of the work done in a government facility or university?
- Was any of the work done under contract with a third party?

# Typical Patentability Questions



- Have you done a prior art search?
- Have you prepared a patentability opinion?
- When was the invention first published?
  - How was it published or disclosed?
- Where is the patent granted? Where there any patentability rejections and where were those rejections?
- Other than the inventors, who knew of the invention prior to filing a patent application?

# Disclosures – Why Buyers Care

- In the United States, if you disclose an invention in “public”, the clock starts to tick and after one year, if you do not file a patent application...
  - Loss of rights
  - The grace period is now much more limited than in the past – best to file before disclosing
- If you are going to present your invention at a conference tomorrow and you do not have something on file today, then upon “publication” you have forfeited your rights nearly everywhere else in the world
  - NO GRACE PERIOD

# 1° and 2° Patents and Loss of Rights Dates

- Often, there is more than one kind of patent at issue
  - For small molecules, often the focus is on “composition of matter” which is the compound itself
  - There could be follow-on patents such as methods of treatment, formulations, kits, manufacturing patents, etc.
- Buyer will want to know “loss of rights date” (i.e. when the patents expire) for each kind of patent
- Buyer may weigh the importance of each differently



# Typical Questions

- When does the primary patent expire?
- Are patent term extensions possible?
- Have there been any challenges made against your patents (e.g., opposition-type proceeding or court invalidity proceeding)
- Are there any imminent filings in the works?

# Infringement Issues

- Patents have value because they can be used to assert rights in patent infringement suits
- If the claims are drawn too narrowly, then it makes it difficult to sue for infringement
  - Example- Claim directed to “A chair” can be used to sue someone who creates a green chair. A claim to a narrower “red chair” would face difficulties in such a lawsuit



# Reps and Warranties



- Representations and Warranties of the Seller
  - These are promises made by the “Seller” (could be licensor)
  - With respect to IP examples include (negotiated)
    - Title is good
    - All necessary licenses are in order
    - Nothing known that would materially affect the IP (or that in fact nothing is wrong with the IP)
    - No known infringers
    - No known infringement of third-party IP
    - To the extent there are exceptions, those are typically set forth in a schedule
      - E.g., “Other than as set forth in Schedule A, there are no known infringers or our IP.”

# Contracts and Due Diligence

- In M&A – contracts seller has with third-parties important because buyer will inherit them
- Licenses
- Exclusivity Agreements
- Key Contracts
- Termination Clauses

# Regulatory

- Data and Market Exclusivity Plan
- Relationship to Patent Term Extension (which patent)
- Which patent will be eligible for listing in the Orange Book?
- Often comes up in due diligence especially in relation to LOE timelines and launch timelines

# University Collaborations

- Conflicts of Interest
  - Inventorship issues (can professors assign to NewCo?)
- Licensed v. “home grown” IP
  - Value
  - Complexity
- Risk of license termination
- Do you need a patent at all?
  - Consider know-how and trade secret
  - Software patent unknowns
- Quality of patent applications
  - NewCo-University Collaboration on University patent process
- Global scope of protection (beyond universities)

# Challenges in Due Diligence

- Nobody expects perfection
- Be able to explain “challenges”
- Good – Have an answer ready
- Bad – Unprepared or unconvincing answer
- If it is a problem and the Buyer still wants to do the deal, it may be scheduled as an exception
  - E.g., There is no pending litigation challenging the validity of the patent except what is set forth in Schedule A



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