IP Due Diligence in Pharma/Biotech Out-licensing

*Presented by **Mihsun Koh** in BioKorea 2013*
EMAIL: mskoh@vorys.com

VORYS

Contents

- What is IP Due Diligence?
- Why is IP Due Diligence Important?
- What will Your Partner Want?
- What Documents do you need to prepare?
- Freedom to operate (FTO) and Solution to Potential Issues
- Exclusivity and Solution to Potential Issues
- Privilege Issues

VORYS

1. What is IP Due Diligence

- A thorough and critical process of gathering information on the merits, issues and risks associated with intellectual property rights (e.g., patents, trade secrets, know-how, trademarks) in a business transaction (e.g., mergers, acquisitions, licenses or litigations).
- Most of pharma/biotech is protected by patents, so IP due diligence will be mostly patent due diligence in pharma/biotech out-licensing.
- Both the licensor and the licensee need to conduct a thorough and complete IP due diligence for licensing.

VORYS

2. Why is IP Due Diligence Important?
- Informed business decision

- Effective IP due diligence based on your business goal for the transaction provides crucial information so that you can make an informed business decision about the potential risks and merits of the transaction and, if possible, so that the weakness can be remedied in order to guide the transaction toward fulfillment of your business goal.
- Early findings of any potential issues on liability and the value of your IP asset and strategic solutions of the issues will make your position stronger in the transaction and lead to a successful out-licensing.

VORYS

3. What Will Your Partner Want ?

- Freedom to Operate
- Market Exclusivity

VORYS

3. What Will Your Partner Want ? – Cont.
FTO & Exclusivity

- Freedom to operate
  - Freedom from the risk to infringe a 3rd party right – no one can stop you from using the technology in the market.
- Market Exclusivity
  - Maximize economic value of the technology - you can stop any one from using the technology in the market.
  - Your patents have claim scope broad enough to cover the technology and alternatives are not readily available to compete with your products.
  - Your patents can stand any future legal challenge.

VORYS

4. What Documents do you Need to Prepare?

- You need to be prepared to answer all the questions from your partner with necessary documents and data
- Product Information
  - Chemical/biological structure/properties, efficacy data, clinical data, etc.
  - Laboratory notebooks, scientific publications by inventors/employees

VORYS

4. What Documents do you Need to Prepare?
- Cont.

- Patent Information
  - Lists and files for all patents and patent applications; assignments;
  - Previously executed agreements: e.g., licensing, material transfer, consulting, research and development, manufacturing, and/or key employee agreements;
  - Results of any previous prior art search
- Confidential agreement (CDA) and Common-Interest (or Joint Defense) Agreement?

VORYS

5. Freedom to operate (FTO)

- Freedom from risk of infringement of a 3rd party patent

- FTO will be a major issue in the evaluation of the technology in view of the impact on potential royalty.
- Investigation for a potential 3rd party patent or published application that may block you from using the technology.
- Conducting at early stage, even embryonic stage and be prepared to answer to your partner's questions regarding FTO issues.

VORYS

5. Freedom to operate (FTO) - Search

- All patents and patent applications issued/filed in a country where the technology will be used or where a potential big market is expected for the technology.
- Involve outside counsel
- Search tools

VORYS

5-1. Solution to Potential FTO Issues

- Legal Solution:

  Legal opinions and/or Challenging patents

- Technical Solution:

  Design around

- Business Solution:

  License or acquisition

VORYS

5-1. Solution to Potential FTO Issues
- Legal Solutions

- FTO/Non-infringement opinion
- Invalidity opinion on a patent at issue
  - Complete search for prior art, including inventors' pre-publication (and after-publication), co-pending or other patents by the inventors or the patentee.
  - Review priority claims; Prosecution history for claim amendment and applicant's statement; Corresponding foreign file history; IDS; Inventorship; Affidavit/Declaration; Maintenance fees; PTA calculation; PTE eligibility and period.
  - Analysis claims over uncovered prior art, considering change in standard for patentability (e.g., *KSR*, *Arid*, *Myriad*)

VORYS

5-1. Solution to Potential FTO Issues
- Legal Solutions -Cont.

- Validity/Patentability challenge

  USPTO:

  - *Ex parte* reexamination (anonymous challenge)
  - *Inter partes* review (active involvement; discovery)
  - Post-grant review (broad reasons for invalidation)
  - Pre-issuance submission (pending application)

  Court:

  - Litigation (e.g., DJ action)

VORYS

6. Exclusivity

- Validity/Enforceability & Patentability

- Economic value
- Evaluate ownership, scope of protection, validity/enforceability, and duration of your patents, as well as your active/inactive patent applications for their patentability and expected scope of protection
- Patent Ownership
- Patent Scope
  - Geographic scope – list all the patents/applications relating to the technology
  - Claim scope - if it is broad enough to cover the technology and/or narrow enough to stand future legal challenge
- Enforceability
- Patent Term

VORYS

6-1. Solution to Potential Exclusivity Issue

- Legal opinion
- Consider
  - i. Ex parte reexamination
  - ii. Reissue application
  - iii. Supplemental examination
  - iv. Continuation or Continuation-in-part application (for patent applications)

VORYS

7. Privilege Issues

- Consult with your patent counsel before communicating with your partner regarding the legal opinions (FTO, Invalidity or Non-infringement opinions)
- You may have motivations to disclose as much information to your partner, but you will want to avoid waiving the privilege.
- Strategy
  - Provide a list of opinions rather than a complete copy
  - Common Interest (or Joint-Defense) Agreement - Depends on jurisdiction
  - Outside counsels' eyes only

- Common Interest (or Joint-Defense) Agreement - Depends on jurisdiction

  - Common *legal* interest

  - Exchanged documents with potential investors during arms-length negotiations ? May not be protected. (*Xerox Corp. v. Google Inc.,* No. 10-136 (D. Del. Aug. 1, 2011; *King Drug Company of Florence, Inc. v. Cephalon, Inc. et al.,* No. 2:06- cv-1797 (E.D. Pa. July 5, 2011)

VORYS

Thank You

Mihsun Koh
Associate

Vorys, Sater, Saymour and Pease LLP
1901K Street, N.W., 9th Fl.
Washington, D.C.

TEL: 202-467-8820 (direct)
EMAIL: mskoh@vorys.com

VORYS