The
Life Sciences Lawyer
Issue 8
GLOBAL REACH, LOCAL KNOWLEDGE
www.lslawmag.com

EU pharmaceutical reform

Will this reform put innovation and investment at risk?

A pivotal year of change ahead with increasing administrative complexities

A bright future
Page 12

Patenting generic scissors
Page 24

Due diligence: key considerations
Page 38

CTC Legal Media

Life science due diligence transactions: key considerations to manage risks and reap rewards

Troy Groetken, Intellectual Property Attorney at McAndrews, Held & Malloy, details the importance of carrying out high-value due diligence and highlights key areas to inspect for issues.

In every due diligence involving a life science transaction, the parties (a.k.a. "buyer/licensee/collaborator/partner" and "seller/licensor/collaborator/other partner") need to identify various risks and obstacles that must be addressed. For example, both parties will want to understand key topics such as valuation modeling, valuation timing, intellectual property, the asset transfer process, representations and warranties, recent case law and governmental considerations (e.g., current TRIPS waiver concerns and possible extensions thereto), and more. The due diligence process allows both parties to review each of these topics, among others, and assess potential risks, deal makers and deal breakers, as well as potential alternative approaches that may be needed to overcome obstacles that are uncovered by the due diligence.

Troy Groetken

Résumé

Troy Groetken has more than 25 years of intellectual property (IP) legal experience and more than 25 years of technical experience in the pharmaceutical, biotechnological, and chemical fields. He is recognized in the IAM Patent 1000: The World's Leading Patent Professionals, and has been listed as one of the Best Lawyers in America since 2012. As a registered U.S. patent attorney, Groetken is known globally as a 'go-to' intellectual property attorney for Fortune 500 clients and others on complex and cutting-edge IP matters, and on strategic global patent portfolio development, implementation, and enforcement. He also advises upon and institutes multi-level, front-end and back-end diligence and licensing programs coordinated with a client-focused business modeling approach. In addition, he assists clients with advanced acquisition, divestiture, and platform-positioning transactions designed to generate institutional growth and increased business valuations.

One size due diligence does not fit all

It should be noted that every deal (acquisition, divestiture, license, joint collaboration, joint development, etc.) has its own nuances. Thus, there is no "one-size-fits-all" due diligence. Rather, each deal requires that a potential buyer and seller strategically consider the scale or extent of the due diligence needed.

There are many variables to consider when properly scaling the due diligence team and process:

- The size of the deal
- The type of deal
- The parties involved (e.g., buyer, seller, and other third parties)
- Additional partners (e.g., manufacturing, distribution, commercialization, banking entities, etc.)
- The complexity of the underlying technology involved in the transaction
- The complexity of the transaction itself
- The intellectual property involved
- The business goals of the buyer and seller
- Timing

Who is doing the "due"

Initially, for either party, the due diligence team may be an internal team tasked to assess key variables such as the technology involved, the initial value of that technology, and the key terms the parties may require for the deal to make sense for the transaction to move forward. Thus, each side's due diligence team is typically limited to key members of the C-suite and supportive business, research and development, regulatory, and legal personnel. If a term sheet

can be completed by the parties, then the due diligence team will grow to undertake the more advanced steps of the diligence process. The scaling of the diligence team (both internally and externally) is fluid. As various needs arise, additional personnel are brought into the transaction to ensure that their skill sets are utilized at the right time and place.

Go for the goal

The goal of the due diligence review is to allow each party of the transaction to become aware of any risks or challenges of the transaction. For example, in an acquisition-based transaction, the seller of the potential assets will want to consider the key pieces of information that a buyer would want to review. The seller may wish to provide the buyer with key manufacturing, biological deposit, clinical, and regulatory information regarding its life science product/asset. The seller may also wish to provide to the buyer access and review of key ownership and intellectual property information that supports and protects the potential assets to be purchased/transferred. The seller might like to provide the buyer with any prior transactional materials involving the asset(s) to be transferred so that the impact of those transactions can be considered during the diligence process and beyond. In addition, the seller may have already completed various financial modeling that impacts and/or supports its valuation position regarding the potential asset to be acquired. The seller may therefore want to provide a financial support package to the buyer so that the buyer may better understand the seller's valuation assessment. Such information also allows the buyer to compare that valuation with its own.

> **"The goal of the due diligence review is to allow each party of the transaction to become aware of any risks or challenges of the transaction."**

The illustrative steps of a hypothetical due diligence for an acquisition, presented above, demonstrate how the due diligence process supports corporate decision-making and ultimately, helps them reach their business goals. This critical review process allows each party, and its corporate teams, to truly communicate better even though they are involved in an arms-length business transaction. It ensures that each party understands and appreciates the goals the other is trying to achieve in the potential transaction, the risks (development, manufacturing, clinical, commercialization, etc.) of the technology to be transferred as an asset, the regulatory climate for that asset, the strengths or weaknesses (short- and long-term) of the intellectual property that supports/protects that asset, and finally the value of the asset (on a domestic or global basis) to be realized should the transaction be completed.

The value of uncovering issues in ownership, IP, valuation, and more

As with any due diligence, a number of issues may come up. Some examples can include confidentiality controls, proper set-up and usage of a "clean room" or "data room," party communication breakdown procedures, valuation position discrepancies or challenges, past transactional encumbrances on the asset(s) in question, agreement language disputes, intellectual property challenges, regulatory challenges, biological deposit difficulties, among many others. For purposes of brevity, a few key pitfall examples to avoid shall be discussed here.

Those key examples include ownership, intellectual property, valuation modeling, and communication breakdowns. Again, these particular topics will be viewed in connection with a hypothetical acquisition-based due diligence process.

- Ownership

A seller must consider both an internal and external ownership review of the asset to be offered for purchase. Those reviews can determine if there are any previous transactions that may impact the ownership of the asset or its sale/transfer to another. For example, if the asset to be transferred has patent coverage, have assignments from all of the inventors of that asset been completed and recorded? If not, what is the impact of that outcome? Does that outstanding inventor have an obligation to assign via an employment agreement? A seller's carefully performed due diligence – whether internally or externally – can uncover such a pitfall before a conversation with a buyer ever begins. The diligence process can also assist in potential solutions to the issue to ensure that the ownership challenge is addressed and remedied. Further, no one likes a last-minute "deal breaker" to appear that could have been assessed and addressed by the diligence process. Moreover, it should be appreciated that due diligence also allows the seller to consider future proactive steps. Having learned of an asset ownership challenge during early diligence, the seller will have the opportunity to improve assignment protocols and procedures to prevent future pitfalls.

- IP

As for the buyer, as part of its due diligence process they should always consider asking if the seller has any opinions of counsel (e.g., freedom to operate, invalidity, white space analysis, and the like) that it could share in a confidential manner that involves the asset(s) to be potentially purchased. Additionally, the buyer should consider inquiring of the seller as to any current or past assertions of infringement by a third party regarding the potential asset(s) to be purchased that can be shared and reviewed. The same holds true for any past settlement agreements that involve the asset(s). Lastly, the buyer should also consider inquiring with the seller if there are any internal communications or external opinions/assessments of counsel with respect to the patent eligibility of the asset(s) to be purchased. This is especially important to the life science space in light of the current case law climate. Those assessments by a seller may impact whether the deal goes forward, if the valuation picture should change, and the capacity for intellectual property protection

A seller must consider both an internal and external ownership review of the asset to be offered for purchase.

Contact

McAndrews, Held & Malloy
https://www.mcandrews-ip.com
Troy Groetken:
Tel: 312-775-8259
TGROETKEN@mcandrews-ip.com

(current and in the future) of the asset to be potentially acquired. Such analyses also allow the buyer to consider those positions of the seller and to have its own internal personnel and external counsel consider if any challenges presented can be overcome or mitigated, or if they change the entire dynamics of the deal envisaged.

- Valuation

What do the parties do if their valuation models differ greatly? The answer: address this contingency upfront in the parties' term sheet and ensure that term sheet is executed. Typically, the parties can set forth terms and conditions as to the types of models either can use to propose their valuation. The parties can also set forth the terms and conditions as to the "data" that will be used to generate the potentially opposing valuation models for review by each side. The parties can further set forth basic terms and conditions for when the models may have disparity.

- Document Management

Tracking extreme levels of detail is obviously critical during the due diligence process. For example, a party may provide a list of documents and other materials that it would like to review to the other party. The second party may provide some, but not all, of the documents or materials requested. A thorough due diligence will carefully catalogue what documents and materials have been reviewed, and which ones have not. This ensures that various potentially critical documents and materials don't "fall through the cracks" as the parties discuss the overall transaction. In any life science transaction, the sheer amount of data, documents, and materials to be reviewed can be voluminous. A carefully planned and set-up due diligence process allows both parties to ensure that physical or digital documents and materials can be properly accounted for, reviewed in a controlled and confidential manner (e.g., the use of a "clean room"), properly returned, and used to provide greater discussion and transparency for the contemplated transaction.

Assessing the scope and magnitude of the subject information allows the requesting party to consider various alternatives, terms, conditions, and approaches, as well as whether it chooses to continue pursuit of the deal. At a minimum, additional representations, warranties, indemnifications, and other provisions should be envisaged by the party requesting the information in order to protect that party's interests should the transaction go forward.