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Patents: Beyond the Basics

Answering Your Top 12 Questions on Strategy Part 2



In this four-part Q&A series, six patent attorneys from <u>Dilworth IP</u> answer 12 patent strategy questions posed by Connecticut Innovations portfolio companies. [Please note that this patent Q&A series is for general informational purposes only and does not represent legal advice by the authors or Dilworth IP, LLC.]



Q: How can/should patents fit into my overall business strategy?

A: Patents are a business tool and should be viewed in that light. Companies should use patents as part of an overall intellectual property (IP) strategy to protect innovation, foster growth, achieve business objectives and improve company valuation. Consider that in today's knowledge economy most of the value of a company comes in the form of intangible assets, of which patents are a component, and yet that valuation is rarely visible on a corporate balance sheet. The day will come when that paradigm is no longer practical. Then, establishing an overall IP strategy will be required, and its value will be reflected on the balance sheet. There are six basic building blocks for an overall IP strategy:

- 1. Corporate IP awareness program
- 2. Robust IP portfolio
- 3. Robust IP licensing provisions
- 4. IP litigation strategy
- 5. Focused IP public policy initiatives
- 6. Valuation of IP



Corporate IP Awareness Program

All employees have a role in a company's intellectual property program, from protecting intellectual property to respecting the intellectual property of others. A comprehensive IP training program elevates the awareness of IP throughout the company and its importance to the business.

Robust IP Portfolio

Protecting key product innovations and market differentiators with patents, copyrights and trade secrets provides the foundation for an overall IP strategy and positions your company to defend against allegations that others were first to innovate. Effective and creative branding programs allow you to increase the corporate value and price point of products.

Robust IP Licensing Provisions

Crafting IP licensing provisions in your agreements enables your company to control how others use its intellectual property. Targeted use of IP licensing models (e.g., open source, standards) enables a company to benefit from lower development costs and decrease its goto-market time.

IP Litigation Strategy

The strategy, which allows your company to protect its opportunities for growth, should have two components: (1) enforcing your contractual IP



rights against those who do not adhere to your IP licensing provisions; and (2) enforcing your IP rights against those who want to use your innovations without taking a license.

Focused IP Public Policy Initiatives

Undertaking public policy initiatives that promote the protection of your innovations, improve patent quality and reform the litigation system allow your company to profitably grow its business.

Valuation of IP

After building a patent portfolio of a suitable size, consider building a program to extract value from your IP, mainly patents, to increase shareholder value.

These building blocks may not be for all companies, but when you invest in a patent portfolio, you should consider how it fits within an overall IP strategy.

When setting your patent strategy, you must first understand the rights a patent conveys. Then consider how those rights can maintain or secure market share for your products and how patents can increase the value of your company. Patents convey an exclusive right to prevent others; they do not grant you a right to make. At a high level, your patent strategy should focus on how you can exclude others from



making, using, selling or licensing, offering to sell or license, or importing your protected innovations.

We recommend focusing on innovations in products with the largest revenue-generating potential or on innovations that are core to the growth of your business. If budget is less of a concern, you can expand your patent strategy to cover innovations that have less of a direct business impact but add value in other ways. A viable patent strategy (and overall IP strategy) for your company should evolve with current economic conditions and will depend upon many factors – most important, budget.

Q: What are some keys to creative patent and product lifecycle management?

A: Product life-cycle management is familiar to many business people. It is the process of managing the entire life cycle of a product from inception, R&D and commercialization through to its obsolescence. However, a less familiar concept is the management of a patent or patent portfolio over a patent lifetime – that is, "patent life-cycle management." Because intellectual property is becoming an increasingly valuable asset for many businesses, a sound business strategy must incorporate patent considerations into the overall business plan. Such a business strategy must integrate both patent and product life-cycle management considerations.



Briefly, patent product life-cycle management is the management of a product over its life cycle in view of its patent life. Let's consider five important areas of patent product life-cycle management for your business strategy:

- Understanding the competitive landscape. Concurrently with, or even before, the earliest stages of product R&D, it is important to understand the competitive landscape. A business cannot afford to squander precious resources developing and patenting a product that it might not be able to bring to market because of the existence of third-party patents. Also, the business must not only look at the then-current competitive landscape but should also strive to understand how that landscape will likely evolve. What competitive products may be on the market, or may come to market, when or soon after your product launches?
- Defining your invention and patent strategy in view of your business goals. Based on the early R&D work and the competitive landscape analysis, the next step is to define the invention and appropriate filing strategy. This is most effectively done as a team effort involving input from scientists, business managers and financial managers, in conjunction with patent counsel. Considerations should include, among other things, when and where to file patent applications, the number of applications and the scope of filing. The goal here is to



come up with a practical and affordable patent filing strategy that aligns with the company's business goals. Furthermore, considerations should be given to timing – for example, filing early enough or before certain key events (such as a public disclosure at a scientific conference or a meeting with a potential vendor). Furthermore, an additional year of front-end patent term can be obtained by filing a "provisional" patent application, followed by a nonprovisional application a year later.

- Managing the patent portfolio in view of product development and commercialization. As the company moves along the product development timeline to commercialization, the patent life cycle will likely move through procurement and toward issuance of the patents. Constant reevaluation of the patent portfolio should be made with the team to determine whether the portfolio is evolving in step with the product development efforts. For example, changes or product improvements should be appropriately protected with follow-on patents. An example of this in the pharmaceutical area might be for a new or improved product form, such as an extended-release drug formulation. Conversely, the patent estate should be pruned to abandon patents or applications that are no longer relevant to avoid unnecessary procurement and maintenance costs.
- Extending the franchise. Just as the business team would continue to seek new opportunities to extend the life of the franchise, it is



important to also consider and take advantage of all tools for maximizing the value of the patent portfolio. It is appropriate to take advantage of all available patent term extensions. For example, under U.S. law, it is possible to recoup patent term lost due to certain patent office delays during prosecution (see 35 U.S.C. § 154(b) relating to patent term adjustment). For products subject to regulatory review, such as pharmaceuticals, it is possible to recoup part of the patent term that was consumed during the often lengthy investigational and regulatory review periods (see 35 U.S.C. § 156 relating to patent term restoration).

• Preparing for challenges. Just as one must begin to assess the competitive landscape at the earliest stages of product development, the savvy business team should prepare for different competitive challenges that arise at the other end of the product life cycle. A successful product will likely have to contend with challenges to the patent portfolio, including potential patent litigation, oppositions, post-grant reviews, and the like. In the pharmaceutical area, there is yet a further complex mechanism by which generic drug manufacturers can seek to bring their products to market during the patent term of the originator's product. This mechanism, which spans the intersection of patent and regulatory law, is called an Abbreviated New Drug Application (ANDA). Again, preparing for these potential challenges before they occur is key. Further information about ANDAs



can be found on the <u>U.S. Food and Drug Administration website</u> and here.

In summary, we've touched on some important considerations of patent product life-cycle management. The key takeaway is that a sound business plan must successfully manage both the product and patent life cycles and their often-complex overlay.

Q: How do I decide whether to license my patent or sell it outright?

A: Choosing whether or not to license or sell a patent is complex. It involves not just a relatively straightforward economic analysis, but also a review of how the disposition of the patent rights would affect the ongoing operation of the company. With respect to the economic evaluation, a company's analysis must recognize that ownership of an enforceable patent for its entire lifetime is not free. Patent coverage is typically maintained internationally, with maintenance fees, typically due annually, required in each country where a patent was granted. Moreover, maintenance costs tend to escalate as patents age, as an incentive to make patented inventions publicly available sooner. In sum, maintenance costs are ignored at a patent owner's peril.

In addition to economic considerations, non-economic factors specific to the patent and the business must be considered. Is the technology



encompassed by the patent claims still of interest to the company? Is the scope of the claims broad or narrow? How easily can the claims be "designed around"? Will industry R&D trends soon render the products and processes covered by the patent obsolete? Answers to these questions will help determine the long-term value of the patent.

Another consideration is whether the company is prepared and willing to defend and/or enforce the patent through litigation. Any related license agreement may require this. If litigation is contemplated, how strong is the patent? These are important considerations because litigation costs can be eye-opening.

Where does the patent fit with respect to the company's processes and product lines? Does the patent cover a business's essential process or product? If this is the case, the best path may be to neither license nor sell the patent because these options could create competitors in the marketplace. Are related development activities ongoing within the company or by its customers? Under a licensing arrangement, the rights and obligations of the parties with respect to improvements in the patented invention can be allocated. However, if the patent is sold, even if rights are retained for the company, that company's customers may have to contend with derivative patents obtained by the purchaser that interfere with their business.



In summary, deciding whether to sell or license a patent is not a simple mathematical exercise. It is insufficient to compare the time value of money for a particular royalty rate to a specific sale value. The analysis must also include an evaluation of the company's product line vis-à-vis the patent and the market, the company's present and planned research activities, and the interests of its customers. Consideration of these factors will help to determine which action is best in a particular situation.

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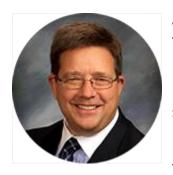


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