Maximizing IP value in an economic downturn (& beyond) in the life science industry

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Current economic woes have corporations slashing budgets wherever possible, and legal budgets are no exception. According to a recent survey conducted by the legal consulting firm Altman Weil, Inc., almost 75 percent of 115 general counsel surveyed said their legal department’s budget would be cut in 2009.

Those in the life science industry know that intellectual property (IP) is a valuable asset, but often IP budgets are the first to be cut by companies desperate to save money. This is not the only option. The short-term monetary gains from making cuts in IP are likely to be more than offset by the long-term ramifications of losing important, and lucrative, IP rights. In the present economic climate, as always, companies should focus on protecting IP and enforcing patent rights as cost-efficiently as possible. Careful management of current and potential IP can help ensure that money is well spent in support of a company’s IP goals.

Given the economic climate, companies are wise to tighten their belts and take a “less is more” approach when it comes to IP. This is likely a paradigm switch because, in good times, the strategy of seeking patent protection for every potentially promising compound or process in the pipeline seems like the best strategy. Tough times, however, call for new approaches.

Biotech companies must now consider how to foster a smaller and more profitable patent portfolio, rather than just cutting back on the amount of money spent on IP. A newly defined strategy should be one that protects core IP assets and inventions while staying aware of IP in the industrial biotechnology industry, to ensure that the IP continues to hold its value. The strategy should also include taking steps to reduce the prosecution costs of the patent applications that a company decides to pursue.

An effective and strategic IP program: (1) prompts the development, acquisition, maintenance, and licensing of IP assets in a proactive manner; (2) treats each piece of IP as an asset that furthers the company’s goals by conferring value to its owners, shareholders, and customers; (3) minimizes expenses by pursuing only those patents that will create strategic value for the company; and (4) focuses on quality over quantity.

A first step is to undertake a critical analysis with respect to new patent applications. Do the inventions to be protected further the company’s goals and create strategic value? The days of indiscriminately filing patent applications are over, considering that it can cost upwards of $30,000 from filing to issuance to obtain a patent in a single jurisdiction. Gaining sufficient international patent protection typically costs in excess of $100,000, while the costs of filing and prosecuting a family of patents in many countries around the globe can exceed $1 million. In the face of shrinking legal budgets, companies need to consider how to get the best return on their investment in IP.

If feasible, it is recommended to assemble an internal patent committee tasked with analyzing invention disclosures. Ideally, the committee should include market innovators (those keenly in-tune with what the market is doing) and traditional innovators (those who examine an invention from a technical perspective). The committee can look for holes in a patent portfolio, determine which inventions will best complement existing patents, and identify which inventions are worth pursuing. After patent counsel weighs in, the committee should consider the commercial impact of the proposed inventions and vote on whether to seek patent protection. Developing this type of “intake process” is essential, because it uses resources currently in place at a company, to analyze each invention and determine how each fits within the company’s strategies and which patents will maximize value, without imposing significant additional costs on your company.

After determining what inventions merit pursuing patent protection, steps should be taken to save money with respect to both the preparation and prosecution of patent applications. For example, costs can be deferred by first filing provisional applications, and then filing PCT applications; this is instead of, rather than in addition to, US utility applications as the first non-provisional filing for lower-tier projects in which patent protection is sought. Commercial developments, new clinical data, and/or information about competing products should be considered in deciding whether conditions
still warrant filing US and/or foreign applications as the 30-month national phase filing deadline approaches.

To enable in-house and/or outside counsel to prepare patent applications most cost-effectively, companies should consider training scientists, investigators, and/or engineers to produce more-useful and relevant invention disclosures and descriptions of data that the patent attorney will need to prepare the patent application. Company inventors can learn to prepare certain portions of the patent application, rather than having attorneys write the application either from scratch or based on reams of data or lengthy grant proposals. It is recommended to work with an outside counsel willing to train company employees to be more effective in providing information in a useful and relevant format. Hiring an in-house patent paralegal, who can interface between you and your outside attorneys, can also minimize the time outside counsel need to spend gathering necessary information. If a company has a large enough portfolio, hiring an in-house patent attorney might be warranted.

Although it may seem counterintuitive, conducting a pre-filing patentability search can be useful. Such searches can be performed in-house, or by outside counsel, but either way will provide valuable information that will help obtain a more concise and well-crafted patent application—one that may cost a bit more to file, but that should provide a stronger application and also reduce the overall cost of prosecuting the application to issuance.

Another cost-saving strategy in preparing patent applications is to focus on the key aspects of the invention. It is generally true that the longer the application, the more it will cost to prepare (and later to translate into foreign languages). Thus, it is smart to insist that inventors and patent counsel focus on the key aspects of the invention(s) and that they do not “throw everything but the kitchen sink” into the applications. Of course, if the invention cannot be concisely defined, it might be wise to reconsider filing of the patent application altogether.

When filing patent applications, if possible, it is recommended that they be filed as complete packages including formal figures, inventor declarations and assignments, and information disclosure statements, to avoid the costs associated with responding to notices of missing parts, attorney reminders, and extension fees. Also, in appropriate situations, the total number of claims filed in the US should be limited to 20, and in Europe (and other countries) to 15, to avoid significant excess claims fees. When filing a PCT application, designating the Korean Patent Office, rather than the US or European Patent Office, as the Search Authority, can save additional money. Use of a translation service when filing foreign applications and provision of the application in the appropriate language, rather than hiring a foreign patent attorney to prepare the translation, are suggested.

Once a patent application has been filed, there are many strategies to work with in-house or outside counsel to save money:

- Use standing instructions for dealing with routine matters to reduce the need for outside attorneys to spend time and incur costs requesting instructions for routine questions.
- File assignments for priority applications, and record changes of assignee (if any) at the World Intellectual Property Organization prior to entry into national/regional phase.
- Reevaluate the application and claims just prior to examination in light of the company’s and competitor’s business objectives and any new prior art. Amend the claims to refocus as required.
- Request a pre-first action interview with the US Patent Office examiner to expedite the prosecution process by getting the examiner’s attention early.
- File all routine responses by the initial response deadline or sooner to avoid extension fees and to cut the overall prosecution time to a minimum. (This also has the benefit of avoiding negative Patent Term Adjustment implications.)
- Work with outside counsel who provide electronic portals and/or electronic reporting to reduce or even eliminate time billed for reporting letters. For example, do you really need a reporting letter for each and every document from the PTO?
- Hold a periodic docket meeting with a primary client point-of-contact and outside counsel to avoid duplicative phone calls and meetings.
- For in-house technical staff and attorneys, respond within a reasonable time frame to requests for information or instructions from outside counsel.

Appropriate measures for cutting patent prosecution costs will vary with the specific circumstances of a specific company. However, as a general rule, the most effective approaches can be developed by working with a specific law firm or small set of firms committed to streamlining prosecution procedures to help focus and prioritize prosecution resources on high- as well as lower-value projects. In addition, they should be flexible to meet varying needs.

A close look should also be given to pending US and foreign patent applications. Is there an application in the works for every project in the pipeline? Now is the time to stop pursuing patents on technologies that do not align with company goals. However, it is important to determine where the patent is in the application process before making this decision. If a patent is close to being awarded, it may be a better use of resources to finish the process (think of the money already spent on research and development, not to mention patent prosecution), and then determine how to maximize the value of the invention.

It is also wise to periodically reassess the company’s issued US and foreign patents. Is there an application in the works for every project in the pipeline? Now is the time to stop pursuing patents on technologies that do not align with company goals. However, it is important to determine where the patent is in the application process before making this decision. If a patent is close to being awarded, it may be a better use of resources to finish the process (think of the money already spent on research and development, not to mention patent prosecution), and then determine how to maximize the value of the invention.

There should be a clear focus on key patents. In the coming years, there will be a premium on filing a smaller number of high quality patents and prosecuting them aggressively, because new US Patent and Trademark Office policies and procedures are significantly reducing allowance rates. The courts, in turn, appear to be making it more
difficult to successfully enforce issued patents though litigation. Strategically, companies need to spend less time slashing IP budgets and more time considering how to obtain valuable, strong patents.

Mining the company’s current portfolio and pending applications to determine what patents have value is another important exercise. Some patents that companies may think of as “lumps of coal” could actually be diamonds in the rough, as unused patents may hold value for others. However, the average effective life of a patent, that is, the average time until a product or feature covered by a patent is replaced in the marketplace by a better product or feature, is only about five years from the date the patent issues. Companies would do well to remember that only five percent of patents generate licensing revenue, and they should be realistic in assessing if anyone else would really want what the company does not.

Finally, it is imperative to set aside a realistic budget both for keeping track of competitors’ IP, e.g., in the form of patent searches/watches and freedom-to-operate opinions, and for potential litigation. This is just another step in protecting the IP that a company already has and in which the company has invested significant time, resources, and money. For example, branded drug companies need to be particularly aware of the possibility of an up-tick in competition from generic drug makers as the demand for less expensive drugs increases. When faced with a challenge from a generic drug maker, a branded drug company must either litigate to protect its patents or consider settlement. In either case, the specter of losing valuable market share looms large, and any money expended to protect IP rights is money well spent.

These steps are not only a way to survive an economic downturn; they provide a general, and practical, approach to maximizing the value of a company’s IP, now and always. While other companies are cutting their IP budgets, taking the time to pay attention to one’s IP now will certainly pay off once the economy (inevitably) begins to recover.

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