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IP due diligence considerations in life sciences deals

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Life sciences companies present tremendous opportunities for venture capital investors. Investing in them, however, is highly risky due to the long product development cycle and the regulatory approval uncertainties. Robust intellectual property protection, especially patent protection, is a critical consideration for investors. IP due diligence allows investors to accurately assess the value of the underlying IP and associated risks. While some aspects of IP due diligence are the same for all deals, certain areas tend to assume particular significance in life sciences investment deals.

Patent Term Considerations

The development of new drugs typically takes many years. Despite this, innovators typically apply for patents early in the process. As a result, many patents do not have many terms left by the time the product is commercialized. Since a patent with only a few years remaining to its term is significantly less valuable than one that would allow a company to enjoy market exclusivity and delay entry of generic or biosimilar competitors for long period of time, patent term is a key consideration when evaluating a patent portfolio.

Generally, a patent expires 20 years from its earliest non-provisional filing date. The term of a patent, however, may be longer or shorter than 20 years for many reasons. For example, in many countries, medical products that require clinical trials may be entitled to patent term extension. The patent term extension, designed to compensate the portion of the term lost during the product approval process, can typically go up to five years. In the U.S., a patent may also be entitled to additional patent term due to delays caused by the U.S. Patent and Trademark Office during patent examination. On the other hand, a patent applicant may have disclaimed a portion of the patent term by filing a terminal disclaimer in order to overcome an obviousness-type double patenting rejection based on an earlier-expired patent.

Life sciences companies have also adopted various strategies to maximize the length of patent protection. For example, in addition to the initial patent filings on a technology, the company may file later generations of patent applications directed toward further refinements, improvements, formulations, dosing regimen, indications, patient subpopulations, etc. For products that are difficult to manufacture, such as biologics, companies may file new patent applications to protect the manufacturing process. Since the earlier filings frequently serve as prior art against the later filings, the scope of later-generation patents tend to be narrower. Understanding the potential value of these later-generation patents and their limitations constitute an important part of the IP due diligence.

In addition to patent protection, approved new drugs may also be entitled to regulatory exclusivity. IP evaluation should also include consideration of the interplay between patent and regulatory exclusivities.

Patentee's Own Prior Art

A valid patent must satisfy novelty, inventiveness, and other requirements. One common reason a patent may be deemed invalid involves the patentee's own prior art. Because such prior art usually discloses the same subject matter as those encompassed in the patent under evaluation, it tends to be the most damaging. Although the U.S. patent law provides a one-year grace period for patent applicant's own prior disclosure, many foreign jurisdictions do not allow grace period. Publications before the patent filing date thus constitute full prior art in those countries.

A patentee's own prior art may be created due to poor IP management. For example, a scientist may give a talk at a conference or submit a meeting abstract for publication and end up disclosing the invention prematurely. The prior art may also be presented as a Ph.D. thesis archived in a library, a grant application that becomes published, or a clinical trial protocol submitted to a public database.

Prior art issues may arise even if a patent application has been filed prior to the public disclosure. For example, under time constraint, a company may file a provisional application containing minimal disclosure. Believing the invention is protected, the inventor then publishes the underlying data in full. If the provisional application was not drafted properly, it may be insufficient to support a patent claim in a later filed patent application. Consequently, the later application may not enjoy the priority benefit of the provisional application, and data published before the later filing becomes prior art against the later application. Prior art issues may also arise from patentee's own patent filings. A company may file a first generation patent application on a new drug and its potential use in treating diseases. Years later, the company obtains

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data on a lead indication and files a second generation patent application on using the same drug to treat the lead indication. If the lead indication has already been mentioned in the first application, the first application may become prior art against the second application. Furthermore, if the scope of the claims in the first application overlaps with the second application, the first application may further serve as the basis of an obviousness-type double patenting rejection. Although companies can overcome this type of rejection by filing a terminal disclaimer, this would undercut the patent term of the second application.

In conducting life sciences IP due diligence, it is important to analyze potential impact of the different types of patentee's own prior art and recommend preemptive actions to strengthen the patent portfolio.

The "Traps" of Collaborations

Life sciences discoveries are complex and frequently require multiple parties with different resources or areas of expertise to work together. The target company may collaborate with another party to co-develop a product or provide proprietary materials to another party for conducting the research. The target company may also engage a research institution to carry out research. Or the target company's research may be sponsored by another entity. Under all these circumstances, the possibility of another party owning or co-owning an IP right should be vetted.

Under U.S. law, patent co-owners own an equal and undivided interest in the patent. Unless there is an agreement otherwise, the patent co-owner may grant license to third parties without permission of the other co-owners or an obligation to share any resultant monetary gain. In addition, all patent co-owners must join as plaintiffs to bring a lawsuit against a potential infringer. By refusing to participate in an infringement action or by sanctioning the allegedly infringing activity, a co-owner could prevent the other co-owners from enforcing the patent. Notably, the question of patent co-ownership frequently turns on the determination of inventorship. Whether someone qualifies as an inventor is an extremely fact-intensive inquiry which may be challenging to sort out in the collaboration context.

A further issue can arise when the collaboration is funded by the U.S. government. Under the Bayh-Dole Act, the government enjoys a nonexclusive license to the invention for use by or on behalf of the United States. The funded entity retains right to the invention but must comply with certain reporting and filing requirements. Failure to comply with these requirements can permit the government to assert title to the invention.

Collaborations involving parties from different countries create further issues. Many countries require that, for an invention substantially made in a certain country, the patent application must be first filed in that country unless a foreign filing license is obtained prior to the filing. If the invention was created by inventors in two different countries, then the requirement in each country must be complied. Failure to take steps to address the issue frontally can lead to inadvertent loss of patent rights.

Thus, collaborations deserve heightened scrutiny and require not only careful review of the material agreements but also asking critical questions and following up diligently.

Freedom-to- Operate Risks

Freedom-to-operate analyses typically involve searching for third-party patents and examining them to determine if such patents would block the target company from bringing its product to the market. Careful freedom-to-operate analyses are critical for IP risk assessment.

A complete freedom-to-operate search can be expensive. Because many aspects of the product may be potentially blocked by a third-party patent, a thorough freedom-to-operate analysis would require searches for patents that are potentially relevant to any of these aspects. Most of the time, however, it is impractical to conduct such extensive freedom- to-operate analyses, especially in the context of venture capital investment. In these cases, it would be extremely valuable if the counsel conducting the analysis already has a good grasp of the technology and the competitive landscape. This would allow the counsel to design focused searches and identify the most potentially problematic patents effectively.

Once a potentially relevant patent is identified, it is equally important to assess the practical risks presented by such patent. In the U.S. as well as some other countries, activities conducted for the purpose of obtaining regulatory approval would not constitute patent infringement. A patent that expires before the projected product launch date would thus be less relevant. Also, although some patent claims may appear broad at first glance, the patent specification may have narrowly defined the claim terms. Similarly, arguments may have been presented during patent examination that would limit the meaning of the claims. Careful review of the patent and its file history would be helpful to understand the scope of the claims and accurately assess the risks presented by such patent.

If a blocking patent is discovered during early stages of product development, one can design around the patent. The target company may also consider acquiring or licensing the blocking patent, or invalidating the patent prior to product launch. Well-conducted freedom-to-operate analyses would not only allow the investor to assess the risks, but also add value by recommending actions in minimizing the risks.

Conclusion

IP due diligence in the life sciences presents unique issues that need be carefully examined and effectively addressed. A firm understanding of the technology and competitive landscape is tremendously valuable. Accurate risk assessment and creative strategies in minimizing the risks can either help prevent a bad deal or add the value investors can bring to the transactions.

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