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Fierce Pharma Competition Fosters Partnerships

Important issues to consider in pharmaceutical-biotechnology alliances

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More than ever, the pharmaceutical industry has become extremely competitive. Large pharmaceutical companies battle to be the first to market with new products, the first to achieve maximum market penetration and the first to create barriers to competition sufficient to provide the freedom to operate. However, pharma companies face an industry-wide product pipeline crunch, patent expiration on key products and increasing drug development costs. Often pharma companies attempt to overcome these and other obstacles and increase or maintain their competitive advantages by entering into strategic alliances with smaller biotechnology companies. In connection with the alliance, the biotech company contributes proprietary technology and patent rights. The pharma company receives access to rapidly developing science and new, innovative products; this access may help the pharma company maintain or increase its competitive advantage.

Likewise, a strategic alliance benefits the biotech company. To bring a new drug to market is an extremely expensive and arduous process, involving millions of dollars and many levels of regulatory approval. Biotech companies often initially obtain financing through venture capital investments. However, as the company grows, the expenses of clinical trials and scientific development are usually too expensive for a venture-capital financed company. An alliance with a pharma company provides access to this much needed capital. In addition, the alliance provides the biotech company with access to the pharma company's regulatory expertise and research and development, commercialization and marketing capabilities. These relationships have become so important to biotech companies that a strategic alliance with one or more pharma companies is a critical part of most biotech companies' business plans.

Previously, pharmaceutical-biotechnology alliances typically involved late-stage products, where regulatory approval was imminent. However, because of the high financial cost to the pharma company associated with these deals and the relative scarcity of late-stage products available, they now often look towards less expensive early stage deals, once thought too risky with a high degree of product failure. These earlier-stage deals include more cost and profit-sharing. This sharing model allows the smaller biotech company to actively participate in the project and retain some control over critical development decisions, such as early-stage clinical trial specifics and regulatory approval.

As a result of the trend towards a sharing model, in addition to the underlying licensing arrangements, co-marketing, co-promotion and co-development arrangements have become standard practice in pharmaceutical-biotechnology alliances. Co-marketing provides for the independent simultaneous sale and marketing by the parties of a defined product under different trademarks. Co-promotion, on the other hand, provides for the sale and marketing of a product under a single trademark, with cooperation between the parties in commercializing the product. Pursuant to a co-development arrangement, the parties cooperate to develop the product.

With co-promotion and co-marketing alliances, the biotech company can bargain for the right to participate in the marketing and promotion of its drug product, often in the U.S. market — the largest pharmaceutical market in the world. Co-development allows the smaller biotech company to retain control over part of the development process — a win-win for both parties. The pharma company can leverage the biotech company's expertise in ongoing and future R&D, without substantially increasing internal costs. The

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biotech company is able to retain some level of control over the clinical development and, sometimes, launch of the end product.

In determining whether to enter into a strategic alliance, management of both companies must consider a number factors, including: (1) the existence of a shared product strategy between the parties; (2) opportunity costs — that the alliance may take capital and resources away from other projects; and (3) service levels and partnering support — understanding what the other company can and will bring to the table in terms of attention, resources and an understanding of the therapeutic and market potential of the product.

Once the parties have decided to partner, they are ready to enter into the proper agreements. General legal considerations in the pharma-biotech alliance include:

• Scope of license. A license grant by the biotech company to the pharma company typically includes the right to "make, use and sell" the product or products emerging from the alliance. It is important to identify the relevant intellectual property and related "know-how" covered by the license and whether the license is exclusive or nonexclusive. Other important licensing scope issues include the duration of the license and the right, if any, of the pharma company to sublicense or assign the license and/or manufacture of the product. In addition, cross licenses and licenses with respect to future developments should be considered.

• Development. The parties must agree upon which party will control and pay for ongoing research and future developments. Often, representatives of the parties form a steering committee to control such development. Preliminary rights and obligations to develop the product are often allocated to the biotech company, with such rights and obligations shifting to the pharma company during later stages of development.

• Pharma's "due diligence" obligations to commercialize. The pharma company should have a due diligence obligation to use at least some minimum level of effort to commercialize the underlying product. This is especially important to the biotch company if a significant portion of the financial consideration that it will receive from the pharma company is tied to royalties on sales of products. Typically, this due diligence obligation is tied to a "commercially reasonable" or "good faith reasonable efforts" standard and is often based on the particular country or region at issue.

• Payment, expenses and risk allocations. The long lead times before a product comes to market, if at all, makes for difficult financial calculations. Considerations typically include the technology type, whether the underlying patents are issued or still pending, alternative technologies, exclusivity, anticipated regulatory hurdles and anticipated litigation. Payment by the pharma company may include an upfront fee (which provide the biotech company with a quick, often needed, infusion of cash and allow the biotech company to recoup some of its investment to date), equity investments (common stock or a special class of preferred stock), milestone payments (which are typically critical revenue generators for the biotech company and are often triggered by the commencement or successful completion of the various phases of the regulatory approval process) and/or royalties on product sales. Royalty terms, in particular, can become very detailed, including concepts such as floors and caps and also reductions and cutbacks in the royalty payments under certain circumstances. Additionally, the financial terms may include loans or financial guarantees by the pharma company.

• Change of control. A critical provision to the biotch company is its ability to transfer the license or other applicable agreements in connection with a change of control of the biotech company. A sale of its assets or business is a fundamental aspect of the biotech company's business plan and the owners' (including venture capitalists) exit strategy. A restriction on the biotech company's ability to transfer the license or other agreements (or the termination thereof upon a change of control) without the prior approval of the pharma company could have serious ramifications on the ability of the company to consummate a sale. If such a restriction is included, it is advisable to the biotech company to also include limitations on such right of consent. For example, such consent right could be subject to a "reasonableness" standard or could be inoperative in the event that the sale of the biotech's assets or business is to a financially and otherwise qualified third party.

• Patents control and costs, etc. Responsibility for patent prosecution (beginning and pursuing the application process) and maintenance is usually linked to ownership. With nonexclusive licenses, a licensor generally retains control of and pays for patent prosecution. By contrast, where exclusive rights are granted, patent prosecution responsibility may run with a licensor or licensee. Universities and nonprofit licensors often require licensees to pay the patent costs. The parties must also allocate which party is responsible for initiating enforcement proceedings against third-party infringers. Often, where the party with responsibility for enforcement fails to abate (lessen or reduce) infringement within a reasonable time (usually 60 to 90 days), the other party has the right to sue.

• Indemnification and insurance. Indemnification and insurance provisions should be included in alliance agreements. Typically, the pharma company bears the responsibility for product liability claims and agrees to indemnify the biotech company for resulting losses. However, when the biotechnology company is also the manufacturer of the product, as is sometimes the case, the biotech company will bear product liability for manufacturing defects. Where the parties share risk, indemnities are likewise shared.

A strategic alliance can be critical to both the pharmaceutical company and the biotechnology company. With properly aligned objectives and synergies, both parties can benefit and realize goals that they would not be able to realize alone. ■