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The Data Room in Patent Due Diligence: Perspectives from Two Doors

Putting yourself at the threshold of the other door and considering the room from that perspective can provide useful reminders of each side's strategic opportunities and concerns, and ensure that the doors to the deal are kept open.

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No matter if you are entering the patent due diligence data room from the buyer's door or the seller's—both parties should have specific strategic objectives related to what should and should not go inside the data room, and how any such content is presented or

analyzed. Typically, sellers initially decide among varying levels of access to strategic and/or confidential documents to include, from contracts and financial statements to those reflecting chain of title and invention details. Buyers, though, should not be afraid to ask for more or to consider why certain documents may not be present. Populating and analyzing a data room during patent due diligence requires a mix of savvy strategy and common sense, all tempered and informed by the strategic business goals of both parties.

A data room is an essential fixture in every IP due diligence process. A data room is the virtual space that holds confidential and potentially privileged information that may need to be shared and/or communicated, generally by the seller to the buyer. In biotech or biopharma patent due diligence, the information can be very sensitive, such as details related to drug structure, function, formulations, clinical data, etc. What does and does not go inside can have critical implications for both sellers and buyers.

The Seller's Door

Typically, the seller gets the first opportunity to decide what to put in the data room. While there are plenty of "checklists" available online, it's best to not become overly reliant on them, as each transaction is unique from both the business and IP perspectives. In general, the data room can include employment agreements, a schedule of the relevant intellectual property, assignments, application copies, unpublished application copies (*sometimes*), contract research organization and other consultant contracts, license agreements, sponsored research agreements, etc.

One of the biggest questions the seller should address prior to this process is whether its chain of title to, and right to claim priority to, the IP are clear. Are there others—perhaps a former employee, consultant or CRO—who might claim inventorship or ownership rights? Are the invention stories and timelines around relevant assets clearly documented and/or catalogued? Have formalities such as assignments, inventorship updates, filing receipts and applicant information been vetted? The much-watched CRISPR/Cas9 intellectual property legal battle serves as a stark reminder that something as simple as timely securing one's

rights to claim priority to a priority application can be critically important in a high-stakes patent dispute. Sellers should be ever vigilant at all stages of their R&D process to ensure that these seemingly little details are buttoned up well before any data room needs to be populated.

There are additional questions the seller should ask before beginning to populate the data room:

- Should the level of content included be phased in concert with the phase of the deal negotiations?
- Who should have access on the buyer side? Should the seller limit access to third-party reviewers?
- Should the seller ask to review the information conveyed in any report to the buyer?
- Should the seller provide specific structures or sequences?
- Should the seller provide any FTO or patentability reports?
- Should the seller include unpublished applications?
- Are there confidentiality issues to consider?

Overall, data room population should be done with an eye toward answering the big questions while making sure certain seemingly small details (title, priority) are clearly addressed. It should also be built with the potential for litigation in mind. Often, disputes borne out of diligence issues have their genesis in information not shared on the claimed premise that it is confidential or privileged. Thus, the seller should ensure that withheld information meets these criteria. While the seller doesn't have to provide everything the buyer asks for, the seller should try to understand the concerns underlying any specific requests and try to provide comfort around those issues in other ways.

The Buyer's Door

Some of the most important questions the buy-side attorneys should be asking occur well before any entrance to a data room is permitted, and relate to understanding the specific scientific, clinical, strategic and intellectual property goals that the buyer is interested in achieving. Unless one understands specifically why the client is interested in a transaction, one will not be able to assess if the data room provides access to the information you need.

While the buyer should take advantage of every opportunity to ask questions and to ask for more information to be uploaded to the data room, it should also be mindful of carefully vetting who is reviewing the information and asking the questions. Typically, more limited access to the information is desirable to protect both the buyer and the seller from inadvertent contamination with confidential information of the other. Furthermore, while additional requests for more information can form the backbone of certain buyer data room strategies, repeated requests can also backfire from a deal-timing perspective, particularly if there are others bidding for the IP, and from ultimate relationship-building perspectives. Instead, the buyer should attempt to review the available information, provide a fairly complete request for any additional information, and limit any further one-off requests unless absolutely necessary.

As noted above, litigation stemming from the patent due diligence process can often be the result of confidential or privileged information being either inappropriately revealed or withheld. The buyer needs to think creatively to determine how to ask questions to get the answers needed in ways that do not violate protective orders or confidentiality agreements. There are many ways to do this: pose hypotheticals, ask around the edges of the information, and follow up on information that is confusing or seemingly withheld without explanation.

From the buy side, particularly for a later-stage clinical asset, it is critically important to understand what may ultimately be needed down the road (at drug approval, prior to and during litigation, to assess generic/biosimilar threat of entry), particularly around high-value transactions. This includes critical documents that substantiate the patent and invention story that are typically entered into evidence in every Hatch-Waxman trial: lab notebooks or other invention records, clinical trial reports, design protocols, etc.

Depending on the deal format, the buyer may not have many opportunities to ask questions, so it should be organized and prioritize key questions. Assuming time is not of the essence and there are days, or even weeks, to spend in the data room, the buyer should try to always get through everything the seller provides first. Then, the buyer should see if

any outstanding questions might be resolved through other resources, including publicly available information and patent office records.

Meeting Inside

As with most negotiations, a good practice for successful IP diligence is to understand both the buyer's and seller's perspectives and approaches to the data room. As a seller, knowing the strategic role of your IP in the bigger picture of the buyer's clinical and IP portfolio, and knowing that the buyer can—and should—ask for more help, can guide decisions regarding what to include initially and to ensure agility when requests for additional information surface.

Ultimately, putting yourself at the threshold of the other door and considering the room from that perspective can provide useful reminders of each side's strategic opportunities and concerns, and ensure that the doors to the deal are kept open.

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