

I.P. DUE DILIGENCE: BEING PREPARED

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Intellectual property due diligence audits have become commonplace in the biotechnology industry. The single biggest asset of many biotechnology companies is their intellectual property portfolio, and is therefore often the subject of intellectual property due diligence in several contexts such as financing and re-financing, the licensing out of intellectual property or even the sale in whole or in part of their business. Often, younger biotechnology companies which are subjected to an intellectual property due diligence audit are unprepared to efficiently respond to the audit. This renders the whole experience particularly unpleasant and disruptive and in some scenarios can even result in lost opportunities.

We will discuss some very basic aspects of in-house preparation and management in respect of potential intellectual property due diligence. The focus here, of course, is on patented or potentially patentable technology, trade secrets and know-how.

Of course, the most obvious advice once can offer on the subject is that a business must be well organized and keep precise easily retrievable records on subjects likely to be of interest to an outside party who seeks any form of commercial arrangement with the biotechnology company.

Briefly put, investors, potential parties to licenses or sub-licenses or potential joint-venturers and the like, are often most interested in ensuring themselves of some very basic facts: that the target company is indeed the sole owner of the subject technology that patent protection has been properly secured and that all of the delays inherent in the various national and regional patent systems have been respected; that inventions have not been disclosed

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publicly to the extent that patent protection is lost; the extent to which other parties may already have had access to the target's technology; the extent to which non-patentable technology has been kept secret and the potential risks of such secret information being disclosed in the future; the possibility that future use of technology of the target company may violate the prior existing rights of third parties. These are not the only concerns which may arise but suffice for the scope and goal of this discussion.

In order to respond to the concerns of the party with whom one may wish to do business with, the biotechnology company should ensure that it has taken certain steps and has clear records in respect to those subjects that are indeed of a concern to potential business partners. For example, the biotechnology company should have on hand all contracts relating to research and development leading up to the creation of the underlying technology of its intellectual property portfolio. This means that the biotechnology company should be able to readily make available properly completed employment agreements, independent contractor or consultant agreements, research agreements with universities or private sponsored research, joint development agreements and material transfer agreements, etc. The company has to be able to clearly explain which technology it owns and which may belong to third parties and by virtue of what right they are entitled to use and even transfer, where relevant, such rights.

Many of these considerations result from the substantive law of patents and trade-secrets, to mention only a couple. Suffice it to say, that an inventor is the owner of any rights in that invention unless it was made in the context of employment and the purpose of the inventor's employment was in fact to invent. Research and development employees generally fall into this category of employees whose inventions are owned by their employers. Any doubt as to the ownership of anything developed within a company or in collaboration with an outside party, should be settled by contract and said contract should be available for review.

Similarly, licenses, joint venture agreements or pooling agreements as well as distribution, marketing or co-marketing agreements should be in place and available for rapid disclosure.

Some fact situations and agreements have repercussions on the biotechnology company that will be of interest to potential business partners. In some cases, these result from restrictions that will have been placed on the business through non-competition agreements it has signed, or restrictive covenants or confidentiality agreements it has entered into with regard to technology it has used to develop its own technology.

The company may also benefit from non-competition and confidentiality agreements signed by third parties in its favour.

Obviously, many due diligence concerns are common to all kinds of transactions and are not necessarily specific to biotechnology transactions. Therefore, more common agreement such as shareholders and partnership agreements should always be maintained up to date along with corporate books and records. Many commercial arrangements with biotechnology companies involve a change of corporate structure and require a proper legal snap-shot of the whole corporate and share-structure of the company. It is easy to imagine the trouble which can result in cases where a venture capital partner is sought or where a strategic alliance is predicated on the creation of a new entity.

In addition to intellectual property rights, much importance is placed on the experience, past success where applicable, expertise and even personality of the principles, management and researchers of biotechnology companies. Biotechnology companies must ensure stability in respect of its human resources and assure itself of stability through the implementation of appropriate contractual arrangements and compensation packages. All of this must be properly documented and records must be kept current. Any doubt with respect to the stability of the human resources aspects could in and of itself can be sufficient to undermine potential transaction making. We should add that it is never the ideal time to negotiate contracts with key people when one is in the midst of negotiating an important transaction.

One of the goals sought in preparing for an I.P. audit is to demonstrate that the business is managed in an orderly fashion. Having clear research and development procedures and policy is one way of reassuring potential business partners of a company's seriousness and the quality of its management. Companies that implement policies concerning the keeping of laboratory notes and log books and who implement proper procedures with respect to confidentiality and its laboratories and R & D facilities will also respond better to a due diligence review and increase its chances of concluding a sought-after transaction. Furthermore, the degree of preparation and organisation of the company usually contribute to the degree of success obtained in the potential negotiation.

Patents and trade secrets are, of course, extremely important in the business transactions of biotechnology companies. It is always advantageous to have on hand physical copies of patents and patent applications and where relevant, documents reflecting ownership in other intellectual property rights.

One should be able to easily convey which patents have been applied for and the status of each patent application. A distinction should always be made between patent applications that have been laid open and those that remain confidential, since confidentiality agreements should intervene in respect of applications that have not been laid-open.

Often, patentability searches will have been carried out by the company prior to filing for patent protection and opinions rendered pursuant to such searches are extremely relevant in the due diligence process. The same can be said for non-infringement searches and state of the art searches. License lists should also be kept by any serious company and periodically the license files of a company should be reviewed in order to determine the status of each license. All of these should be properly filed and readily accessible.

As stated at the outset, we have sought to set out, in very general terms, a summary explanation of some of the main concerns which arise in the context of intellectual property due diligence and ways in which a company can prepare in advance to address those concerns. In so doing biotechnology companies, especially smaller, younger biotechnology companies, who for one reason or another have never had the opportunity to proceed to a proper audit of their own records and business methods will actually by necessity improve the overall management and organisation of their business. Being prepared in this way, adds value to the company since it is done in relation to the company's most important assets and increases the chances of success in desired business transactions.

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