Buyer beware: an IP checklist for life sciences investors

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Whether caused by the paucity of new products in pharma pipelines or the lure of a highly marketable new technology, investors often become comfortable with a deal before effectively evaluating the target's intellectual property portfolio. IP issues that are overlooked often decrease the value of the investment and open the door for future debilitating litigation. The range of due diligence failures by pharma and biotech investors and companies that have come to light in US courtrooms in recent years should serve as a caution to every investor in life sciences to do more than just scratch the surface in IP due diligence. How would you answer to your stakeholders if you spent a billion dollars acquiring a biotech company only to discover that its patents were based on a theft of trade secrets or that the technology was really invented by others to whom the court has now awarded the patent? And what value is there in spending millions in developing a product in a licensed technology where the licensor's patent turns out to be unenforceable against your competitors? Whether you seek to acquire a target company or merely to license a specific technology or invest in a royalty stream, the validity and enforceability of the target's IP is critical to protecting your investment. Asking the following 10 questions and performing diligence tailored to the specific goals of the deal can make an effective IP due diligence possible on a budget commensurate with the size and strategic importance of your investment:

1. What is the goal of the deal?
2. Is the core technology covered by IP?
3. Was the IP adequately protected?
4. Does the target company own the IP?
5. If patents, are they valid and enforceable?
6. What is the effect of recent case law and legislative reforms?
7. Is there freedom to operate?
8. What competing technology is there?
9. Are there potential liabilities or risks of litigation?
10. What regulatory issues bear on the deal?

A clear understanding of the answers to these questions will inform a more accurate appreciation of the value, and risk, of the deal. While uncovering serious problems with the IP key to protecting the core technology may kill the deal, less serious issues can often be worked around and can be parlayed into a higher equity stake or a re-evaluation of the cost of the transaction.

1. What is the goal of the deal?

Be clear on what you hope to gain from the deal. The scope, depth and budget of IP due diligence depend on the structure and business goals of the deal. Diligence requirements will be different for internal IP audits, IP auctions, venture-based financing, strict licensing deals, strategic alliances, spin-outs and mergers and acquisitions. The scope of the due diligence will be determined by the magnitude of the business transaction; a merger or acquisition will require much more diligence than a licensing transaction. The more valuable the IP, the greater the diligence it merits. Getting started should include setting a budget and determining the scope of the diligence. Getting the target's in-house counsel involved early in the deal can make the diligence more efficient and more cost effective.

2. Is the core technology covered by IP?

Investors back companies where the technology has commercial potential and need to know that the market can be protected from competition. A life sciences company's IP portfolio may include patents, trademarks or service marks, trade secrets and copyrights. But it is the patents that are

the real "currency" of life sciences companies and they are often the company's only asset. Generally, issued patents are more important to consider than patent applications in the diligence process. An issued patent is an identifiable right that you can use to assess the target's market exclusivity, while patent applications are rights the target hopes to develop; but where the target is at an early stage and has no issued patents, then the applications are worth examining. Ask the target to identify the patents which cover the core technology. If the target cannot do that, it is an indication that the target's patent strategy may not be in line with its marketing strategy. Any identified patents (or trade secrets) should be examined against the core technology to evaluate whether the technology is protected. There may be ways to improve coverage if it is less than optimal or it may be a level of risk that needs to be figured into the deal evaluation.

3. Was the IP adequately protected?

Many interesting technologies are left on the laboratory shelf because appropriate steps were not taken to secure valid IP protection. Biotech and other start-up life sciences companies are usually short of funds and, as a result, securing good IP protection often falls through the cracks. In addition, scientists notoriously like to communicate with their peers and many patents have been invalidated by the presentation of an abstract about the invention more than a year prior to the filing for patent protection. So a prior art search for the inventors is always a worthwhile diligence exercise. Other areas that must be scrutinised are collaborations with third parties and business transactions or proposed business transactions where information about the technology may have been disclosed. These agreements should be evaluated to determine whether the target took appropriate measures to retain and protect its IP. If the IP is a trade secret, you must ask whether the target did everything necessary to maintain its confidentiality in all transactions.

4. Does the target company own the IP?

Determine ownership of the IP in addition to the scope or latitude and status of those IP rights. This is the single most overlooked aspect of diligence in life science deals and has resulted in the most debilitating litigation of all the issues discussed in this article. Lovells has litigated many of these kinds of fact-intensive disputes, on both sides, and our experience has shown that some relatively simple and inexpensive inquiries at the time of entering the deal would have alleviated most situations.

Patents owned by the target should be properly assigned to the company and the assignment properly recorded. The target should be able to convey clear title. Without the exclusive rights to it, the patent cannot be asserted. In the United States, title to a patent initially rests with the inventors. If not all of the inventors have assigned their rights to the company, any outstanding inventors own an equal and undivided interest in the patent with the company. Recently, the failure to secure assignments from each of the inventors resulted in the dismissal of a significant infringement suit against a Fortune 100 company. So it is important to evaluate whether the target has clear title and/or an exclusive licence to the IP.

Resolve any uncertainties about inventorship. Ask the target for evidence of its independent development of the invention (including lab books) and scrutinise the potential rights of any collaborators. Search the inventors' publications that possibly relate to the invention and ask about the contribution of any co-authors not listed as inventors on the patent. Establish whether any of the IP rights have been transferred, or whether any third party may have a claim to ownership based on inventorship claims or contract rights. Review all material agreements. Ask the target to identify relevant licence agreements, material transfer agreements, collaboration agreements and research agreements, and then, if necessary, do follow-up research into those arrangements if something seems to merit additional diligence. Establish whether maintenance fees have been paid.

5. If patents, are they valid and enforceable?

In the US, the patent validity analysis should include analysis for the requirements of 35 USC Sections 101, 102, 103 and 112 including enablement, best mode, written description, anticipation and obviousness. Prior art searches can be obtained using a specialised vendor and the results analysed by your patent adviser. The strength of the target's patents should be analysed in light of the most recent case law such as the Supreme Court's decision in *KSR International Co v Teleflex, Inc*, which lowered the standard for accused infringers to prove the obviousness of an invention. Important lifecycle and gene patents which may be more vulnerable to an obviousness challenge under *KSR* (and its progeny) should be closely analysed. Most

importantly, do not take the patents at face value; if possible, review the underlying lab books and patent filing files to assess independent development, enablement, best mode and potential claims of inequitable conduct. If the due diligence finds vulnerability to claims of invalidity or infringement that could curtail the company's ability to maintain exclusivity of its products, it need not necessarily kill the deal since the purchase price may be adjusted. Enforceability of the patents should be evaluated in light of any evidence of inequitable conduct in obtaining the grant of the patents, such as failure to submit known prior art or bad results to the examiner or the submission of a false statement upon which the examiner relied in issuing the patent. Inequitable conduct can be hard to unearth and this may be an area where the risk can be covered by representations and warranties from the target.

6. What is the effect of recent case law and legislative reforms?

Investors need to be informed about developments in the law that affect the biomedical industries and that may impact on the value of their investments. Recent developments in US patent law aimed at protecting high-tech industries from the abuses of patent trolls threaten to have, inadvertently, a detrimental impact on the biomedical industries. This is reflective of the differences between the two industry sectors: high-tech tends to have a short innovative cycle and companies have thousands of patents on small inventions, whereas in the biomedical sector it is the reverse. Research and development and obtaining regulatory approval take a long time, inventions are few and the resulting products must have a long lifecycle and strong patents to allow the investment to be recouped. In the last two years, the US Supreme Court has reduced the availability of permanent injunctions, made it easier for a patent licensee to challenge the validity of the patent being licensed and lowered the standard for obviousness, making it harder for applicants to obtain a patent in the USPTO and easier for defendants to invalidate a patent in litigation.

Also, the proposed Patent Reform Act of 2007 includes provisions tailored to meet the needs of the software, IT, high-tech and financial services industries, that threaten to harm life sciences investment and innovation. In addition, the PTO's proposed rule changes regarding the limitation of continuation claims would have a disproportionately negative effect on the life sciences industries. However, the implementation of those proposed rules was preliminarily enjoined by the district court in the Eastern District of Virginia at the behest of numerous life sciences companies, and whether they go into effect will have to await a trial unlikely to occur before the end of 2009.

7. Is there freedom to operate?

Determine the target's freedom to operate. Typically, it is not necessary to start the freedom to operate analysis from scratch; instead, you can usually piggyback on the target's own analyses relating to infringement, validity, right to use and/or clearance searches on patents. If the target's searching is of reasonable scope and relatively recent, the target can share relevant results and identify third-party patent issues. Additionally, ask whether the target has obtained any third-party opinions of counsel, but do not require the target to share them. Doing so may waive attorney-client privilege. Instead, obtain the serial numbers of the relevant patents and analyse them independently.

8. What competing technology is there?

Ask the target to identify its competitors. Identify whether there are alternative technologies or treatments available to achieve the same end result. Obviously, a pioneering technology which fills a long-felt need will be a more attractive investment than one in an already crowded field populated with multiple players and a myriad of patents. Risk varies depending on when the investment is made in a pioneering technology. The risk is higher long before the technology has gained Food and Drug Administration (FDA) approval, but so is the payoff for a successful early investment. A savvy investor should try to keep abreast of products in the pipelines of other companies to avoid investing in a technology that will be rendered obsolete when the other product is introduced to the market.

9. Are there potential liabilities or risks of litigation?

Ask the target to identify any threatened, pending or settled litigation. This inquiry should also identify situations where a third-party patent licence was obtained or sought, and situations where a covenant not to sue was executed or negotiated. Understand third-party contact with the target. Determine whether the target has received any cease and desist letters, informational letters or offers to license. Such communications highlight possible freedom to operate issues and potential for

future litigation. In any given business transaction the seller will seek to achieve the highest price for its business, and as a result has an incentive to polish (if not cover up) any blemishes that would reduce the value of the business or preclude the transaction from occurring. It is the responsibility of the buyer to uncover these blemishes and to determine how that affects the deal.

10. What regulatory issues bear on the deal?

Likelihood of FDA approval and market exclusivity are obvious areas of concern in the life sciences diligence process. Many life sciences products require some sort of FDA approval and, depending on how close the target's product is to approval, the investment may be a higher or lower risk. If the target technology is in the pharmaceutical area, then the market exclusivity depends on when the New Drug Application (NDA) for the drug was approved and the remaining term of any patents listed for that drug in the FDA's Orange Book. Under the Hatch-Waxman statutory scheme, generic manufacturers can begin to seek regulatory approval for a generic version of a drug one year before FDA-granted exclusivity expires. However, if there are patents listed in the Orange Book for that drug, the generic applicant must certify that its product, if approved, would not infringe those patents or that the patents are invalid. Upon receipt of this notice from the generic applicant, the NDA holder has 45 days in which it may bring an infringement suit against the generic company for an injunction to prevent the FDA from granting approval to allow the generic version to come to market. Upon the filing of that suit, FDA approval of the generic product is automatically stayed for 30 months or until the patents are shown to be not infringed or invalid. The value of a blockbuster drug drops off exponentially once generic competition enters the market, so understanding the useful lifecycle of the product is key to evaluating an investment in the pharmaceutical arena. The target's analysis of the expiration date of the listed patents should be confirmed and term extensions and adjustments should be re-evaluated to ensure the correct patent term.

Conclusion

No two deals are the same, but by walking through these 10 steps during the IP due diligence with your adviser you can streamline the process and gain salient information that can be used to tailor the deal documents and shift risk to the target on issues uncovered during diligence that are not deal breakers. This approach should provide you the comfort you need at a cost you can accept.

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