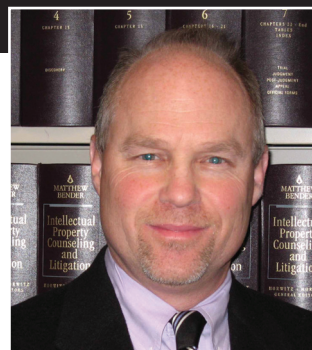


IP Portfolio Management Strategies for Medical Device Manufacturers



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Management of a company's intellectual property (IP) is all about two things: **controlling the innovation produced** by the Research and Development (R&D) staff and transforming these ideas in valuable assets, and **coordinating the R&D innovation output** with the sales and marketing strategy of the company. A company's IP is unique in that it functions not only as an asset by protecting a product's market position and price, but also as insurance against competitive legal action and market penetration. The IP can also assist in developing strategic alliances or attracting a possible merger/acquisition candidate. Achieving efficient and comprehensive portfolio management can only occur if the business and R&D sides are integrated during the IP development and implementation stages. More specifically, a strategic approach to IP portfolio management must span from the time an idea is conceived in the lab to when the product is released into the marketplace. Accomplishing this task can only occur if procedures and processes are put in place and followed by all of the medical device manufacturer's departments.

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In order to manage a portfolio of intangible assets, like IP, the person in charge needs to know what should be included in the collection. IP portfolios are inclusive of all four types of IP. **Patents** are typically the most prominent and valuable category of IP because of their limited 20-year monopoly status that enables the inventor or owner to exclude others from making, selling or suing the claimed invention. **Trademarks** are the next most prominent type of IP for a company. This asset covers a company's name, its slogans, product names and colors. For certain situations, trademarks may also extend to a company's domain names. **Copyrights** would also be included in an IP portfolio. These assets would include written materials (brochures, teaching manuals, surgical techniques), video productions, images and graphic designs. Finally, **trade secrets** round out what would be included in the portfolio. Trade secrets protect information that is critical to the success of the company

and would be beneficial to a competitor operating in the same market as the company. Essentially, a trade secret is information that is more valuable if it remains a secret than if it was in the public domain.

When a company is developing a comprehensive management strategy for its IP, it needs to ask several questions.

Who is in charge of managing the portfolio?

The first question is obvious: who will be in charge? A medical device company needs to be careful that they don't fall into the trap of only putting a technical person in charge. Many are of the opinion that it is a mistake to leave IP decisions in the hands of engineers and patent attorneys, because these people are too technologically focused to the detriment of the commercial benefit of the technology. When this occurs, the portfolio ends up being too heavily weighted on flashy technology ideas that have little use to the company. The appropriate person or persons should be cross-pollinated among the technology, science and business sides. Further, the company must provide that person with enough clout within the organization to be able to implement and enforce the procedures and processes necessary to manage the IP portfolio.

What is the value of your IP?

The next question to be addressed is, what are my patents, trademarks, copyrights and trade secrets worth? The answer can be very complicated, because the valuation process for each of these types is quite involved and sometimes very subjective. Typically, for patents, there are two types of evaluation: quantitative and qualitative. The quantitative evaluation provides an estimated monetary value to the patent, while a qualitative evaluation identifies its strengths and weaknesses. When a quantitative evaluation is performed, one of the following methods is usually used.

The first is the **cost method**, which looks at the associated costs necessary to develop and patent a similar invention. Unfortunately, there is no direct correlation between the cost of invention development and future revenue from the patent. This method is usually used for accounting purposes.

The second method is the **market method**, which values patents by comparing market prices that have been garnered in a recent comparable IP transaction. This is a fairly straightforward process, but is only useful in an active market and when similar patents are being exchanged between the two parties.

Access to actual pricing may also be difficult to achieve, because these transactions tend to be confidential.

The third, called the **income method**, measures potential income that can be derived from the patent. This is a rather simple process that requires calculating the present value of the patent based exclusively on anticipated income. The drawback to the income method is the reliance upon subjective market and consumer assumptions.

Valuation of trademarks is almost identical to the methods used for patents. Experts typically use either the income, market or cost approach for placing a set value on each of their trademarks.

Copyright valuation is much more variant than the methods described above. A baseline determination usually involves looking at the future revenue that may be attached to a copyright. The problem lies with how one looks at each copyrighted work. For example, the value of software may be determined by whether it is used for a specific application or for general company operations, the number of active lines of code, the number of function points or the number of hours of development time. In comparison, a brochure, surgical video, sculpture or painting will be valued in a much more subjective manner with a high emphasis on market demand being used to estimate the value of the copyrighted work.

For trade secrets, determining inherent value will be unique for each case because of the specific role the secret plays within the business. For example, the recipe for Coca-Cola derives its value from the fact that, without knowing the exact ingredients of the syrup formula, no competitor can offer an exact replica soft drink as that sold by Coke. Some trade secrets gain their value from depriving the competition of knowing how the business is run. An example of this is a customer list. The key element in valuing a trade secret is considering the industry in which the trade secret owner competes, looking at the information that is being kept secret and determining how useful it would be from a competitive viewpoint. Other factors to be reviewed are the costs to develop the secret, and the fair market price if the information is sold within the industry.

What are the offensive and defensive strategies for the IP?

How does the company want to use its IP? Will it be used as a “sword” to generate revenue and block others, or will it be used as a “shield” to mitigate litigation risk? The offensive strategy would focus on the company’s philosophy on patent filings related to its products that generate revenue, as well as filings that protect the profitable products by blocking competitors from design-around. Such blocking patents are useful from a portfolio licensing standpoint. Licensing revenue has grown in recent years to become an important part of the medical device manufacturer’s bottom line.

The defensive strategy for IP management revolves around keeping the company out of court. This would entail ensuring that any methods of manufacturing the products as well as the product themselves being offered for sale are clear from infringing any third-party patents. Avoiding infringement of trademarks and copyrights are also key elements of the

defensive strategy. It is critical to retain outside counsel to perform preemptive patent, trademark and copyright clearance searches to avoid possible infringement and costly law suits.

What is the ex-U.S. strategy for the portfolio?

The answer to this important question will depend upon where the company plans to make and sell its products, inside or outside the U.S. Because IP protection exists on a per-country basis, if your company has plans to sell, use or make a product in a certain foreign country, then you will likely want to file for protection in that jurisdiction. The caveat is that filing in countries outside of the U.S. can be extremely expensive, so a company must choose wisely where they plan on filing for patent and trademark protection and be prepared to enforce their rights, once in place. Prudent use of PCT application for inventions and CTM Trademark applications allows a company to efficiently add to its IP portfolio while also managing costs.

What are the long and short term product offerings?

In the same vein as the ex-U.S. question above, in developing the appropriate strategy to manage the IP portfolio, the company must know what its short and long term plans are for product development and the corresponding IP. To maximize the value of the IP portfolio and efficiently manage the inventory, long range business plans must factor in how the IP portfolio value can be maximized while also protecting current

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product offerings. As products evolve over time, the contents of the portfolio will need to follow and be able to address the changes in technology, customer preferences, expiration of IP and competitor behavior, like design-around and reverse engineering activities.

Does the company own everything in the portfolio?

It would seem that the answer to this question is absolutely yes, but surprisingly this is not always the case. Many companies are lax in enforcing procedures for ensuring that assignments are signed simultaneously with the filing of patent applications. Further, companies fail to put in place “work-made-for-hire” agreements with their employees at the time of employment to ensure that copyright ownership flows to the employer. To properly manage the IP portfolio, the IP manager must have strict rules in place that require all IP to be assigned to the company. In addition, should the company be involved in any merger or acquisition activity, ownership of all acquired IP must be immediately transferred to the purchaser or surviving entity.

Are the contents of the IP portfolio integrated with the business?

An overriding trend that can be identified from the previous queries is the basis for the last and *most important* question. Is the IP portfolio being coordinated in conjunction with the execution of the company’s business plan? If the answer is yes, then the company should be successful in efficiently maintaining its portfolio. A company must always make the portfolio a chief element when the business plan is being developed in order to ensure that profitable products (now and in the future) are protected by a patent or trade secret and that the corresponding logo has been registered and is being properly used. If such integration is not occurring, then the IP will have little value and not contribute to the company’s success. It is critical that the IP portfolio manager be fully involved with the business strategy to enable the portfolio to stay aligned with the goals of the company.

Five Easy Steps to Manage your IP Portfolio

Once the questions above have been answered, the medical device company can use the following five key steps to strategically manage its IP portfolio. Remember, these are ongoing and require diligence and creativity.¹

The first step is finding out **what IP is in your portfolio now**. Included when making this assessment is identifying the protected technologies and determining the strengths and weaknesses of the coverage. All of these questions can be answered by performing an IP audit, which has been previously discussed in depth in an earlier edition of *BONEZONE* (Winter 2009).

The second step is **determining your IP needs** for the portfolio. This gap analysis is done to determine what technology

your company needs to beat its competitors. To accomplish this, all of your competition needs to be looked at closely. This includes finding out how many patents do they have, their covered technology areas, their strengths and whether these actually pose a threat to your products and technology.

The third step is to **formulate a portfolio investment strategy**. This means identifying what IP is needed to round out your existing portfolio. Taking such action does not just mean going out and buying certain patents or technology, but rather working with the R&D department to identify and build on existing strengths and strategizing ways to cure weaknesses of the current portfolio. This also includes identifying key inventors inside and outside of the company. Other actions that are taken to correct portfolio weaknesses include actively entering into licenses and building cooperative alliances with non-competitors.

The fourth step can be used with the third step. This is to **divest unused, non-core IP** to generate licensing revenue or cross-licensing relationships. Remember, managing a portfolio is about building value and not about trying to accumulate as many IP assets as possible.

The last step for strategically managing a portfolio is to **institute a system to monitor and maintain the IP inventory**, thus ensuring that it remains current and is being used properly. Putting in place a comprehensive system for making maintenance payments, filing renewals and tracking the expiration of the IP is key to keeping the existing IP portfolio current and mitigating any possible surprises.

Medical device manufacturers compete in a highly-competitive technological industry. Progressive management of IP portfolios is key to survival. Understanding the need to fully involve marketing/sales with R&D and proactively monitor the marketplace will go a long way in meeting the company goal of strategic management of its IP portfolio. Please remember, this article is for informational purposes only and should not be interpreted as legal advice to the reader.

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1 Bob Stembridge and Breda Corish, *Patent Data Mining and Effective Patent Portfolio Management*, Intellectual Asset Management, Oct-Nov 2004 at 30-34.