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Due diligence for a successful acquisition
Reed Smith LLP

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Due diligence for a successful acquisition

By **Toni-Junell Herbert** and **Mark R Shanks**,
Reed Smith LLP, Falls Church

Today's pharmaceutical and life sciences companies are more focused on investment and collaboration than ever before. Their environment and peers are now truly global rather than national; this has created a situation where acquisitions and mergers are taking place under shortened time constraints and with intense pressure from competitors.

This demand for externally developed technology has created significant competition among the larger companies to identify and acquire the best technologies. As competition has increased, so has the need for quick decisive action, lest opportunities be lost to the competition. Despite this, care needs to be taken. Investing hundreds of millions of dollars in a new technology or billions in an acquisition is not something that can be taken lightly. Not only does such a decision have a significant impact on the future performance of the company, but in the post-Sarbanes-Oxley world management has greater accountability than ever. As a result, the due diligence analysis is key. Not only does it minimise risks associated with financial reporting and compliance with SFAS and Sarbanes-Oxley, but it helps management make informed, value-based decisions prior to any acquisition and assists in the valuation reporting to stakeholders after the transaction or prior to the final decision-making.

One strategic mishap and management can turn from hero to goat virtually overnight. A wrong step or acquisition of a product line covered by a third party's patent and you can find your company embroiled in a costly legal battle, the outcome of which can strip all value from the deal. In real terms, the worst-case scenario is your company could end up facing an injunction that prohibits it from commercialising the technology it based the valuation on, and a damage award

of up to three times the financial loss suffered by the competitor. Few will contest that the consequences of such an outcome can be catastrophic, as the recent settlement of Research In Motion, maker of the popular BlackBerry handheld device, illustrates. Faced with a potential injunction and customers delaying orders, the company settled for US\$612.5 million.

Similarly, if the intellectual property protection turns out to be less than was thought, it may prove no deterrent to competition. While the unplanned loss of revenues to one's competitors is bad enough, the ramifications of such an outcome can go far beyond the actual operating revenues of the company, as the news of such a debacle can have a profound impact on investor confidence. Just ask Eli Lilly, which in mid-2001 saw its market capitalisation cut by one-third in a single day after key patents for its Prozac product were held to be invalid. Although the value of IP varies from industry to industry, perhaps nowhere is it more valuable than in the pharmaceutical sector, where entry of generic competition typically results in a 60% to 80% erosion of revenues within a few weeks to months.

Picking a winner

With all of this pressure to be first in line to ink a deal before a competitor steals the opportunity, how does one pick a winner – technology that will add significant value to the company and be free of costly surprises? And what is a reasonable price to pay for it? Difficult questions, no doubt, but as the successful know well, determining whether the deal is right is not a matter of reading tea leaves, crystal balls or a game of chance. Rather, success in the technology acquisition arena is more a matter of hard work than luck, and requires a thorough investigation and objective analysis of the technology being acquired.

In the legal jargon of director and officer responsibilities, it requires the exercise of “due diligence.” However, to be useful, this analysis must go well beyond an examination of the salient features and potential demand for the proposed product(s); it must go to the very foundation of the profitability of the undertaking, the ability to market the product and avoid or limit competition.

Irrespective of the merits and advantages of the technology, it has little commercial value if competitors can block it from reaching the market or if competitors can copy its attributes into their own products. However, unlike the features of the products which can typically be analysed, tested and evaluated prior to signing the deal, the strength of the IP protection and the extent of marketing clearance will generally not be tested until long after the deal is done. While only time will tell whether the deal lives up to expectations, the more diligent the investigation, the more likely it is that the pre-deal expectations will be borne out as the future unfolds.

Knowing the field

Knowledge of the playing field, and the intellectual property rights staked out by each of the likely competitors, is of fundamental importance in such an investigation. To avoid costly legal battles and potentially adverse rulings that enjoin commercialisation and/or require the payment of money damages, one must carefully evaluate the freedom to market the proposed products in the desired territories that will exist after the deal is done. This involves not only knowing what competitors are doing presently, including what they have protected with issued patents or are trying to protect with pending patent applications, but also predicting where they are likely to go in the future and whether they are ahead or behind in the race to get there.

If the road ahead is already mined with competitor’s patents that appear to cover the technology under consideration, and after thorough analysis these patents appear to be valid, then the opportunity may be no bargain at any price. On the other hand, if the problem patents are of questionable validity or would have to be stretched to cover the new technology, then these contingencies may leave sufficient value in the deal to proceed at the right price.

Additionally, even if the road ahead appears clear, unknown dangers may nonetheless exist because patent applications are not published in the US until

18 months after filing. Accordingly, investigation into the directions the competitors are moving and the discoveries they have made, and anticipation of what they may have already covered in pending but unpublished patent applications, are necessary to complete the picture.

Even if the path to the market is unencumbered by third-party rights, the ability to protect your business from competition will also be of paramount importance in deriving value from the acquisition. Thus, an introspective view of the intellectual property protecting the technology of interest is also necessary.

Licence agreements

It is routine for due diligence teams to review licence agreements within the target’s portfolio. A thorough assessment will involve customisation of the review to the particular technology and industry. Although some of the licences in the review may relate to deals that are worldwide in scope, more often they are territorially limited, with the licensee acquiring rights in certain countries of interest and the licensor retaining the rights to exploit the technology elsewhere. While such a licence can prove to be quite valuable to the deal, depending on the countries of interest, the return on the investment may be subjected to price erosion from parallel imports. Therefore, a thorough due diligence review involves a determination of whether licences key to the valuation may be subject to price erosion from parallel imports. A detailed review of such licences can then focus on whether financial accommodations have been built into the agreement to maintain profitability.

Once again, depending on the particular industry, the review of licences and agreements is key. For example, if the target has government contracts, as many start-ups do, these contracts should also be reviewed in depth. Key provisions such as the Statement of Work definitions are extremely important and need to be compared to the technology and/or products involved in the valuation. Further, the company may have contracts with the government that result in automatic ownership by the government in the invention, such as contracts performed outside the US, NASA or DOE (Department of Energy). In its government contracts, has the target complied with required monitoring under the standard FAR/Bayh-Dole provision – ie, has it filed the annual and final report on the status of invention? While savvy start-

ups may have asked to have such provisions waived by the government, this is rarely the case. This is not a minor point because if they have not followed these basic requirements, the invention may ultimately be deemed to have reverted to the government and be lost by the company.

All IP rights

As discussed, the assessment can take many forms, but the threshold enquiry is the same: how difficult will it be for your competitors to market a product that copies the main features and advantages of the technology? This obviously not only implicates patents – trade secrets, trademarks and copyrights can also offer significant protection.

This analysis requires an objective assessment of the strength of the patent estate protecting the technology, including the validity and enforceability of any issued patents, the likelihood of pending patent applications issuing with valid and enforceable claims and the scope of coverage of such patents. Here, too, knowledge of where competitors are today and where they are going in the future can be very important in assessing the capacity of your patent estate to prevent or limit competition.

Accordingly, the basic core of any intellectual property due diligence investigation involves assessing the following:

- The freedom to operate for product lines of interest.
- The patent portfolio protecting the technology of interest to determine strength and scope of coverage.
- Whether the IP covers any of your competitors' products.
- Any transactions in which the company is involved that may affect its IP valuation.
- The likely outcome of any pending infringement claims or IP disputes for or against the company.
- Any other information that may affect the value or risk associated with the IP – ie, employment agreements, confidentiality agreements, ownership and title documents, etc.

Analysis of these basic factors is necessary in virtually any merger or acquisition to arrive at a proper valuation of the opportunity. It allows management to evaluate the level of market exclusivity it may enjoy in the future, as well as any potential liability it may face for infringement of patents or IP rights of others.

While the objectives of the analysis are easy to identify, conducting the investigation is by no means a simple task. Are there patents out there that will block commercialisation? Are there competing products in existence or development that will not be covered by your patent estate? Will your patents withstand a validity challenge?

The answers to these questions rarely present an all-or-nothing picture in favour of or against a particular acquisition or investment. Rather, the vast majority of due diligence enquiries lie on a continuum in a grey area where there is no definitive yes or no answer, but rather the exercise of well-informed judgement. Judgement that requires looking beneath the surface to assess the strengths and weaknesses of the positions the company may find itself in and objectively evaluating the likelihood of prevailing.

While this can be a demanding undertaking in any context, it is particularly difficult in the pharmaceutical and biotech venues, where the intellectual property and regulatory regimes intersect to create additional complexity. Although the basic questions remain the same, there are far more variables that must be considered in assessing the utility of the patents in limiting competition.

Duration of exclusivity

Assessing marketing exclusivity involves determining how long that exclusivity can be maintained through either patents or regulatory exclusivities. This involves looking at the status of product development and regulatory approval and what patent protection exists or will exist at the point of regulatory approval. Depending upon the nature of the product approval (new chemical entity versus new clinical indication), there will automatically be a period of regulatory exclusivity awarded. The value of the patents is then how far they extend beyond that period of time. In this regard, the expiration of the patents is not as straightforward as it might appear; there can be patent term extension due to PTO delay, patent term extension due to FDA approval delay, as well as patent extension via paediatric exclusivity.

The analysis then progresses to assessing the availability of patent term extensions due to either PTO or FDA delay. Whether patent term extension has already been applied for and granted or not, it should be included in the inquiry. In addition, when considering the timeframe for the extension, consideration should also be given to a review of the FDA log or patent

prosecution to determine whether there has been diligence to ensure that the time period granted or requested is supported and is not overreaching. Any overreaching or mischaracterisation of the delay and diligence could result in the unenforceability of the patent.

Generic competition

With successful pharmaceutical products, generic competition is inevitable and, due to its devastating impact on profitability, must be considered. Thus, the question is not if, but when and how the generic will try to enter the market. This is primarily an issue as to the strength of the patents. If the patents are strong, the generics may have no choice but to wait until the end of their term. On the other hand, if the patents appear weak, generics may well seek approval to market prior to patent expiration asserting that the patents are invalid, unenforceable or not infringed by the generic product. Such assertions provide jurisdiction for bringing an immediate patent infringement suit; and if suit is brought within 45 days, the FDA will be enjoined from approving the generic for 30 months. However, the decision to sue must be made quickly and is not without risks of its own. With state attorneys general and other third-party payers poised to levy antitrust allegations whenever such patent actions are unsuccessful, a negative result can cost far more than facing generic competition earlier than expected.

If the product is a biologic approved by the BLA under the Public Health Service Act (rather than NDA under Food, Drug and Cosmetic Act), it is not eligible for any Hatch-Waxman market exclusivity that would otherwise be available for chemical entities or small-molecule drugs (ie, five-year new chemical entity; three-year new indication). However, if the product of interest is a biologic approved by the BLA, it is not currently subject to generic competition via either ANDA or the so-called hybrid abbreviated NDA/ANDA commonly referred to as a 505(b)(2) application.

There is the caveat that Congress and the FDA are presently considering whether to implement some sort of abbreviated approval pathway for generic biologics. Although the timing, scope and specific parameters of such a pathway are as yet unknown, it is likely that such a pathway would be based on some sort of spectrum, from simple biologics on one end (abbreviated) to more complex on the other

end (either not subject to abbreviated at all or still requiring extensive original clinical safety and efficacy data).

An invaluable aid to decision making

As with most business endeavours, there is no guarantee of future success. Unexpected events can always lead even the best-laid plans astray. Although the results of these analyses do not usually result in a black-and-white picture in favour or against a particular acquisition, they should provide a fairly clear picture of the risks involved and allow the development of a risk-weighted valuation. In this regard, they are invaluable in making an informed decision. And should the future include litigation, and less than favourable results occur, a diligent effort by competent counsel should go far in protecting directors and officers.



Reed Smith LLP

3110 Fairview Park Drive, Suite 1400,
Falls Church, VA, 22042, USA

Tel: +1 703 641 4200

Fax: +1 703 641 4340

www.reedsmith.com

Toni-Junell Herbert

Partner

therbert@reedsmith.com

Toni-Junell Herbert was a founding partner of Shanks & Herbert, an intellectual property firm which joined Reed Smith in January 2004. Her practice and expertise span the full spectrum of IP and she represents companies in all phases of their intellectual property development. This work includes litigation, patent prosecution and licensing/tech transfer, as well as other corporate issues relating to product development. Ms Herbert also assists clients in determining which legal services are appropriate to advance their business objectives; this work has involved valuation and auditing of IP portfolios and providing due diligence counsel to numerous corporations, investment banking entities and venture capital groups.



Reed Smith LLP

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Mark R Shanks

Partner

mshanks@reedsmith.com

Mark was a founding partner of Shanks & Herbert, an intellectual property firm which joined Reed Smith in January 2004. His experience and expertise reside in the representation of parties in intellectual property litigation, including, most recently, the representation of branded pharmaceutical manufacturers in patent infringement actions brought under the Hatch-Waxman Act against makers of generic drugs. He also has extensive experience in patent prosecution; the evaluation of patents in the chemical, pharmaceutical and mechanical arts with respect to enforcement or marketing clearance; and the analysis of patent portfolios accompanying the purchase or license of intellectual property assets.

Reed Smith LLP

3110 Fairview Park Drive, Suite 1400,
Falls Church, VA, 22042, USA

Tel: +1 703 641 4200

Fax: +1 703 641 4340

www.reedsmith.com