Legal Times
WEEK OF JUNE 20, 2005 • VOL. XXVIII, NO. 25
ALM

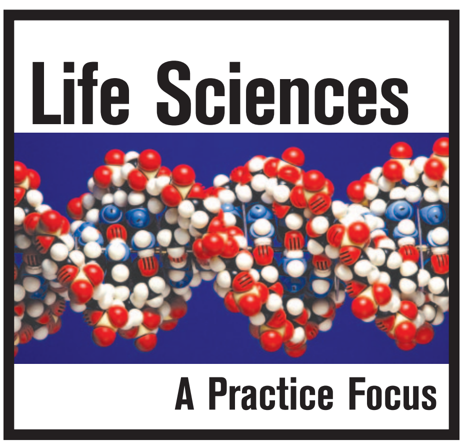
How to Set a Patent Strategy

To add the most value, companies need to do more than file applications early and often.

By Geoffrey M. Karny

Getting a new drug to market may cost as much as $800 million. With this type of investment, patents are necessary to protect market exclusivity.

But patents provide a company with much more than the opportunity to protect a market space or product franchise. Patents provide potential leverage for obtaining cash, technology, and desired collaborations through licensing. They are also attractive assets to potential investors, collaborators, and acquiring companies. And they can help remove roadblocks set by third-party patents through cross-licensing.



The maximization of such value requires a strategic approach by the company and its patent counsel, and that approach needs to be much more sophisticated than simply filing patent applications early and often. It also requires a significant additional investment of money, but that investment will be paid back many times.

Such a strategy must be based on the company's business model and its business plan. It also must take into account the larger picture of the company's business environment and its endgame.

But grand strategy alone is worthless without implementation. Patent counsel must work with senior management not only to develop the strategy but also to develop the procedures and infrastructure to implement it.

Consider the case of a startup biotechnology company. Frequently, the company begins by obtaining a license for its initial core technology from a university and then develops and enhances that technology through its own research and development efforts. Eventually, the company seeks to partner with a large pharmaceutical company for further research, development, regulatory approvals, and marketing. What should patent counsel be doing to help this type of company maximize the value of intellectual property?

Due Diligence

The first step in the patent strategy comes when the company begins negotiations to license its core technology from the university. It starts with a strategic analysis of the patent rights supporting that technology, typically through a due diligence process.

For reasons of cost and time, senior management may be satisfied with only a limited due diligence. The company's transactional counsel might see this as something that patent counsel does near the end of the deal with a simple checklist to fill out. But in view of the importance of the asset being acquired, the significant upfront fees and other considerations often associated with such license agreements, and the fact that such due diligence should begin the development of the company's patent strategy, patent counsel should encourage senior management to start the process early and to devote sufficient resources to it.

Such due diligence is fairly straightforward. The ownership and chain of title for the patent rights need to be confirmed. Any potential restrictions must be identified, including not only financing liens filed under the Uniform Commercial Code, but also restrictions arising under other license agreements that may be related to the technology.

Moreover, the patent rights need to be examined to assess their realistic scope and significance. Obviously, the company has already decided that the rights are critical to its business strategy. But the company's understanding of these rights is all too often based on cursory readings of the titles and abstracts by businesspeople and scientists, rather than on a careful analysis of the claims by patent counsel. That legal analysis should also include an analysis of the patent application file histories to identify any potential impairments.

Finally, patent counsel should conduct a "freedom to operate" assessment of the technology. Any third-party patent rights that might be infringed by the use of the technology must be identified and analyzed. Often, this analysis is rejected for cost reasons, although the $5,000 to $10,000 for the search and initial review of third-party patents is not great compared with the total legal costs for the licensing transaction.

Entrepreneurs may also have a misguided notion that a startup company will operate under the radar screen. But any future big pharma collaborator will insist on doing this kind of due diligence on the company's technology, and thus the company can never hope to escape scrutiny on these issues.

Of course, good due diligence can add significantly to the legal costs involved in the transaction. Yet it can provide dividends not only down the road but also today. A sound understanding of the value of the intellectual property rights being licensed provides a basis for rational pricing of the deal and offers leverage in negotiating with the licensor for a reasonable price.

Developing Strategy

Transactional due diligence leads naturally to the development of a detailed patent strategy that will guide the company by setting goals and priorities. One of the first outcomes of due diligence may be the identification of gaps in the patent portfolio or of potential blocking patents that may impede the company's ability to exploit its technology. The gaps may be filled through additional licensing or the company's research and subsequent patenting. The problem patents can also be addressed through licensing or other legal strategies.

Another outcome of due diligence may be the identification of weaknesses in the patent applications themselves. Applications from universities can be especially problematic. Since patent filing decisions are often made before a licensee has been identified, there is significant pressure to keep costs down. Moreover, there may have been limited time to prepare the application. Many a tech transfer person has had to scramble to get an application filed after learning that a professor will be speaking at a conference the next day. The company may choose to overlook these weaknesses to get the deal done, but they still must be addressed going forward.

Beyond the initial results of the due diligence, a strategic plan represents an ongoing process that evolves as the company's business plan evolves.

One basic issue is what to patent. The plan should define categories of technologies that are specific to the particular company and, starting with core products, determine how aggressively to pursue patent protection for each category. With respect to tangential technology, for example, the company may only be interested in protecting its own freedom to operate; therefore, it may file only a limited number of "defensive" patent applications and, perhaps, only in the United States.

The plan should also set decision-making criteria for each point in the process of obtaining a patent. For example, what factors will the company consider before filing a provisional application in the United States, and before filing counterpart applications in multiple foreign countries?

In addition, the plan should provide a long-term approach for identifying and neutralizing third-party patent rights that may block research, development, or marketing of the biotech's products.

One of the most important tasks of patent counsel in developing a plan is to obtain senior management buy-in. The patent strategy must reflect the larger business plan. This sounds obvious, but is often given insufficient attention as patent counsel gets caught up in routine filing and prosecution.

A more difficult step is assessing certain intangible aspects of management's attitude toward intellectual property. For example, how willing is management to litigate or take other steps to enforce the company's patent rights? A litigation-averse management may require the development of quite a different strategy from that provided to a management that will aggressively enforce its rights.

Implementing the Plan

Great strategy is useless without implementation. One effective implementation tool is an intellectual property committee comprising senior scientists and businesspeople along with patent counsel. This committee should meet regularly to consider matters such as potential new patent filings and maintenance of existing rights. Patent counsel can also consult the committee as larger issues arise in developing the general strategy.

Another useful tool is a yearly review of the patent portfolio for purposes of overall planning and weeding out marginal applications. In this context, it is helpful to have historical cost figures for each patent family and to develop projected costs for the next one to three years.

A few additional points are worth noting. First, while consensus is fine, a cost-effective strategy should be based upon final approvals by the businessperson or head scientist responsible for the product or area of research. If such a person cannot see the value added by a particular patent application, for example, it probably should not be pursued.

Second, it is important to look at the total estimated cost of obtaining a patent on a particular invention. Too often, the focus rests instead on the cost of the very next filing—for example, the $5,000 to file an initial Patent Cooperation Treaty application—instead of the $200,000 to $300,000 that will ultimately be required to obtain reasonable foreign protection on a single biotech invention.

Third, it is usually a mistake to pursue marginal applications under the notion that someday the patent rights could be licensed to another company. In a small biotech company, that is highly unlikely to happen, despite the best of intentions, because the business development people only have time to pursue major transactions.

If a biotech company has developed and implemented an intelligent patent strategy and has successfully done the many other tasks necessary to develop its products, then the company is ready for its collaboration with big pharma.

It can be certain that a large pharmaceutical company will do a comprehensive, across-the-board due diligence, including a very careful look at all the relevant patent rights. At this point, however, the biotech company should be in an excellent position to address any significant concerns raised by the pharmaceutical company.

A comprehensive and well-implemented patent strategy requires more management involvement and significantly greater expense than a plan that simply focuses on filing and prosecuting applications at the lowest cost. Any sound asset-building activity requires a real investment of time and resources. But when the big pharmaceutical company prices the technology deal or perhaps even offers to buy the company, the biotech's investment in patent strategy will be returned many times over.

Geoffrey M. Karny is a special counsel in the Reston, Va., office of Cooley Godward, where he specializes in patent counseling and prosecution for biotech and other life science companies. He may be reached at gkarny@cooley.com. The views expressed here are his own and should not be attributed to Cooley Godward or any of its clients. *Karny wishes to thank Cooley special counsel Jayme A. Huleatt for her contributions to this article.*