Evolution of a Bio-Product The Biotech life cycle: a primer.

THE COMPLEX PROCESS OF TAKING A BIOTECH PRODUCT TO MARKET REQUIRES A GENERAL COUNSEL OR lead outside business lawyer who takes the long view to product development and understands the need for different types of legal expertise along that path. With this focus on expertise, the biotech life cycle can be divided into four phases: start-up, early development, later-stage development and product approval, and maturity.

PHASE I: START-UP

The start-up phase has two distinct elements: idea inception and company formation. Ideas drive biotech companies, which convert scientific discoveries into products. Significant investment is necessary to grow and protect the intellectual property.

■ IP Protection

Failure to protect IP creates great risk and can foreclose future business opportunities. It is important to find IP counsel with appropriate expertise (patent, trademark, and copyright) and involve them early in both product development and strategic business planning. IP planning involves more than just the specific product. Early involvement helps to find gaps and protect related products and applications.

■ Company Formation and Investment Capital

Strategic biotech company formation is critical to keeping the company, its key executives, and its scientific brain power together for the entire life cycle from idea formation to market, which can take more than ten years. Counsel must think ahead in setting up and planning adjustments to corporate form in order to anticipate the future business issues. Pick outside counsel who offer sophisticated advice in technology and capital markets, and in the legal risks associated with new investors. The challenge is to form a company that protects the founders' interests while also remaining flexible and attractive to essential investors.

JAMES STEINBERG

■ Management

Outside counsel often can assist in finding senior management candidates and selecting a strong board of directors and science advisory board. The right combination of business and scientific management will help guide the company during the tumultuous early years and create a business détente between investors and inventors.

PHASE II: EARLY DEVELOPMENT

Phase II is marked by the start of the regulatory process, the all-important search for development partners and investment, and the transition from an informal effort to a complex organization.

■ The Regulatory Path

Regulatory approval usually requires years of testing and trials. Missteps in developing agency relationships or complying with regulatory protocols can cause serious delays that strain the time/money critical path (the company's ability to maintain its schedule and meet its funding deadlines in time to satisfy its developmental and regulatory obligations). A Food and Drug Administration legal expert can help the company plan for this process and appropriately place the product within FDA guidelines.

■ Business Growth and Complexity

Once the fledging biotech company

grows beyond the founders, it becomes a more complex business organization, complete with employees and consultants with their own agendas. Employee and consultant agreements that reward success, as well as protect IP and avoid competition, are critical. Courts generally disfavor noncompete agreements, so it is important to tailor such agreements narrowly to the company's specific needs. These preventive efforts may not stop the departure of brain power but might prevent loss of critical IP.

PHASE III: LATER-STAGE DEVELOPMENT AND PRODUCT APPROVAL

The earlier phases of the process are a mere warm-up for the all-crucial clinical trials and agency approval. Navigating clinical trials requires legal proficiency in various regulatory disciplines and a great deal of money. In addition to FDA approval (and European Medicines Agency approval, where needed), the company often must satisfy other agency requirements and ensure that the product is thoroughly vetted for reimbursement approval with Medicare, Medicaid, etc. FDA approval requires the company to satisfy research protocols, product testing, clinical trials, record keeping, marketing, labeling, and packaging. Business counsel will need support from additional lawyers in these specialties.

PHASE IV: CHALLENGES FACING THE NOW MATURE COMPANY

Successful completion of clinical trials is not the last regulatory hurdle to market entrance. Postapproval regimens require extensive monitoring, record keeping, and reporting of trends in treatment. In addition, marketing usually requires partnership with local distributors or combination treatments with other products.

■ Commercialization

An approved product makes a company more attractive to outside investors and other large established biotech corporations. This is the point at which many biotech companies investigate strategic alternatives, such as a merger or initial public offering. In addition, the international marketplace requires compliance with separate regulatory schemes in each new jurisdiction. Since the company's exclusive IP right to produce and market its product is limited to a term of years, "stand still and die" should be a warning for every biotech company. The company must leverage that limited monopoly through marketing licenses, additional product applications, and new follow-on products. Achieving these objectives requires a legal team effort.

■ Litigation

In addition to typical civil litigation, biotech companies often face claims relating to IP rights, licensing or marketing rights, and the safety of the products. The commercially successful product may entice infringers. A strong IP enforcement program can deter infringement and increase company value. Likewise, continuous monitoring of product performance coupled with responsible action can deflect potentially crippling product liability suits, protect the brand, and ensure customer and investor confidence.

CONCLUSION

Biotech has expanded from the largely exclusive realm of a few major corporations and research organizations to include a multitude of new biotech entities looking for a stake in this boom. Biotech legal practice involves specialized subject matter and regulatory schemes that are not part of most counsel's repertoire. Knowing when to consult other legal experts is critical to the long-term success of the biotech company.

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