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Medical Device Innovations and the Importance of IP to the Medical Device Industry

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The medical device industry is driven by innovation, where great ideas are developed into successful businesses and products to improve patient care and outcomes. As patent attorneys at one of the largest medical device intellectual property practices in the U.S., we witness many different pathways to innovation and guide IP strategies for innovators of all types. From garage start-ups that become global industry leaders to incubators and university-funded research programs, innovation has no common starting point. One certainty exists, though. A properly executed IP strategy, tailored to the medical device industry, is critical for protecting innovation, creating company value, and ultimately supporting the commercialization of products that will benefit patients.

Sources of Medical Device Innovation

One common starting point for medical device innovation is the physician. Many new innovations start from individual practitioners, such as a surgeon or other specialist who works first-hand with

the types of devices that he or she improves upon. Whether orthopedic, cardiovascular, neurological, or other, physicians with first-hand experience in the causes of medical conditions, the outcomes from devices and treatments, and the implementation of the devices and treatments are often the best equipped to recognize a need for improvement and to foster innovation. This is the reason why a significant number of medical devices come from or are developed in consultation with physicians.

Medical device innovation is an iterative process, and a significant amount of engineering work is needed to translate an initial concept into a viable product. Some physicians are garage inventors themselves, building prototypes using household parts or buying and assembling components into something that can be tested in trials. Frequently, physicians seek out partnerships with engineers who can assist in this process, and many important medical technologies have resulted from the physician-engineer collaboration. Engineers themselves are also often inspired by new medical ideas and will seek out the clinical perspectives of a physician to refine and improve upon these ideas.

Protecting IP is especially important to the solo inventor, who often starts with only an idea and needs to secure some degree of protection, typically with a provisional patent application, before disclosing the idea to others. Solo inventors and early-stage companies should also take care in securing ownership rights to their inventions when seeking the help of others. Non-disclosure agreements, while helpful in maintaining confidentiality, do not typically include IP assignment clauses. Without an IP assignment agreement, the solo inventor runs the risk that one of their collaborators improves upon the invention and claims ownership of the improvement for themselves.

While many innovations are the result of spontaneous inspiration, incubators, who form another important group of innovators, follow a more structured process. Incubators are organizations, including university-sponsored entities (sometimes called bio-design programs), that usually comprise individuals

having orthogonal skill sets and backgrounds that form a multi-disciplinary team. Incubators often include physicians, engineers, scientists, and business professionals. Some incubators study the industry, look for unmet patient needs, and brainstorm ideas. Innovation is a primary focus. Accordingly, the filing of patents, often for a number of different ideas and alternatives, plays a significant role in building asset value.

Universities and other not-for-profit research institutions comprise another important group of innovators. Here, innovation may be driven by a professor or physician focused on a particular area of research. With these types of entities, IP tends to be owned by the respective university or institution, and once it is found to have value, the IP is often licensed to a start-up company, which may sometimes be founded by the university professor. This can provide the start-up company with access to advanced technology at an early stage and sometimes at a lower cost than it would have taken for the start-up company to have developed the technology itself. There can be significant strings attached, however, including royalty obligations, non-exclusivity, not having complete control over the prosecution of the licensed patents, and not having total or partial ownership of improvements to the licensed technology. These and many other IP-related issues should be carefully reviewed and evaluated by the licensee to the technology.

Start-up medical device companies can be formed from any of the above sources. Once established, and as these companies become larger and more successful (*e.g.*, through investment or acquisition), the companies themselves may devote substantial resources to research and development and provide processes and incentives to employees to promote innovation. Large, commercial medical device companies provide the largest share of new commercialized products and patents in the medical device market. These companies often employ a large R&D staff tasked with identifying unmet needs and developing innovative solutions, and typically have large IP budgets to build extensive patent portfolios.

Medical Device IP Strategies and the Importance of IP to the Medical Device Industry

Regardless of the source of innovation, IP protection provides a powerful mechanism for protecting innovative ideas and supporting the development of products that will ultimately benefit patients.

Because medical devices often take years to develop and obtain regulatory approval, for the early-stage company that is making no revenue, a strong IP portfolio can be a valuable asset. It prevents others from copying a company's innovation and demonstrates to investors the company's ability to establish a future market. For commercial-stage medical device companies, a strong IP portfolio is important to preserve market share, and to exclude and possibly enforce against competitors.

It goes without saying that a product's success in the market will breed competition, and the level of competition will likely be commensurate with the pioneering product's success. Equally apparent is the tension between IP budgets and other budgets (and funding generally) in the development stage, regardless of the source of innovation. Because of patent bars and the race to the patent office that exist in nearly every country, IP protection must be started early to be successful. But, as in any industry, there are no accurate predictors of a product's success in the medical industry. This leads many to question when the right time is to invest in IP protection, and how much to invest.

For medical device innovations, it should be expected that the product design will change, often significantly and many times, between initial concept and final product. While it is always important to file early, and especially before there are disclosures to outside parties, some amount of testing, and brainstorming of possible alternatives, can lead to better, more robust initial patent filings that will remain relevant even if the design changes. Innovators and companies should also expect to file additional patent applications as the designs change and significant improvements are made.

When deciding where to file, companies should seek to protect their core technology with patents in the major global markets. As an example, a company that is developing an improved implantable device may wish to put a greater focus on protecting the device in more countries, and file in fewer countries for ancillary components such as delivery accessories or alternative non-commercial medical applications or variations of the device.

Especially important in some countries, particularly the U.S., are "method of use" patents. Unlike most of the world, claims directed to methods of treatment are patentable in the U.S. and can often achieve broader level protection than device-specific patent claims. Method patents can also be easier to obtain through the U.S. Patent Office. Proving infringement can be difficult, however, because a successful claim of infringement would require that

the medical device manufacturer instructs the use of the device in the infringing manner. But as part of an overall medical device patent portfolio, patent filings should include detailed descriptions and claims for both the device and its method of use.

For medical devices, utility patents provide the primary means of patent protection globally. In addition to utility patents, design patent protection in the U.S. and design registrations in other parts of the world may be worth considering. These can provide a more diverse scope of protection at minimal additional cost. Design filings can be considered for the medical device itself, such as implantable devices, delivery devices, electronic components and medical equipment, as well as for other aspects such as graphical user interfaces and medical packaging.

While generating a valuable IP portfolio requires significant investment, the insurance and value that a strong and well-developed patent portfolio can provide far outweighs its cost. In the U.S., as an example, patent holders have achieved damage awards in the tens and hundreds of millions of dollars for infringement of medical device and medical process patents. Injunctions against competitors are also possible, to prevent the sale and distribution of infringing products, though the granting of an injunction by a court is balanced against the public interest served by the medical product. Other benefits of IP protection include licensing revenue, thwarting competitive innovation, defensive strategies, increasing a company's valuation, and more.

Cross-licensing and defensive strategies can provide a significant source of value to a patent holder. Companies may file patents that are peripheral to the company's core technology or principal products but are still comprehensive in detail and provide alternative solutions to a problem to be solved. Patents rich in detail and alternatives can be used to support claims that cover competitor design-arounds, for example. These patents may be obtained for leverage or defensive purposes in competitive or litigious fields. Even for a start-up company, these patents may provide value because of their possible future importance to a larger, acquiring company facing a threat from one of its competitors.

Not all medical device innovations result in commercial products. For some individuals, start-ups,

or other entities, when commercialization of a product stalls or fails, selling the IP assets may be an attractive option that likely justifies its consideration. Possible buyers include commercial companies and competitors who may be infringing the IP rights or are looking to develop the technology for themselves. Another possible group of buyers are non-practicing entities (NPEs). As is undoubtedly familiar to IP professionals, NPEs are companies that acquire patent and other IP rights, but do not sell any products or processes to the marketplace. For practicing entities, the increasing frequency of NPE litigation and assertion of rights emphasizes the importance of comprehensive IP clearance searches and analyses. It is an important reminder that patents do not need to be held by major competitors, practicing companies, or even well-funded or litigious parties, to pose a threat to commercial products and services now or in the future. The bottom line is that the NPE market can present opportunities, or possible risks, to any innovator or practicing entity in the medical device market and should not be overlooked.

In addition to patents, trade secrets can provide significant value to a company if they are properly protected. Manufacturing procedures and techniques, key formulas, future solutions or development plans, materials or ingredients, assays, vendor and supplier lists, customer lists, patient data, and other information not generally known or readily accessible outside of the pioneering entity can all form the basis of protectable and valuable trade secrets. But, like patents, trade secret information must be carefully and properly protected from the earliest stages to ensure its protection and value. Appropriate organization and safeguards adopted at the onset and throughout the lifetime of trade secrets are critical to maintain their value.

Through constant innovation, the medical device industry is able to improve patient care by bringing new products and technologies to market. Developing a thoughtful and comprehensive IP strategy is a critical part of the process. A sound IP strategy enables innovating companies to reap the benefit of their investment and enables advancements in an industry that benefits people around the globe.

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