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PERSPECTIVE

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Life sciences startups: patent, FDA considerations

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Innovator companies at all stages seek patent protection in order to limit market competition. Many early-stage companies seek patent protection with the additional goal of attracting investment. However, even if patent filings are accelerated in order to raise funds, it is important that early-stage companies not discount the value of developing a thoughtful and comprehensive IP strategy from the outset. Careful IP planning is especially important in the life sciences, in which companies often rely on only a handful of patents to protect a high-market value product such as an FDA-approved drug. In one aspect of this planning, close attention to the interrelationship between patent and FDA regulatory considerations may not only improve a company's ability to protect its most valuable assets over the long term; it may also increase an investor's confidence in the entrepreneurs and the technology, thereby increasing the scale and likelihood of investment.

Patent Term Extension

Life sciences companies must balance the advantages of early patent filings with the realities of a regulatory process that requires years of research and clinical trials before a product may enter the market. It is not uncommon for more than half of the 20-years-from-filing term of a patent to elapse before a new drug is approved. Where FDA approval is the first marketing authorization for a drug, biologic, or medical device, Patent Term Extension (PTE) may prolong the term of a single patent by up to an additional five years. The protection during the PTE period of a patent is limited to coverage of the approved product. However, this can translate into millions or even billions of dollars for a successful product.

The length of PTE available for a given patent is based on the time consumed by regulatory activities that occur after issuance of the patent and until marketing approval. It is advantageous to have PTE attach to the strongest, most enforceable patent in the portfolio, which is often the patent that claims the specific composition of matter (e.g., the specific drug compound, biologic, or medical device per se). Prioritizing the early issuance of such a patent can provide a basis for a lengthy and strong term extension. If it is not clear early on what the lead product will be, a strategy that employs multiple, staggered patent filings may serve to maximize flexibility as a research program progresses. Close attention should be paid to the anticipated publication dates of the various patent filings, to minimize the risk that a company's own patent filings will be available as invalidating prior art against later filings.

Even if an innovator company seeks to extend market exclusivity via life cycle patent filings directed to formulations, crystalline forms, methods of preparation, or new methods of use, these later patents may be weaker or easier to design around compared to the early composition-of-matter patents. Investors will sometimes discount the value of such later patent filings, and therefore it can be important for early-stage companies to have significant PTE available to extend the term of the key composition-of-matter patent for as long as possible. Furthermore, PTE can provide substantial value independent of regulatory exclusivities, in that the PTE period can potentially extend beyond the regulatory exclusivity period, a generic manufacturer has to contend with the threat of costly patent litigation, and the scope of protection is not limited to data exclusivity, as is the case for some types of regulatory exclusivity.

PTE considerations are sometimes overlooked in licensing transactions for early-stage companies, even though there can be a significant impact on the marketing exclusivity period. When in-licensing technology from another company or a university, the agreement should explicitly address who will be the marketing applicant and who will control the choice of patent to be awarded PTE. This is particularly important if the license has a limited field of use, such that more than one entity may have an opportunity to become the first marketing applicant. Similar considerations apply to the out-licensing of technology, especially if the licensor company is developing a compound in-house for some clinical indications and out-licensing it for others.

Orange Book

Patents covering an approved drug substance, drug product, or method of using the drug may be listed in the FDA's Orange Book. This can be of immense value in protecting pharmaceutical products from competition, as it can delay the FDA's approval of a generic version of the drug by 30 months if the patentee opts to enforce the patents through litigation. If the drug is also entitled to New Chemical Entity exclusivity, this 30-month period may not even begin until four years after the first approval. Thus, the Orange Book, listed patents can serve to keep generics off the market until at least six-and-a-half years after the first approval.

In order for patents to be listed in the Orange Book, they must correlate with the product label. Early on in the development of a drug, when the precise label formulation and indication are not known, the focus may be on obtaining patents directed to the drug compound itself, general pharmaceutical compositions, and a variety of methods of use. In later stages of drug development and clinical trials, the focus may shift toward obtaining patents to specific formulations and methods of use that closely and narrowly match the language of the product label. Due to the length of the drug development process, a strategy of filing successive continuation or divisional patent applications will preserve opportunities to obtain additional patent coverage that closely matches the product label as approval nears. This approach has the added benefit of maximizing opportunities to obtain additional patent coverage in the event a patent is challenged in inter partes review or other post-grant procedure.

If there is a possibility that the drug will be approved for more than one clinical indication, it is advantageous to have patents covering each of the approved indications. This is particularly important if there are no drug-substance or drug-product patents available for Orange Book listing, or if such patents would expire before the end of the 30-month stay of the generic manufacturer's marketing application. If only method-of-treatment patents are listed in the Orange Book, and there is an approved indication for which there is no patent coverage, a generic manufacturer can avoid the 30-month stay entirely by seeking approval for only the non-patented indication. Because Orange Book listing of the portfolio patents impacts the ability to exploit certain exclusivities and litigation advantages, investors often want to see how an innovator company's patent strategy takes advantage of these opportunities.

Whether the long-term trajectory is for an acquisition or an IPO, attention to the interplay between patent and FDA regulatory considerations can signify to potential investors that a life sciences company has a comprehensive understanding of how to maximize its future market position and create value.

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