Know your target

Edward C Britton and John A Hurvitz of **Covington & Burling** outline the most important factors to consider when making a successful acquisition or partnering agreement in the biotech sector

The biotech industry depends heavily on inter-company transactions. In some instances these take the form of traditional acquisitions, but more frequently various types of partnering transactions take place. In either situation, a successful transaction requires that the acquirer be sensitive to the special characteristics of the biotech company.

Biotech companies differ from those in other industries in several ways. Many have no customer base. Instead, their business consists of collaborations through which they acquire technology and conduct research and development. A biotech company may have few tangible assets – its value usually resides in its intellectual property, scientific and regulatory data, collaborations and employees. Finally, biotech companies do not have free access to the marketplace – they can reach the market only through the testing and review procedures that apply to drugs and biologics.

The need for a multi-disciplinary approach

These unique attributes require an acquirer to utilise a multi-disciplinary approach if it is to properly prosecute an inter-company transaction. The typical biotech transaction will require the availability of corporate, commercial, regulatory and intellectual property legal expertise in order to investigate the target and to structure and negotiate the transaction. For a successful outcome, it is crucial that both the intellectual property and regulatory lawyers who perform the legal review of the target understand the commercial and business goals of the proposed transaction, and that the business lawyers negotiating the transaction clearly understand the intellectual property and regulatory issues.

Intellectual property

The principal value of a biotech company in almost all cases resides in its intellectual property. Proper examination and analysis of the target's intellectual property is therefore crucial to a successful acquisition.

In many instances, acquirers mistakenly focus only on the target's patents. Typically, however, patents constitute only a portion of the intellectual property required to realise the value of the target's technology. A patent provides the acquirer with the right to exclude others from making, using, selling, offering for sale or importing the target's products, but does not necessarily enable it to perform those activities itself. Manufacture of biotech products typically requires information on the production processes and other expertise.

If an acquirer focuses only on patents, it can miss either key rights that it needs to commercialise the target's technology, or problems with non-patent intellectual property that may impede commercialisation of the target's technology. To avoid these problems, an acquirer should review the know-how on which exploitation of the target's technology is dependent. An acquirer should ensure that the target's operating procedures and other know-how are properly documented, and that those techniques and procedures are reproducible. To the extent that the target's business relies on the expertise of particular scientists, this should be documented and other employees of the target should be trained to perform crucial activities in case the scientists depart. The acquirer should verify that there are appropriate confidentiality agreements with all relevant employees and other persons who may have received access to the target's technology, and that all those involved in the development of that technology have signed appropriate assignment agreements.

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Access to data

An acquirer must ensure that the transactional documentation will provide

it with adequate rights to the target's scientific and regulatory data so it can proceed with development of the target's technology and with regulatory applications for resulting products. At a minimum, the acquirer will need access to such data, and the right to reference it in applications for regulatory approval. Ideally, the acquirer will want to gain exclusive ownership of the target's data.

Licenses-in

Licenses-in often constitute a crucial part of the target's intellectual property estate. Many acquirers, however, focus only on the scope of licenses-in (ie whether they are exclusive/non-exclusive, the field of use and the territory) and fail to examine their business terms. They thereby miss issues that can dramatically affect the prospects for successful commercialisation of the target's technology and the financial viability of the acquired business.

Biotech companies are frequently parties to licenses-in that contain commercially unreasonable provisions. Such licenses-in reflect the quite reasonable focus of a pre-commercial biotech company on acquiring rights to needed technology, with little concern wasted on issues relevant only to what is the then far-off goal of commercialisation. For the commercially focused acquirer of a biotech company, however, such agreements can present serious problems.

The acquirer should carefully review the target's licence portfolio to determine which licenses-in, if any, will be relevant to post-closing operations, including not only the target's ongoing business but also the acquirer's existing business. Relevant licenses-in should be reviewed for terms that are unreasonable or incompatible with the acquirer's plans and forecasts. The acquirer should look for licenses-in that impose excessive royalty rates, do not provide royalty offsets upon the issuance of a blocking patent, or impose potentially undesirable constraints on the acquirer's post-closing operations.

The acquirer should also look out for situations where a number of independently negotiated license-in agreements apply to a single product and, without provision for offset or reduction, impose multiple royalty obligations (so-called 'royalty stacking'). Other provisions that require careful scrutiny, and possibly renegotiation, include milestone payments due to the licensor (amounts, timing, adequacy of acquirer's financial resources for scheduled payments) and performance obligations on the licensee (satisfaction of obligations to date, ability to meet post-closing obligations, penalties and their implications).

Those provisions of license-in agreements that deal with patent prosecution and infringement matters can also be important. Such provisions determine which of the licensor or licensee controls proceedings, bears the costs of litigation and damages, and enjoys the fruits of successful litigation.

Attention should also be given to sublicensing and assignment provisions. Acquirers should consider whether any restrictions they contain are consistent with their post-closing plans. They should also examine how payments arising out of sublicences are allocated between the licensor and the licensee.

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Collaboration agreements and licenses-out

Acquirers should review the target's collaboration agreements and any licences it has granted. Even if these agreements are not to be assumed to (or do not) directly involve the technology to be acquired, they may present problems for the acquirer. Among relevant issues are:

- whether technology related to that in which the acquirer is interested has been disclosed to others;
- whether third parties are entitled to rights to the acquired technology by way of grant or joint development; and
- whether the target is subject to non-competition or similar agreements that could adversely affect the ability of the acquirer to exploit the acquired technology.

Difficult issues may arise if the target has licensed technology to a third party for some indications, but has retained the right to use the same technology for other indications. Under many national regulatory regimes, including that of the United States, physicians are free to prescribe approved products for the treatment of diseases that are not included on the approved product labelling. The potential for 'off-label' use can present significant commercial problems if a compound can be used to treat multiple diseases of differing commercial and pricing potential. The party holding the right to market products containing the compound for use against a disease with higher commercial potential may find its market siphoned away by 'off-label' use of a product which contains the same compound but which is labelled for treatment of a disease with a more restricted commercial and pricing potential.

Conversely, if the target has already entered into a collaboration in respect of a compound for an indication with greater commercial potential than those which the acquirer intends to exploit, the acquirer should check the collaboration agreement

for 'cross-over protections' or other provisions designed to protect the profits of the collaboration partner. Depending on the facts, such 'cross-over protections' can make it commercially impracticable to commercialise the subject compound for indications with more restricted commercial and pricing potential.

Regulatory issues

An acquirer must pay careful attention to the target's compliance with industry standards and regulatory requirements. It must confirm that the target's development activities, including its operating, data collection, manufacturing and record-keeping procedures, meet applicable requirements. The value of a biotech business can be significantly compromised if the acquirer must repeat or perform additional studies or other activities because the target's previous efforts failed to meet the relevant standards. As a part of this inquiry, it is important for the acquirer to gain a full understanding of the target's dealings with regulatory authorities. The acquirer should confirm that neither the target nor any of its key employees has been disbarred by any regulatory agency, or cited for any failure to comply with regulatory requirements.

In addition to the rules relating to drugs and biologics, biotech companies are likely to be subject to other regulatory requirements, such as those covering the use of nuclear materials, environmental matters and employee health and safety. The acquirer should ensure that the target has obtained appropriate permits to conduct these aspects of its business and that any such permits will be available to the acquirer.

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Supply arrangements

Many biotech companies rely on others to supply key materials or, conversely, have themselves agreed to supply collaboration partners with products that incorporate the company's technology. Such arrangements can be a significant commercial stumbling block and, as a result, require examination in the context of an acquisition. The problem may be as simple as a supply chain that is inadequate to support the acquirer's commercialisation plans. More serious difficulties may arise if the target has committed to supply product to a collaboration partner. The target may in turn have entered into agreements with suppliers for raw materials or bulk active or finished product. The acquirer should verify that the terms of the target's arrangements with its suppliers mesh seamlessly with its obligations to its collaboration partner. The target may face significant commercial risks if it has committed to supply specific quantities of product, to provide specific product warranties or indemnification, or to undertake other supply obligations if it has not obtained substantially similar commitments from its suppliers.

Conclusion

Ultimately, there are many factors that determine the success of an inter-company transaction, many of which are common to all industries and others of which are unique to the specific deal. In transactions involving biotech companies, however, sensitivity to the special characteristics of the biotech industry and to the unique issues to which they give rise can substantially enhance the prospects for success.

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PERSONNEL

As with companies in other knowledge-intensive industries, the value of a biotech company is often associated with the expertise of a limited circle of scientists immersed in the company's technology. Ensuring that this expertise will remain available to, and can be fully exploited by, the acquirer may be crucial to the future success of the business.

The acquirer should identify the target's key employees and analyse the methods that are being used to retain them. This entails reviewing employment and consulting contracts, non-competition covenants, equity compensation plans and awards, and other relevant materials.

The acquirer should verify that there will be no unexpected restrictions on the ability of target employees to provide post-closing services. Obviously, the acquirer will need to verify that there are no existing breaches of third-party non-compete covenants by the target's employees by virtue of their involvement in the target's business. In addition, however, the acquirer needs to consider whether the affiliation of the target's personnel with the acquirer (whose business may be more extensive than or differently oriented to the target's) could result in any such problems.