An Introduction to Intellectual Property Issues Associated With the In-Licensing Due Diligence Process

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Executive Summary: This article provides an overview of some of the more important IP issues that should be reviewed and analyzed when in-licensing technology. Conducting this IP due diligence will let you know the risks involved with completing the deal. Among the due diligence steps discussed herein are obtaining all necessary documents from your licensing partner; conducting your own patent searches and analyses; searching for any previously terminated relationships; and reviewing inventor/employee contracts and issues.

1. Introduction

One of the most important, but often overlooked, aspects of in-licensing a technology is conducting a full due diligence analysis of the IP surrounding that technology. Conducting a due diligence analysis early on is a critical step, as it will let you know whether you will only be buying a problem and, if so, whether you are willing to accept this risk.

2. Documents You Should Expect to See

The first step in conducting a complete due diligence analysis is obtaining all necessary documents from your potential licensing partner. The critical documents you should want to see include any patent and patent application files; all supporting documentation (e.g., Assignments); any previously executed agreements (such as licensing, material transfer, consulting, research and development, manufacturing, and/or key employee agreements); laboratory notebooks; scientific publications by inventors/employees; SEC documents; and the results of any previous prior art searches.

3. Patent Searches and Analysis You Should Conduct

In addition to reviewing these documents, it is important to conduct your own patent search and analysis as well. There are two critical, distinct patent searches that should be done during any due diligence analysis: a freedom to operate search and a patent validity/enforceability search.

a. Freedom to Operate Searches

The focus of the freedom to operate search is whether there are any third party "blocking" patents. That is, would the claims of any third party owned patents prevent your ability to sell the licensed product? Of course, the freedom to operate search should be independently conducted for each country where you expect a big market for the product, or where the product is manufactured.

If any such blocking patents are identified, they represent a potential risk associated with the technology at issue. Accordingly, each identified blocking patent should lower the purchasing price the licensor is demanding, as they represent potential additional costs in the form of further licenses and/or future litigation.

Another way to minimize the risk associated with any uncovered blocking patents is to conduct an invalidity search and analysis with respect to that patent. A successful invalidity analysis will provide you with arguments and support to 1) prevent the need to pay for any further patent licenses in the future; 2) force future cross-licenses; and 3) establish a defense in future litigation.

In addition to searching for blocking patents, you should look for any third party pending patent applications as well. While such pending applications cannot be enforced as such, once granted they can potentially be enforced back in time if the granted claims are substantially similar to the previously published claims. While this is not a common occurrence, it is certainly something to be wary of. Further, even without this ability to reach back in time, pending applications represent potential future issues you need to be aware of and consider properly. While we usually do not recommend canceling a deal solely based on the presence of a third party pending application, it is important to note what future liability issues may occur.

b. Patent Validity Searches

Regarding the patent validity search, you will want to know how secure the protection is for the desired in-licensed product. Namely, how likely is it that you will be able to keep others off the market for a sufficient lengthy time to be able to maximize profits?

The critical steps to conducting the validity analysis include 1) identifying the relevant patents; 2) checking that all maintenance fees have been paid; 3) reviewing the patent inventorship; 4) determining the scope of coverage; 5) identifying the most important claims; 6) reviewing the relevant file histories to determine claim scope; and 6) conducting a search. Unlike for a freedom to operate search, a proper validity search should not be limited to a review of patents only. Rather, any documents that were publicly available before the patent application filing date need to be reviewed and considered, including journal articles, poster presentations, abstracts, and dissertations.

Even if your search and analysis shows that there are potential validity or enforceability issues with the patent(s) in question, there may still be options available for continuing with the licensing discussions. For example, you may still want to license the patent, only at a reduced rate based on the results of the invalidity analysis. Another option would be to insist on instituting a reexamination proceeding against the patent, to resolve any potential validity issues before it needs to be enforced in litigation.

4. Looking for Others Who May Have Rights to the Technology

Another important area to look at is whether the potential licensor has had any previously terminated relationships. Any such relationships should be closely scrutinized, as the previous partner may still own residual rights and obligations, or may possess unexercised options to the technology. In addition, any patent applications filed after the previous agreement was first executed may be in question, as there may be issues concerning the source of any data, and whether the proper owners and/or inventors have been named. Lastly, you may want to look into why the previous relationship is terminated before you enter into an agreement with the licensor. After all, it is good to know who you are "marrying"!

Another important issue to investigate is whether the invention arose from a university. If the company you are talking with is a university spin-off, there may be some uncertainty or disagreement between the university and the spin-off as to who owns all of the patent rights. This is an important issue to resolve early on; otherwise you may just be buying another headache.

5. Other Issues You Should Be Aware Of

Two other sources of potential issues include the presence of non-employee inventors and negotiating with international companies. For non-employee inventors, you will want to make sure that the inventor has already assigned all rights to the licensor in case he disappears in the future, and that the inventor's primary employer has given permission for consultations and assignments of patent rights. Regarding international companies, just be aware that non-US companies may have different ways of doing business than you are accustomed to, and that it may be difficult to enforce any agreement outside the US.

6. Conclusion

We are often asked how much time, effort, and resources should go into the due diligence analysis. At the end of the day, it is up to you, and to how much risk you are willing to accept. Remember, the goal of conducting the due diligence is to avoid any future problems or surprises. If any product coming out of the license agreement is a hit, the chances are that you will face third party competition in the marketplace. Rest assured, if there is anything you have not looked at, someone else will!