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Chapter 22

Protective Provisions in Biotech Strategic Alliances

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PROTECTIVE PROVISIONS IN BIOTECH STRATEGIC ALLIANCES

Strategic alliances continue to be an important component of the product development and commercialization process in the life sciences industry. These transactions are highly individualized, and, as such, can be used creatively by the parties to advance their particular needs and goals.

Protecting Your Economic Interests

If your Company is large and looking to license technology from, or collaborate with, a smaller company, one of your main objectives is to maximize your rights with respect to that technology and to protect your investment. Typically, a larger company would like to control decision-making with respect to the collaboration, especially as it relates to commercialization, and make sure that the collaboration has tied up any successor or improved technology so that the smaller company cannot compete against the collaboration with a new or next-generation product. Conversely, if your Company is small and looking to outlicense or obtain a corporate partner for your technology, you would want to maximize the consideration you receive in the shortest amount of time and preserve as many rights as possible. Because these can be polar opposite positions, it is important that each party understand the objectives of the other to create protective provisions in the strategic alliance that will minimize downside while maximizing potential upside.

One of the easiest ways for a smaller company to increase the purchase price of its technology is to use an auction to create a bidding war. Auctions create competition in terms of the consideration the larger company is willing to pay for the technology, and they put pressure on the larger company to accept other contractual provisions that have a key impact on the collaboration. However, it is important that the smaller company look not only at the total up-front dollars but also at what resources and efforts the larger company is committed to devoting to the technology after it has acquired the rights to it. Accordingly, in addition to the absolute dollar values, the smaller company should have clear criteria and processes for selecting the larger company with which it wishes to partner.

In an auction, the larger company must distinguish itself from the other bidders while at the same time ensuring that it is not paying too much for the technology. The larger company should perform appropriate and adequate due diligence to minimize any surprises down the road, especially with regard to the intellectual property (IP) and the development activities that have advanced the

technology to its current state. If the larger company comes across any potential issues or uncertainties about the technology, the strategic alliance agreement should be drafted with representations and conditions tailored to the specific facts. By addressing the issues through specific provisions in the agreements that account for potential eventualities rather than waiting to see if problems arise, the parties may be able to avoid unnecessary surprises and potential disputes.

Next, the parties must agree on how to structure the financial provisions. The smaller company may want to receive most, if not all, of its payments up front, but the larger company usually wants to pay for the technology as it is developed in order to minimize development and commercialization risks. The larger company could make smaller, but more numerous, up-front payments in addition to funding the smaller company's employees who are performing research and development (R&D) work for the deal. Such smaller payments could continue to fund the smaller company and advance the technology. In exchange for accepting smaller, up-front payments, the smaller company could then be paid larger amounts when it achieves certain later development or technical milestones or be paid a greater royalty or profit share percentage when a product finally reaches the market. With this option, the smaller company receives a greater total cash return while the larger company ensures that it is paying the larger dollar amounts only after the technology has been proven. Alternatively, if the smaller company requires larger up-front payments, there could be protective provisions put in place for the larger company dealing with reimbursements for certain of the up-front payments if milestones are not achieved or if there are delays in development. In addition, these transactions sometimes include royalty reductions for generic competition, competitive products, and required payments to third parties.

No matter how you slice it, there is no one correct answer for structuring a strategic alliance. Remember, however, that this is not a zero-sum game, and if each party understands the needs of the other, it is much easier to protect against downsides while maximizing the upsides.

Protecting the Progress of the Collaboration

As noted previously, a strategic partnership between Big Pharma and a biotech company may make excellent sense from both companies' perspectives. The biotech company, looking for growth, may want its technology to have the opportunity to be fully developed and commercialized. The Big Pharma company, looking to augment its internal R&D pipeline, will share this interest in seeing the collaboration progress, but it will also desire to protect its financial interests. One of the main objectives of Big Pharma in collaborating with a biotech company is to have the flexibility to match its obligations to future events and assessments of the profit potential of the alliance. Because each side has different priorities, each party should strive to understand the other party's objectives and create protective provisions in the strategic alliance that meet both parties' needs.

Diligence provisions are customary in a strategic alliance agreement. These provisions serve as guidelines for the parties to act appropriately throughout the relationship. Parties' diligence obligations are often benchmarked against a commercially reasonable efforts standard, perhaps one that is

customary in the biopharmaceutical industry or one that is customized to a party's particular characteristics. Occasionally, strategic alliance agreements set forth timetables for targeted achievements. However, the internal and external factors that can have an impact on these timetables need to be understood so that the parties can avoid subjecting themselves to unclear or unacceptable obligations, giving up property rights, or conferring unintended advantages on others.

In addition to diligence provisions, the parties should establish mechanisms for monitoring the collaboration in order to keep an ongoing strategic alliance thriving. One such mechanism is to set up a joint committee consisting of representatives from both parties for that purpose. Second, or as an alternative, each party should have the obligation to supply to the other periodic reporting, detailing its activities, achievements, and future objectives. Additionally, the agreement should provide for prompt notification to the other party upon the occurrence of certain events (e.g., the achievement of milestones or adverse events). These checks and balances will allow the parties to monitor their progress toward a prosperous strategic partnership.

Next, the parties must know how to deal with potential problems to ensure continuous success throughout the collaboration. Protective provisions addressing these sensitive subjects are often heavily negotiated between the parties. Having a noncompete provision can prevent potential problems by restricting a party from competing with its strategic partner during the collaboration and potentially for a period of time after the partnership has terminated, thereby ensuring that the parties focus on the collaboration product and are not distracted by other opportunities. Restrictive clauses can prevent a company from using or disclosing, without authorization, the trade secrets it learns from its strategic partner prior to the termination of their venture. In addition, it may be appropriate for the agreement to provide mechanisms governing vote-casting decisions and tie votes between the parties. Because litigation can be time consuming and expensive, the parties should also consider including dispute resolution clauses in their agreement. If there are disagreements requiring settlement, having such protective provisions provides earlier awareness of legal ramifications, which can allow those disputes to be addressed before they are unnecessarily escalated.

Needless to say, no one expects failure, but what if the relationship falters? Because remedial provisions are fundamental to any legal agreement, the applicable remedies should be addressed broadly in the strategic alliance agreement. The agreement may set forth penalties for delays that are within either party's control and termination rights available to the parties (whether with or without cause). However, upon termination of the agreement, certain rights should remain intact and certain covenants should survive. For example, if termination is due to a party's breach, the nonbreaching party, rather than terminating the agreement, may want to retain its licenses to the product and continue without the participation of the breaching party and on different economic terms. Similarly, it may be appropriate that certain covenants, such as noncompete and nonsolicitation, survive the agreement notwithstanding termination of the alliance.

Protecting Against Distractions and Disalignment

We have come to understand how both Big Pharma and biotech companies can structure an alliance to protect their financial interests as well as the progress of the collaboration, but how does each party ensure that the other does not become distracted and lose interest in the collaboration? A biotech company may see the collaboration as a means to grow its capabilities and reputation. After entering into the alliance, it may seek a very hands-on role in continued R&D or it may be content to assume a passive role and dedicate its efforts to its next great idea. Conversely, Big Pharma may see the collaboration as a strategic building block, or it may want to pursue other internal or third-party projects in order to diversify its risk. The strategic alliance agreement needs to provide flexibility and also ensure that each party remains focused on the collaboration's goals.

First, by specifying the downstream rights among the parties, the agreement can establish expectations and responsibilities for the parties and the future of the product. The parties may find that maintaining focus on the collaboration is best served by having the parties co-develop and co-promote the product. In such cases, these rights may be fixed and linked to a profit-splitting financial arrangement or may be further enhanced with conversion options into a royalty structure. In addition, depending on the nature of the collaboration, it may be appropriate for the agreement to set forth the respective responsibilities of the parties for other key activities, such as manufacturing and supply.

Second, the collaborative agreement should identify which party will lead the development and commercialization responsibilities. The parties should clearly identify any niche indications for the collaboration technology, where perhaps the other party could take the lead role. The parties may want to prioritize certain indications, products, or territories over others. These decisions regarding lead roles and first-priority products should help to define each party's responsibilities in communicating and meeting with regulatory authorities. If both parties will be involved in commercialization activities, it must also be decided which party is in charge of booking sales for the product.

Third, commitment is important to a successful collaboration. One way to ensure commitment is for the strategic alliance agreement to define a scope of exclusivity for the technology and product involved in the venture. The exclusivity can continue for as long as R&D continues or for the entire term of the commercialization of the collaboration product. The exclusivity clause may allow exceptions for internal or third-party programs, keeping in mind that such other programs should not distract a party from achieving the goals of the collaboration.

Fourth, if the parties authorize the use of collaboration technology outside of the venture, the parties should clearly define any limitations to be placed on such use (e.g., field or territory limitations). Alternatively, the parties could establish mechanisms for sharing any returns from the use of the collaboration technology outside the collaboration. Terms for royalties or other reward-sharing mechanisms in connection with such usage should be unambiguously stated in the agreement to

avoid confusion. The parties should also establish mechanisms for sharing any information that is generated using the collaboration technology outside the partnership.

Some collaborations also include a provision for Big Pharma to offer a quid product to the biotech company. Often, the quid product may be one that is complementary to the collaboration product and can serve to prepare the biotech company for its responsibilities in the alliance. A quid product can provide the biotech company with a second product to promote, while placing much-needed additional resources behind Big Pharma's product. If a quid product is part of the collaboration, the parties will need to delineate the scope of rights that accompany the quid product, the mechanism for choosing the quid product, and the point in time at which the smaller company obtains rights to the quid product, as well as what happens to the quid product if the collaboration is terminated.

In sum, before committing to a long-term partnership, each company should evaluate the relative benefits and consequences that come with such an arrangement. The collaborative agreement should be negotiated in detail to carry out the parties' joint intent and to protect each party's goals and interests. The agreement should address the activities for each stage of product development, the parties' scope of rights from co-development to co-promotion to booking of sales, and their level of independence in the collaboration, as well as how the collaboration may be terminated if the relationship falters.

Throughout the course of negotiations for a collaboration, both parties should remember that they need to work together over an extended period of time for their mutual benefit. Detailed terms and provisions in the definitive agreement can help protect the parties' interests, but a successful strategic alliance will require each party to commit to the collaboration and understand the other party's goals and objectives, in addition to its own.

Although there are a number of common overall protective provisions that can be used to ensure a successful strategic alliance, the exact terms of such an arrangement are extremely variable. It is critical that the parties consult with their attorneys, accountants, and financial advisors to carefully craft their intents into the strategic alliance agreement, thus ensuring that each party is able to protect against potential adverse effects while maximizing its upside.