What Medical Device Companies Need to Know about Intellectual Property

As innovative devices and creative ideas proliferate, the need to properly protect intellectual property becomes an increasingly vital aspect of both the design process and the business strategy.

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Intellectual property rights are key to securing exclusivity and the ability to profit from a company's innovations. This can be seen in the so-called "smartphone wars" where mobile phone companies are suing each other on patents in an attempt to secure marketplace dominance or in order to monetize their inventions. Likewise, medical device companies have relied on patents to help their company grow.

The American patent system is authorized by Article One, Section 8(8) of the U.S. Constitution, which states, "The Congress shall have Power...To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Generally, in the U.S., a patent is a right to exclude others from making, using, selling, or offering an invention for sale for a limited time. In addition, a patent can be used to exclude others from exporting components to be assembled into an infringing device outside the U.S., importing the product of a patented process practiced outside the U.S., inducing others to infringe, offering a product specially adapted for practice of the patent, and a few other specific categories.

Often, however, companies focus first on developing the next big product or solution and put off legal assessment of their innovation position, only to discover too late that significant hurdles to robust protection have arisen. The story is often the same: an ounce of early prevention can save a pound of painful cure. What, then, should every medical device company or start-up know from the outset? The list of the most common pitfalls is actually quite short, but the threats they pose are too significant to be ignored.

First, confirm that the company actually owns its valued intellectual property. Employers commonly assume they own intellectual property rights developed by employees and consultants, but in the United States, sometimes the *creator* is the presumptive owner. Companies must therefore use agreements to require employees and consultants to assign any and all intellectual property rights to the company. In addition to assigning the intellectual property rights, these agreements should also obligate employees and consultants to safeguard confidential information. Joint venture agreements (with other companies or universities) should also be carefully scrutinized to establish proper ownership. Finally, prior employment obligations of employees could affect who owns certain intellectual property. In some situations, a current employee's "inventions" may be owned by a former employer.

Second, because medical device companies and start-ups are almost always based on a brilliant idea or solution, the nuclear option of intellectual property must be deployed: patent protection. Typically, trade secrets, copyrights and trademarks do not rival patents for the ability to prevent others from making or using an invention. Without patent protection, once the idea is publicized there is no way to stop an often larger, better-funded company from simply taking or copying your inventions. This is particularly true once FDA approval has been granted. The awful truth is that FDA approval is expensive and time-consuming. To use a cycling analogy, a competitor can lurk in the peloton while your company leads the struggle to gain FDA approval, and emerge from the pack just in time to claim substantial similarity and gain streamlined FDA approval for its competing product. Without patents in place, this tactic may be perfectly legal, granting the competitor a significant financial advantage.

Venture capitalists certainly know the value of a patent portfolio. Venture funding often hinges on the strength of a start-up's patent portfolio and how effectively that portfolio protects the ideas behind the start-up. A family of strong patents is often the most persuasive and alluring ingredient in a sophisticated venture funding proposal. For example, Figure 1 illustrates the relationship between patents and start-ups. From this we can see that start-ups have a higher percentage of patents in part because funding possibilities increase with the number of patents.

There are, however, some important pitfalls when seeking patent protection. The most important pitfall is a partial or complete forfeiture of rights caused by undue delay in filing a patent application. A patent application must be filed as early as possible and before a public disclosure or commercial activity. Avoid the trap of assuming that filing a patent application automatically results in enforceable rights: obtaining an enforceable, issued patent typically requires multiple rounds of negotiation with the Patent Office and can take two to five years.

Another pitfall is the assumption that a single patent filing is sufficient. In fact, multiple patent families or groups are typically required for effective protection. Patents, no matter their size, hinge on a few words found at the end of the patent in the "claims." The claims define the scope of the invention and, consequently, what one company can prevent another from doing. Thus, competitors can use the information in a patent and nevertheless avoid infringement if they figure out a way around the language of your claims. The more patents and the more claims you have, the more difficult this will be. A large patent portfolio in and of itself often scares away would-be competitors simply because of the expense of figuring out how to get around the volume of protection.

Third, patents are not like off-the-shelf, form contracts. Each patent is specifically tailored to the new idea it is meant to cover. In the world of patent drafting, the quality of your patent is driven by the quality of the drafter. It is possible to find attorneys who will lower costs by cutting corners, but more often than not your patent will suffer for it. Serious protection is not inexpensive and requires significant attention and care from your attorney. For example, a skilled patent drafter will strive to obtain not only strictly "defensive" patents—those that cover their own products in various ways, but also to obtain patents that cover the relevant marker and competitive alternatives, as in Figure 2.

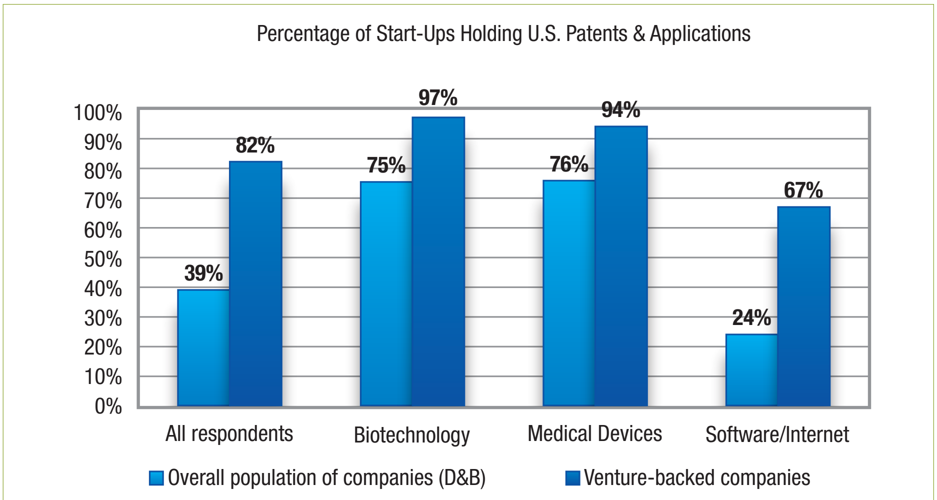

Figure 1 Source: *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, Graham et al., Berkeley Technology Law Journal, Vol. 24:4 (2008).

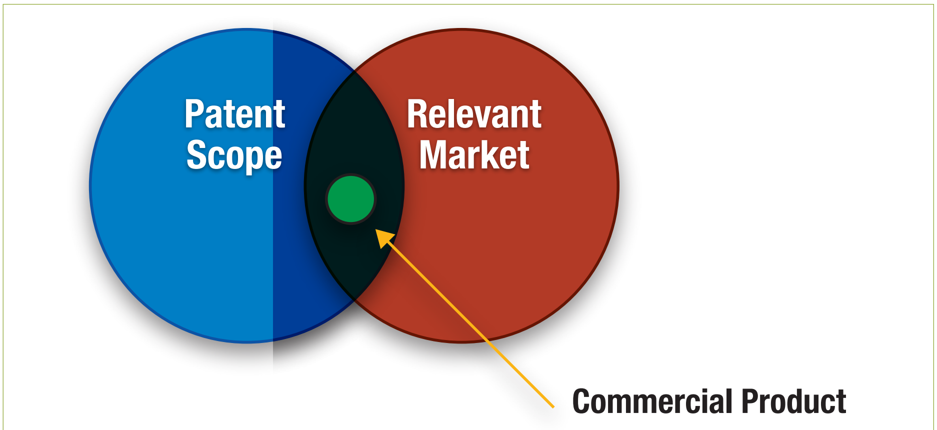

Figure 2 The scope of a patent should be considered with a view to protecting the potential market, not simply the specific product.

Here, the hypothetical patent scope covers the commercial product that a company wants to market, but not the entire relevant market for that product. That means that another company could avoid the patent claims and enter the market. In this case, the company should have spent more time, and money, considering a broader patent claim scope to secure better protection. The goal of a robust patent portfolio is to protect a market space, not just a product.

For example, consider the case of a hypothetical ECG device. There are many aspects of it that could be patented. Figure 3 illustrates the varying aspects of the device that can be potentially patented.

Because various aspects of a new product can be patented, companies should evaluate their patent strategy in light of their business plans. For example, if dispos-

Figure 3 Careful consideration should be given to aspects of a product that may be of particular value and/or subject to potential infringement if not properly protected.

able sensor sales are going to drive profits, then it may be beneficial to invest more resources on patenting aspects of the sensors so that others cannot jump into that business. On the other hand, if the signal processing is the key to success, not only the company's current implementation, but also variations should be patented.

Fourth, search for patents that may pose potential infringement issues to you. A patent provides the right to stop others from using your invention, but it does not grant your company permission to actually use that invention. You may have a great idea to improve a product, but if that product is still covered by a valid patent, then your improved version may nevertheless infringe another patent owner's rights. This can and often does result in expensive litigation and costly settlements that a small start-up typically cannot afford. So, before marketing a commercial product, do the necessary diligence to discover what claims others may have made in that space. Typically this entails performing a search of patents that may cover aspects of your product. After gathering those patents, the company and the attorney can determine if there are any issues. If there are, then the company can consider design alternatives to alleviate any infringement issues or by potentially obtaining a license to the patent.

Finally, companies should systematically and reflexively employ robust non-disclosure agreements. Start-ups often talk to vendors, investors, suppliers, etc. about their innovations. However, these discussions can divulge intellectual property. Because these discussions cannot be avoided, companies should use non-disclosure agreements to preserve the confidentiality of trade secrets, pending commercialization, patent strategy, etc. Companies should not forgo negotiating NDAs in order to gain an audience.

While the above discussion is not exhaustive, following its suggestions and identifying potential intellectual property issues early can save significant expense later on. When the time comes to consult a reputable intellectual property attorney, this knowledge will put your company several steps ahead of the competition.

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