

Intellectual Property

Patent Law

Biotechnology

Grab the Efficiencies and Minimize the IP Risks of International Life Science Outsourcing



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Life science companies have embraced outsourcing research and development, manufacturing, and other business functions, as they seek to become more capital efficient. The outsourcing relationships can vary widely from sponsored research with not for profit institutions, fee for service agreements, joint development agreements and even joint ventures. Ideally, the company (buyer) gains access to the specialized knowledge, skills, and equipment of a service provider that can perform the outsourced services better, more quickly and at lower cost than the buyer. In exchange for these efficiencies, the buyer necessarily surrenders control of the project to the service provider, and

assumes a number of risks that are inherent in surrendering control. Typically, the risks of greatest concern involve ownership and use of the buyer's pre-existing intellectual property ("IP") and IP that might be developed during the project. These IP risks can be particularly difficult to quantify and manage when the buyer and service provider are located in different countries.

Strong IP rights are considered essential to the success of emerging and established life science companies because new product development cycles are long, development costs are high, and successful products generally have a long commercial life. Yet, life science companies of all sizes are increasingly accepting the IP risk and outsourcing, even to service providers located in countries where the ability to effectively enforce IP rights is questioned. This article explores the activities and contract provisions that a life science company should consider when outsourcing to a foreign service provider in order to minimize IP risks.

At the outset it is important to recognize that the buyer typically shares its valuable pre-existing IP with the service provider in order to enable the performance of the requested services. For example, the buyer's know-how and trade secrets might be required to perform the requested services. In the course of providing the services, the buyer's IP might be improved or new IP might be developed. The buyer will need to control and limit the use of its pre-existing IP by the service provider, and may determine that it needs to own any improvements or new IP, particularly if they relate to core aspects of its business. As the buyer is no longer in exclusive control of its IP, there is a risk that the service provider will use the buyer's IP for unauthorized purposes, such as providing similar services to the buyer's competitors, or may fail to protect improvements or new IP. These risks are particularly significant when the service provider is located in a country where effective protection and enforcement of IP is uncertain, and where the service provider might be owned, in whole or in part, by the state.

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Due Diligence and Service Provider Selection

The importance of selecting a well-established service provider with a proven track record of protecting the buyer's IP, improvements, and new IP, cannot be overstated. Choosing a good service provider is the best way to mitigate IP risks, particularly when the service provider is located in a country where recourse for IP misappropriation or infringement is limited. The company should conduct thorough due diligence on potential service providers and conduct site visits if possible. The due diligence should confirm the existence of the service provider and that it is not an imposter company, and include investigation into the ownership, financial condition, and past business dealings of the service provider. The service provider should have a demonstrated track record of successful relationships, and have systems in place to protect the buyer's know-how and trade secrets, and to capture and protect improvements and new IP. In some countries, like China, information of this type is difficult to obtain and may be restricted. In such situations, the buyers should consider engaging in-country legal counsel to assist with due diligence.

Buyers should also look internally and identify the IP that they will need to provide to the service provider, before engaging in negotiations to define the outsourcing relationship. The buyer should take any necessary steps to protect the IP that will be provided to the service provider and to obtain any permission from third parties that might be needed before certain IP, such as licensed IP, is shared with the service provider. Buyers should also determine whether patent applications that are directed to expected results of the outsourced activities can be prepared and filed, before detailed planning with the service provider begins. Typically, this is possible when the service provider is engaged to create prototypes that embody the buyer's design concepts and specifications, or to runs tests that demonstrate that the buyer's innovations provide the anticipated advantages and benefits.

Carefully Drafted Agreements Reduce IP Risk

Even when a well-established and respected service provider is selected, the buyer should carefully negotiate the terms and scope of the outsourcing relationship and ensure that the IP risks are minimized. The agreements may be the only basis for recourse in the event of an IP dispute.

The outsourcing agreements must impose strong confidentiality and non-disclosure obligations on the service provider in order to protect the information buyer will need to disclose to the service provider as well as information that is developed under the agreements. Service providers sometimes believe that they will need to disclose their confidential information to buyers, for example, in order to allow the buyer to understand the results produced by the service provider. Buyers should try to avoid obligations to protect information the service provider discloses to them. After all, the buyer is paying for the services and the results. However, under certain circumstances it might make sense for the confidentiality obligations to run both ways. In this

situation, the buyer should negotiate a limited ability to use and disclose the information for particular purposes, for example, if necessary to obtain regulatory approval.

Some countries do not have well developed laws for the protection of confidential information and trade secrets. In such countries, the confidentiality provisions in the agreements may provide the only basis to prevent disclosure and misappropriation of the buyer's confidential information. Accordingly, the agreements should identify and define all existing confidential information that will be disclosed, as well as confidential information that might be developed under the agreement, as precisely as practicable. Both parties should acknowledge the confidential nature of the information and the value of the information. The agreement should unambiguously define the purposes for which the service provider can use the buyer's confidential information, and prohibit its use in the general course of business and for providing similar services to third parties.

Allocate Ownership and Rights to Use the IP

The outsourcing agreements should allocate ownership and rights to use all IP, including the service provider's right to use the buyer's pre-existing IP for the requested services, and ownership and rights to use any improvements or new IP. In many countries, the right to apply for patents belongs to the presumptive owner of the invention, which is usually the party that conducted the research or the inventor. However, in many countries, such as China, the buyer and service provider can allocate ownership of future inventions and the right to apply for patents in the agreements.

When negotiating the allocation of IP rights, the buyer should seek to own all IP that is necessary for the future manufacture, use, or sale of buyer's products. Buyers should resist co-ownership of improvements or new IP, as this form of ownership can create complexities and impediments to the future transfer or enforcement of the IP in some countries. Negotiations to allocate IP can be contentious. Both parties should try to objectively understand the relative value of certain types of IP to their businesses and to the other party, and use this as a guidepost when negotiating. For example, the service provider may develop tools that are valuable to its business, but will not be needed for future manufacturing, use, or sale of the buyer's products. The buyer should have no objection to allowing the service provider to retain ownership of such tools. On the other hand, the service provider may develop know-how that will be transferred to the buyer and used to manufacture a product. In such situations, the buyer should seek to own the know-how and, at a minimum, restrict the service provider from using or disclosing the know-how to assist third parties developing competitive products.

Buyers should also carefully analyze the benefits and potential risks before agreeing to license, rather than own, IP that is developed under the outsourcing agreement. Licensing is often seen as an expedient way to resolve difficult negotiation points, but buyers need to understand the potential risks. For example, before agreeing to any licensing arrangement a buyer should

consider how its business might be affected if the service provider fails to obtain or maintain the IP rights, or if the service provider becomes insolvent.

Ideally, the outsourcing relationship works well for both parties and produces the desired results. However, because the results of the services, particularly research and development, usually cannot be guaranteed, some consideration should be given to the possibility of failure of the outsourcing relationship. Depending on the nature of the services that are to be provided, it might make sense for the allocation of IP rights to differ in the event of material breach or early termination by one party. For example, in some situations it might be desirable for the service provider to lose certain rights to use new IP if the service provider terminates the relationship prior to completion of the requested services.

Define a Dispute Resolution Process

Buyers fear that the laws of some countries may not provide adequate recourse if they find themselves in a dispute with a foreign service provider over ownership or use of IP rights. For example, the local courts may have a poor record of enforcing IP rights, the local courts may be biased toward the local service provider, local laws may not provide a cause of action or sufficient remedies, and the service provider may be owned in whole or in part by the government. One approach to address these concerns is for the buyer and service provider to agree to mandatory arbitration of IP disputes in a neutral country, and that any arbitration award will be globally enforced. This mechanism should allay buyer's concerns because courts in many countries will enforce such awards. Of course, the location of the arbitration, controlling law, and mechanism for selecting the arbitrator(s) will need to be negotiated and included in the agreements. Local counsel in the service provider's country should be consulted to ensure that all local requirements for the enforcement of an off-shore arbitration award are met.

Conclusions

Life science companies are understandably cautious when it comes to out-sourcing research and development, manufacturing, or other business functions to service providers in countries that have weak IP laws and enforcement records. The most important step a company can take to minimize IP risks inherent in outsourcing is to perform due diligence and carefully select the service provider. The agreements should be negotiated and drafted with care to ensure that they contain adequate provisions to protect confidential information, allocate IP ownership and use rights, and provide for fair and objective processes to resolve IP disputes. By taking this approach, life science companies can enjoy the efficiencies provided by outsourcing, while minimizing the associated IP risks.

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