As seen in

The Journal of New England Technology

Mass High Tech
THE JOURNAL OF NEW ENGLAND TECHNOLOGY

www.masshightech.com
January 17 - 23, 2005
Volume 23, Issue 3
Life Sciences Strategies

Top five things to consider when negotiating an R&D partnership

By Beth Arnold and Jeffrey Quillen

At the end of each year, many of us become preoccupied for a while with countdowns and top 10 listings. We like to hear what the pundits list as significant and feel like geniuses when we guess what's on a list.

In the spirit of the season, we've put together a list of five items that are critical to consider at the term sheet stage of negotiating an R&D partnership. In our experience, these items are not always adequately addressed, if at all, in an ultimate agreement. Why? They involve patents, and business people and non-patent lawyers typically don't like or understand patent issues.

Our perspective and experience comes from negotiating drug and medical device development agreements, where strong patents that cover resulting products are critical for thwarting generic competition and recouping the always-substantial R&D investment. However, patent issues are no less important for R&D collaborations directed to other technologies and products.

1. Value of existing patents

A collaborator's ultimate compensation will depend to a certain extent on what it brings to the table and what it contributes during the collaboration. Money and research effort are relatively easy to value. Patents and technology are less so but are every bit as important.

That a patent application has been filed provides no assurance that a patent will issue with valid claims covering the ultimate products and technology. Accordingly, a patent lawyer is needed to confirm the patentability of pending patent claims and determine if patented or patentable claims will indeed cover what is to result from the collaboration.

2. Potential restrictions on in-licensed patents

In addition to patents that it owns, a collaborator may contribute in-licensed patents or applications — in other words, patents or patent applications that are owned by someone else, like a university, but under which the collaborator has certain rights. In-licensed patents and applications should also be evaluated by a patent specialist.

In addition to the patents themselves, the underlying license agreement must be studied to understand the scope of the in-licensed patent rights and to verify that the appropriate rights can in fact be transferred to the collaboration. Even where sublicensing is permitted, many license agreements require that the licensor pre-approve any sublicense and require the licensee to pay a percentage of all compensation that it receives for the sublicense. A thorough understanding of the potential restrictions on in-licensed patents, therefore, is important for collaborators to understand as they structure the deal.

3. Ownership of new patents

It is hoped that R&D collaborations result in new patents. Beware, however, that terrible battles may be waged over the ownership of collaboration patents. Unless otherwise specified, inventors equally own all rights in patents to their inventions. The law further provides that joint owners may separately apply for and obtain patents, practice under the patent rights and grant sublicenses to others, all without the consent of or accounting to the other inventor-patent owner.

The collaboration agreement should clearly contemplate the ownership of new patents, preferably to the collaboration entity or to one or the other collaborator. If not, and ownership is determined by inventorship, disputes are likely — particularly since the case law on what constitutes an inventive contribution is not always clear. If the result of an inventorship determination is joint ownership, neither will have exclusive rights, which impairs the patent's value.

4. "Blocking patents"

A patent lawyer's perspective is also critical for identifying potential "blocking patents" (i.e., patents that may be infringed based on the manufacture, use or sale of the product or technology "to be developed" but that are not owned by a party to the collaboration). At worst, blocking patents can mean what the phrase suggests, that the results of the collaboration cannot be commercialized.

Identifying blocking patents as early as possible may provide an opportunity to develop an effective "design around" or at least to negotiate a license on more favorable terms than could be obtained once the product is on the market.

In our experience, successful R&D collaborations begin with a realistic appreciation of potential blocking patents and provide, in the agreement, for a procedure to identify and deal with blocking patents that may issue during the term of the collaboration.

5. Patent prosecution and enforcement

Whoever controls the patent prosecution can select the patent lawyer and influence when and where patent applications and patents are to be filed and maintained. Clarifying who controls the patent prosecution of new patents is important to include in the agreement. Although it may sound equitable, joint control is usually not a good idea, because of the coordination efforts and likelihood for disagreements. It is usually best to have the party responsible for paying patent prosecution costs control all decisions pertaining to patent prosecution.

The value of a patent is that it confers on the owner the right to prevent others from making, using or selling the invention defined by the patent claims. It usually makes sense to have the company that will ultimately sell the product determine when and where to enforce patent rights against competitors or to provide licenses.

So, did you correctly guess the five items that are critical to consider at the term sheet stage of an R&D partnership? If not, you have plenty of company. Despite the recent increase of R&D collaborations, there are no standard forms or structuring for these types of deals. In most cases, you would be well served to add an experienced patent lawyer to your negotiating team at a very early stage.

Beth Arnold and Jeffrey Quillen are partners with Boston-based law firm Foley Hoag LLP (www.fhe.com).