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## Emerging Life Sciences Companies

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### Chapter 23

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Strategies for Preparing and Negotiating  
a Strategic Alliance with Big Pharma

## Chapter 23

# STRATEGIES FOR PREPARING AND NEGOTIATING A STRATEGIC ALLIANCE WITH BIG PHARMA

This chapter focuses on some of the more heavily negotiated provisions of strategic alliance agreements, illustrating some of the considerations you may find useful in developing a strategy for the preparation and negotiation of the agreements, including license agreements, development and marketing agreements, marketing or distribution agreements, co-promotion agreements, and even joint ventures.

### Initial Considerations

A license may be described as a covenant by the licensor not to enforce its right to exclude others under its IP rights for the practice of technology within certain specifically defined parameters. The license grant, whether implied or explicit, is the foundation for any strategic alliance, and the parties should focus on ensuring that the description of the technology and the parameters for the use of the technology, including the territory, the technological field of use, and the extent of exclusivity, accurately reflect and achieve their respective business objectives.

If a physical embodiment of the patented technology is being sold by the IP owner to another party, such as in a supply agreement, a license grant may not be necessary. Such an agreement is subject to an implied license and the first sale or exhaustion doctrine. An implied license only applies to the actual physical embodiment of the patented technology that is being sold. Hence, in essence, it constitutes the narrowest description of the technology possible.

In considering whether an agreement with a license grant is necessary or desirable, parties should consider; (i) whether it would result in the licensor sharing its manufacturing margin with the licensee; (ii) whether the licensor may lose control of its technology and create a competitor; (iii) whether a royalty stream is the most efficient way of achieving income; (iv) whether control of the physical flow of the goods is desirable or necessary if the licensee is in breach or if other problems, such as a gray market, develop; and (v) whether activities are contemplated in countries where restrictive competition rules apply more to the licensing than to the sale of goods.

Business alternatives to technology licensing include co-promotion arrangements, distribution agreements, a license to a joint venture in which the licensor holds an equity stake and has some control over the joint venture business, and establishing a local branch or subsidiary. Each of these

alternative vehicles brings its own set of legal issues, including laws affecting termination of agency arrangements and local laws and regulations governing joint ventures or stand-alone businesses.

## **Scope of the Grant**

If an implied license constitutes the narrowest description of the technology, at the other end of the spectrum would be a description of every technology covered by the IP position in question. The parties need to determine what is necessary to accomplish their inherently different business objectives. If the scope of the license is too broad, the deal may be tantamount to an acquisition. If the scope of the license is too narrow, the licensee could find itself competing with the licensor's related technology. Finally, consider how the scope of the license could affect the licensee's ability to merge with or acquire another company with related technology—would the newly acquired technology fall within the scope of the field and be subject to the royalty?

The licensor is seeking to maximize the value of its IP by, among other things, licensing to companies with a greater ability to exploit technology covered by the IP or by maximizing the number of licensees actively developing technology covered by the IP. The licensor must clearly define the technology that is being licensed and calculate the expense of the licensing program and the liabilities that may accrue.

Thus, in preparation for licensing, the licensor should determine, at a minimum, the following for each technology:

- What technology and proprietary rights are being transferred, both currently and in the future?
- What is the product or the fields of use? If the fields of use are broad, does the licensee have the capability and commitment to develop the technology in multiple fields? Are there others who have the capability to develop the technology in any of the other fields?
- For manufacture, use, or sale in what territories?
- What is the degree of exclusivity?
- For what period or time?
- What other obligations does the licensor have (e.g., development, support, technical assistance)?
- For what payments?
- What are the potential risks/liabilities?

The licensee is primarily focused on maximizing the value of the IP rights and technical assistance to be provided by the licensor to the licensee as compared to its competitors. In addition, the licensee must contend with the liability arising from the licensed IP. The licensee must ensure

that licensing the technology will not affect its independent exploitation of the technology or future innovation.

Thus, in preparation for licensing, the licensee should determine, at a minimum, the following for each technology:

- What technology/proprietary rights are being licensed, and what competitive advantage do these rights offer? How strong are the proprietary rights?
- What assurances does the licensee have that the technology will achieve the desired results, and what assistance is required?
- What payments will the licensee be required to make, now and in the future?
- If the licensee is required to make investments in commercializing the technology, what protection will the licensee have against commercialization by the licensor or its other licensees?
- If the field of use is narrow, are there other companies that may develop the same technology in different areas?
- Who will enforce the proprietary rights and in what circumstances?
- Who will protect the licensee against claims of infringement of third-party rights and in what circumstances?
- What other liabilities may the licensee incur?
- Will restrictions in the license affect the licensee's ability to exploit its own independent technology or to develop new technology?

## **Considerations in Addressing Key Terms of the Agreement**

### ***Exclusivity and Commercial Diligence Requirements***

The parties need to make a determination as to whether or not the relationship is going to be an exclusive relationship. In making the initial determination as to the level of exclusivity, the licensor should consider (i) the strategic value of its technology to the licensee, (ii) the licensee's expertise and resources available to develop and commercialize the technology, and (iii) any competing technologies the licensee may have in its pipeline.

The licensee should take considerable care to determine the scope and the strength of the licensor's proprietary position. The parties may find that they will maximize the value of the technology or that it is necessary due to prior encumbrances to have some aspects of the proprietary position be granted nonexclusively while other aspects are granted exclusively.

The exclusivity discussion rapidly evolves into a conversation about the commercial diligence requirements the licensor will impose. The licensor needs to ensure that (i) the licensee will develop

its technology and not “shelve” it; at a minimum, this should include commercially reasonable efforts to develop and commercialize the technology; (ii) it receives a product development plan with a time line that specifies consequences for failing to meet certain development benchmarks within the time frames outlined; (iii) there is a basis for frequent communications with the licensee about the development process; this should be constructed so as to allow for continuous monitoring of the licensee’s commitment to pursue various areas; and (iv) there is a product champion at the licensee.

The nature of commercial diligence obligations is limited only by the creativity of the parties. Minimum royalties or minimum annual sales commitments are standard; however, care should be taken to ensure that the consequences of the failure to achieve commercial diligence do not have worse consequences on the licensor than on the licensee. For example, if the licensee returns a product because it would be forced to pay minimum royalties, the associated negative publicity may substantially outweigh the value of minimum royalties.

The licensee should consider (i) if the future conduct of the licensor is important, for example, for technical assistance, that the licensor has the capability to deliver; (ii) if it has the capacity to meet the benchmarked obligations in the time frames proposed, and, perhaps more importantly, that it has not created obligations that it will find in the future are unnecessary to the successful development of the product; and (iii) that the consequences for failing to meet benchmark obligations are not overly onerous (for example, an obligation to pay the next milestone payment as compared to termination of the agreement).

### ***Responsibility for Sublicensee***

A particularly contentious issue may be responsibility for and control of sublicensing arrangements. The licensor does not have privity with sublicensees, and the licensee frequently does not wish to take responsibility for the sublicensees. Also, the licensee may need to have the ability to sublicense in order to enter into distribution arrangements in certain countries.

This issue has three primary components: (i) enforcing financial obligations due the licensee and hence the licensor, (ii) other obligations with which the licensee must ensure that the sublicensee complies, and (iii) what happens to the sublicense if the license is terminated.

The first issue seems to be particularly sensitive when one party is an academic or research institute. The licensor would like to reach only the licensee and not have to attempt enforcement against each and every sublicensee. The licensee would prefer to have the licensor bear the expense of enforcement if there is a dispute.

The second issue is also heavily negotiated. The licensor would prefer that all of the sublicenses include at least the provisions in the license. The licensee would prefer to have the freedom to negotiate each and every provision itself. Generally, the parties are able to identify specific clauses in the license agreement that sublicensees must comply with by having the licensor review and approve the sublicense within a specified time period. The parties should be aware that, unless specifically provided for, the licensee could be prevented from allowing the licensor to review

the sublicense agreement by confidentiality obligations. Hence, at a minimum, the licensor should provide that it receive copies of all sublicense agreements within a specified time period from their effective or execution dates.

Finally, the third issue is particularly important because when the license is terminated the parties are frequently not on the best of terms, so it is best to clearly delineate from the outset which sublicenses will continue to be in effect. Generally, if the licensor had the ability to approve the sublicense agreement in advance, then the sublicense agreement would remain in effect. If the licensor did not have the ability to preapprove the sublicense agreement, then it would have the ability to terminate the agreement at its option.

### ***Treatment of Improvements***

The treatment of improvements tends to be a highly contested matter. The licensor will not wish to give away potential future royalties for improvements or be forced to charge the same price for manufacturing a different technology. Depending on how it is defined, an improvement could have a significantly different valuation than the underlying technology. On the other hand, a licensee has a legitimate concern in that it does not want to end up with a superseded technology or competing with a new generation of products licensed to a competitor.

Frequently, parties use their right of first refusal or first negotiation to resolve this issue, but these types of provisions are often difficult to deal with on a business level. There is a potential risk that the licensor's core technology—its entire business—will be encumbered by these rights, frequently requiring long and drawn-out processes to resolve the issue. The licensor will soon find that other parties are reluctant to negotiate with it for technology because confidential information may have to be conveyed to the first licensee or the deal is subject to the first licensee's right of first refusal. On the other hand, the licensee may often find that even minor changes to the technology are subject to renegotiation, as well as to the time-consuming right-of-first-refusal process. The best way to ensure that the parties' business objectives are met may be to carefully define what constitutes the base technology and what constitutes improvements thereto.

### ***Allocation of Responsibilities***

While a straightforward license agreement does not generally require the parties to interact in a collaborative manner, many strategic alliances do contemplate an ongoing relationship. Such agreements require that the parties set forth ground rules of varying degrees of complexity for the collaboration. Some agreements may also require that the parties essentially structure a virtual joint venture between the two parties. At a minimum, the parties should ensure that there is a strong dispute resolution provision. The parties should also consider whether there are particular areas of strong interest for either party, such as development or manufacture, about which one party or the other would like to maintain a casting vote in the decisionmaking processes.



### ***Risk of Infringement of Third-Party Patents and the Cost of Pursuing Infringers***

Another pertinent issue in negotiations is the determination of which party shall bear the risk of infringement of third-party patent positions. The risk is generally allocated to the party that has control of the product development because that party is in the best position to control the risk; for example, it would more likely be aware of competing patent portfolios and products and therefore be in the best position to “design away” from such proprietary positions. Thus, if the product is in the later stages of development when it is licensed, or if it is being manufactured and sold by the licensor, then the licensor should bear the risk.

Often, the parties will share the risk of paying third-party royalties by decreasing the royalty owed to the licensor if third-party royalties are required. In any event, both parties should consider a mechanism for terminating the agreement if it is not economically feasible to continue the sale of the product under such circumstances and for determining which party shall engage in negotiations with the third party. Keeping in mind that the parties’ interests will differ significantly; the licensee, for example, may have the opportunity to offset any royalty it owes the third party against that which it owes the licensor.

In exclusive arrangements, the determination of which party shall bear the responsibility for enforcing the patent position against third parties is a critical provision. The cost of patent litigation may dwarf the royalty stream to the licensor and may be a major concern to the licensee. The provision is generally not addressed in a nonexclusive arrangement because the same rights cannot be granted to several licensees, and, in any case, they may have different interests.

The licensor and its licensees certainly have different interests in protecting the patent position. While the licensee may have an interest in excluding others from practicing the technology in its field, this interest is significantly diminished if, for example, the third-party infringer has a strong patent position and is offering a lower royalty rate. Under those circumstances, the licensor may find that the licensee would prefer that the licensor’s patents were invalid and that the licensee’s technology fell within the ambit of the third party’s patent position. On the other hand, the licensee may find that the licensor is not willing to expend the resources necessary to pursue infringers or to put its patent position at risk, in which case the licensee may be paying a royalty for exclusivity while its competitors practice the same technology.

The parties’ interests are generally reconciled by allowing the licensor to have the initial opportunity to pursue the alleged third-party patent infringers. If it fails to do so within a specified amount of time, the licensee would then be allowed to pursue the patent infringers. In either case, the other party may be represented in the action by its own counsel to ensure that its interests are addressed. The licensor has the leverage in this provision because generally it must be named as a party to a patent infringement action.

### ***Prosecution of IP***

Another critical issue in IP development is the responsibility and control over patent prosecution (the drafting and amending of patent applications). There are significant costs associated with patent prosecution. While the licensor may question the benefit derived from developing a strong patent position in, for example, a country such as Somalia, the licensee may see that there is some benefit, particularly if the licensor is bearing the expense. However, if the licensor has control of the prosecution, the licensee may have difficulty ensuring that the licensor drafts claims that cover its commercial embodiment. On the other hand, if the licensee has control over the patent prosecution, it could simply abandon claims that are critical to other aspects of the licensor's patent strategy or draft and amend claims such that they diverge from the licensee's technology and concomitant obligation to make royalty payments. Further complicating matters is the ownership and prosecution of patents associated with jointly developed IP.

Generally, the agreement should first clearly delineate which party owns which patent position. The party owning the technology will most often control and pay for the patent prosecution. Then, if the other party has a legitimate interest, it may have the right to do everything from reviewing the patent applications to providing substantive comments that must be considered by the other party. Jointly owned patents or patent applications are generally jointly controlled. However, the parties should ensure that one party takes the lead role and instructs the patent attorney. Any number of mechanisms may be used to determine which party takes the lead role, including, for example, selecting the party that has contributed more in the way of money or inventiveness. Care should be taken to ensure that this mechanism is not easily manipulated by either party. Keep in mind that joint ownership of patents has a different meaning and effect in the United States than it does in other countries.

### ***Allocation of Product Liability Risks***

In many instances, the parties spend a significant amount of effort in determining which one takes responsibility for product liability actions. The determination generally hinges on an interplay between which party has responsibility for product development and which party is in the best position to cover the risk. There may be circumstances in which the party that develops the product may not be in the best position to cover the risk. For example, if the developing party is selling the product to another party under a simple manufacturing agreement, and the other party is selling the retail product and hence is in a position to pass along the costs of the potential liability, or if a licensor has licensed foundational technology to a licensee that develops a product, the party selling or licensing the technology is in the best position to cover the risk.

### ***Termination***

In strategic alliances in which the parties contemplate an ongoing interaction or joint development arrangement, the time spent negotiating the termination provisions frequently constitutes the bulk of the time spent on the agreement. These clauses are tantamount to a prenuptial arrangement or property settlement in a divorce proceeding. They serve to divide the property, both tangible



and intangible, upon termination—at a time when the parties may be functioning in what may be an emotionally charged and hostile environment. Hence, these provisions must clearly reflect the parties' intent. They should address the disposition of rights to anything that was contributed to or developed during the term of the relationship, including, for example, technology, improvements, manufacturing processes, data, and regulatory filings. Consequences should take into consideration whether the termination was for cause or without cause and frequently may include additional royalty or other financial provisions.

### ***Expenses and Revenues***

It is important to ensure that expenses do not exceed revenues. Careful consideration should be given to issues such as patent prosecution costs, patent litigation costs, third-party claims, costs of providing technical assistance, costs of obtaining necessary third-party licenses, and withholding taxes or other local laws to ensure that anticipated expenses do not exceed anticipated revenues.

Provisions addressing revenue sources must be carefully reviewed to ensure that they are objectively determined by a certain event (e.g., upon the execution of the agreement) rather than when a committee internal to the licensee makes a particular determination to proceed with the technology. Revenues may take the form of:

- **Up-Front Payments.** The negotiations of up-front payments are generally focused on the amount of the payments because the timing is generally tied to the execution date of the agreement. Such payments are higher if the risk of product development is lower. Up-front payments can take several forms, including lump-sum payments, prepaid royalties (which offset future royalties), direct R&D funding, or milestone payments.
- **Running Royalties.** Running royalties are generally tied to the revenues subject to the royalty. Beyond the definition of revenue, which must be closely scrutinized, the royalty itself may be subject to change. For example, the royalty may be a fixed percentage of sales, a graduated royalty percentage based on volume, or a variable royalty percentage to account for rights and contingencies. In the case of some patented technologies, such as research tools, care must be taken to properly address and document reach-through royalties.
- **Profit-Sharing.** Profit-sharing has been an increasingly popular mechanism for revenue sharing in co-development and co-promotion agreements. Generally, the division of profit is tied to each party's contribution to development costs, with adjustments made for the contributions to such matters as manufacture and supply.
- **Milestones.** Milestone payments are perhaps the largest element of the precommercialization compensation. The most common error in establishing milestone events is ensuring that there is an objective mechanism for determining if the milestone has been met.

Having a specific mechanism for dispute resolution pertaining to milestone payments is helpful.

- **Manufacturing Payments.** In certain circumstances, manufacturing payments may be included in the revenue equation. Negotiations in this arena focus on the mechanism for calculating the supply price. Complex mechanisms are frequently generated to account for the fact that the cost of goods may rise or fall depending on a broad variety of factors, including volume, increased efficiencies, and escalating prices of raw materials. Common mechanisms include cost-plus and a percentage of resale price.
- **Equity Investments.** Equity investments have become an increasingly popular method of compensation. This mechanism may allow the licensor greater discretion over spending for product development while giving the investor diversification over an entire portfolio of products and IP. Such equity investments may include loans.

### ***Miscellaneous Additional Considerations***

The parties should also review the agreement to ensure (i) that it addresses the potential development of gray markets; (ii) that any restrictions on the licensee are enforceable under local law; (iii) that termination is available if the arrangement is no longer advantageous to the parties' businesses; (iv) that the license is either transferable or not, depending on the parties' needs and desires; and (v) the desirability and enforceability of any noncompete or change of control provision.

### **Conclusion**

Frequently, parties forget that no deal is better than a bad deal. It is always better to be in a position of explaining why your Company has not closed a deal rather than having to explain why the Company has entered into a deal that encumbers its core technology indefinitely or obligates the Company to pay expenses that are far greater than anticipated revenues. By reviewing the applicability of and addressing the appropriate key considerations outlined in this chapter, the parties can begin to minimize the risk of finding themselves in such an awkward situation.