

Patent Strategies Create Value in Life Science Business Development and M&A Transactions

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INTRODUCTION

Patents play an important part in every business development and M&A transaction. Almost every acquirer, strategic partner, or licensee requires satisfactory completion of intellectual property due diligence as a condition for closing. (We will refer to acquirers, strategic partners and licensees as “buyers.” Counterparties will be referred to as “sellers.”) Buyers’ conclusions from due diligence either support the negotiated terms, provide reasons to ask to renegotiate terms, or serve as a rationale to walk away from the transaction. “No change” is the best sellers can expect from patent due diligence.

Sellers communicate a great deal of information about market potential, competition, stage of development, and underlying science to influence buyers’ valuations. They do not do the same for intellectual property, typically providing a list of issued patents and publicly available patent applications. Buyers then calculate value, assuming the patents only prevent competitors from marketing exact copies of sellers’ product. Assumed patent protection neither limits competitors-in-kind nor competition from therapeutic alternatives. Buyers thus assign the smallest possible value to patent protection. Should patent protection turn out to be broader than assumed, buyers have acquired value for nothing more than a possibly larger royalty payment. Sellers, meanwhile, have lost an opportunity to negotiate terms that realize the full value of their patents.

Our life science transaction experiences have repeatedly shown that too often sellers fail to fully realize the value of their patents or fail to pursue strategies that allow them to have value-creating patents. This article

suggests ways to use patent information to create value in transactions and strategies leading to value-creating patents. We start with a discussion of how patents create value.

VALUING PATENT COVERAGE

Valuing patent coverage depends largely on the breadth of coverage. Breadth of coverage creates market share and pricing opportunities for the patent owner by the degree of difficulty it imposes on others wanting to market competitive products. Value created by breadth of coverage can be considerable. The breadth of coverage in Palmaz-Schatz U.S. patents on balloon expandable stents enabled J&J to be the sole marketer of balloon expandable stents in the United States for over a decade. Europe, where balloon expandable stents had no patent coverage, was flooded with balloon expandable stents.

Financial analysts have estimated the value of U.S. patent coverage to J&J to be in the billions. Our discussion of patent value will focus on breadth of coverage. How patents affect competitors’ behaviors, the benefit to patents owners, and the advantages of broad versus narrow claims are summarized on the Table 1.

Our points can be demonstrated with a case study intended only to illustrate our points about how patents create value and are not based on any specific product or competitive situation.

Case Study

No Coverage vs. Narrow Coverage vs. Broad Coverage

Patent value is determined by the difference in the product’s financial performance with and without a patent. Here we determine the value of a patent with narrow claims and a patent with broad claims where the alternative is having no patent protection at all. The benefits of narrow claims and broad claims compared to no patent protection are summarized in Table 2 and the chart. (These apply solely to our case study.)

The value of the broad and narrow patent coverage is the difference in the present value of the cash flows compared to having

TABLE 1

<u>Effect of Patent on Competitor</u>	<u>Benefit to Patent Owner</u>	<u>Advantages of Broad vs. Narrow Claims</u>
Off the market – cannot justify investment to develop non-infringing product	Fewer competitors during life of patent	More companies likely to have infringing products and unable to justify investment to develop non-infringing alternatives
Delay in launching a non-infringing product	Fewer competitors until introduction of noninfringing products	Longer time until noninfringing product is launched
Noninfringing product lacks important features of patented product	Potential to build and maintain market share	Patented product has greater product differentiation with potential to build and maintain market share

TABLE 2

	<u>No Patents</u>	<u>Narrow Claims</u>	<u>Broad Claims</u>
Protection from generics	3 years post-launch	9 years post-launch	9 years post-launch
Limitations on competitors’ ability to offer key product features	NA*	NA*	6 years post-launch
Peak market share	10%/Year 2	15%/Years 4-8	30%/Year 6**
Price premium	None	None	25%/Years 1-5**

* No effect on nongeneric competitors

** Broader patent coverage results in nongeneric competitors being off the market until Year 6. During that time our product gains additional market share and sells at a premium price.

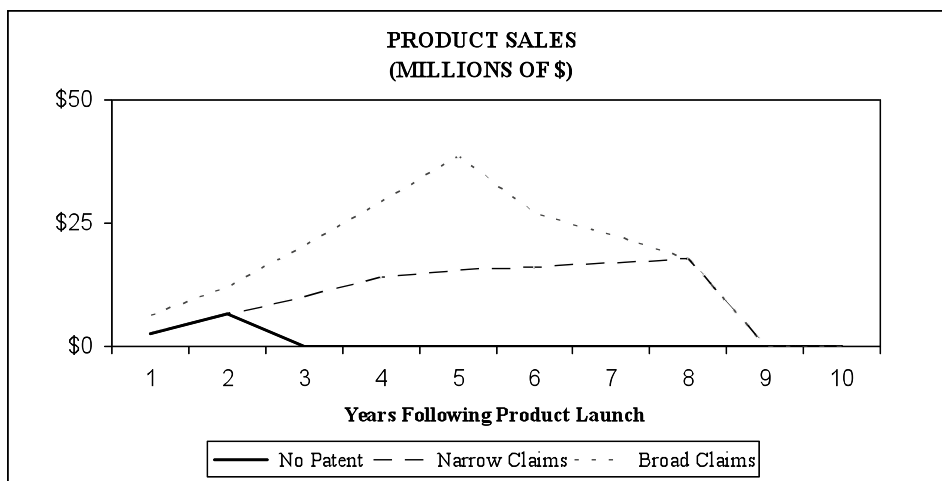


TABLE 3
Value of Patent Protection (Millions of \$)

Patent Claims	Narrow	Broad
Present Value	\$17	\$37
Present Value with No Patent	\$2	\$2
Value of Patent	\$15	\$35

no patent coverage. The values are for the patent inventor and for buyers whose alternatives are ownership¹ or wait until patent expiration to launch a generic.

Consistent with our sales projections, broad coverage has significantly more value than narrow coverage. In the absence of patents, the product would have virtually no value. In many instances where there are no impediments to competition, such as trade secrets, one can assume that the no-patent case has a value of zero.

Our case study values patents for buyers without the capability of developing a noninfringing product. For buyers with the capability of developing a noninfringing product, patent value is the difference between the value of owning the patent and the value including the development cost of a non-infringing product and its commercial performance. A competitor whose product does not infringe will put less value on the patent unless the patented product is vastly superior to its own product or the performance of the company's product can be enhanced by having access to the sellers' patent. Again, the broader the patent protection on the key elements of the product the more difficult it will be and the longer it will take for the competitor to bring to market a comparable, noninfringing product.

A patent strategy that develops the broadest possible coverage is detailed in the following section. Executing a patent strategy to provide broad patent coverage

can be expensive and sellers should compare the benefits of having broader patent coverage with the expense of executing the strategy prior to deciding the patent strategy they want.

PATENT STRATEGIES

A patent strategy describes how patents will be used to create an adverse effect for the longest possible time on competitors' behavior and the performance of their products. There are four steps in developing and executing a value-creating patent strategy:

1. Determine what claims are likely to be patentable and, more importantly, why the claims should be patentable.
2. Decide how to use possible claims to protect a product's most important features or capabilities.
3. Decide how to use broader possible claims to provide additional value²
4. Revisit and revise patent strategy as information on patents issued to others becomes available.

Each step is described below.

It is important to evaluate the claims to ascertain which of them are likely to be patentable. Typically, this step can be as simple as evaluating the known references for any disclosure of the claimed limitations. If a single reference discloses each limitation in a manner similar to claims, patentability is more likely to be foreclosed. If a feature of the invention is completely

absent or can only be found by combining multiple references, the odds of obtaining a patent increase. However, it is also important to evaluate why the claims are patentable in order to convey the story of patentability to the patent examiner and/or potential partners.

Evaluating the scope of any proposed claim and determining whether a particular claim should be patentable at the time of patent application development can be a very long, involved, and often expensive endeavor. Undertaking this expense makes sense only when the claims provide robust protection for the product's most important features and capabilities. Otherwise, the patents have minimal effect on competitors and their value diminishes significantly.

Patent coverage can be thought of as an umbrella, a picket fence, or a combination of the two. An umbrella patent provides broad, complete protection. For example, a patent claim to a new chemical entity covers the compound as well as administrable formulations of that compound. A picket fence provides more modest, or "spot," protection, depending on the distance between pickets and the length of the fence. An informed idea as to what claims are patentable guides the determination of whether umbrella coverage is possible and, if not, how an effective picket fence may be possible. By undertaking this analysis early, the patent application can be drafted to maximize the chances for obtaining the broadest or most meaningful claim coverage, thereby getting the maximum benefit for the expense incurred.

The next step is to decide how to structure a patent strategy that protects a product's most important features and imparts the largest possible effect on competitors. This can be accomplished, in most cases, by first building a picket fence and holding off on opening the umbrella. We can start by trying to build a 10-mile-long picket fence with minute spaces between the pickets. Or, we can start more modestly by lengthening the fence and shrinking the space between the pickets as we go. We have found that the best way to build a picket fence is to begin moderately and improve the fence over time.

A strong picket fence can be built by combining patents owned by different companies. This most often occurs when there are no more than three realistic alternatives to address a clinical problem. Company A has patents protecting one of these. There can be considerable value to Company B,

one of Company A's competitors, to have a broadly protected product that covers another of these alternatives, assuming that Company B's product does not infringe upon Company A's patents. The combination of the two patents may make it very difficult for a third competitor to enter the market.

It is a good idea to revisit the strategy regularly starting 18 months after the most recent search, 18 months after filing, and again after receiving the first office action from the Patent Office. Patent documents typically publish 18 months after filing, and therefore any intervening art that may affect patentability and scope can be reviewed to most effectively realign the patent strategy.

Proactive dialogue between the inventor and patent counsel plays a key role in developing and getting the most from a patent strategy. An effective patent strategy must respond to changes in product design, competition, and patent office actions. This can be expensive. Inadequate patent protection can be even more so.

USING PATENT INFORMATION TO NEGOTIATE TRANSACTION TERMS

Transaction terms depend on the buyers' perception of the value of the transaction and how much of the value of the transaction goes to each party. Increasing the buyers' perceived value requires convincing buyers that issued patents and executing the patent strategy does more than cover the product's key features or capabilities.³ To do this, sellers have to link the breadth of patent coverage to its likely effects on buyers and their competitors. Buyers may lack the ability to make this link. Those who have the capability have no motivation of letting sellers know this.

Integrating patent information into product information is the best way to link patent coverage to their likely effects. (Patents written with clear claims help enormously here.) As discussed above, a patent's value is a combination of market, product features/benefits, competitive, and patent factors. Sellers now provide information about the market, the product, pricing, and competition, and the product's sales potential. Adding the anticipated effects of patent coverage on pricing and competition is a logical extension of the information sellers currently provide. A suggested outline of how to integrate product and patent information follows.

Integrating Product and Patent Information Suggested Outline

- Product features
- Benefit of features to customers
- Differentiation from competitive product in terms of benefit to customers
- Patent strategy
- Breadth of protection from issued patents and patent strategy
- Possible effects of issued patents and patent strategy on competitors' abilities to market product with comparable customer benefits
- Possible effects on buyers should one of their competitors acquire the patent
- Breadth of patent protection for future iterations of product

The outline intentionally omits detailed patent information. The objective is to convince the potential buyers' R&D, marketing, and finance people to assign more than the minimum value to patents. Providing information beyond what is needed to meet the objective can be distracting.

Patent information can help build sellers' negotiating strength so that they get a greater share of total value. Convincing buyers that the patents have significant value is one way. Attracting several buyers is another. Attracting several buyers may require including patent information in conference presentations and nonconfidential Executive Summaries. Disseminating patent information widely should be done with at least the same degree of caution as disseminating product information widely. An additional degree of caution is needed so as not to jeopardize the patent strategy. So long as sellers observe these caveats, patent information can play an important part in attracting several buyers and building sellers' negotiating strength.

Sellers may be reluctant to make claims about their intellectual property. They are not similarly reluctant to make claims about potential for commercial success and speed of regulatory approval, often with incomplete supporting data. Sellers' claims about the product's commercial potential and likelihood of regulatory approval are the sellers' best, and often most optimistic, guess. Aside from legitimate concerns about disclosing information that might affect patent strategy, we believe sellers should use patent information as aggressively as they use other types of information. Sellers, rightly, assume that buyers will validate

their claims' nonpatent issues. Sellers should assume the same for patents.

CONCLUSION

Sellers invest in their products and technologies so that they create value and an attractive return on the time, effort, and money used in their development. Their products' differentiation from the products of their competitors is one of the critical determinants of the value created. The patents, in turn, create value by determining how well and for how long competitive differentiation can be maintained. Patents are most effective when they are the result of a well-thought-out and well-executed patent strategy, and their scope and its financial implications are communicated to buyers with the same intensity and enthusiasm as the products' or technologies' features and benefits.

Sellers have to be proactive to use patents to create value following standard marketing principals. First, know what the customer wants — identify the dimensions in which breadth of coverage creates value for potential buyers. Second, create a product or service that meets these wants — execute a patent strategy that provides, or can provide, the necessary patent coverage. Third, communicate to the customer — convey patent information in a way that affects positively the buyer's valuation. Sellers use these three steps in developing their products and technologies. They should do the same with their patents. **IPT**

ENDNOTES

1. Ownership includes having a license to use the patent for the product under consideration.
2. Decisions here include the decision not to pursue broader patent claims
3. We are assuming that current and future patent coverage does more than narrowly cover the product's features or capabilities.