Intellectual Property Strategies for Chinese Biotechnology and Pharmaceutical Companies

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Importance of Intellectual Property

Intellectual property ("IP") rights are critical in today's knowledge-driven economy. This is especially so in industries where innovation and creativity define and drive commercial success, such as the pharmaceutical and biotechnology industries. For many Chinese pharmaceutical and biotech companies that are in the initial phase of transformation from generic-focused to innovation-driven, effective patent strategies are critical to global competitiveness and long term commercial success.

Why Need Good IP Strategies

Innovators distinguish themselves from imitators through innovative products. Patent protection of unique products allows the innovators to enjoy exclusivity in the market place. Such patent-derived exclusivity enables the innovators to protect their competitive advantage and enjoy business leverage against competitors. Companies that develop a new technology can use patent positioning to protect its investment in developing the new technology and the corresponding products. Competitors and customers alike must deal with the innovators in order to gain access to the new technology and related products. As such, patents also help companies build their credibility and standing in the industry.

Having a portfolio of well-crafted patents and patent applications covering marketed drugs and drug candidates under development are hallmarks of innovative biotech and pharmaceutical companies. Biotech and pharmaceutical products typically take a long time to develop, usually ten years or longer, and a large amount of capital investment, averaging over $800 millions. The drug candidates also have a high failure rate as they move through preclinical and clinical development and regulatory review process. Therefore, effective and reliable long-term protection through patents is a key component of the commercialization plans for biopharmaceutical products. Biotech companies and investors alike need the assurance of strong patents to justify the large amount of investment of capital and human capital.

Biotech companies, therefore, are well advised to develop and execute an effective patent strategy designed to help the company in various aspects of its business, including fund-raising, R&D collaboration, market and commercial planning, and product life cycle management.

An effective patent strategy and its successful execution may also allow alternative commercial strategies, such as out-licensing, where a strong IP position is necessary. This is especially true when a company owns a platform technology desired by others. Some companies have been able to build themselves through licensing and collaboration on core technologies, such as on PCR, phase-display, and RNAi.

In parallel to patent protection is freedom-to-operate, i.e., a product is clear of third party patents. Lacking freedom-to-operate could potentially paralyze a product. Cost and uncertainty of litigation, risk of product delays and treble damages if the product is found to infringe a third party patent after product launch are potentially debilitating to businesses and must be addressed effectively and timely. Freedom-to-operate, therefore, is critical to the viability of products and should be assessed objectively with advice of competent patent counsel. Imagine a product that is finally approved for marketing after many years of development only to be found to infringe a third part patent. Biotech executives should be wary of such IP traps that could derail development and commercialization effort and address them as early and as effectively as possible. Thorough and continued IP landscape monitoring and review is advisable, especially in connection with each milestone decision on the future of a program or product candidate.

What Are Effective IP Strategies

A common hallmark of effective IP strategies is that they advance business objectives. For biotech and pharmaceutical firms, IP should be viewed as a business tool. The issue to address is how to use IP to advance the business goals, and as such, IP strategies and patent portfolio development should be driven by the short, medium and long-term business needs. A company should integrate IP as part of its product development plan.

For example, timing of venture financing and business development could in certain ways impact one's strategy on patent portfolio development. Timing and subject matters of patent filings and licensing should address partnership and corporate development needs. Scope of patent claims are preferably both offensive and defensive. Thus, IP should be developed to protect one's current and future business interests, opportunities and products and, to the extent possible, products of key competitors. This should be carried out with a good understanding of the commercial landscape, the competitors, and the competing technologies.

Good IP strategies, therefore, identify and address patent protection as well as freedom-to-operate issues and develop leverage against identified present and potential threats. To the extent in-license needs and/or opportunities are identified, management should work with legal counsel to evaluate them, along with any design around options. Many times companies ignore IP risks and potential fixes (through licensing or design-around, for example), only to pay a dear price later.

Good IP strategies also identify any potential need for IP enforcement and prepare accordingly. Patent enforcement decisions should be guided by business objectives. Options other than litigation should be evaluated before litigation is initiated, for example, licensing and collaboration. In the context of patent infringement litigation, one should know the strengths and weaknesses of a competitor's IP as well as that of its own.

How to Achieve Effective IP Strategies

The first and most important step in achieving a good IP strategy is for the chief executive of a business to recognize the importance of IP and obtain competent legal advice from an experienced counsel. Senior management should view IP as a powerful business tool that they can use to their advantage, rather than thinking about IP as simply a cost center or even a business nuisance. The question for the IP counsel is how IP can help the business objective, which often means how to use IP to build and protect the immediate and long-term value of the business. Effective communication between senior business, technical and legal functions is important. As many small and mid-size companies do not have in-house legal or patent capabilities, retaining experienced outside counsel can help with crafting and executing winning IP strategies. In this regard, the outside counsel should be familiar with the competitive landscape of the industry in which the company operates as well as the relevant technologies, products and the commercialization plan. Be wary of patent lawyers

who focus on the technology alone without considerations of how the technology impacts the business. A solid understanding of the products and the competitive market landscape is important to provide effective legal advice.

IP and Biopharmaceutical Innovation

IP often is a critical factor of the commercial viability of many therapeutic or diagnostic products. Product development in the biopharmaceutical industry usually entails large capital requirement, long R&D and clinical trial processes, uncertain regulatory outcome, and un-forgiven investors and capital markets. IP, therefore, should be an essential part of milestone reviews along the development path. The goal should be to identify and evaluate a product's IP-related strength and weakness. Any issues identified should be timely addressed.

Sometimes a drug developer learns, during the discovery or development process, that certain third party-owned patents could potentially cover a drug candidate. In such circumstances, a thorough review of the IP landscape is critical and strategic in-license opportunities, design-around options, and validity of the third-party patent should be evaluated. If any third-party patent is key to the future IP position of the drug candidate, efforts should be made to investigate and evaluate the impact and availability of the IP and potentially secure such position before substantial capital is invested in the compound.

Ignoring a serious IP issue of a drug program could be detrimental and potentially fatal to the business future of a biotech company. Because of regulatory and financial reasons, biotech companies often must partner with pharmaceutical companies in order to move a compound through clinical trials and FDA regulatory approval. Any patent weaknesses (e.g., lack of appropriate protection or freedom-to-operate risks) are likely to be identified by potential collaborators during their IP due diligence prior to the closing of a deal. Thus, it is important for a biotech company to review proactively what its IP needs are, what it already has and does not have, and what the strengths and weaknesses are.

When entering into a partnership or collaboration with regard to a drug candidate, it is important to structure the deal such that the parties know exactly what their rights, responsibilities and benefits are from the deal. Among the critical aspects of such deals are the ownership of the IP generated from the collaboration, the nature and scope of the license or the option to license, commercialization rights, geographical and field of use restrictions, as well as milestones and downstream royalties.

Patent Protection for Therapeutics and Diagnostics

For new therapeutic agents, the best patent protection is often composition-of-matter claims on the active agent itself which, supplemented by use and/or formulation patents, can provide strong protection against potential generic challengers or me-too drug developers. Sometimes, composition-of-matter claims are not available because the active compound is a natural product or a known compound. In such situations, patent protections often must be based primarily on use or formulation patents. If the intended use of a natural product is also known in the prior art, one could be left with limited protections from so-called "secondary patents," for example, patents with formulation and dosage claims. Thus, before embarking on costly clinical development, one may wish to explore medicinal chemistry of the candidate, for example, to see if it is possible to develop a modified candidate with fresh, attainable and defendable IP position.

Another important consideration for a biotech company is the global nature of drug development and commercialization. The complete value of a good drug is tied to the geographic reach of the underlining patents. Given the fact that the United States, Europe, and Japan remain the largest pharmaceutical markets, lack of solid patent positions in these markets will severely impact a drug's commercial value and desirability to global pharmaceutical companies, which are often the desired partners to biotechnology firms. The drug markets of China, India, Brazil, and Korea are fast growing, joining the ranks of Australia and Canada as the second tier markets. Patent protections in these countries are becoming more and more important, and depending on the target diseases, could be the primary markets as well. Global patent portfolio development strategies, therefore, should be

consistent with the overall commercialization objectives and the specific characteristics of the drug program at hand.

With regard to diagnostic products, patent protection can sometimes be different from therapeutics. Having composition-of-matter patent protection on an underlining biomarker would still be the preferred protection. Often times, however, the innovation is not on the underling protein or nucleic acid biomarker but rather on either the detection probes or the analytical or data processing components of the diagnosis process. One needs to determine how best to approach IP protection in light of the specific target analyte, the biological process underling the diagnosis, the data analysis software, as well as the detecting agents. Strategic in-licensing of critical patents, for example on the underling genes and gene products, often is critical to a solid patent position.

Conclusion

Patent protection and freedom-to-operate are important aspects in developing and commercializing biotech and pharmaceutical products. For the Chinese pharmaceutical and biotech companies striving to become leading innovators in this global industry, developing and implementing effective IP strategies are critical to sustained competitiveness and long term commercial success.