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Negotiating Biotechnology Strategic Alliances

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In today's environment of depressed biotech stock valuations and limited access to investment capital, strategic alliances are becoming a more widely used and more important vehicle for both biotech companies and pharmaceutical companies to extend their reach and create value. For example, GlaxoSmithKline has boasted that it entered into approximately 11 agreements to in-license compounds for further commercialization and has stated that it wants to be viewed as the partner of choice for such collaborations. Furthermore, industry leaders predict that the next generation of biopharmaceutical companies will continue this trend and that the nature of these alliances will become more creative as the parties explore ways to take advantage of each other's strengths and mitigate their weaknesses.

Alliances usually involve much more than licensing technology but something less than an outright sale or acquisition of a business. They may include, among other things, shared and ongoing R&D and/or clinical trial efforts, manufacturing relationships, and co-promotion and co-marketing efforts. For example, a 2001 strategic alliance between ICOS Corporation and Biogen, Inc. had the following attributes:

- The parties cross-licensed LFA-1 antagonist technology and patents;
- The parties agreed to share costs for ongoing development, but Biogen loaned certain amounts to ICOS to cover some of ICOS' share of the development costs under a loan that is forgivable if certain milestones are met;
- Biogen agreed to contribute its expertise in psoriasis clinical trials;

- ICOS received an upfront payment and is eligible to receive other success-based milestone payments from Biogen; and
- The alliance contemplates joint project management and decision making as well as co-promotion activities and equal profit sharing.

Given the increased importance and complexity of strategic alliances in the biotech industry in years to come, lawyers and business people negotiating these transactions need to understand the fundamental techniques for preparing for and negotiating a strategic alliance and the key issues arising in these transactions.

Preparation for Negotiation

Why Does the Company Want to Do the Deal?

The company must be able to identify its reasons for desiring to participate in the alliance, in other words, what the company believes are its needs or weaknesses that will be remedied and reinforced by entering into an agreement with the proposed partner. Two parties may be motivated to work together and enter into an ongoing commercial relationship for numerous reasons. These reasons can include:

- A desire for more R&D funding;
- Diversification of risk;
- Access to a certain technologies or expertise that would be too costly or time-consuming to develop successfully on one's own;
- Development of a critical mass to sustain the company, economies of scale in manufacture; marketing or distribution of a product; or
- Building of market share.

Understanding the company's strengths, weaknesses, and goals provides a guiding principle for the company and its lawyers in evaluating and negotiating the strategic alliance.

What Is the Deal?

The company and its lawyers should quickly develop a solid understanding of the proposed transaction prior to negotiating so that it can be structured appropriately. In order to do this, those persons from the company who are most knowledgeable about the deal and the technology at issue should be identified, and the lawyer should discuss with them the following foundational issues:

1. The company's overall understanding of the deal and its structure;
2. The technology being licensed (*i.e.*, is it a therapeutic compound, such as recombinant DNA, isolated protein, etc., or a discovery process or tool);
3. The current and proposed uses of the technology in this deal and in the future generally;
4. The company's goals and expectations regarding the deal and the resulting use of the technology, as well as the company's understanding of other party's goals and expectations; and
5. The company's strengths and weaknesses, as well as the company's understanding of the other party's strengths and weaknesses.

Participants in the negotiation should also understand (1) how the technology is protected (*i.e.*, is it covered by patent, copyright, and/or trade secret protection?); (2) how ownership of the technology and improvements will be allocated between them; and (3) whether any trademarks or branding will play a role in the transaction.

The company and the lawyers also should gather and review any existing company documentation that may be useful in understanding the transaction. Such documentation may include (1) any term sheets, existing contracts, side letters, email, and other correspondence between the parties discussing their preliminary understanding, (2) any presentations, requests for proposals (RFPs) or responses to RFPs regarding the proposed transaction, or (3) any relevant inbound or outbound agreements entered into (or proposed to be entered into) between the company and third parties that relate to the proposed transaction. Previous contracts the company and the other party have entered into with third parties for similar deals may also be insightful to see how each participant has dealt with similar deal structures in the past.

Who Will Be Involved in Negotiating the Deal?

Establishing an effective negotiating team, and identifying the key personnel who should be on that team, is vital. In addition to the lawyers and business people, it may be necessary to include others within the company. The team should have the authority to make decisions regarding the negotiations, or have access to the higher-level executive(s) with the necessary authority. The team should (1) understand each member's role in the negotiation and the process to be used to keep the members informed of the negotiations; (2) identify what additional resources and/or experts may be required to deal with isolated issues, such as, for example, working with regulatory experts (and ensure their availability, if required); and (3) know the proposed target date and deadline for closing the deal.

Understanding the Proposed Partner

With a specific partner identified and engaged, as much as possible should be learned about the other contracting party prior to entering into negotiations. The proposed partner should be evaluated for such factors as size, financial stability, executive management, competition, corporate culture, and past partnering success (or

failure). In the wake of current corporate accounting scandals, the company and its lawyers should pay particular attention to the financial health and business reputation of the proposed partner. Although a proposed partner's weak financial health may help the company gain negotiating leverage to obtain a very favorable deal, a partner that does not have the resources to meet its obligations is probably not a good choice.

Assessing Negotiation Leverage and Negotiation Posture

The lawyer and negotiating team should work closely together to assess each party's negotiating leverage, how much each party to the proposed transaction "wants the deal," and if either side has any particular pressure to have the proposed transaction finalized by a certain date. Based on this assessment, the lawyer and negotiating team should consider how leverage will be a factor in the negotiations. The team should also discuss what it views are the "must haves" for the company, and what it anticipates will be the "must haves" for the other party. This analysis should include preparation of a list of strategic objectives and risks in going forward with the agreement for the company, as well as what the team believes are the objectives and risks for the proposed partner. Based on each party's "must haves," the assessment of the negotiating leverage, and each side's goals and objectives, the company's negotiating posture (and alternatives) should be structured to most effectively meet these goals and objectives.

Using Preliminary Documents Prior to Negotiating the Final Deal Agreement

Using Nondisclosure Agreements

The parties should execute a nondisclosure agreement (NDA) prior to exchanging any information in preparation for the proposed transaction. The purpose of an NDA is to facilitate protected disclosure of confidential or proprietary information during the negotiation process by obligating the receiving party to maintain the confidentiality of the other party's confidential information. The NDA should be structured to make any disclosures at the discretion of the disclosing party, set reasonable parameters around the scope and identification of information that is subject to confidential treatment, and to last only so long as is reasonable given industry standards and the nature of the information disclosed. Even with a signed NDA in place, the company should be judicious about avoiding unnecessary disclosures and disclosing information at the right moment and in an effective manner as part of the overall strategy of the negotiating process.

Using Material Transfer Agreements

Generally, a material transfer agreement (MTA) is necessary when one of the prospective parties wants to evaluate a therapeutic compound, delivery system, or other material of the other party. The MTA permits the evaluator to receive and evaluate the material at issue while protecting the developer's rights in that material and permitting the developer to disclaim any warranties regarding that material. The duration of the experiment and the research protocol to be implemented should be described in the MTA in order to control the bounds of the evaluation. The MTA, as well as the NDA, should also state that no implied or express license is being granted by the agreement.

Using Term Sheets

In addition, the company should consider whether it wants to use a term sheet or a similar document prior to negotiating the final deal. A term sheet can help the parties reach (or determine that they will be unable to reach) a preliminary understanding regarding the material business terms of the transaction. Because these documents are relatively short, they can usually be prepared, negotiated, and agreed upon much faster than the final deal agreement. The lawyer should closely review the term sheet because substantial legal obligations might arise from these documents. The lawyer can also attempt to identify and resolve any remaining ambiguities and issues.

The term sheet may be signed or not, and if signed, may be binding or non-binding. If the parties intend the term sheet to be non-binding, the document should expressly state this fact. With non-binding documents, the parties may be less likely to walk away or change their minds if the document is signed as opposed to unsigned. A binding term sheet may require more negotiation than a non-binding document, and after reaching agreement on a binding term sheet, the parties may forego entering into a final agreement entirely

Continued Due Diligence

While preparing for the negotiations and pursuing the negotiation process, the company and its lawyers should continue to perform due diligence to ensure that the science is sound, that the technology is adequately protected, that there is a market for the final product, and that the partner will help in realizing that market potential. This continued due diligence should include review and evaluation of not only the partner attributes already noted, but also a thorough analysis of, among other things, the (1) strength of the technology at issue; (2) intellectual property that protects that technology and any agreements the partner has entered into regarding that intellectual property; (3) strength and value of the expertise or other capabilities to be brought to the deal (*i.e.* regulatory expertise, promotion and marketing prowess, sales force, manufacturing capabilities, R&D

facilities, etc.); (4) any competing technologies that the proposed partner may have in the pipeline; (5) key employees; (6) the anticipated market for the final product; and (7) the source(s) of funds to pay for the final product. Selecting the right partner can be more important that the wording of the final agreement.

Key Negotiation Issues

While biotechnology strategic alliances can take on various structures via the creation of a separate joint venture entity and/or complex contractual relationships, they often share the following key issues, depending on the scope of the alliance.

Scope of the Intellectual Property License

The license is one of the most important provisions of an alliance agreement as it identifies the intellectual property contributions made by each party to the alliance and sets out the boundaries of the parties' rights to exploit that intellectual property. The license grant(s) should clearly specify each of the following:

1. What technology is being licensed (*i.e.*, is it a therapeutic compound, such as recombinant DNA, isolated protein, etc., or a discovery process or tool);
2. What intellectual property rights are protected and what intellectual property rights are being granted (*i.e.*, can the licensee do any of the following: use, reproduce, modify, improve, create derivative products, make, manufacture, have made or manufactured, market, promote, license, sub-license, sell, offer to sell, import, distribute, transmit, or otherwise exploit);
3. Whether the license is limited to a particular field of use (*i.e.*, must the technology only be developed for a particular disease indication, delivery system, route of administration, etc.);
4. Whether any of the rights is limited to a particular geographical location or territory (*e.g.*, the licensor reserves the right to exclusively market the drug in its own country);
5. Whether the license is exclusive (licensor may not practice for itself or license others to use it), sole (the licensor may use it, but not grant sublicenses to others), or nonexclusive (licensor may grant sublicenses to others), and if exclusive or sole, if the exclusivity is limited to a particular field or use and/or geographic market;
6. What is the duration, or term, of the license (*i.e.*, perpetual, renewable, or for a fixed term);
7. Whether the license is irrevocable or not;
8. Whether the license is assignable or not; and
9. Whether the license grant is sublicensable and whether "affiliates" of the licensee may use the license.

Depending on the deal, some or all of these items may be heavily contested issues. The following are two examples of licensing issues that often arise in biotechnology strategic alliances.

1. If the transaction involves the development of certain compounds by a large pharmaceutical company (big pharma) and a small biotechnology company (small biotech) primarily for use in treating solid tumors that are based on targets identified by small biotech, big pharma may want exclusive, worldwide rights to exploit all of the compounds developed that are derived from those targets. However, small biotech may want to limit such rights to only those compounds which the venture decides to exploit in treating solid tumors, and to reserve for itself the right to exploit any rejected compounds or compounds derived from the targets that do not treat solid tumor growth, possibly even if such compounds are identified via the alliance. In any situation where exclusivity is contemplated, the parties must carefully define the technology at issue and the field of use and geographic market to which the exclusivity pertains in order to ensure that enough rights are granted to permit the alliance to operate as intended while at the same time avoiding an inadvertent "sale" of the licensor's assets by granting an exclusive license that is too broad.
2. In the first example, big pharma may also want the right to permit its affiliates and/or third-party sublicensees to exploit the technology. Often, sublicensing to these affiliates is generally acceptable to the licensor and may help to exploit the technology. However, the licensor will want to ensure that the licensee maintains responsibility for its duties and payment obligations, and that it receives an appropriate portion of the profits from any sublicensing arrangement. With respect to third party sublicensees, the licensor may want approval rights over any such sublicensees to ensure that it has control over who may exploit its technology.

Operations

Strategic alliances may involve basic research and development, clinical trials, manufacturing, distribution, and/or marketing and sales. The parties should identify each party's rights and duties regarding these activities to the greatest extent possible. However, because the scope of these activities is fluid and the direction that the alliance will take may depend on the results of the development and clinical trial activities, it is important to set up steering committees to make and manage key decisions about operational matters.

In addition to the technological and financial contributions, the parties should determine what other resources the parties will contribute to the research and development effort. This may include scientific,

clinical trial, or regulatory expertise, as well as the contribution of certain source materials (such as antigens, cell lines, compounds, etc.), or R&D facilities. The parties should also identify the key milestones in the development process, the party that will be primarily responsible for meeting those milestones, and the procedure for determining whether those milestones have been successfully achieved. Often key milestones include identification of a validated target, completion of pre-clinical trials, the filing of an investigational new drug application (IND), phase 1, phase 2, and phase 3 clinical trials, approval of the new drug application (NDA) or biologic license application (BLA), and/or similar regulatory approvals in other jurisdictions. In addition, the parties should consider who will have authority to deal with the US Food and Drug Administration (FDA) or similar regulatory authorities for gaining market approval and what the other party's rights will be regarding such regulatory processes.

The parties should consider who will manufacture and supply the product or perform the service that results from the alliance. The biotechnology company may have a strong desire to reserve the right to manufacture the product in order to gain further profit and to control the intellectual property and manufacturing know-how. However, if the biotechnology company does not already have a manufacturing operation in place, it may be costly to establish a new one, often requiring loan or credit assistance and the pharmaceutical may be resistant to relying on an unproven source of supply. On the other hand, the pharmaceutical company may already have manufacturing capacity with greater experience in manufacturing similar products in the past. As another alternative, if neither the biotechnology nor the pharmaceutical company wants to make a manufacturing commitment, a manufacturing agreement can be entered into with a third party. Regardless of the alternative selected, the parties should identify a back-up manufacturer to step in if the primary manufacturer cannot meet demand.

No matter which party will bear primary responsibility for the manufacturing, the terms for manufacturing should be negotiated well in advance of the initiation of the manufacturing activities. Besides deciding who will manufacture the product, the parties should also determine (1) the cost and budget for manufacturing and the transfer price for the product; (2) the quantity of the supply; (3) the facilities where the supply will be warehoused and inventoried; (4) quality control; (5) warranty terms; (6) product liability indemnification and insurance requirements; (7) the term of the manufacturing arrangement; and (8) termination and triggering events. The party without manufacturing obligations may want to reserve the right to take over if the quality or quantity of the manufacturing becomes unsatisfactory. In any event, the parties should keep in mind that the product is likely subject to regulatory control, and therefore impose on the manufacturer the obligations to comply with FDA and other applicable regulatory requirements. The parties should also have a plan for how to deal with FDA inspections or orders regarding the manufacturing process.

Because successful marketing and distribution are vital to a product's success, the parties should address and provide for the following issues: (1) price setting and price adjustments; (2) specification of products covered; (3) geographic or territorial divisions in marketing rights; (4) co-marketing or co-branding efforts; (5) protection of trademark rights; and (6) regulatory compliance concerns, including export control and the regulation of drugs, biologics, and/or medical devices in the various jurisdictions where marketing and distribution are contemplated.

The smaller company often desires to take advantage of the larger company's sales force, distribution channels, and name recognition. However, the smaller company also wants to increase its own name recognition and may desire to achieve that goal by co-marketing and co-branding the product. The larger company may be unwilling to give up too much control regarding marketing activities, especially if the marketing efforts deviate too far from its standard sales protocols. The larger company also may be unwilling to associate its good name with the smaller company's brand. Regardless of whose brand is used, guidelines should be set to ensure that each trademark owner does not lose or dilute its trademark rights.

In addition, the parties also should keep in mind that the marketing and distribution of the products is likely subject to regulatory oversight. Thus, they should consider what and how often commercialization information should be shared between the parties and how they will deal with product complaints, FDA warnings or inspections, any adverse events that may occur regarding the product, and the need for a voluntary or mandatory product recall.

As noted, the activities contemplated by a strategic alliance are often complex and the issues that arise cannot always be negotiated and agreed upon in advance. Therefore, alliances often use steering committees to oversee and manage the development and commercialization activities contemplated by the alliance.

Typically, a management committee is established that consists of top-level executives from both companies to run the alliance. The parties should agree up front to the following: (1) the size of the committee; (2) each parties' representation on the committee; (3) the frequency of committee meetings (for example, quarterly); (4) the procedures and manner in which committee decisions will be made; (5) the procedure for handling dead-locks; and (6) the scope and boundaries of the committee's authority. Responsibilities of the committee often include reviewing the overall progress of the alliance, establishing timelines, dele-

gating responsibility (such as assignment of continuing due diligence obligations), assessing costs and budgets, and addressing various problems that arise. This regular and structured communication between the parties helps to strengthen the relationship.

Similarly, the parties may establish a research committee that consists of scientific representatives from both companies to review the progress of the R&D. Research committees often meet more frequently than management committees in order to conduct scientific reviews of the research and clinical trials, manage the project teams, and address various problems and questions that arise relating to development of the technology. The smaller company should actively promote the alliance through its membership on both types of committees (in addition to having a "cheerleader" or "product champion" with influence who will represent its position within the larger company) in order to keep the project at the top of the larger company's list of priorities.

In addition, the parties may want to set up a manufacturing committee and/or a joint marketing and sales committee. These committee(s) can, among other things, determine what party is in the best position to manufacture the product and the budget for such manufacturing, develop a joint marketing strategy, consider various manufacturing, supply, marketing and trademark issues as they arise, handle customer service issues, and formulate mutually agreeable solutions to such issues.

An important function of these committees that cannot be overemphasized is their role in informally resolving various problems, disagreements, and decision-making deadlocks before they escalate into larger, alliance-threatening scenarios that would require turning to the more formal methods of dispute resolution, such as arbitration or litigation. The parties may decide that in the event of a dead-lock with respect to certain issues, one party or the other will have ultimate authority over the issue, or that the committee chairman will have the swing vote, and that the parties will take turns in appointing that chairman. Alternatively, the agreement may grant each party equal voting power on the committee(s), and rely on escalation of the dispute through each party's ranks and the threat of deadlock to resolve issues. In any event, the alliance agreement often requires mandatory escalation of the dispute through the management committee and then each party's executive team before resorting to more formal dispute resolution procedures.

Additional Intellectual Property Considerations

As continued development and improvements are often the primary goals of an alliance, the parties should address who will own such improvements, who will be responsible for obtaining intellectual property protection on such improvements, and who will have the right to enforce such intellectual property rights.

Determining ownership of improvements and further developments of the technology made during the course of the alliance can become highly contentious, so the assignment of ownership should be negotiated in advance. Often, the party funding the development believes it should own the technology because it paid for the development effort. However, the party performing the development activities may insist on ownership because the improvement is its innovation and may be closely related to its existing intellectual property. When both parties contribute some development activity and some funding for the development effort, ownership may go to the party with the greater interest in the improvement or development and often includes the granting of a comprehensive license to the other party in such improvements.

Sometimes, parties will resolve these issues by agreeing to be "joint owners" of improvements and new developments made in the course of the joint collaboration. However, this may become problematic if the parties' interests in such improvements later diverge. This is because as co-owners (and in the absence of any contractual restrictions to the contrary) both parties will have the right to commercially exploit the improvement any way they see fit *without* the need to obtain the other party's permission for such exploitation. This means that neither party would be able to grant a true exclusive license regarding the technology to any third party. In addition, depending upon how the improvement is protected, the parties may or may not be required to provide an accounting of profits regarding such exploitation to the other party. There may be additional issues regarding how the co-owners deal with prosecution, maintenance, and enforcements of patents on the technology. Thus, while joint ownership often appears as a simple and fair solution to issues regarding ownership, the parties must consider fully what co-ownership rights entail, and whether the parties need additional contractual agreements to limit certain ownership rights in order to further the alliance.

The parties should determine who will be responsible for prosecuting, maintaining, and enforcing not only the existing patents, but also any patentable inventions that arise from the alliance. These activities may include selecting which countries to file patent applications, which patents to continue, which patents to abandon, and which patents to enforce against infringers. While the invention owner often wants to control these activities to ensure its assets are protected, exclusive licensees often insist on controlling these activities because they have a similar position in protecting the assets. Whichever party bears these responsibilities may want to negotiate reimbursement from the other party for the related expenses of patent prosecution and patent enforce-

ment because such expenses can become considerable. On the other hand, the other party may want to reserve the right to take over the responsibilities of patent maintenance and enforcement if the party with primary responsibility does not want, or fails, to do so. Another alternative, particularly for larger alliances, is to establish a patent committee with representatives from both companies to make all decisions regarding patent prosecution and enforcement.

Economic Considerations

Because of the long duration of most biotechnology/pharmaceutical alliances with many potential pitfalls along the way, the parties can choose from a variety of payment mechanisms. With these choices, the parties should tailor a payment scheme that best reflects the particular division of risks and responsibilities in their alliance and is both fair and motivating. Generally, the licensor will want guaranteed payments, preferably at set time intervals, while the licensee will want to defer large payments until the later stages of development or FDA approval when a profitable product is imminent.

Typically, parties will agree on a guaranteed initial payment upon signing the alliance agreement. This upfront payment can be thought of as an access fee or a buy-in fee that the licensee must pay to enter the project. For the licensor, it is a chance to regain at least part of its initial investment in the technology. Of course, the amount of the initial payment, as well as subsequent payments, will vary depending on the stage of development, degree of innovation, value of patent protection, and market potential of the technology.

Subsequent payments are often due upon the achievement of predetermined benchmarks or milestones. Usually, the milestone payments increase at the later stages of development and approval. For the biotechnology company with the primary responsibility for R&D, these payments operate as an incentive for diligence and efficiency, as well as a cash infusion to help cover company costs. Traditional milestone events are based on the beginning of a new stage of development, for example, at the start of preclinical development, at the start of clinical development, at approval of the first NDA or BLA, and so forth up to product launch. Smaller milestones based on the securing of intellectual property rights or advancing through each phase of the clinical trials can also be included to increase the number of payments and better balance the risks.

Later stage payments may be made as royalties based on product sales. Generally, for the licensee, this type of payment is preferable because no amount is due until product development has been successful and revenues are available from which to satisfy royalty obligations. Running royalties are usually defined as a percentage of net sales. Negotiating the terms of the royalty obligation may require lengthy discussion between the parties. "Net sales" should be precisely defined and distinguished from net profits. Royalties are typically not paid on products used during clinical trials or products that are donated. The parties should also consider sales by distributors or sublicensees and whether or not such sales should be considered "final" in calculating royalty payments. Other terms to consider include the duration of the royalty obligation (which is often set for the life of the patent), whether to set maximum and/or minimum royalty obligations, whether to provide credits against royalties, and whether to set tiered royalties. Finally, the party receiving the royalties should require careful record keeping and reserve the right to examine the information being relied on to calculate royalty payments.

In addition, the parties may decide to split the expenses incurred in developing and commercializing the product, rather than having each party bear its expenses incurred in performing such activities. This may help balance the parties' risks and rewards when on balance one party is performing more development or marketing activities than the other, or when it is unclear at the onset of the alliance who will bear the major share of responsibility for these activities.

If the parties decide to use a cost-sharing approach, the agreement should include mechanisms for setting up a maximum budget for those costs, limits or parameters around the price associated with full time employees who perform such activities, reconciliation provisions, and audit rights so that the parties can confirm the costs incurred by the other party.

Alternatives to strict cash payments include equity investments, loans, and loan guarantees. An equity investment by the larger company in the smaller company can have many variations. Often the stock will be purchased at a premium price. The stock can be common or preferred, with or without further stock options or warrants. Payment for the stocks can be in the form of a lump sum or by periodic installments. It is important to remember that in any equity investment, the parties must comply with federal and state securities laws. In addition, any tax consequences of an equity investment should be considered. Loans and loan guarantees have their own sets of terms that must be negotiated by the parties. Terms to consider include whether the loan is secured or unsecured, full or limited recourse, convertible into equity, and/or forgivable on the achievement of certain specified milestones. In either case, the company providing the funds should establish measures that enable it to ensure that use of the proceeds is limited to furthering the purposes of the alliance.

Just as the term of the alliance should be set forth in the agreement, so should provisions detailing the triggers for termination. These provisions should identify circumstances that justify termination, the party entitled to terminate, procedures for termination in whole or in part, and the effect of termination on the rights and obligations of each of the parties.

The common triggers for termination include (1) material uncured breach or other type of default; (2) failure to meet certain milestones; (3) a change of control in the other party; (4) force majeure; (5) a deadlock; or (6) mutual agreement. Triggers for termination should include applicable notice periods, and if related to a curable breach, permit the breaching party to cure the event within a specified period before the other party may terminate.

In addition, the parties may want to permit either party to terminate the agreement for convenience after some date or event has occurred or some event has failed to occur. Circumstances under which termination for convenience is acceptable should include terms for reimbursing or compensating the other party. Establishing these thresholds to exit creates an incentive for the parties to try to resolve problems and continue the alliance.

In any event, the parties should specify the effect of termination on each party's rights and obligations. Effect of termination provisions often address what continuing rights, if any, each party has to the licensed technology, how the parties will deal with jointly owned technology, who may or will handle manufacturing, supply, marketing and distribution of the product after termination, who will be responsible for any wind down or other costs, whether any transition services need to be provided from one party to the other, and whether either of the parties has any additional remedies based on the reason for termination. The agreement will often also address whether either party will be subject to a non-compete for some period of time after termination regarding the subject matter of the alliance.

Representations and Warranties

Care should be taken to balance the representations and warranties needed to give each party comfort to move forward with the alliance with the parties' desire to limit their respective representations and control liability exposure. Because these alliances often involve contributions of intellectual property and services from both parties, each party's representations and warranties often mirror those of the other party, and this reciprocity helps to achieve such a balance. Typical representations and warranties include general corporate warranties (*i.e.*, duly organized, due authorization, binding agreement, etc.), adequacy of intellectual property right and some form of non-infringement warranties, warranties regarding ownership and confidentiality of technology to be developed under the agreement, and warranties to follow good laboratory practices, good clinical practices, and good manufacturing practices, as well as general compliance-with-law warranties. Both parties often desire to include disclaimers of all other warranties, whether expressed or implied.

Indemnification

The parties should consider the types of third party liability claims that may arise in connection with the activities proposed by the alliance, and determine if either party should indemnify the other in the event of such a third-party claim. Potential third-party claims include, among others, intellectual property infringement and product liability claims. In reaching a compromise regarding each party's indemnification obligations, the parties should consider which party is best able to mitigate the risk of such a claim.

Dispute Resolution Procedures

Unfortunately, the most cost-effective means for resolution of disputes, voluntary settlement by the parties, often fails. Because the parties are likely to agree on very little when they are unable to resolve a dispute voluntarily, litigation will likely be the only available avenue to resolve the dispute unless the parties have provided in their contract for a different alternative.

Usually in these alliances, the parties will specify an escalation procedure for such disputes that runs through the steering committees and up to the executives in each company before either party can resort to more formal dispute mechanisms. In determining whether to request binding arbitration versus litigation as the formal dispute mechanism, a need for expert fact-finding, confidentiality of the proceeding, and enforcement of a judgment against a foreign party may argue in favor of binding arbitration; the potential need for injunctive relief argues against it. However, the right to seek injunctive relief can be reserved in an arbitration provision; usually, arbitration is preferred.

Conclusion

In preparing for and negotiating a strategic alliance in the biotechnology industry, it is vital that the parties do their homework. Before investing heavily in the negotiation process, the parties should understand their own as well as their proposed partner's strengths, weaknesses, and goals for entering into the alliance. In addition, the parties should perform thorough due diligence on the science and the intellectual property that protects it as this is one of the prime value enhancers of the alliance, as well as continued due diligence on the proposed partner generally. During the negotiation, the parties should seek clarity to ensure that the alliance obtains the rights it needs to succeed without jeopardizing the future of either of the parties. A deal that by its terms continues to provide substantial incentives to both sides will increase the chances of sustaining a long-term arrangement.

Finally, the negotiating parties should keep in mind that finalizing the contract is only the beginning of

the alliance. Often, the nature of their negotiations (*i.e.,* friendly and cooperative or contentious, etc.) will carry forward into the alliance. If disagreements subsequently arise, which they invariably do, a tone will have been set during the negotiations as to how to deal with future issues.

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