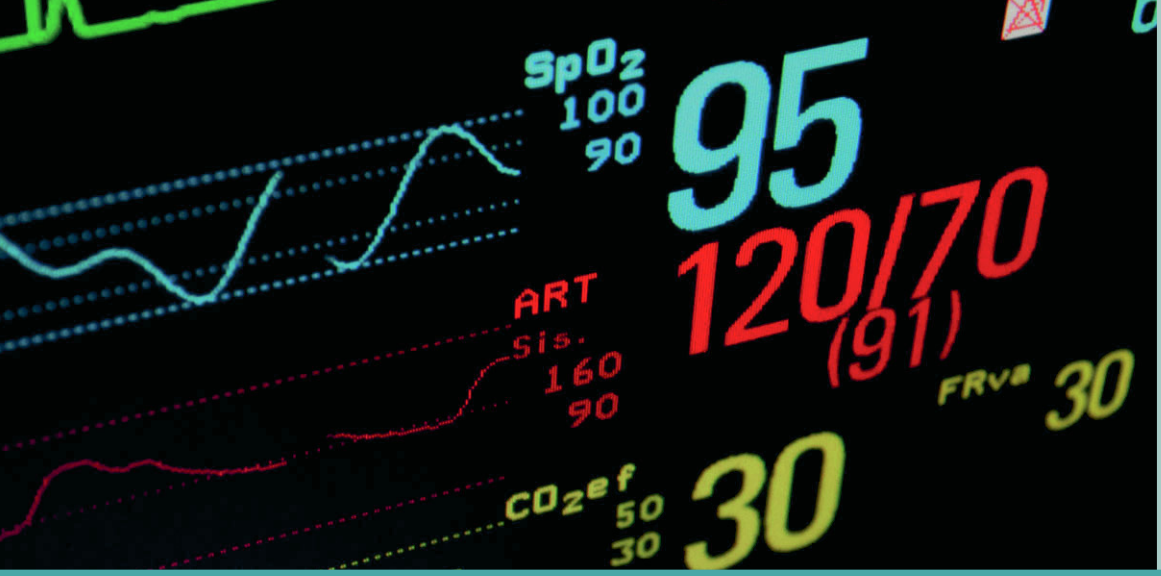

5.1 IP Strategy

INTRODUCTION

The team submitted the original provisional patent six months ago, and a second provisional last month. A venture firm has just completed IP diligence and, although there are no nasty surprises, they have raised concern that a potential competitor is moving in the same direction. The team needs to develop a plan to protect its core ideas and decide where it can afford to pursue patent coverage outside the US. The venture firm is recommending that the team hire the law firm it has used for the diligence, but it could make more sense to recruit an in-house patent council.

Intellectual property (IP) is a particularly important strategic business asset in the medical device field. Not only can a strong IP position help mitigate costly legal settlements, but it can serve as a barrier to entry for competitors, an early source of potential revenue through licensing agreements, and an important overall form of collateral for an entrepreneur or business. Further, an innovator's IP position is a major factor considered by investors in deciding whether or not to fund a technology or its associated company. The best way to develop an effective IP strategy is to establish a solid working knowledge of the patent process, employ experienced IP counsel, work diligently in pursuing patents, and – importantly – understand that patenting is an ongoing activity that requires continual monitoring of the IP landscape and adjustments to one's patent portfolio.

While 4.1 Intellectual Property Basics provides an overview of fundamental IP concepts, the purpose of this chapter is to help innovators understand the value of taking a strategic approach to IP and developing an effective patent portfolio.


See ebiodesign.org for featured videos on IP strategy.

OBJECTIVES

- Understand strategies involved in filing provisional and utility patent applications.
- Appreciate how to conduct and utilize a freedom to operate (FTO) analysis.
- Understand when and how to hire a patent attorney.
- Review basic strategies of international patent filing.
- Appreciate the importance of an ongoing patent management strategy based on continuous internal and external monitoring.
- Consider different defensive and offensive IP portfolio strategies.

IP STRATEGY FUNDAMENTALS

With more than 2.1 million **patents** in force in the United States alone,[1] effectively navigating the IP landscape is undoubtedly complicated. The number of US-based IP lawsuits filed annually continues to increase, crossing the 5,000 case threshold in 2012.[2] The **medtech** industry is especially litigious, with large teams and significant budgets directed toward pursuing and protecting patents.

Against this backdrop, there are two main categories of IP strategy to consider – first, issues that the innovator should keep in mind while pursing patentability and **freedom to operate** and, second, strategies to establish and maintain an integrated and ongoing IP management process.

Strategies in pursuing patent coverage

There are many strategic issues to consider regarding patentability, but a handful of them are particularly important concerns, especially for first-time innovators. One frequent question is whether to file a **provisional** application or proceed directly to a full **utility patent**. In general, a carefully prepared provisional patent has the advantage of gaining the inventor an effective extra year of protection, comparable to the situation of an inventor filing outside the US. The utility application has a 20-year life (from its filing date) and can be filed up to a year after the provisional. So the provisional can be used to firmly establish the **priority date**; then, once the device is in sales (typically a few years later), the protection offered by the utility patent will last a year longer than if the utility patent was filed immediately. Another important consideration is that, in some cases, it may be faster to file a provisional patent application than a non-provisional application. The US is now a "first to file" patent system, as described in chapter 4.1, so receiving an early priority date with the **USPTO** can be important in order to increase the probability of being the first inventor to file for a patent to a particular invention. Additionally, there can be a cost advantage to a provisional patent compared to a utility application if an attorney is not used to draft the provisional application. This can be a false economy, however, if the resulting provisional patent application is not thorough and of high quality. As described more fully in 4.1 Intellectual Property Basics, a careless provisional application can create enormous downstream trouble and expense for innovators and their companies.

A second question that comes up frequently is whether it is possible to "improve" a provisional patent application once it is filed. The short answer is that it is not possible to add to or modify a provisional application. If there is a substantial new discovery related to the initial disclosure, the innovators have the option to file a new provisional application or to initiate a utility filing that includes both the original and the new material. However, the priority date of a new provisional patent application will become the date of the second filing. Once an initial provisional patent application is filed, it may be beneficial to file additional provisional patent applications in the year leading up to the first provisional conversion deadline. These additional applications should be filed in a timely fashion to cover new incremental changes in a product or product features as they are developed over the course of the year. By waiting to file a single non-provisional patent application that includes all of the new subject matter invented since the first provisional patent application, innovators may risk losing the right to obtain a patent to the new subject matter if another party files a patent application or otherwise discloses the new subject matter first.

Innovators often wonder whether to bundle all aspects of their invention into a single patent, or try to divide it up into multiple patents. For a provisional application, this issue is usually not critically important. At the time of filing a utility patent application, an IP attorney can generally advise the innovators on whether or not to file more than one application. At this point, there are several considerations that may come into play. On the downside of filing multiple patent applications, there is the issue of the cost (which is magnified greatly if there will be international filings, too). However, multiple filings may be attractive if some piece of the original **concept** is more clearly novel and unobvious than the rest. Creating a separate filing for this piece of the original provisional patent could help the innovators gain

approval more quickly for a particular subset of claims, which could be desirable, for instance, in advance of an upcoming product release. Similarly, if the innovators have a possibility of **licensing** some part of their IP to an existing company for **royalties**, it may make sense to isolate that aspect of the technology in its own patent filing to make the licensing agreement more straightforward.

Separating a patent application into parts can be accomplished by filing continuation applications, described in more detail later in the chapter. Another way that carving up a patent application occurs is in response to an **office action** (OA) by the patent office in which there is a restriction requirement. This occurs when the patent examiner deems that the original filing covers more than one invention (patent law allows only one invention per patent) such that it needs to be divided into several applications. The filing mechanism for dividing a patent into parts in this setting is called a **divisional**, which is a new patent application that claims a distinct or independent invention based upon pertinent parts carved out of the specification in the original patent.

A more sophisticated patent filing strategy issue – one that is more often dealt with by companies than individual inventors – is the question of whether to pursue **trade secret** protection rather than a patent. As described in chapter 4.1, a trade secret is information, processes, techniques, or other knowledge that is not made public but provides the innovators with a competitive advantage. In the medtech field, trade secrets often have to do with how a particular device is made (materials, manufacturing process, etc.). There is no application for a trade secret and no official granting of this right by the government. Innovators or companies assert trade secret protection by taking protective measures within their own operations and then suing any entity which wrongfully obtains the protected information. In order to prevail, the company with the trade secret rights must demonstrate that it has taken reasonable precautions to protect the information (for example, having its employees sign an agreement not to disclose, creating a special, high-security room where the trade secret is protected, and so on).

In some circumstances trade secret protection is much more effective than a patent, something which first-time innovators tend not to realize. For a start, if an invention is kept as a trade secret, no competitor should become aware of it. In contrast, a utility patent publishes 18 months after filing. Perhaps more important, a properly kept trade secret can potentially last forever, as long as the company is careful to keep the information secret (the most famous example of this is the formula for Coca-Cola). Although trade secret protection does not involve any filing fees up front, the costs and organizational effort involved in keeping a process secret can be considerable. Commonly, in the medtech field, a company might consider protecting its manufacturing methods as trade secrets, particularly if they are not easily reverse engineered by examining the commercial product.

Relying on trade secrets to protect intellectual property assets can be especially attractive in markets where traditional patent protection is weak and infringement is rife. Yoh-Chie Lu, the chairman of Biosensors International, was faced with such a situation in China when his team began to collaborate with a Chinese medical products manufacturer called Shandong Weigao. The partnership was a 50–50 joint venture called JW Medical Systems (JWMS), which manufactured and sold drug-eluting stents (DES) in the Chinese market.[3] Biosensors, the foreign partner, owned the intellectual property and the technical know-how necessary to manufacture the innovative DES, while Shandong Weigao had a local Chinese presence, deep connections, and a cost-effective manufacturing facility. Although Biosensors had patent protection in China for its novel drug-polymer coating for stents, Lu knew that the expense and time involved in taking an entity to court in China for patent infringement was not worthwhile. Instead, Biosensors chose to implement several strategies to protect its trade secrets, even from its local partner. JWMS set up a separate compound within the Shandong Weigao manufacturing facility and employed its own security team. Engineers from Shandong Weigao were not permitted to enter JWMS facilities and only a few select JWMS employees were authorized to view critical documents. Biosensors' CEO, Jack Wang, was the only JWMS employee who knew the formula to

mix the drug and polymer to create the novel stent coating. With such strict trade secret protection strategies in place, Biosensors was able to maintain its position in the Chinese market as the sole manufacturer of the novel drug-polymer coated stent, and JWMS grew to become the third largest DES company in China.[4]

Freedom to operate strategies

It is a common misconception among first-time inventors that gaining a patent on a device means that the device is free and clear to commercialize (see 4.1 Intellectual Property Basics). The device may indeed have a patentable feature, but it may also have other features that infringe on claims of existing patents that are in force. With medical devices, inventors often discover potential freedom to operate (FTO) problems once a careful analysis is performed for a new invention. In certain heavily trafficked areas of medical devices – vascular stents, for example – it is extremely difficult to come up with an idea that has complete FTO.

An FTO analysis begins with a comprehensive search of patents that are currently active (generally in the past 20 years). The inventor is looking for **prior art** that is in the same area as the new invention. Importantly, a thorough search will almost always turn up prior art that is potentially of concern. It is easy to get discouraged by a superficial look at the abstract or drawings of an existing patent. However, inventors should not automatically assume that there is no FTO if a device pictured in a patent or described in the abstract looks or sounds similar to the device they invented. *The key is in the claims*.

The way to understand whether the new invention is distinct from the prior art is to carefully assess whether one or more claims of the potentially infringed patent apply to the new invention. In order for an existing patent to prevent an inventor from going forward with an invention, every part of at least one of the independent (stand-alone) claims has to fit the invention. For example, suppose an inventor has developed an angioplasty catheter (a catheter with a balloon used to dilate a narrowing in a blood vessel) where the key feature is that the balloon is wider in the middle than at the ends. In a patent search, the inventor might find an existing patent where the claim is: "A tubular member with a balloon at the distal end in which said balloon has a larger dimension in the middle region than at both ends of the balloon and said middle region has a generally convex outward shape." The good news is that if the new invention does not have a convex shape in the middle, it is not covered by this particular claim. In fact, this claim may suggest that these inventors thought that anything besides a convex shape would not work, leaving room for a different shape to be patented. The bad news is that the existing claim covers the general idea and, thus, would potentially make the new invention obvious and not patentable. Furthermore, the inclusion of specific language about the convex shape raises the possibility that somewhere in the patent world is a more general claim covering the broader case (otherwise, it might not have been necessary to make this independent claim so specific). In this situation, it would be helpful to look at the prior art cited in the patent to see where this claim might lie. Another helpful place to look is the prosecution history of the claim. A lot can be learned about a claim and where it fits into the broader patent landscape by reviewing the amendments and arguments that were made to bring the claim in question to allowance. The prosecution history of any published application can be retrieved from the USPTO Public Patent Application Information Retrieval (PAIR) system. In practice, it can be difficult to determine whether or not there is an FTO issue. A patent attorney with medical device domain expertise can be extremely helpful in clarifying the situation. Ultimately, the final decision about FTO may be made in court through the litigation process.

During an FTO analysis, the innovators should keep in mind that under US patent law inventors may "act as their own **lexicographer**" in a patent application. This means they can give common words or phrases meanings that are specific and different from their normal definition. However, all such terms must be described or defined in the description section of the patent specification. If a term is defined in the description, it must be construed in the remainder of the patent and claims in accordance with that definition; otherwise, the plain meaning of the word (as determined by a how a regular

person in the field would understand the term) will be used. In medical device patents, it is common to list examples to help clarify the use of a term without limiting it. For example, in the classic Palmaz® stent patent, the key claims referred to an "expandable intraluminal vascular graft." What this term means for this patent is clarified in the second paragraph by examples: "Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs ... and expanding stainless steel stents ...."[5] Sometimes patent attorneys will define a key term by saying it "includes *but is not limited* to X, Y and Z" to keep the definition as broad as possible.

There is a range of possible outcomes from an FTO analysis, which vary from low to high risk as shown in Figure 5.1.1. If a thorough analysis suggests that there may be an FTO problem, there are a number of conditions to check that may help the inventor avoid the issue:[6] (1) the patent may not have been applied for, or granted, in the country where the company is seeking to operate; (2) the patent may have lapsed (e.g., if the patent-holder has not kept current with the required maintenance fee payments); (3) the patent may have expired (be sure to check expiration dates); (4) the patent may be invalid (sorting this out will take legal expertise).

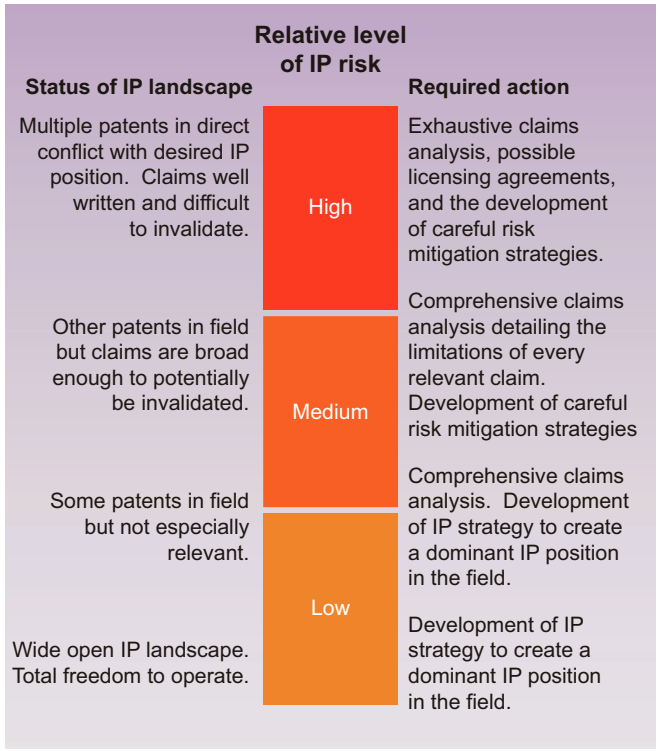

FIGURE 5.1.1
The level of risk associated with protecting a technology has profound strategic implications on the inventors and their company (developed in collaboration with Mika Mayer and Tom Ciotti of Morrison & Foerster LLP).

If there is a clear, high-risk FTO problem, the innovators still have potentially fruitful options to pursue. First, they can try to "design around" the claims of issue by modifying the invention so that the patentability is maintained but the features that infringe current patents are removed or altered. This is a routine part of the biodesign innovation process, which most inventors go through with their inventions. It is a perfect opportunity to convene **brainstorming** sessions and in particular to bring in fresh advisors to see if there are other approaches that avoid infringement. In many cases, this process of re-inventing leads to important and unanticipated improvement in the fundamental invention.

If the feature revealed in the FTO analysis is absolutely essential to the new invention, the second option is to pursue licensing of the problematic patent from the entity that owns it. Medtech patents owned by universities may be readily available for an innovator to pick up, since these can be complicated and time-consuming for the university to license to large companies. Licensing of a key patent from a company is generally more challenging. It is sometimes possible to get a license to a limited **field of use** (usually a clinical area) that the company is not interested in pursuing. A company may also be willing to trade IP, such that the innovator gives rights to the new invention (perhaps in a limited field of use) in exchange for rights to the critical patent from the FTO analysis. See 6.4 Alternate Pathways for more information on licensing strategies.

The Spiracur example illustrates how one emerging company managed a complex patent landscape analysis as part of developing its IP strategy.

FROM THE FIELD SPIRACUR

Building an effective IP strategy

Moshe Pinto, Dean Hu, and Kenton Fong began working together while students in the Stanford Biodesign Program to address the need *to promote the healing of chronic wounds* (see Figure 5.1.2). This team, which eventually became Spiracur, initially developed an IP strategy through extensive prior art searching and the filing of a provisional patent application. However, these steps were just the beginning of Spiracur's activities.

The team also went to work right away on an in-depth patent analysis. Spiracur recognized the importance of working with strong IP counsel to guide its IP activities and the development of a holistic IP strategy. However, the team also felt strongly about performing much of the early work themselves, so they could save money on fees by providing the IP attorneys with a concrete, comprehensive analysis from which to start. This work would also help them become more knowledgeable in the field and increase their credibility with investors and other **stakeholders**. For these reasons, the three entrepreneurs initiated the analysis on their own, performing extensive searches using resources such as the USPTO databases and Free Patents Online.

In terms of performing patent searches, Pinto commented, "You have to be savvy about the search strings you use."[7] While many start-up companies use a funnel approach – starting broad and then getting more specific – Pinto offered another suggestion, which he called "inverting the funnel." The idea is to start with highly specific search strings that yield a relatively small number of relevant patents. After examining these patents, the team can then use the reference charts within the patents to identify other relevant patents. It can also mine this information for clues for developing new, slightly broader search strings that yield a greater number of results. "Through this approach, the inventors quickly gain familiarity with the IP landscape in their space and can more effectively separate the wheat from the chaff as they continue their analysis with the broader search terms," Pinto explained.

FIGURE 5.1.2
Hu, Pinto, and Fong of Spiracur (courtesy of Spiracur).

To support the patent analysis, the team carefully analyzed each search result. Without any patent law training, the team was at somewhat of a disadvantage in analyzing them. "Dean was an engineering PhD and Kenton was a resident of plastic surgery," explained Pinto. The team, however, worked out a process. Hu and Fong would utilize their scientific training to screen the initial search results for subject matter that might have some threshold interest to them. These interim results were then passed to Pinto, who had more of a business background, and later to their attorneys.

Pinto admitted that the patent analysis could, at times, seem daunting. "If, for example, you run a search on the words 'pressure sores,' you'll get 60,000 patents. There is an initial evaluation of the patents that almost anyone can do just by looking at abstracts. But when it's time to derive conclusions based on what you find, it's important to have someone who is legally savvy to perform this work."

In total, Pinto estimated that the team reviewed the abstracts and drawings of more than 1,000 patents and identified roughly 250 to 300 patents for their IP attorney

to evaluate and use to help them develop a patent strategy for their technology. When Spiracur initiated its Series A funding round, the team was prepared for the due diligence performed by the investors' IP attorneys and was able to successfully close the funding round.

In terms of offering advice to others who are building an IP strategy, Pinto emphasized that IP needs to be a primary concern for entrepreneurs. "Inventors need to realize that their exit from a medical device venture is pretty much constrained or determined by the strength of their IP position," he said. "If there is one thing I learned in retrospect, it is that we should have dedicated more time and effort to the entire IP endeavor than we did." When asked to estimate the amount of time a start-up company should invest, he commented: "The investors have it calculated. If we look at it from a budget perspective, they want to see the ongoing time of an IP lawyer at roughly $20,000 dollars a month. That translates to about 25 to 30 hours of an IP expert per month."

Pinto also stressed that one's focus on IP had to be continuous and progressive. "What I suggest is that even after you submit a provisional with claims with the help of a legal expert, revisit it after a month. Don't wait for the end of the 12-month period to say, 'Now, let's see how we can convert this into a utility patent application.' Do the iterations sooner as more information is gathered." Finally, he said, "Remember that quantity does matter." A sound IP strategy must seek to consistently improve the coverage and protection surrounding the company's technology. "When later-stage investors asked what we had done in IP, I told them that we had eight provisionals and three pending utility patent applications," said Pinto. "This kind of ongoing activity assures them that you are paying sufficient attention to IP."

Hiring legal help

While medtech innovators sometimes file provisional patent applications on their own, it can be highly beneficial to have an expert attorney prepare these or at least review them before filing. To file a utility patent application, it is almost always essential to hire a professional. The cost of an IP attorney varies significantly. Usually an initial consultation can be obtained without any charge. Hourly rates thereafter range from $300 to $800. This means that the costs of preparing a utility application on a relatively simple medical device will be in the $8,000 to $14,000 range, including a relatively narrow patentability search. A utility patent application on a complicated technology may run as much as $30,000. A search with a patentability opinion might be $3,000 to $5,000. A complete, formal FTO opinion may cost $25,000 to $100,000 (this expense not only reflects extensive search work, but the fact that, in some cases, the attorneys issue a detailed, written opinion on FTO). Some medtech patent attorneys offer an intermediate approach, consisting of a careful search for prior art and a discussion with the inventors (and potential investors) about the broad scenario for FTO. The cost of this less formal analysis may be in the $5,000 to $10,000 range, depending on the complexity of the patent landscape.[8]

Law firms recognize that inventors are cash-challenged in the early stages of the biodesign innovation process and some will offer alternate payment strategies, including deferring payments or taking equity (stock). Because it is fairly easy to run up a large patent "tab" quickly, many established firms are not willing to defer payments or take equity alone. Another option, which can often be less expensive than working with a patent attorney, is to engage a patent agent. Patent agents are registered to practice *only* before the USPTO and, as such, cannot conduct patent litigation in the courts or perform services, which the local jurisdiction considers as practicing law (for example, providing opinions on patentability, ownership, or validity, or performing FTO analyses).[9] Usually, patent agents are engineers who have successfully passed the USPTO patent office exam,

or have served for four years or more as a US patent examiner before entering private patent practice.[10] Patent agents can offer a cost-effective approach when the innovator's IP needs are relatively straightforward, there is broad FTO in the field, and/or the innovator does not anticipate litigation. Note that many law firms employ patent agents and patent attorneys in their IP practices, so that a client company can benefit from a full range of services, for example, by using agents to draft applications and associates and partners to help with IP strategy and litigation.

There are several guidelines to consider in finding a patent attorney or agent.[11] It is important to seek someone with experience filing similar medtech patents (in the same technology and clinical area, if possible). The better medtech patent firms will have previously performed detailed patent landscape analyses in many areas, and these provide attorneys in these firms with substantial background. In some situations, certain attorneys may not be able to work on a filing because their firm has another case that represents a potential conflict of interest. The law firm will make this determination before agreeing to begin the contract. As with engaging any consultant, it is helpful to get recommendations from experienced inventors and entrepreneurs in the field. Note that faculty or student inventors may be steered to a particular attorney by the university's office of technology licensing (**OTL** – see 6.4 Alternate Pathways). However, it is worthwhile doing an independent validation of the expertise of the attorney before proceeding.

Working with an attorney or patent agent who is geographically located near to the innovator is of course convenient. Yet, given the ease of electronic communication, it is generally more important to find someone with expertise in the technical and clinical domain of the invention than someone who is co-located. Make sure there is an explicit understanding of how (and how much) any attorneys will charge for their time to avoid unpleasant surprises. Ask for a face-to-face consultation to gauge the attorney's approach and assess the "chemistry" between the attorneys and the individuals with whom they work most closely (open, clear communication is essential).

In meeting with the attorney, do not ask general questions that can be addressed by reading a book or performing online searches. Invest time in advance to become educated on IP issues so that the attorney's time can be used more effectively to address unique and complex issues (rather than basic questions). Consider creating an initial draft of the application and/or the claims before getting too deeply into the patent drafting process. While the attorney will surely modify the draft, it will likely save time and money by ensuring that everyone has the same understanding of what the patent application will look like.

International filing strategies

An international IP strategy should be developed with the costs and benefits associated with the filings outside the US clearly in mind. Every foreign patent application will require a significant financial commitment (e.g., $250,000–$500,000 over the life of the patent, not including the cost of any potential litigation required to enforce it). This high cost is driven primarily by the need for specialized legal and translation services for each country (the European Patent Organization is an exception, see 4.1 Intellectual Property Basics). To justify such a sizable financial commitment, an innovator or company must be certain that the benefits of the foreign filings will be measurable and central to the overall business strategy. Particularly during the early stages of a company's development, foreign filing should be made when there is a clear strategic rationale (e.g., the product is anticipated to generate a sizable percentage of its revenues internationally). The selection of countries varies from case to case. For many medical devices, it is common to include Europe, Japan, Australia, Canada, and Israel in international filings of US patents. Increasingly the BRIC countries (Brazil, Russia, India and China) are of interest because they can offer attractive emerging markets. Mexico is sometimes considered because it is a cost-effective location for manufacturing.

Other special considerations – and geographies – may come into play depending on the nature of the technology and business strategy goals of the start-up company. Consider Neodyne Biosciences as an example. Neodyne develops and commercializes tissue repair devices that

minimize scar formation, which the company has initially targeted at providers in the aesthetic and reconstructive plastic surgery fields. Given the attractiveness of aesthetic surgery markets outside the US, Neodyne began to analyze its international patent protection strategy early. According to Bill Beasley, the president and chief operating officer of the company, "Neodyne looked at two main questions when selecting countries in which to seek patent protection. First, is there a strong market opportunity for our product in that country? And, second, how do those countries value intellectual property?" Another factor that can come into play is the cost and complexity of filing IP in certain countries, which has to be weighed against the risks of the company's technology not being protected in those markets. "Certain investors are more interested than others in comprehensive patent protection, which may guide a start-up's decision to invest in their IP strategy," said Beasley. Neodyne filed patents in China and India due to their enormous market size; in Brazil, Japan, and South Korea because of the large, local aesthetic products markets; and in Israel because "it's a good place to secure a strong patent position," explained Beasley. The company also filed in Europe via the European Patent Office (**EPO**), in Australia for **clinical trial** access, and in Canada to establish access a neighboring geography from its headquarters in the US. Beasley advised innovators to think early about their commercialization strategy, and which markets are most attractive for their technology. "Think of your IP as assets that have value, for instance, to potential acquirers. It is also important to understand your company's overall appetite for investing in IP and whether the technology and market opportunity warrant a large investment."

Innovators should also take into account the fact that they may ultimately want to *manufacture* in a different country. To the extent they can anticipate this, it is critically important to file in the candidate locations (major medical device manufacturing capabilities exist in Belgium, Costa Rica, Ireland, Mexico, Taiwan, and several other countries). If innovators are targeting a particular large company as a potential acquirer of their technology, it is also worth considering where that company has its deepest roots. For example, a German medical technology company like Maquet might have some hesitation in acquiring a technology for which no patent rights have been pursued in Germany.

Strategies in managing a patent portfolio

Many early-stage innovators put much more emphasis on the filing and obtaining of an initial patent than on developing a comprehensive and ongoing patent strategy. This kind of approach to IP carries with it sizable risks that can negatively affect an innovator's ability to raise funding, not to mention threatening the viability of the company once it gets started. In contrast, innovators and companies that strategically manage their IP portfolios stand to minimize their IP-related risks, differentiate themselves from their peers, and increase the value of their businesses. By taking an active approach to managing IP, the value a company receives from its IP investment can evolve from merely protecting its inventions to controlling (and even preempting) competition, building markets, delivering revenue, and driving business strategy.[12] It is useful to think of these benefits in the form of a hierarchy, as shown in Figure 5.1.3, in which protecting inventions is the base upon which increasingly important benefits are built.

There are two basic features of an effective and valuable patent portfolio. First, the patents must actually cover the products that are developed. This sounds trivially obvious but, in practice, there is a real risk that the development and refinement of a medtech device will outrun the patent coverage. This happens due to a lack of continued attention to IP during the development process (i.e., in response to **prototyping** and testing, the team adds key features to the design that may or may not be patentable). In the hurry and pressure to get a product to market, the team may simply forget that new IP has been created (or that the new features may infringe existing patents).

The second characteristic of an effective patent portfolio is that it creates real barriers to entry. It is not sufficient for the innovators to patent the features of their new device. It is essential to anticipate who might be able to develop a similar device or a next-generation product and then develop patents to block that from happening.

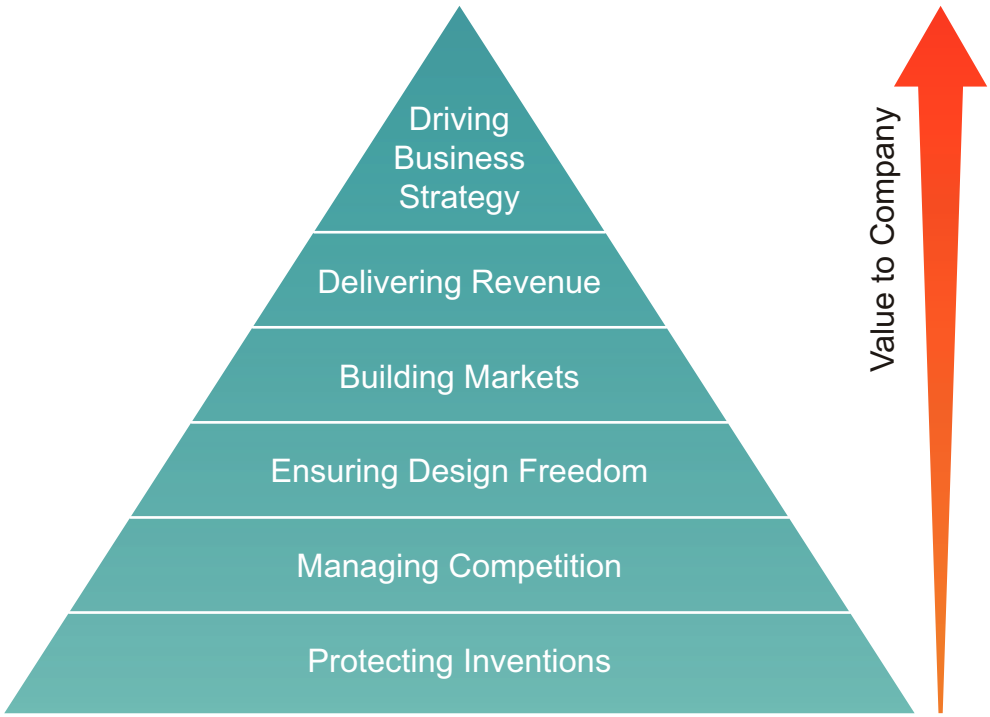

FIGURE 5.1.3
As innovators and companies take a more strategic approach to managing IP, the value they receive from their IP investments increase dramatically (based on Ron Epstein, "Building a Business Relevant IP Strategy," IPotential, LLC; reprinted with permission).

This requires an in-depth understanding of the competitive landscape – not only the patent portfolios and filings of the main competitors, but their business strategies as well.

The mechanism for developing and maintaining a valuable patent portfolio is *continuous internal and external monitoring* of IP. Internally, IP must be integrated into the ongoing research, development, and business planning strategies – that is, it must be an active part of the awareness and work of all team members. Time and attention need to be explicitly allocated to correlate the progress being made in prototyping and testing with the approach to patenting. As new team members are added, it is essential that they be educated in the importance of keeping careful **innovation notebooks** and in the dangers of **public disclosure**. External monitoring means that at least some member(s) of the team must focus on surveying and understanding what competitors and potential competitors in the field are doing on a regular basis. Effective ways to gather this information include talking with physicians and attending symposia, courses, and trade shows. This will also help the team stay up-to-date on the other relevant developments in the field (including the clinical science).

The ongoing monitoring of internal and external IP activity leads to two basic types of proactive patent strategies: *defensive* and *offensive*.

Defensive strategies

Defensive strategies represent the more familiar of the types of approaches innovators can pursue. They refer to developing patents and claims that will exclude others from making, using, or selling the technology that the innovator has invented. The key issue is to understand where the innovation is going as it moves toward clinical practice. This means that in thinking about an invention it is essential to consider not only the device in isolation, but also how it will be used. Is it part of a system (and if so, are there other parts of that system that also need to be protected)? How will it be packaged? Will it come in a kit? Are there certain methods of use that should be patented along with the device claims? Are there other indications (other places in the body or alternate procedures) in which the device could be used? If so, are there other components or aspects that need to be added? Using these considerations to create a series of secondary patents and claims that serve as a barrier to competitors is

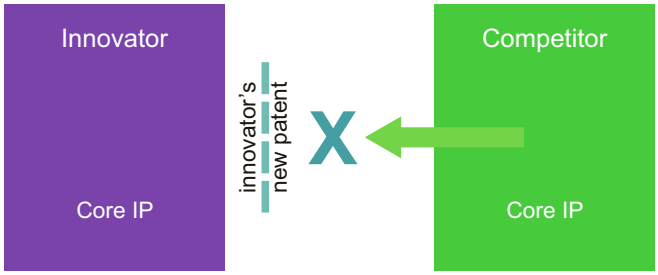

FIGURE 5.1.4
A picket fence strategy gets its name because it uses adjunctive patents to surround the core intellectual property, keeping a competitor outside of the innovator's core patent territory.

sometimes called a picket fence strategy (see Figure 5.1.4).

To illustrate this approach with an example, consider a new vascular stent that has the property of being bioresorbable (it dissolves within the body over time). The inventors are clearly interested in protecting the stent itself – the special, resorbable material and the strut configuration that gives the stent enough radial force to prop open the artery. This is the core IP. But there are other, potentially patentable aspects of using the stent that could also be covered. How is the stent expanded (e.g., with a balloon or some other deployment mechanism)? Does the catheter delivery system have special features, perhaps related to the deployment method chosen? Does the packaging need to be specialized, for instance, to preserve the shelf life of the new stent material? Is there a need for this kind of stent in some other application (e.g., to open the esophagus in children with atresia (narrowing))? Pursuing patents in some (or all) of these different areas would provide the innovators with a defensive shield around the core IP. Just be aware that laws in this area are constantly changing and recent efforts to target "non-practicing entities" may potentially limit a company's ability to protect patents that cover areas that they are not directly pursuing.

One extremely important tool in building a defensive patent strategy is through continuation patent applications, which allow inventors to refine the claims structure during the patent prosecution process. Basically, a continuation is an application that is filed to pursue additional claims to an invention using the identical description or specification from the original patent. A continuation must list at least one of the same inventors as the original patent. Claims filed as part of a continuation will receive the same filing date priority as the original application.

The power of the continuation process for defensive strategy is significant. As the team gains experience with the original concept, including further prototyping and early-stage testing, important aspects of the invention become clearer. With time, the team is also likely to gain a more informed idea of what potential competitors in the field are doing and what will be necessary to protect the core IP. The continuation process then allows the team to submit new claims that provide a sharper focus on the invention, based on continued experience, thinking, and surveillance of the marketplace. Although obtaining new claims for an invention can seem like "getting something for nothing," keep in mind that claims are meant to clearly define what constitutes the invention. The invention or inventions – as described in the specification – cannot change with continuations, which is why it is important to include multiple well-described embodiments in the original filing. The new claims provide a way to communicate more exactly what the invention is. Keep in mind, also, that the continuation process does not extend the life of the patent – the priority date goes back to the filing date of the original patent specification and the expiration date is based upon the priority date.

In developing a defensive strategy for patent protection, it is essential to promote an active dialog between the patent attorney and the development team. Early teams tend to be worried about the expense of frequent meetings with an attorney. This can be mitigated by having a regular but brief check-in, perhaps by phone, where the team has prepared a succinct update of new test results, development milestones, and the concepts that have come from these. In addition, as the team grows, every member needs to be educated about the basics of intellectual property, either by the attorney or by savvy members of the team. This kind of communication and education is the best way to prevent the loss of rights of a patent either in the US or internationally.

One mechanism to employ the creative talents of the team in building the defensive patent portfolio is to organize invent-around (or design-around) brainstorming sessions. Have the team pretend they are working for a competitor and challenge them to design approaches that will bypass the existing patent claims. These sessions are of course worthwhile for the patent attorney to attend. The results can be used to fill in the gaps in the defensive position, either through new patent filings or new claims through the continuation process.

With respect to claims, an important approach in developing a defensive strategy is to create a range of broad and narrow claims, sometimes called "layered" protection. Broad claims are of course desirable, but keep in mind that they are also at higher risk of being declared invalid in litigation. Narrow claims do not offer as much protection (i.e., they are easier to work around), but they can be granted more quickly. Narrow claims, for example, can include language that is targeted toward specific commercial embodiments. A layered combination of broad and narrow claims provides the best chance to maintain an effective defensive barrier after the patent prosecution process. The timing of product entry into the market can be an important factor in suggesting an appropriate mix of broad and narrow claims. If **FDA** approval is anticipated to be relatively quick (a **510(k)** clearance, for example) and the product can be brought to market easily, it may be strategically important to have some narrow claims already issued on the device to protect its introduction to the marketplace.

To benefit from the defensive protection of a patent, the owners must threaten or take legal action (e.g., filing a lawsuit) against anyone who infringes on their IP. In the realm of medical devices, the company that has been assigned the IP or licensed the patents (from a university, for example) is generally the one that takes on the responsibility of pursuing potential infringers. Occasionally, universities will also take on this role, although in medtech there are a relatively small number of "blockbuster" patents that rise to this level of attention on the part of the university.

There is a cost-effective variation on the picket fence defensive patenting strategy that some innovators and companies employ – namely, to intentionally publish information on incremental improvements and new uses related to a core IP asset in order to create a buffer of publicly disclosed prior art to keep competitors away. This has the same effect as additional patent coverage in terms of keeping competitors from owning these improvements, but has the advantage of being fast and free.

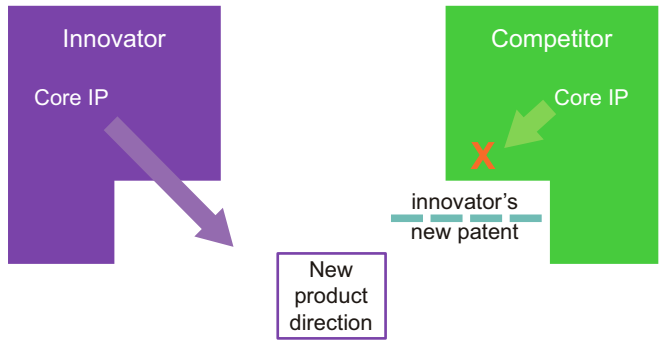

FIGURE 5.1.5
One offensive IP strategy is to preempt a competitor's ability to move toward a new product design by means of a blocking patent.

Offensive strategies

Offensive patent strategies refer to approaches that look outward to the competitive landscape and try to take advantage of the patent position of other companies. These strategies tend to be less intuitive and more difficult than defensive strategies for first-time innovators (who are typically focused on developing and protecting their inventions). However, understanding the direction of competitors in the marketplace and moving in an intelligent and proactive way in reaction to (or anticipation of) their IP portfolios is an absolutely essential means of ensuring that the innovator's product will successfully make it into clinical care.

The first offensive strategy is to anticipate the direction that a competitor may be headed and create IP that blocks that approach (see Figure 5.1.5). Sometimes an innovator can see the competitive pathway clearly enough to create new IP just for the purpose of blocking a particular competitor. In other cases, the block arises from both groups independently seeing the same general technical direction, and one group inventing earlier than

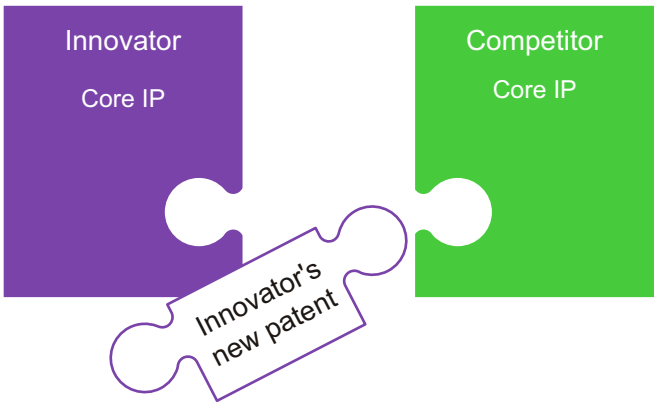

FIGURE 5.1.6
An offensive bridging strategy that complements and/or fills a gap in a competitor's IP portfolio can be effective for an innovator seeking to license or sell a technology to a larger company.

the other. In the case example on Intuitive Surgical, Dr. Fred Moll recounts a classic situation in which Intuitive Surgical, a robotics company, became concerned about patents owned by a competitor, Computer Motion. The patents, which described fundamental software-controlled mechanisms of translating hand movement to instrument tip movement, were directly in the path that Intuitive wanted to pursue in developing its da Vinci® robot. After a great deal of wrangling, this offensive block ultimately led to the **acquisition** of Computer Motion by Intuitive.

A second offensive strategy is also based on an intimate knowledge of a competitor's IP portfolio and business strategy, but in this case involves explicitly linking into the competitor's IP by building a bridge to it with a new patent, as shown in Figure 5.1.6. This strategy should be used specifically when there is a candidate company that the innovators thinks would be a good fit to acquire the new technology. It requires the innovators to have a good understanding of both the basic IP position of the acquiring company and at least some sense of the company's priorities with respect to new technology directions. In practice, this latter information may only become apparent as the inventor has discussions with the company about potential licensing of the core technology.

All of these offensive and defensive strategies require a high level of diligence in pursuing information about competitive companies. With respect to IP, it is important to perform regular and ongoing searches of US and international patent databases using the appropriate keywords, competitor companies, and known inventors in the field. In addition to patent searching, the team must keep up with the clinical literature in the area, stay current on new product releases, and periodically perform Google searches around the technology itself, key companies, inventors, and also clinicians. In an active technology area, it is not uncommon to find 50 or more "hits" a week of potentially interesting new information.

Strategies related to timing of patents

Real patent coverage begins when a utility patent is issued. Between the date of publication and the date of issuance of a utility patent, innovators cannot prevent another company from operating in the space of the invention. Having additional companies operate in the same space, even if just for a short while, can erode prices, thus, impacting long-term revenues even once the other companies are restrained. Ideally, innovators will have patent coverage (under an issued utility patent) at the time their product goes to market.

A relatively new tool from the USPTO is the Prioritized Patent Examination Program, known as "Track One."[13] This program allows applicants, for a fee, to receive a final action from the USPTO on their patent application within twelve months. This expedited process can be helpful in coordinating the timing of patent issuance with a company's entry into the marketplace. It can also be used to ensure the company had at least one issued patent in its portfolio as it approaches other important milestones, such as those related to fundraising. Furthermore, in a space with a competitive IP landscape, Track One can be used beat competitors *through* the patent office and give the company a basis from which to defend its IP position (i.e., patent lawsuits cannot be initiated based on a pending patent application). Track One is best suited for patent applications with narrow claims because they move through the patent office more quickly and stand up better in litigation. The primary reason not to pursue Track One is if the company cannot afford it. Additional fees must be paid to the USPTO, and this expedited approach also condenses the amount of

attorney time the company spends on its application into one year, starting very soon after filing.

An alternate approach is for the company to delay its filing to extend the patent term as long as possible. This strategy also can prevent competitors from learning about new devices and methods, since a patent application is not public knowledge until it is published. However, the delay should not be so long that a competitor is able to negatively affect the innovator's desired IP position. There is also a risk that the company may inadvertently disclose the invention prior to filing.

A slightly technical but important timing issue is called "provisional protection" and refers to the fact that if claims are issued in substantially the same form in which they were published, a company can seek back damages starting from the date of publication. That is, if a company B infringes the claims of company A, company A may collect damages dating back to the time those claims were initially published (generally 18 months after filing) rather than the date the claims were granted (which may be several years after filing). This makes it important to write at least some claims in the initial filing that have a strong chance of being granted (as opposed to trying only to get the broadest conceivable claims in the first round).

In some cases, it is possible to extend patent coverage beyond the conventional 20 years when the innovators or company can make the case that the introduction of the product in the marketplace has been delayed for legitimate reasons. This strategy has been relatively widely used in the pharmaceutical industry where development times are so long that the 20-year life of a patent is perceived as a major limitation (by the time a drug or biologic is approved by the FDA, there may be only 10 years or less remaining of patent coverage). Under these circumstances, a company can apply to the patent office for an extension of the term of the patent, which is calculated based on the length of time the development was held up in clinical trials and regulatory approval. However, a company is only allowed to do this for a single patent on the technology and there is a relatively short window once the company receives FDA approval to apply for the extension. In the past, medical devices – which tend to have a much quicker approval process than drugs or biologics – generally have not had patents extended through this mechanism. Recently, however, with the evolving complexity of medical devices (particularly with drug-device combinations) this approach to extending patent covered is being pursued with increasing frequency in the medtech industry. For instance, Abbott Vascular applied for an extension of the Rapid Exchange™ delivery system for the Xience drug-eluting stent based on the relatively long FDA approval process for this device. Generally, innovators should keep their patent attorneys updated on their FDA timelines so they can help determine if this is a viable strategy (and be prepared to take action once clearance or approval is received).

A related IP timing strategy employed by some innovators and companies is colloquially called "**evergreening**" – a process of introducing modifications to existing inventions and then applying for new patents to protect the invention beyond its original 20-year patent term. Again, this strategy has been much more widely applied in the drug industry compared to medtech. In certain situations, however, devices lend themselves to this approach. For example, during the rapid expansion of the stent market in the 2000–2010 period, companies brought out new stent and stent delivery designs with patentable modifications on a frequent basis, every 12–18 months. This provided ongoing IP protection that in some cases extended beyond the life of the original patents.

Patent litigation

Strategies for patent litigation are beyond the scope of this text, since they generally come into play at a later stage of product development within a company and involve company management and legal experts in the decision making. However, a few basic issues are important for the medtech innovator to understand at the outset of developing an IP strategy.

There are several potential outcomes to be aware of in medical device patent litigation. In rare cases, the courts may perceive a case to be clear enough that they will issue an injunction against the party that is accused of infringement (violating the patent rights of the plaintiff). Consequently, the company accused of infringing the patents must stop the manufacturing and sales of the

device. Much more commonly, the case goes to trial or is settled without an injunction. The outcome of a trial may be decided by either a judge or a jury, depending on the nature of the lawsuit. If the patent holder wins (that is, proves that there was infringement), that innovator or company is awarded damages that typically reflect a reasonable royalty based on the sales of the infringing company (e.g., something on the order of 5 percent of net sales). In recent years, there have been a number of multimillion-dollar medical device patent infringement settlements paid by large companies to individual inventors who hold key patents, particularly in the cardiovascular and orthopedic fields. If the courts make a determination of "willful infringement" – that is, the courts believe that the infringing company acted in bad faith, with full knowledge that it was infringing and no mitigating circumstances – then the damages can be tripled (treble damages).

Attorneys who perform patent litigation in court are generally different from the attorneys who write and "prosecute" (pursue the approval of) patents, although both types of attorneys may work for the same firm. It is not unusual for venture capitalists or companies that are doing serious due diligence on an innovator's IP to pay a litigator to evaluate the robustness of the patent protection, particularly in a space that is known to be litigious.

Patent litigation is a time-consuming, expensive, and emotionally draining experience for the participants. The big companies that dominate the medtech industry have large "war chests" for IP litigation. At present, it is part of the culture of the industry sector that important products are, more often than not, embroiled in patent litigation. Practically speaking, if the innovators develop an important medical device they can essentially rely on being involved in significant litigation at some later stage. The burden of litigation, in terms of productivity alone, can be considerable. The inventors and other key contributors to product development are required to participate in depositions in advance of a trial, which are formal opportunities for counsel – from both sides – to discover essential facts about the case. These can be highly adversarial and tricky encounters, which require a great deal of careful preparation. The discovery process may go on for many months before a trial or a settlement occurs, with the process consuming hundreds or even thousands of hours of potentially productive time from inventors and other personnel.

Alternative mechanisms to challenge patents

The America Invents Act (**AIA**) of 2011 introduced a suite of new or improved procedures that companies can potentially utilize to either strengthen their own patents and/or challenge competitive patents. These tools include preissuance submissions, supplemental examination, Post Grant Review, and Inter Partes Review.[14]

Preissuance submissions provide a mechanism by which third parties can monitor and potentially affect the course of prosecution of a competitor's patent application by submitting publications, along with an explanation of their relevance to the examination of a pending patent application. The publication and explanation of relevance will be made of record in the prosecution history of the application, which may prove useful in a future infringement action.[15]

Supplemental examination provides a means for a company to strengthen its own patents against future invalidation. Specifically, supplemental examination provides for the post-issuance examination of an issued patent to "consider, reconsider, or correct information believed to be relevant" to an issued patent.[16] For example, supplemental examination may be used to address issues that may relate to an applicant's duty of candor and good faith before the USPTO, including the duty of disclosure.

Post Grant Review and Inter Partes Review proceedings offer third parties an alternative to patent litigation for invalidity issues. The rules for Post Grant Review proceedings permit a party other than the patent owner to file a petition to institute a Post Grant (after issuance of the patent) Review of the patentability of one or more patent claims for any reason (not limited to prior art issues). The petition must be completed and filed within nine months after the date of the issuance of the patent. Therefore, it is important for companies and/or their patent attorneys to closely monitor pending competitive patents of interest to be able to file the petition within this timeline.[17] A petition for Inter Partes Review is

similarly used to challenge the validity of patent claims based on patents and printed publications, but it may be filed *after* nine months from the date of issuance.[18] However, there are significant differences between Post Grant Review and Inter Partes Review, including the fact that the grounds upon which invalidity is based and the evidence that may be submitted are limited under the second option.[19]

The Intuitive Surgical story provides an example of the importance of IP strategy in effectively managing competitive threats. Although, in general, innovators do not face litigation until some years into development of their product (typically after sales begin), the seeds for successful litigation can be planted from the beginning of the biodesign innovation process. Focusing on the basics, as presented in chapter 4.1, provides a good chance of avoiding the biggest problems in litigation. Careful and honest record keeping, engaging a competent attorney early in the process, and diligence in uncovering prior art and publications are the key success factors.

FROM THE FIELD INTUITIVE SURGICAL

Using IP strategy to manage risk and opportunity

Intuitive Surgical was founded by physicians Fred Moll and John Freund, as well as engineer Robert Younge, to pioneer the field of minimally invasive, robotic-assisted surgery. The company's primary product, the da Vinci® Surgical System, translates the surgeon's natural hand and wrist movements on instrument controls on a console into the corresponding micro-movements of specialized surgical instruments positioned inside the patient through small incisions.[20] By combining the technical skill of the surgeon with computer-enhanced robotic technology, da Vinci enables a minimally invasive approach to procedures such as prostatectomy, hysterectomy, myomectomy, gastric bypass, and mitral valve repair (see Figure 5.1.7).

Moll, who became the company's first CEO, learned of the technology through a non-profit research organization called the Stanford Research Institute (now SRI International), which had developed an initial prototype under contract to the US Army. Seeing the potential of such a system to accelerate the viability of minimally invasive surgery for a broad range of procedures, Moll and team licensed SRI's core IP surrounding surgical robotics and founded Intuitive Surgical. According to Moll, "We were lucky early on in that we licensed a significant patent portfolio that had

FIGURE 5.1.7
The da Vinci system (courtesy of Intuitive Surgical).

early dates on inventions that were important to the system and the core capabilities that we wanted to develop in surgical robotics." By adding some of its own proprietary technology and collaborating with IBM, MIT, and other institutions and thought leaders in the field, they developed the da Vinci system,[21] which received its preliminary FDA clearance in 2000.

Intuitive Surgical placed great importance on its IP strategy early in the company's existence. Regarding the licensing agreement with SRI, Moll explained the steps the company took to ensure it would maintain adequate control over the IP: "When you license intellectual property from the inventors, you can do it in various forms. But the important points are to get an **exclusive worldwide license**, which we were able to get. We also secured the ability to manage the patents ourselves. By that, I mean that we took over the prosecution of the IP." This allowed Intuitive Surgical to add to the patent portfolio and protect it in the way that best covered the specific product it was developing. "If we didn't have this ability, it could have been a real disadvantage," said Moll.

In terms of expanding the company's IP position, Moll noted, "We were able to do follow-on continuations to the patent portfolio in certain areas that were important to continuing to protect the Intuitive product. By that I mean we used the dates of these early patents to expand the breadth of the filings to cover features and capabilities that were anticipated but not specifically covered in the first filings by SRI." The company also took a systematic and proactive approach to managing its IP position. "You need to have a disciplined way to continuously look for prior art that would somehow modify your view of what patent positions are possible or the strength of your patents, as well as continuing to have a strong system to collect invention disclosures and turn them into a continuous stream of new filings that protect the newer aspects of the technology that you're developing on a weekly or monthly basis," Moll explained. To accomplish this, Intuitive added an in-house IP attorney to its team in the company's early days. "It makes a lot of sense, even for start-up companies, to hire in-house IP counsel sooner rather than later," Moll said. "In-house counsel is always going to understand better than an outside law firm what's going on within the company and what's most important to the product because they're just a lot closer to it." Relative to the value that medtech companies extract from their patent portfolios five or more years into their existence, "most people tend to under-invest in IP, which can be a big mistake," Moll added.

Although Intuitive Surgical established a leadership position in the surgical robotic market, the field quickly became competitive with the entry of companies such as Computer Motion. While there were important differences between da Vinci and Computer Motion's Zeus® system, they competed head-to-head. Before long, the companies became entangled in a series of patent disputes. Moll described the issue at the core of the conflict: "Computer Motion had some early patent filings with a number of broad claims that had to do with fundamental ways of controlling rigid tools and how you translate hand movement to instrument tip movement if the connection is electromechanical and software related rather than directly mechanical .... And, arguably, a couple of these patents had the potential to inhibit our ability to control instruments the way we wanted to control them to make sense to the **user**."

The Intuitive Surgical team believed that it had a strong IP position and a good chance of invalidating the Computer Motion patents. However, "The risk, not only the cost, associated with going through the legal process to find out whether their patents were valid was very significant. If we went through a litigation process and were unsuccessful, meaning that we were judged to be infringing on their very broad claims about how you control an instrument, it would be a difficult situation from a business standpoint and put the company at risk of having to redo a lot of what we had done," Moll said.

Despite this risk, "there was no settlement in sight," recalled Moll. Intuitive Surgical briefly considered cross-licensing, but determined that this was not an attractive

solution. According to Moll, "It progressed to the point where it was clear that it would probably end up in a jury trial. As a lot of litigators will tell you, a company's chances of winning a patent dispute that makes it all the way to a jury trial is about 50 percent. Most juries have a difficult time understanding a highly technical dispute. So you don't want to get all the way to a jury because your chance of winning isn't entirely related to the strength of your case."

The team continued to believe it could win the suit, but the risk of losing was so great that it decided to pursue one more option. "It became clear that there was an opportunity to buy the company," Moll recalled. "The upside of an acquisition was not that we would be getting a new product line, because we didn't consider the Computer Motion product line additive to ours. It was competitive and, we believed, not as clinically useful. But what we would be getting was a very strong position with the combined IP portfolios in the area of surgical robotics controlling rigid instruments." Ultimately, he explained, "It came down to a judgment call on how much it was going to cost us to litigate the dispute versus how much it would cost to buy the company, in addition to the certainty of outcomes on each path." Fortunately for Intuitive Surgical, the company's balance sheet was strong enough that acquiring Computer Motion was a viable alternative. The two companies joined forces in March 2003.

The breadth of the combined IP position gave Intuitive strength in the surgical robotics market that Moll believed had deterred some competition. "We always worried that the Japanese would enter the market for surgical robotics. To date, they haven't in a significant way. I think some of that is due to our success in technical development and the know-how associated with building the Intuitive system. And, I think some of it is also due to the perception of a very strong IP barrier, or picket fence, around the system that we developed," he said. Since the sale of its first da Vinci system, Intuitive Surgical has expanded its installed base to more than 2,500 hospitals and has sustained its position as the global leader in the field (see Figure 5.1.8).[22]

FIGURE 5.1.8
Surgeon Thomas Krummel and surgical resident David Le use the da Vinci system at the Lucille Packard Children's Hospital (courtesy of Thomas Krummel).

Reflecting on his experiences, Moll underscored the importance of a strong IP strategy: "You can't just start a company, file a patent, and hope for the best. You need to file, as early as possible, continuations of the invention that surround the initial technology effort. In other words, you should have a rigorous process of invention disclosure by employees, new filings, and refinements of existing filings that's continuous, throughout the life of the company. The idea of continuously monitoring prior art and other inventions going on within the field is also very important. At almost every company I've been involved with, there are problems with intellectual property that the company doesn't own. If this blindsides you late in the game, it can be devastating."

Finally, he said, "IP gets more and more important every year in the medical device business for principally one reason: the cost associated with clarification of who owns what has gotten so enormous. If you start with and maintain a strong IP strategy, it helps ensure that you don't get into situations where you're spending as much on IP litigation as you are on product development."

Online Resources

Visit www.ebiodesign.org/5.1 for more content, including:

- Activities and links for "Getting Started"
  - Understand the IP landscape
  - Validate freedom to operate
  - Hire IP counsel
  - Devise defensive and offensive IP strategies
  - Develop a comprehensive IP strategy and implementation plan
- Videos on IP strategy

CREDITS

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