4.1 Intellectual Property Basics

INTRODUCTION

The first months of the project have sped by without any real roadblocks. The team's prototypes are working better than expected in the preliminary animal model. The regulatory pathway appears straightforward. Existing reimbursement codes are in place to cover the new technology. And the project has begun to attract some investor interest. Then an email arrives from the patent attorney: "See attached Patent Cooperation Treaty publication from Israel – just uncovered. Please call immediately."

As soon as a team has identified a promising new concept, it is time to start exploring intellectual property (IP) and developing an approach to patenting. A patent is a legal document that gives an inventor the right to exclude others from commercial use of the invention. The presence of existing patents in the field can complicate or even derail the innovator's ability to launch a new company or R&D program. Alternatively, a strong patent position can add tremendous value to an invention, even at an early stage of development.

This is the first of two chapters on IP. It covers the fundamentals of medtech patents, focusing on the initial steps required to obtain a patent. The subsequent chapter, 5.1 IP Strategy, describes how to build an effective medical device patent portfolio and addresses strategies, tactics, and methods for asserting the inventor's rights.


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OBJECTIVES

- Understand the different types of US patents, including the basic elements of provisional and utility patents.
- Recognize the requirements of patentability, including practical aspects of the filing process for medical devices.
- Develop familiarity with the patent search process.
- Understand the fundamentals of international patent coverage.
- Appreciate how to use intellectual property risks as a screen for prioritizing concepts.

INTELLECTUAL PROPERTY FUNDAMENTALS

IP is defined as any product of the human mind or intellect (e.g., an idea, invention, expression, unique name, business method, or industrial process) which has some value in the marketplace and, ultimately, can be reduced to a tangible form, such as a device, medical method, drug, software program, process, or other invention.[1] IP law governs how individuals and groups may capitalize on innovations by determining who owns the IP, when owners can exclude others from using the invention for commercial purposes, and the extent to which courts will enforce the patent holder's rights.[2]

There are several categories of intellectual property that are of major interest to the medical device innovator – **patents**, trademarks, copyrights, and **trade secrets**.[3] A patent is a grant of **exclusive rights** from the government to make, use, sell, or import an invention. Although it is commonly described as a "monopoly," it is more accurate to say that a patent is the right to *exclude others* from making, using, selling, or importing the technology. Governments are willing to grant this right to the inventors for the life of the patent – generally 20 years from the time of filing – in exchange for the inventors disclosing the details of the invention. Patents benefit society for two main reasons: (1) without this guarantee, innovators and companies would not have the incentive to invest the time and resources needed to bring a technology forward, and (2) the right to exclude others from making or using the invention encourages them to try designing alternatives.

In the United States, the most common type of patent sought for medical devices is the **utility patent**. Utility patents, which are granted by the US Patent and Trademark Office (**USPTO**), describe an apparatus or method wherein the novel invention is *useful* for accomplishing a specific end result. In the **medtech** industry, utility patents cover devices themselves, as well as methods of use and how the devices are made and manufactured. It follows that utility patents are by far the most important category of medical device IP. There are also *design patents* which cover the unique ornamental, visible shape, or design of a non-naturally occurring object. These are particularly important in the consumer products area (one example would be the ornamental features of adhesive bandages). **Provisional patents** are preliminary filings that are generally submitted in order to secure a first filing date for subsequent utility patents (see below).

A *trademark* is a word, phrase, or symbol that is consistently associated with a specific product or medical method and gives the holder exclusive rights to use a word, phrase, or symbol as a brand name, tagline, or logo. Trademarks come into play when devices or medical methods are named or logos are created for companies or products. Trademark rights arise automatically from use of the name or logo in connection with the goods or services (that is, no formal application is required to obtain trademark protection). However, registering a trademark generally strengthens the holder's legal position for asserting the validity of the mark in court and prevent others from using it.[4] Trademarks cannot be the generic name of a product or surgical method. They can be thought of as adjectives in front of the generic product name. For example, Xience® stent, Adapta® pacemaker, or Contiuum® hip replacement.

A *copyright* grants authors and artists of written and graphical materials the right to prevent others from using their original works of expression without permission. In the medtech industry, copyrights are important for software (for example, the programs that run an ultrasound scanner or the algorithms that decipher heart rhythm disturbances in wearable monitors). Copyrights also come into play with advertising and educational materials (written, web, audio, and video). Works are automatically copyrighted when they are placed in some tangible form. As with trademarks, federal registration of a copyright leads to additional procedural rights.

Trade secrets are information, processes, techniques, designs, or other knowledge not generally understood or made public, which provide the holder with a competitive advantage in the marketplace. With some medtech products, trade secrets may be more important than patents. For example, a knee joint device may involve a special manufacturing process that creates smoother contact surfaces. In this case, the company may choose *not* to pursue a patent for its manufacturing process in an effort to keep it a secret and avoid "tipping off" competitors about an innovation that could improve their products. Instead, the company may attempt to protect the process as a trade secret, putting in place various safeguards to keep other companies from finding out anything about this manufacturing know-how. Some strategic considerations regarding trade secrets versus patents are provided in 5.1 IP Strategy.

The remainder of this chapter explores three basic patent considerations: criteria for obtaining a patent, **freedom to operate**, and **prior art** searching. It then provides an overview of provisional and utility patents, identifies important information related to international patenting, and addresses a number of other fundamental IP concepts, such as confidentiality.

Criteria for obtaining a patent

There are three basic parameters for judging the *patentability* of an invention:[5]

1. **Utility** – The invention must do something useful.
2. **Novelty** – It must be new with respect to other patents, products, or publicly available descriptions anywhere in the world (collectively known as the "prior art").
3. **Obviousness** – The invention must not be obvious in light of the prior art to someone of ordinary skill and knowledge working in the given field.

Only if an invention objectively meets these criteria is it considered to be patentable. In practice, the first criterion – utility – is rarely a problem for a new medical device invention. However, an inventor's ability to demonstrate novelty can be trickier. Prior art may exist in the field that would naturally lead to, or anticipates, an inventor's innovation but it may not yet be published (e.g., patent applications that are filed but not published). Beyond this is the world of medical device innovators who are constantly developing new technologies, testing them, and making **public disclosures** in some fashion (sometimes in fairly obscure places). It is not uncommon for an innovator to come up with a new device only to discover, for example, that a scientist working in some other country tested a similar **concept** in animals. In order for a patent to be granted, at least one feature of the device must be novel relative to any previous patents, publications, abstracts, speeches or other presentations – in short, *any public disclosure, from anywhere in the world, in any language, over all time*. The only way to uncover such information is to diligently and patiently search the literature. The advent of the Internet and powerful search engines (such as Google) has made this discovery process easier in recent years (see section "Patent searching" below). Still, this is a daunting task, with over 8 million patents in existence worldwide and a vast store of published information to consider.[6]

Another factor of great practical importance regarding novelty is the timing of the filing of the patent relative to other patent applications. The America Invents Act (**AIA**) of 2011 fundamentally changed the law in the United States from a "first to invent" strategy to a "first to file" approach (making the US similar in this respect to most other countries). This means that the date of the patent filing, also known as the **priority date**, is the critically important timing factor in determining whether the patent can be issued over competing patents.

The point that most often becomes the focus of both patent prosecution and litigation in the medtech field is whether or not the invention is obvious. Obviousness can be complicated, and no inventor is ever completely secure on this point. The criterion that the invention is not obvious to someone "of ordinary skill and knowledge" has a specific legal meaning. As a commonsense guideline, think of this hypothetical person as someone working in the field that uses the invention (say a gastrointestinal endoscope) and who magically has complete knowledge of the prior art in the field of endoscopy. If the invention would be obvious to this hypothetical person, it is not patentable. In practice, the determination of obviousness becomes an issue that the patent examiner decides; later on, it may become a subject of litigation and be determined by the courts. In recent years, the patent office and the courts have tried to base decisions on objective measures of non-obviousness, including commercial success of the invention, prior lack of a solution to a longstanding **need**, and failure of others to come up with the invention.[7] An experienced patent attorney is the inventor's best source of advice on the obviousness of an invention.

Beyond the three essential criteria for patentability, the law specifies that a patent must describe the invention in a clear, unambiguous, and definite way so that a person with knowledge in the field would be able to make and use it. Patent law also requires that the innovator include a description of the *best mode* for the invention, which generally means the "embodiment" or way of practicing that is, in the innovator's opinion, the most effective configuration or version of the invention. This may seem like a difficult requirement but it really just asks the inventors to include the approach they favor at the time of filing regardless of whether a different approach proves to be better later. For example, if the inventor of a particular stent structure described the best mode at the time of filing as the use of stainless steel in the construction of the stent – and, in subsequent development and

testing, cobalt-chromium proved to be superior material – the requirement for disclosing best mode would be satisfied. The AIA has softened (and potentially confused) this requirement by stipulating that a patent can no longer be *invalidated* for failure to include best mode – though the original law requiring that the inventor include the best mode in the patent submission is still in force.[8] The resulting uncertainty will likely be resolved through court decisions over time but, for now, it is strongly advisable that innovators disclose the best mode of practicing their inventions in patent applications.

Reduction to practice

Reduction to practice is another important factor for patentability because it shows that the idea is being diligently pursued. With medical devices, this can mean building a **prototype** and performing some kind of bench-top or animal testing. The model making and testing can occur after the patent filing, and there are no strict guidelines about timeliness of this reduction to practice other than what is reasonable for that type of technology. As an alternative to making and testing a model, an invention can also be reduced to practice "constructively" by a careful description in the patent, with sufficient detail and in an "adequately predictive" manner that someone knowledgeable in the field could construct the device. This is particularly useful when the development of a working model will be extremely costly, time intensive, or difficult to accomplish. Constructive reduction to practice via a patent application has the same legal effect as evidence of an actual reduction to practice.[9]

Freedom to operate: an introduction

In addition to patentability, the other key aspect of patent law that determines the commercial usefulness of an invention is freedom to operate (FTO). FTO is often confusing for first-time inventors to understand. The key concept is that *receiving a patent on a device does* not *guarantee that the inventor is free and clear to make, sell, use, or import the technology (that is, has freedom to operate)*. Despite the fact that the new device may have some new, patentable feature, there may be existing patents that describe other necessary features of the new device. For example, an inventor could patent a new kind of intraocular lens that has a high resistance to infection – this would be a patentable feature that is not covered by any prior art. However, despite being able to obtain a patent with claims on this new feature of the lens, the inventor may not be free to commercialize this invention if there are current patents in force with claims that cover other important features of the general structure and function of an intraocular lens – features that are also necessary parts of the new device. *A new device has FTO only if the features of the device are free and clear of valid claims from patents that are still in force in the country in question* (generally patents that are 20 years old or less). More specifically, there should be no single claim in any prior patent that describes the features that are included in the device in question *and nothing more*. Another way of saying this is that if there are features in the prior claim that are not part of the new invention, then FTO is preserved (even though there are some features that are comparable). This concept is diagrammed in Figure 4.1.1.

Because it affects whether or not a device can actually be sold, determining FTO for a new invention is equally important as determining patentability and requires a diligent search of the prior patent art (see below). Strategies for dealing with FTO issues are outlined in 5.1 IP Strategy.

Before filing: the prior art search

Understanding the prior art landscape for a new invention is one of the most critically important parts of the biodesign innovation process. Inventors naturally hope to discover that their idea is indeed completely new. However, even if the search reveals that there is troublesome prior art, the team benefits greatly from finding this information as quickly as possible. Such discoveries can potentially save an inventor huge amounts of wasted time and resources in pursuing the wrong idea. There is also the opportunity to modify the invention into an approach that is patentable and has freedom to operate.

Prior art searching is as much an art as a science, and at a later stage it is almost always wise to have a professional search conducted by an attorney or patent agent before the filing of a utility patent (see 5.1 IP Strategy for

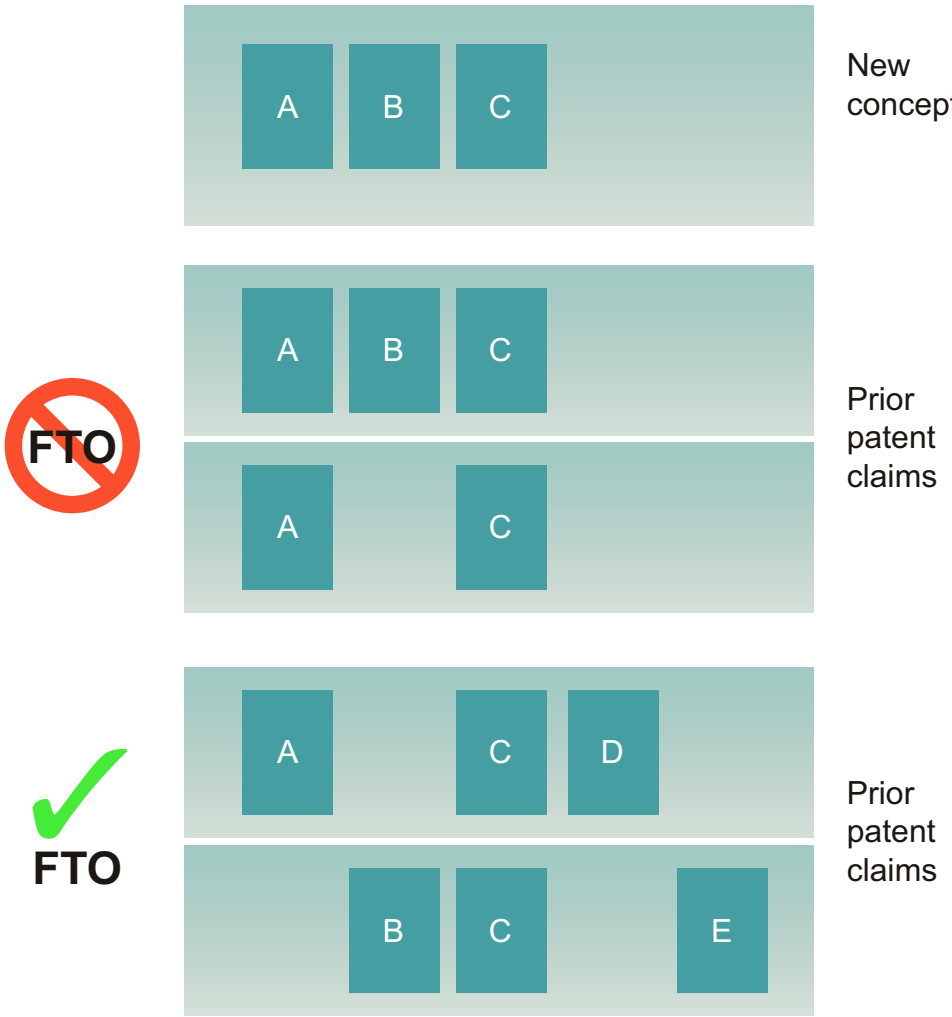


FIGURE 4.1.1
A schematic explanation of freedom to operate (FTO). Suppose the new concept has features A, B, and C. If a claim from a prior patent has features A, B, and C, or even just A and C *but nothing more*, there is *no* FTO. On the other hand, if a claim from another patent has features A and C, but also has additional feature D; or B and C with additional feature E; then FTO is maintained.

considerations about hiring an attorney). These experts will usually locate prior art that the team has not uncovered. Still later in the process, it is not uncommon for the patent examiner to find art that the expert attorney has not discovered. Despite the fact that the initial search will not be perfect, it is essential for inventors to conduct their own search early in the process. They will learn a tremendous amount about the field, and this upfront diligence will make the work of the attorney or agent much more effective and economical.

For the inventor just launching a search, the vast scope of the territory for prior art may at first seem intimidating. As mentioned earlier, in the search for patentability the inventor is looking for any previous disclosure of the idea in a public manner – not only patents, but all written descriptions and public presentations at anytime, anywhere in the world. In practice, searching patent databases is an effective way to start since most commercially significant technologies are patented (especially in the medtech field). One subtlety that is often overlooked is the fact that abandoned and expired patents are also public information and, thus, constitute legitimate prior art.

Given the large scope of the search territory, the prior art search process is unavoidably time-consuming. Depending on the invention, it is not excessive to allocate as much as half (or more) of the team's time to searching during the concept screening stage. Like other steps in the biodesign innovation process, searching should be performed at multiple points in the sequence. This is because there is a continuous flow of potential new prior art coming into public view, both in the form of patents (published in the US every Tuesday) and patent applications (every Thursday), as well as in public disclosures at conferences, in the literature, and in the press.

Additionally, the patent search process is complex, involving many combinations of different keywords and expressions. So searching must be an ongoing process. Looking at patents and publications uncovers new keywords and expressions. This information should be used, in turn, to conduct additional searches.[10]

In the biodesign innovation process, patent searching is usually deferred until after concept generation, the logic being that too much early information about patents may prematurely inhibit the team from developing concepts in an area that might turn out to be highly fruitful. However, a preliminary patent search *should* be completed in relatively short order after initial concept selection to avoid the risk of getting locked into a particular solution before the major features of the patent landscape are understood. As with so many other parts of the biodesign innovation process, identifying and understanding IP is an iterative process, with progressively deeper dives into the material as the concept moves forward. As a potential invention is developed, continued patent searching helps refine the idea and almost always leads to a stronger patent application.

In the US, inventors have a legal requirement to disclose any relevant prior art they uncover to the patent office upon and after filing. Practically speaking, a careful cataloging of prior art can help the patent examiner more quickly assess the technology and review the application.[11] It is a foregone conclusion that any significant prior art will be uncovered at some point – either during the careful examination by the patent office or in litigation once the patent is issued – so it is in the inventor's best interests to find and disclose these materials as early as possible.

Search basics

Before starting a patent search, the inventor must have reached a precise understanding of the invention that will be claimed. This underscores the requirement for the idea to be developed in some detail before an in-depth patent search is performed. A concise summary should be written that captures the most fundamental elements of the invention, including the need or problem that the invention addresses, the structure of the invention, and its function. It can be useful to draft a few hypothetical claims that help clarify the scope of the invention in advance of the search. These do not need to be written in "legalese" – just a plain language description of what characterizes the invention.

Several conceptual points are important to understand about the actual search process (see the Getting Started section for more practical tips and guidelines). First, there are different types of searches that are conducted depending on the stage of development of the product and the purpose of the search. In the initial stages following an invention, there are two basic types of searches. A search for *patentability* focuses on novelty and obviousness in light of the prior art. This search is intended to locate any information within any of the parts of a patent (most commonly the detailed description and the drawings – see below for more details) that would make the examiner conclude that the current concept is obvious or not novel. A *freedom to operate* search is directed toward finding *claims* of patents currently in force that specifically describe features of the new concept so that it is not possible to commercialize the device without designing around or licensing the patent (see chapter 5.1). Claims, as described more fully below, are the numbered paragraphs at the end of the patent that stake out precisely which aspects of the invention will be exclusively owned by the innovator or company. This is the reason that the claims are the focus of the FTO search.

Second, there are two primary ways to approach searching. The most intuitive method is text searching, also called *keyword* searching. This is a familiar process in the Google era in which keywords are entered into a search engine that looks through a patent database (Google itself now maintains an excellent patent database – Google Patent Search – along with the USPTO and others listed in the Getting Started section). The text search usually starts with keywords that describe the invention, though it can also be productive later on to search for known inventor names in the field, assignees (companies that own an important patent), competitor companies, etc. The precision of a text search can be greatly improved by combining keywords using *Boolean logic operators* such as AND and OR. One other practical piece of advice is to be careful about the fact that there may be many versions of keywords for the same

technology. For example, the guidewire used in angioplasty is variously described as "guidewire," "guide-wire," "guide wire," "guide element," "wire," "wire guide," and probably other terms. The search engines have a feature that helps with this problem called *wild card symbols* or "truncation limiters." These are symbols attached to the root of a keyword that allow the searcher to find any other words that have that same root. For example, by searching "guide*" (the exact wild card symbol depends on the search database), the searcher can look for all keywords with "guide-" as a common root.

The other general category of search is by *classification*. The USPTO and other international patent agencies have systems for grouping and coding patents that are based on the industry, the structure, and function of the invention and its intended use. The database developed by USPTO is called the patent classification (USPC) index. (Note: The US is migrating to a Cooperative Patent Classification system, or CPC, being developed jointly with the European Patent Office.[12] At the time of writing, the use of this system by the USPTO is expected to be mandatory in early 2015.[13]) It can be useful to perform a search by the assigned classes and subclasses, since the keywords prior inventors have chosen to describe their concepts may not be standard or intuitively obvious (such that a text search using "reasonable" keywords may miss some important prior art). Some inventors like to start with a classification search as a quicker way to understand the landscape of their invention than a keyword search. The classification systems used by USPTO and other international agencies are not themselves necessarily intuitive or consistent, so some patience and serendipity may be required. More search tips can be found in the following Working Example.

Working Example
Tips for keyword searching

Start by evaluating three basic questions:[14]

1. What problem does the invention solve (in the context of the biodesign innovation process, what is the basic need)?
2. What is the structure of the invention?
3. What is the function of the invention (what does it do)?

In developing the answers, generate as many relevant terms as possible. These terms will provide the basis for the search. For example, for a new angioplasty catheter, a sample response is shown in Table 4.1.1.

Use these keywords to search either the USPTO or Google Patent website (other patent databases can be used in subsequent rounds). Make use of Boolean logic operators and the advanced search techniques available through the site to refine the searches. For example, search "atherosclerosis AND angioplasty" to find patents using both of these keywords; or "angina OR myocardial infarction" to find patents covering either of these two conditions. To make the search more efficient, use the wild card symbols or truncation limiters to reach all keywords that have a common root. The use of these symbols is usually described on the search site.

Table 4.1.1 An effective way to approach keyword searches (based on an approach outlined by David Hunt, Long Nguyen, and Matthew Rodgers in *Patent Searching: Tools & Techniques* (Wiley, 2007)).

Issue	Possible search terms
Need addressed by the invention	Atherosclerosis, arteriosclerosis, coronary artery disease, coronary stenosis, arterial blockage, arterial stenosis, arterial flow, coronary flow, myocardial infarction, heart attack, angina, chest pain, etc.
Structure of the invention	Catheter, balloon catheter, angioplasty catheter, atherectomy, tube, balloon, flexible member, etc.
Function of the invention	Dilate, expand, open, inflate, pressurize, remove blockage, compress, compact, etc.

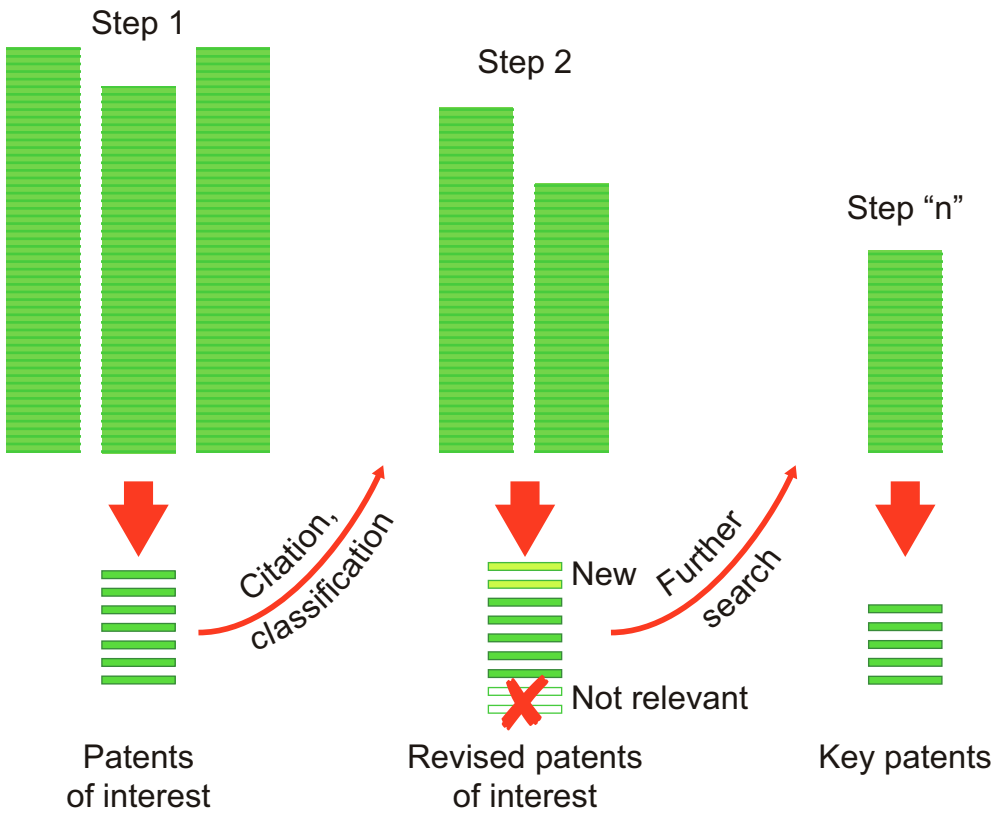


FIGURE 4.1.2
The cycle of patent searching: a repeated process of going out broadly into the patent literature, finding patents of interest, and using information from these patents to launch a new, more refined search.

Once a core set of interesting patents is identified by keyword and/or classification searching, it is helpful to use the citation search functions to look forward and backward in time to see what other patents are linked to these core examples. Search backwards in time using the citations (references) that are listed on the face sheets of the key patents that have been identified. For forward searches, start with patents where the drawing and specifications suggest that the patent represents a major advance in the field, then search forward in time using this patent number itself as a search term to see what other, newer patents have referenced this invention.

In practice, combining these different methods leads to a search process that is cyclical in nature – a repeated process of looking out broadly into the patent art and then narrowing it down to progressively more relevant patents. (This iterative process is illustrated in Figure 4.1.2.) The first search may yield many hundreds, or even thousands, of patents. Through a careful review of these, the innovator can filter the list down to perhaps 10 to 20 key patents. In step 2, these patents of interest are used to create another expanded search, triggered by citations in the patents of interest or classifications of the inventions (or both). This results in another large group of patents to search but, typically, this group is smaller than the patents identified in step 1. Careful review of this art in step 2 produces a few new patents of interest (and probably also leads to the exclusion of some of the initial patents), resulting in a revised set of patents of interest. This process is repeated again, often several more times ("n" times in the figure), until there is a stable group of key patents – perhaps 5 to 15, depending on the area – that continue to be clearly relevant. This is the group of patents to focus on in moving forward.

Once the innovators identify a set of search terms that they believe produces the most relevant results, that refined search should be run repeatedly (i.e., weekly or

Title	Assignee (Company)	Key Claims	Search terms	Patent #	Inventor	Pub Date	File Date
Satiety - Flow Rate							
Gastrointestinal electrical stimulation	UT Austin	Retrograde feedback control of GI action by a stimulating electrode and a detection sensor. Method of external implantation.	"gastric bypass"	6826428	Chen, Jiande; Pasricha, Punkaj Jay	30-Nov-04	11-Oct-00
Adjustable Sphincter System	Ethicon Endo-Surgery, Inc	Artificial sphincter that encircles a passageway that adjusts with fluid. Also discusses invasive and non-invasive manual adjustment methods.		20050272968	Byrum, Randal; Huitema, Thomas; Hassler, William	8-Dec-05	2-Jun-04
Gastric ablation followed by gastric pacing	N/A	Method of ablating pacemaker cells in stomach and then replacing them with electrical stimulation from a pacemaker.		20050240239	Birinder, Boveja and Widhany, Angely	27-Oct-05	29-Jun-05
Satiety - Space Occupying							
Endoscopoic stomach insert for treating obesity and method for use	N/A	Upon release in the stomach, flexible blades for a dome shaped cage, applying pressure to stomach.	"gastric bypass"	5868141	Ellias, Yakub A	9-Feb-99	14-May-97
Endoscopic gastric balloon with transgastric feeding tube	N/A	A gastric balloon that also allows a transgastric feeding tube to go through it and nourishment to pass to the jejunum.		20060025799	Basu, Patrick	2-Feb-06	26-Jul-05
Satiety - By Neural Means							
Treatment of obesity by bilateral vagus nerve stimulation	Cyberonics	Prevent overeating by stimulating vagus nerves to condition the neural stimulus of the stomach.	"gastric bypass"	6587719	Burke, Barrett; Reddy, Ramish K; Roslin, Mitchell S.	1-Jul-03	1-Jul-99
Treatment of obesity by electrical pulses to sympathetic or vagal nerves with rechargeable pulse generator	N/A	Full system (pacemaker, programmer, leads) for stimulating or blocking sympathetic response		20050149146	Birinder, Boveja and Angely	7-Jul-05	31-Jan-05
Methods and devices for the surgical creation of satiety and biofeedback pathways	None	Sensors built into stomach restrictive devices to sense changes in the volume of the restrictive device; sensor then discharges a signal to induce satiety		2005/0267533	Gurtner, Michael	1-Dec-05	15-Jun-05

FIGURE 4.1.3

A sample format for capturing information from a prior art search related to the treatment of obesity as developed by a team in Stanford University's Program in Biodesign. Note that the team's analysis has been removed from this example for the purpose of confidentiality (courtesy of Jennifer Blundo, Darin Buxbaum, Charles Hsu, MD, Ivan Tzvetanov, and Fan Zhang).

monthly) to stay abreast of new information as it is published.

In conducting searches, it is important to develop a system for capturing the output. This is essential because the volume of information is high, the search will likely go on in stages over a long period of time, and the information that is gathered is critically important. Some type of worksheet or spreadsheet is extremely helpful (see Figure 4.1.3 for one example). For the most relevant patents, this worksheet should include the patent number, title, assignee, key claims, inventor(s), publication and filing dates, and agency classification.

A summary of the invention in the words of the searcher and a cut/paste of key claims and figures can also be useful. Additionally, it is a good idea to have a section for comments from the searcher about what is important about this invention and claims (though remember that this information is potentially discoverable in litigation, so it would be wise not to record a comment such as, "This looks identical to our idea . . ."). Beyond the key patents of interest, it is important to keep track of any interesting patent unearthed in a search, since that patent may emerge again in a later search and it is efficient not to have to restudy it. It is also worthwhile to keep track of the search terms used, and the number of "hits" generated by different combinations of terms.

Because the search process is often a complex and time-consuming undertaking, it is wise to plan the work flow ahead of time and divide tasks among the members of an innovator's team. For instance, one team member could start with a classification search while other members divide up the keyword list and begin these inquiries. It is very useful for the different team members to use the same central spreadsheet for recording search results – this can be web-based for convenience.

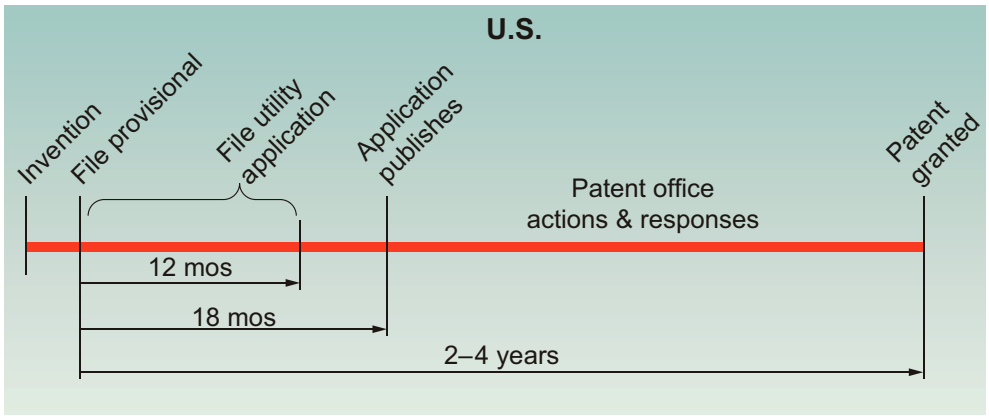


FIGURE 4.1.4
Typical timing associated with US patent filings.

Remember that, in searching for patentability, any publicly disclosed information can serve as prior art. This includes scholarly papers in journals, popular articles, trade show presentations, conference abstracts, newspapers, analyst reports, and many other potential sources. Careful searching with Google, Google Scholar, PubMed, and other appropriate resources is essential. Talk to experts in the field for leads on where to look for public disclosures that may be relevant to the invention but are not yet published. Company booths at medical meetings can also be a great source of information.

A final general comment about searching is particularly important for the first-time inventor: It is essentially *inevitable* that the search process will uncover disclosures that appear to be similar to the new idea, particularly in a dynamic technology domain like medtech. Searching can be an emotional rollercoaster for this reason. Do not be immediately discouraged if something potentially problematic comes to light during a patent search. There are almost always ways to work through the issues, whether by modifying the invention or partnering with owners of existing IP. The important thing is to be thorough and accurate in the search in the first place, so that these issues surface as quickly as possible.

Provisional patents

Medtech inventors frequently file a provisional patent application before pursuing a utility patent in the US. Basically, a provisional patent is an initial description of an invention that establishes a priority date that will ultimately be used by the patent examiner to help determine patentability, but only after the inventor files a utility patent on the same invention. Provisional patent applications typically require less time and expertise to prepare than a utility patent, and are often written by inventors rather than attorneys (although it can be a good idea to have an attorney at least review a provisional patent application before filing). They are also relatively inexpensive to file with the USPTO, costing approximately $150 for an individual or small business entity. However, the provisional patent is *not itself examined by the USPTO* and can never become an issued patent with enforcement rights. In order to ensure the art contained in the provisional application can become protected IP and that the priority date of the provisional application can be utilized, the inventor must file a nonprovisional (utility) patent that is clearly derived the art described in the provisional application *within 12 months* of filing the provisional application (see Figure 4.1.4).

It is important to note that the provisional patent application is never published, so after filing it is possible to work on the new invention in complete secrecy. It is only after a US utility patent application is filed claiming priority to the provisional application that the invention will ultimately be published (18 months after the provisional filing date).

In order for a utility patent application to claim the priority date benefit of a provisional patent application two criteria must be met. First, the written description and any drawing(s) of the provisional patent application

must adequately support the subject matter claimed in the later-filed non-provisional patent application. Note that this does not mean that the written description and any drawings filed in a provisional patent application and a later-filed non-provisional patent application have to be identical. However, the non-provisional patent application is only entitled to benefit from the *common subject matter* disclosed in the corresponding provisional patent application. Second, the non-provisional patent application must have at least one inventor in common with the inventor(s) named in the provisional patent application to claim benefit of its filing date.

Many medtech inventors choose to write their own provisional patents. This is a reasonable approach, provided that the application is thorough and sufficiently detailed to communicate the basic invention and support the claims of a later utility patent. However, it bears repeating that it is wise to have a patent attorney review the application prior to filing, if at all possible. There is no required format for the provisional application. The application should, however, include descriptions of:

1. The need or problem that the invention addresses.
2. Shortcomings of current solutions.
3. Motivation for the new invention.
4. Description of the invention (in enough detail that someone skilled in the field would know how to make and use it).
5. Advantages of this solution to the problem.

In addressing these different parts of the application, the inventor is providing the important details for making a compelling case to the patent examiner for what is novel and non-obvious about the new device. The more that the provisional patent application looks like a utility application, the better the chance that the utility application will be able to successfully claim the benefit of the provisional filing date. Drawings can be very helpful in clarifying an invention and should certainly be included in the application. It is not necessary for a provisional patent application to include claims, although it may be advisable to write claims if they help to clarify the invention (and thereby support the subject matter in a later utility application). The decision of whether to include claims is made on a case-by-case basis and optimally should be discussed with an attorney.

It is a common misconception that the provisional patent application process was developed to enable inventors to file "quick and dirty" applications. In fact, the process was put into place to give inventors in the US the same rights as inventors overseas with respect to patent term. The 20-year patent term is based on the date a non-provisional patent application is filed. However, inventors outside the US have one year from their ex-US filing date to file a patent application covering the same subject matter in the US. In this way, they gain an early filing date without impacting the term of their US patent (that is, they have the full 20 years after the filing of the US patent). Since, with the provisional patent approach, inventors in the US now have exactly 12 months from the filing date of a provisional patent application to submit a non-provisional patent application, this process creates a US patent term equivalent to the term afforded to those who originally filed first outside the US.

Beyond preserving the term of the eventual utility patent, there are additional advantages to consider with provisional patents. One circumstance where a provisional patent is extremely useful is when an inventor is confronted with an unavoidable and urgent public disclosure – for example, a physician-inventor who is about to give a talk or abstract presentation at a conference. As long as the provisional patent application is received by governmental authorities prior to the presentation, which is verified by obtaining a postmark (a sign that the government postal service has taken possession), the priority date is established and the ability to gain foreign as well as US patent rights is preserved. A more subtle advantage is that the provisional patent application constitutes a legal reduction to practice of the invention without actually building the device (provided there is sufficiently clear and detailed information about construction and use in the application). If there is litigation about the date of the invention later on, the provisional patent is a clear and unambiguous time point regarding both the invention and reduction to practice.

The main disadvantage of the provisional patent alternative is that it can give a false sense of security. Inventors should be aware that filing a last-minute cocktail napkin sketch or a PowerPoint presentation that includes a few high-level ideas about an invention may not provide sufficient support to provide a priority date for the ultimate utility patent. If the inventor does find him/herself in an urgent need-to-file situation, it is important to include as much detailed information as possible in the provisional submission. Many IP attorneys recommend investing nearly as much time in the development of a provisional patent application as a non-provisional patent application. (See online Appendix 4.1.1 for a sample provisional patent application.)

Basic structure of utility patents

A utility patent has three primary parts: a specification, drawings, and claims.

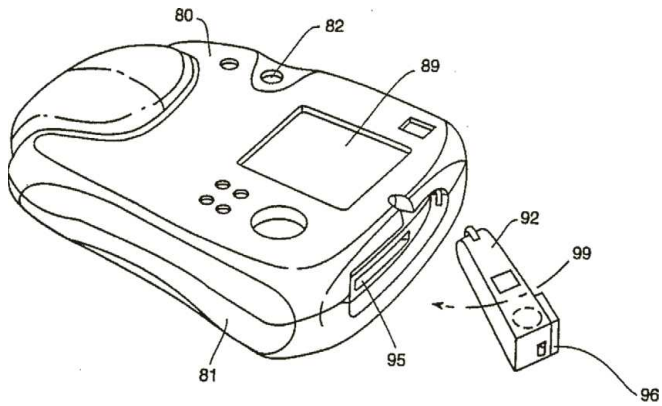
Part 1: Specification

The specification is a description that explains the essential features of the invention. This is where the innovator must provide a detailed enough description to teach a person who is skilled in the field of the invention how to make and use the invention. For a medical device patent, the specification usually begins with a brief background section that clearly describes the need or basic medical problem (including a description of the disease or condition and a discussion of existing approaches to treatment – see 2.1 Disease State Fundamentals and 2.2 Existing Solutions). Within the specification, uncommon medical terms should be explained so that anyone reading the patent, including the examiner, clearly understands the context for the invention, regardless of their level of medical background. The writing should be targeted to the "*Scientific American*" level – intelligible to a bright reader who is not necessarily versed in the field. The specification also must describe in detail what the new device does, how it is to be used (referring to diagrams with labels, as appropriate), and how it is made. This section can describe several different approaches for using the device but, as noted above, the inventor has a legal obligation to describe the best mode of the invention, as well as sufficient detail to enable others in the field to be able to make and use the invention claimed in the patent.

Part 2: Drawings

Drawings refer to illustrations, typically with a series of reference numbers labeling each of the key features that convey the structure of the invention and how its parts work together. For medical device patents, it is often valuable to include anatomical figures to show the interaction of the device with the organ or system where it is intended to be used. Patent attorneys often employ illustrators who can help render complicated figures based on sketches provided by the inventor.[15] Figure 4.1.5 shows a sample patent drawing next to a

(a)



(b)

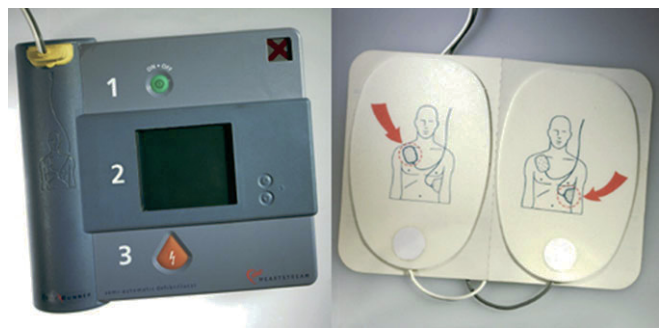


FIGURE 4.1.5

Patent drawing of an external cardiac defibrillator for public use, and the commercial product that was ultimately manufactured and sold (courtesy of Philips Intellectual Property & Standards; reprinted with permission).

photo of the commercial device that ultimately evolved from the invention.

Part 3: Claims

Claims are technically part of the specification, but are presented as a numbered list of points at the end of the patent. Claims are written statements that define the invention and the aspects of that invention that can be legally enforced. As such, they are the real "teeth" of the patent. During prosecution of the patent application, it is the claims that provide the basis for comparison with the prior art to determine patentability of the invention. Upon issuance, the claims provide the basis for a determination of third-party infringement – a ruling that another technology uses features covered by the patent, thereby making it illegal to make, use, sell or import that device without a license. In this sense, the claims are like a deed to a piece of real estate – they specifically describe the boundaries of what is owned. Claims spell out, in precise terms, exactly how an invention or discovery differs from the prior art. Writing claims is such an arcane and expert exercise that inventors are advised to seek the assistance of an IP attorney. However, even when working with an IP expert, the inventor should have a basic familiarity with the art of claims writing in order to effectively understand and assist the work of the attorney.

US utility patents can include two basic types of claims. *Independent claims*, as the name suggests, stand on their own. *Dependent claims* are claims that refer to one or more independent claims and generally express particular embodiments (typically they add additional elements or steps of carrying out the invention).[16] Dependent claims are used to clarify the language of an independent claim, so each dependent claim is more narrowly focused than the independent claim upon which it depends. Independent claims are typically written in broad terms to prevent competitors from circumventing the claim by modifying some aspect of the basic design. However, when a broad term is used, it may raise a question as to the scope of the term itself. For example, if there is any question about whether or not a "base" described in a patent application includes a "set of legs," a dependent claim that included the phrase, "wherein said base comprises a set of legs," would clarify that, in at least some variations, it does.[17] While the independent claim broadly describes the invention, each dependent claim may describe specific aspects or variants that build on the embodiment or invention captured in the independent claim (frequently, there is a string of dependent claims attached to an important independent claim). Strategically, dependent claims provide a safety margin in the case where the independent claim is invalidated by some prior art that comes to light after the filing (the dependent claim, when combined with the independent claim, leads to something more specific, which may still be valid). Figure 4.1.6 shows how independent and dependent claims work together in the classic Palmaz patent for the intravascular stent.

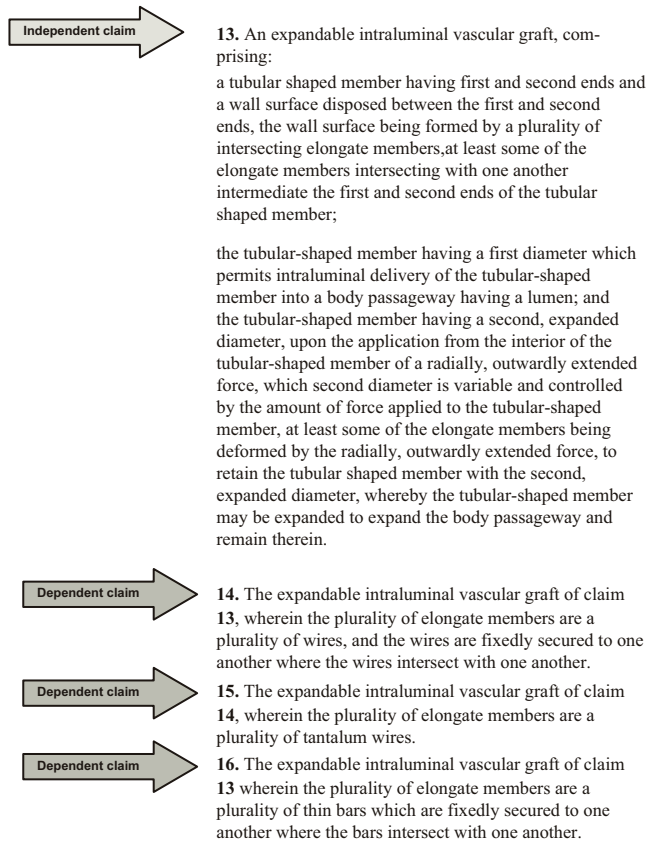


FIGURE 4.1.6
Independent claims can stand alone, whereas dependent claims rely on a parent claim (from US utility patent 4,733,665).

Another way to think about claims is to categorize them based on what they cover. *Product or apparatus claims* cover a physical entity, such as a material, system, or device. *Method claims* cover an activity, such as a process or method of use or manufacture – for example, the way a medical device is deployed or used in the body. Note that certain method claims covering surgical or diagnostic procedures are not allowed in most countries outside the US (see more about international patenting below).

In addition to the major components in the body of the patent, the *face* or front page includes important summary information that is very useful for searching (see Figure 4.1.7).

Key information to review includes:

- **Patent number** – Assigned by the USPTO.
- **Filing date** – The date the inventors submitted the application and the start of the 20-year period of coverage.
- **Issue date** – The date in which the patent is officially granted.
- **Assignee** – The legal entity that has rights to the patent, often a company.
- **References cited** – The patents and literature cited by the inventor(s) and/or examiners in obtaining the patent. Note that this is not the full list of patents or references that could be related to the patent, as would have been uncovered during the patent search process, but specifically the ones referenced in the patent itself.
- **Abstract** – A brief description of the invention.
- **Classes** – A list of the classes and subclasses assigned to the invention by the patent office.

Preparing a utility patent

Utility patents are the "workhorse" form of IP in the medical technology industry. As such, it is important for the inventor to understand them well. For practical purposes, drafting of the patent should almost always be performed by an expert attorney or patent agent. However, the inventor can save considerable time and expense by providing the attorney or agent the detailed background required for the specification, drafts of the drawings, and the results of the prior art search with analysis and comments. It is important for the inventors to make sure that all of the alternative ways of making the device are described, and all of the alternative devices they can think of that can be used to perform the method are also described. The point is to stake a claim to as broad an IP position as possible, as a defense against competitors who might pursue the same general concept with a different embodiment or version of the technology.

The inventors will also want to provide a detailed review and editing of the application that is drafted by the attorney or agent prior to filing. For most inventors, the most alien and difficult part of this process is trying to understand the claims. When reviewing claims, an inventor should seek to ensure that they cover all commercially relevant aspects of the invention while not being too limiting or narrow in scope. This includes an invention's physical form, materials, and methods of use. Too often, inventors emphasize the structural elements of the device without paying adequate attention to the clinical significance or the important functionality of the invention. For example, it would not be uncommon for an inventor to submit a claim such as, "A device comprising X, Y, Z ...." However, a much more valuable and strategic approach would be to think about the clinical advantages that the device enables (e.g., it is faster, easier to use, less expensive, etc.) and reflect in the patent the functionality that reveals those unique advantages. For example, a device that enables faster surgical times because it deploys elements simultaneously, as opposed to individually and sequentially, may read, "A device for use in X procedure wherein the device enables simultaneous deployment of elements ...." Similarly, a device that is easier for a surgeon to use because it requires only one hand may read, "A device for use in X procedure wherein the device may be fully operated with a single hand ...." In addition to protecting the invention in a way that is more difficult for competitors to circumvent, this approach to drafting claims also protects the inventor as the device evolves through ongoing product development.

When developing claims, it is important to try to understand the IP activities of the inventor's competitors (other individuals and companies working in the same

United States Patent [19]

Yock

[11] **Patent Number: 5,061,273**

[45] **Date of Patent: Oct. 29, 1991**

[54] **ANGIOPLASTY APPARATUS FACILITATING RAPID EXCHANGES**

[76] Inventor: **Paul G. Yock,** 1216 San Mateo Dr., Menlo Park, Calif. 94025

[21] Appl. No.: **548,200**

[22] Filed: **Jul. 5, 1990**

Related U.S. Application Data

[63] Continuation of Ser. No. 361,676, Jun. 1, 1989, abandoned, which is a continuation of Ser. No. 117,357, Oct. 27, 1987, abandoned, which is a continuation of Ser. No. 852,197, Apr. 15, 1986, abandoned.

[51] **Int. Cl.**[5] **A61M 25/00**

[52] **U.S. Cl.** **606/194;** 604/96

[58] **Field of Search** 604/96, 101, 102; 606/192, 193, 194

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Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—Fulwider, Patton, Lee & Utecht

[57] **ABSTRACT**

Apparatus for introduction into the vessel of a patient comprising a guiding catheter adapted to be inserted into the vessel of the patient and a device adapted to be inserted into the guiding catheter. The device includes a flexible elongate member and a sleeve carried by the flexible elongate member near the distal extremity thereof and extending from a region near the distal extremity to a region spaced from the distal extremity of the flexible elongate element. The device also includes a guide wire adapted to extend through the sleeve so that the guide wire extends rearwardly of the sleeve extending alongside of and exteriorally of the flexible elongate element into a region near the proximal extremity of the flexible elongate element.

6 Claims, 3 Drawing Sheets

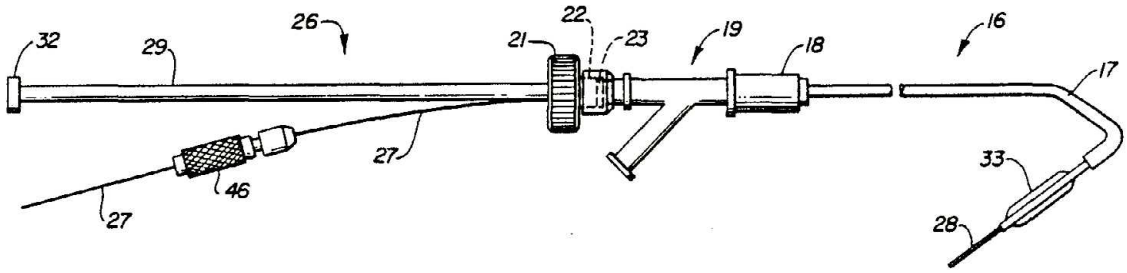

FIGURE 4.1.7

The face page of a patent includes a summary of important information (from US utility patent 5,061,273; the complete patent is shown in online Appendix 4.1.2).

field). Actively review what information is being published and what patents are being issued in the field and evaluate this information against the inventor's established and desired claims. More information about developing an ongoing patent strategy is presented in 5.1 IP Strategy.

Filing and review of utility patents in the US

A patent application can be filed by mail or electronically. The USPTO manages a large volume of patent applications (the office received 576,763 utility patents in 2012[18]) and has been struggling to reduce a substantial backlog, estimated at more than 600,000 applications.[19] Several new programs have been piloted to deal with the backlog, including "Track One," which provides a prioritized examination timetable for an additional fee ($4,000 as of 2014[20]). Basically, while there are some strategic limitations with this path (described in more detail in chapter 5.1), the Track One option allows inventors to move to the front of the line and receive a final action within one year of filing. For regular filings, it can take anywhere from 18 months to up to three years for the patent examiner to pick up the patent application for initial review.

When a utility patent application is submitted, it is opened, sorted, given a serial number, scanned, and checked for completion by the Office of Initial Patent Examination (**OIPE**). A USPTO drawing inspectors also reviews the quality of the figures for clarity and conformity with guidelines. Complete applications (that meet all USPTO submission guidelines) are then routed to a "technology center," which is the organizational unit of USPTO responsible for that type of invention. For medtech, the main technology center is 3700 (Mechanical Engineering, Manufacturing and Products) which includes 37D (Medical and Surgical Instruments, Treatment Devices, Surgery and Surgical Supplier), 37E (Medical Instruments, Diagnostic Equipment, Treatment Devices), and 37F (Body Treatment, Kinestherapy, Exercising). If the application is missing information or otherwise incomplete, the OIPE issues a notice to the filer and sets a time period for submitting the missing information. Failure to submit missing or inaccurate information during the time period will result in abandonment of the application.

Within the technology centers, utility patent applications are assigned to a patent examiner who is considered an expert in the subject area. This person researches previous patents and available technical literature to determine whether a patent should be granted based on the parameters outlined above.

Utility applications are made public after 18 months from their earliest priority date, usually the filing date of the provisional patent application on which the nonprovisional utility patent application is based. Inventors can file a "Nonpublication Request" to the USPTO to prevent having their inventions published; however, this process requires an inventor to forego any foreign patent protection for the invention.

Once a thorough examination has been performed, the USPTO issues a first **Office Action** (OA) to the filer. A patent is almost never approved in the first OA. The letter from the examiner will instead outline his/her objections to the application (e.g., it may cite prior art that, in the examiner's opinion, renders the new concept obvious or not novel; it may list the claims that are rejected; or it could call out any problems in the specification and drawings). The filer is given three months to respond to the office action in writing (an additional three months will be granted if an extension fee is paid). In the response, the filer can either argue against the rejections and objections stated in the office action and/or make the required changes in a document called an amendment, which modifies the claims language in a direction intended to make the claims acceptable in light of the examiner's analysis. The filer has an option to meet with the examiner to discuss the application, which can be a highly productive and efficient way of understanding and addressing the examiner's concerns. The office action/amendment process is often repeated a number of times before the patent application is in condition for allowance – or is finally rejected. On balance, there are two points in the patent application process where a patent application may be allowed or rejected. If a **Notice of Allowance** is granted, the USPTO issues the patent upon receipt of required Issue Fee. The complete process from the initial filing to an allowance usually takes between two and four years. For applicants who ultimately do not get the approval they seek, there is an

appeals process through the USPTO Patent Trial and Appeal Board, or they can refile the patent application (request for continuing examination). Decisions from the Board may be further appealed to the US Court of Appeals for the Federal Circuit.

One confusing feature of an issued utility patent is the priority date, which is effectively the date against which prior art challenges to a patent will be adjudicated. For international filings, any prior art published before the priority date can be used to help invalidate the patent. In the US, non-patent publications by the inventor that are dated within a year before the priority date do not invalidate the patent filing. For example, if a provisional patent was filed on January 1, 2015, any publication by the inventor in the prior year (subsequent to January 1, 2014) would not be considered as prior art. In practice, this means that an inventor who publishes a paper has a year in the US to obtain patent protection.

If an inventor has filed a provisional patent and then follows with a utility patent, the date of filing the provisional patent is the priority date. If the original filing is made as a utility patent, the utility patent filing date becomes the priority date.

There are several layers of costs associated with utility patents. Attorney costs are reviewed in more detail in chapter 5.1 but, in general, will typically run from $10,000 to $20,000 for the filing of an uncomplicated medtech utility patent. The basic filing fees paid to the USPTO depend on the number of claims in the patent and some other factors, but are approximately $1,600.[21] If the patent is granted, there is an additional USPTO issue fee followed by three maintenance fees at 3–3.5 years, 7–7.5 years, and 11–11.5 years. The total of the issue and maintenance fees are on the order of $13,000.[22]

International patenting

The protection provided by a patent issued by the USPTO stops at the US borders. To obtain patent protection outside the US, an inventor must file patent applications in each country in which patent protection is desired. Under a treaty called the Paris Convention, most countries in the world (with the exception of Taiwan) give patent applicants one year to file a corresponding patent application in their patent office and use the US priority date as the effective date of the foreign filing. In addition, through the international Patent Cooperation Treaty (**PCT**), an inventor can file a unified patent application to seek patent coverage in each of a large number of contracting countries. As of 2013, there were 148 countries participating in PCT, representing most major nations (excluding Iraq, Pakistan, and Taiwan among other countries).[23] The PCT is administered under the auspices of the World Intellectual Property Organization (**WIPO**), a specialized agency of the United Nations, which manages this program and over 20 other international patent treaties. As with other Paris Convention filings, international inventors have one year from filing an international application under PCT to file a utility patent application in the US. (This timing is parallel to that for the US inventor who files a provisional patent, which means that the inventor will often be filing US utility cases and foreign and/or PCT cases simultaneously on or before the one-year anniversary of the provisional filing date.)

Some patent applicants file a PCT first and enter the USPTO through the PCT in the national stage (discussed below). If the PCT is the first patent application filed, the international filing date becomes the priority date in the US.

Under the PCT, a single filing of an international application (called a PCT or international application) is made with a Receiving Office in a single language (the receiving offices are typically the patent offices of the PCT contracting states). An International Searching Authority (**ISA**) performs an extensive international patent search and delivers a written opinion regarding the patentability of the invention.[24] Importantly, this is a non-binding opinion. There is no collective "international patent" that results from PCT process – patents must be reviewed and granted individually by patent agencies in each of the countries in which coverage is sought. What the PCT provides is a way of starting the application process in an efficient and relatively economical way (typically a few thousand dollars) and receiving a preliminary opinion on patentability from an expert international agency. In some cases, the applicant can further request a preliminary examination by an International Preliminary Examining Authority, whose opinion can supersede that of the ISA.

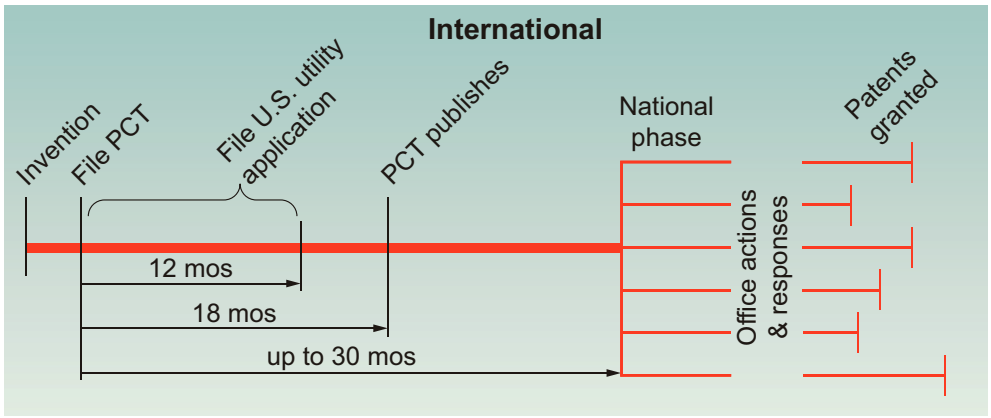

FIGURE 4.1.8
Typical timing associated with international patent filings.

The process of pursing country-by-country patent coverage is called the national phase or stage. Depending on the number of countries selected, this can be an expensive step, consuming hundreds of thousands of dollars. Some strategies for selecting countries for filing are reviewed in 5.1 IP Strategy. The PCT allows inventors to delay national phase filing in PCT member countries for up to 30 months from the priority date, which can allow for substantial development and testing prior to making this major financial commitment (see Figure 4.1.8).

The international application is published by the International Bureau of WIPO, 18 months after the filing date. The WIPO patent database can be an invaluable source of search information about patents in process, particularly those being pursued outside the US.

Although the national phase must generally proceed country-by-country, the European Patent Office (**EPO**) constitutes an important exception.[25] The EPO provides a uniform application procedure for individual inventors and companies to be granted patent coverage in up to 37 European countries through a single application process that is consistent with PCT guidelines. However, the European patent must be validated in each of the European countries the inventor wishes to pursue and usually must be translated into the local language, which represents additional expense. Obtaining the European patent is still an advantage to the inventor because it allows a delay of expenditure for national coverage until the European patent issues and there is more clarity around the value of the claims received. There is movement to establish a Unified Patent Court among a number of the EU countries, which would create a central authority for deciding matters of validity and infringement of European patents.[26]

Regardless of the specific country in which international patent coverage is being sought, innovators should keep in mind a few important considerations. For US inventors who file a PCT application, the USPTO may serve as the searching agency and will render the patentability opinion. (Some inventors choose to use the European Patent Office, Russian Patent Office, or the Korean Patent Office as the search authority in order to have someone other than a US patent examiner perform the search in an effort to save some money and uncover different prior art.) As noted above, under the PCT, an inventor can wait until one year from the first patent filing in the US to file in other countries and still use the US filing date as the effective filing date on the non-US patent applications.[27]

IP and patenting in India and China

Because of their relatively large size and emerging economic importance, India and China are of particular interest in international patenting. Both countries have had a history of relatively weak IP rights and patent enforcement, which has been a barrier to foreign interest in many technology sectors, including medtech. While both countries are improving, they remain on the Priority Watch List of the Office of the US Trade Representative (along with eight others).[28] The activities of the nations on this list are carefully scrutinized for the adequacy of the IP protection and enforcement rights provided to inventors.[29]

In India, patenting is managed by the Indian Patent Office (IPO). The state of IP enforcement is in flux after an unusual history. Before the Indian Parliament passed the Indian Patents Act of 2005, India enforced product patents but not process patents. As a result, companies could legally sell reverse-engineered products in the Indian market. Although this phenomenon helped fuel the growth of a large generic pharmaceutical industry in India, it also contributed to lax IP protection, a problem that persists.

The 2005 Indian patent law recognized utility patents, copyrights, and trademarks as protected IP, similar to other World Trade Organization member countries.[30] India follows a first to file rule, with patent protection extending 20 years from the priority date. Innovators can take one of two primary paths for pursuing patent coverage in India. The first is to file a patent application directly with the IPO. Indian patent offices are located at Delhi, Kolkata, Mumbai, and Chennai, and inventors must file with the appropriate office based on their location. After preparing and making a filing, the inventors have 48 months to submit a request for examination in order for the patent office to take up the application. Typically, an initial examination report is issued and the inventors are given the opportunity to address any objections raised by the patent examiner. They must comply with the requirements before the stated deadline, otherwise the application will be treated as though it was abandoned. If/when all patentability requirements are met, the patent is granted and recorded in the Patent Office Journal.[31] It can take as much as three to four years to obtain a patent from the IPO.

The second approach is to file a PCT application since India is a contracting state to the Patent Cooperation Treaty. This approach allows the priority date or date of patent application to be recognized in other countries.[32]

Despite recent progress, India is still criticized for the unpredictable enforcement of its patent law, the growing backlog in the patent office, a slow judiciary process, and the theft of proprietary information.[33] Patent protection in pharmaceuticals has been particularly contentious, with several high-profile patent denials of oncology drugs by the Indian Supreme Court.[34] Yet, the indigenous pharmaceutical industry is increasingly making progress in creating and protecting IP as legitimate source of revenue in the Indian healthcare market. The Indian medical technology industry is less well developed than the pharmaceutical industry, and there is not yet a dominant pattern of patent activity.

In China, the State Intellectual Property Office (SIPO) governs patenting, as well as the country's membership in the PCT. In 2011, the SIPO overtook the USPTO to become the patent office that receives the most patent applications in the world (see Figure 4.1.9).[35]

Using a first to file system, the SIPO issues three types of patents: invention patents, utility model (UM) patents, and design patents. The invention patent is the closest form of protection to a US utility patent in China. It protects "any new technical solution relating to a product, a process or improvement"[36] for a period of 20 years from the date of filing. Typically, invention patents take three to five years to be issued. The UM patent protects "any new technical solution relating to the shape, the structure, or their combination, of a product, which is fit for practical use,"[37] and cannot be used to cover methods and processes. UM patents are somewhat easier and faster (5 to 10 months) to obtain because, unlike invention patents, they are not substantively examined. These patents are valid for 10 years from the filing date.[38] Design patents in China are similar to design patents in the US, providing protection for "any new design of the shape, the pattern, or their combination, or the combination of the color with shape or pattern, of a product, which creates an aesthetic feeling and is fit for industrial application."[39] Design patents, like UM patents in China, are not substantively examined (issuing in roughly four to nine months) and have a term of 10 years from the filing date. Although foreign companies working in China overwhelmingly file invention patents, they are increasingly being advised to more fully consider the benefits provided by all three types of patents available under Chinese law.[40] In contrast, the majority of domestic

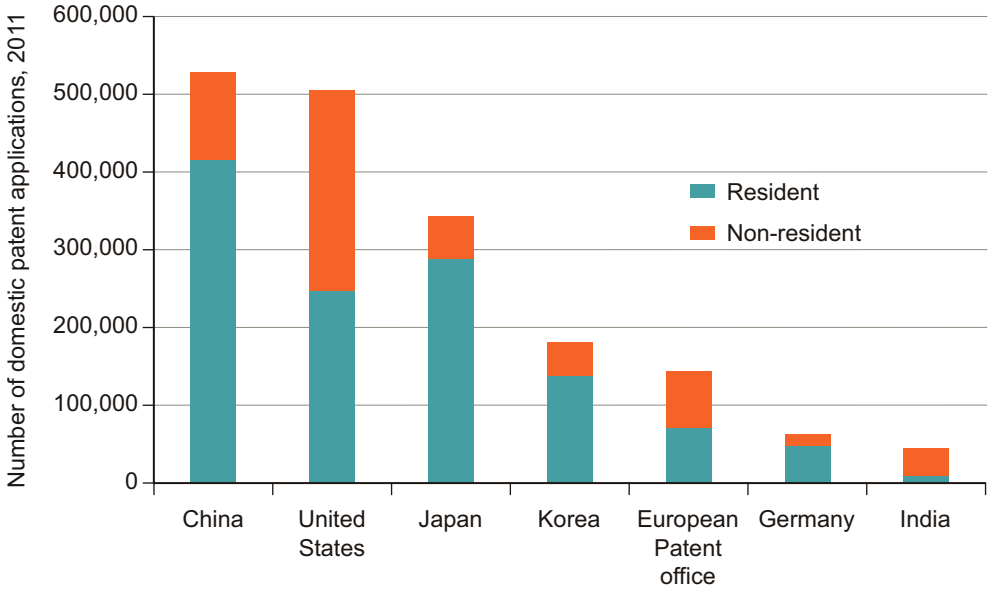

FIGURE 4.1.9
China's SIPO now receives more patent applications each year than the USPTO (compiled from "World Intellectual Property Indicators," WIPO, 2012).

companies and Chinese individuals file for utility model and design patents.

As with India, China moved to strengthen its IP position following its ascension to the WTO in 2001. The country has successfully improved its legal framework and amended its IP laws and regulations, but critics charge that China has been remiss in enforcing these new rules, that the support requirements applied to foreign entity invention patent applications are too strict, and that the flood of unexamined utility model and design patents in the country has created (and continues to create) a large mass of low-quality patents. They further charge that these issues have the consequence of making it difficult to obtain important invention patents and enforce IP rights. Another consequence is that in this environment it is easier for non-inventors to potentially secure patents on technologies that are not their own.[41] In particular, because UM and design patents are granted without a full investigation, they can be perceived as providing an unfair advantage to those who obtain them without actually inventing the technology or process in question, since the burden of proof is on the inventors or company challenging a patent to show that the innovation in question rightfully belongs to them.[42] Moreover, the Chinese government provides incentives, such as financial remuneration and tax breaks, in exchange for filing patents, which has been blamed for the focus on patent quantity rather than quality.[43]

In general, the Chinese patent landscape has become significantly more litigious recently, with more patent lawsuits filed in China than the US.[44] A number of cases have been brought by multinational corporations, alleging that Chinese companies have appropriated foreign technologies covered by the multinational corporation's patents in China. However, given the relatively unpredictable results they achieve, some foreign entities are hesitant to file patent lawsuits within China.[45] Foreign companies are also finding themselves as defendants in patent infringement actions. As one article put it, "Foreign companies face a growing risk that Chinese entities may unscrupulously patent foreign technology in China and demand a toll to do business there."[46] Such cases often move through the courts rapidly, and foreign defendants often consider themselves to be at a significant disadvantage against Chinese plaintiffs due, in part, to uncertainties associated with litigation procedures.

In most regions around the world, there are significant challenges associated with working in an area with a crowded IP landscape, as the story about CoreValve and its transcatheter aortic valve replacement technology illustrates.

FROM THE FIELD COREVALVE

Assessing intellectual property in a competitive space

One of the major technical advances in cardiac therapy in recent years is transcatheter aortic valve replacement or implantation (which is known as TAVR or TAVI). TAVR was pioneered as an alternative for treating aortic stenosis, a relatively common and deadly heart condition (particularly in the elderly). Aortic stenosis is a degenerative disease in which the leaflets of the aortic valve become fibrotic, calcified, and stiffened. As a result, the valve does not open fully, restricting blood flow from a patient's heart into the aorta and onward to the rest of the body. Aortic stenosis is life threatening because it weakens the heart, ultimately causing heart failure. This final deterioration occurs relatively quickly – after the onset of symptoms, which can include chest pain, shortness of breath, and dizziness, half of untreated patients die within an average of two years.

Historically, aortic stenosis has been treated primarily via surgical valve replacement in patients who could tolerate open-chest surgery and cardiopulmonary bypass. However, a significant portion of the population suffering from the condition is considered inoperable or too high-risk to receive open surgery. Balloon aortic valvuloplasty, in which a balloon catheter is used to expand the narrowed aortic valve, is available to some of these patients but typically does not provide a lasting solution.

Physicians had been intrigued by the idea of minimally invasive valve replacement for decades. Danish cardiologist Henning Rud Andersen was the first to experiment with a valve-stent device in animals. Interventional cardiologist Alain Cribier performed the first transcatheter aortic valve replacement in a human patient in France. Cribier then co-founded a start-up company in Israel, Percutaneous Valve Technologies (PVT), to develop and commercialize the experimental technology.[47]

Shortly thereafter, another physician, Jacques Seguin, began working on a minimally invasive solution when he was a professor of heart surgery at Paris University. As he explained in an article, "My focus was on heart valve therapy and while performing such surgeries, I just knew that what I was doing every day – basically, opening the sternum, arresting and opening the heart, and changing out valves – should be able to be done in a less invasive way. That's the reason why I started design work and experimentation on animals. Eventually, I left the university and my practice to create CoreValve in 2001 to pursue this vision of developing a technology to allow for a heart valve replacement by a catheter-based technique."[48]

The fundamental procedure developed by Cribier, Seguin, and others worked by first dilating the diseased aortic valve with a balloon to make room for the new valve. The prosthetic valve, attached to a wire stent, was then guided by catheter (a thin, flexible tube) to the heart. Once in the proper position, the stent was expanded to hold open the old valve tissue and secure the new valve into place, thus allowing the new aortic valve to open and begin pumping blood. Because the treatment was delivered without the use of a heart-lung machine and did not require sternotomy (opening of the chest cavity), it promised to be appropriate for patients contraindicated for standard valve replacement surgery and potentially for other patients for whom surgery represented a significant risk.

In Sequin's case, he went on to develop a first-generation version of what he initially called a ReValving system (see Figure 4.1.10). After successful **first-in-human** implantations, he expanded his engineering team and decided to pursue the development of the solution in earnest. In parallel with his early experimentation, Sequin approached Antoine Papiernik of French investment firm Sofinnova Partners to see if he would be interested in helping fund the project. At first, Papiernik was skeptical about the need for an alternative to traditional valve surgery, but he and his team started looking into the idea. "We learned that another French physician had just done

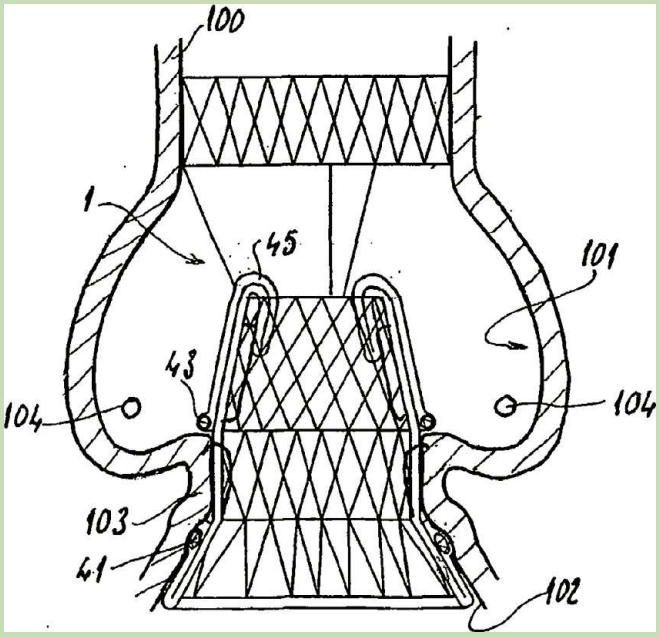

FIGURE 4.1.10
A drawing of the valve from a patent application filed by Jacques Seguin in 2002 (from US utility patent 20,050,043,790 A1).

the first few cases with an Israeli start-up company called PVT (Percutaneous Valve Technologies)," Papiernik recalled, referencing Cribier, "so we realized that Seguin wasn't the only one who saw an opportunity."[49] Intrigued, Sofinnova initiated a formal due diligence process.

"PVT was a little bit ahead," Papiernik said. Cribier and his company had filed multiple patents in the space, so intellectual property was a primary focus during due diligence. "We went to a specialized patent lawyer with strong litigation experience," he explained, "and sought his guidance on the potential risks. We wanted to know if this was going to be a problem for CoreValve. We concluded there were strong positions that supported going forward with the investment." Papiernik continued: "If you are clinically successful with a disruptive technology, somebody almost always will come after you." Entering into a complicated IP landscape was certainly not Papiernik's first choice, but he had become convinced that CoreValve was going after an important clinical need that could translate into a blockbuster market opportunity. He decided to invest.

"At least we went in with our eyes open," he said. "It was a leap of faith."

Sofinnova Partners offered CoreValve a term sheet and ultimately became the sole investor in the company's Series A round of fundraising. Even before the deal was finalized, PVT was acquired by US-based Edwards Lifesciences. Now with the backing of a much larger company, Papiernik anticipated that PVT/Edwards would act aggressively to defend its position.

The first lawsuits were filed within just a few years, first in Germany and the United Kingdom, and then eventually in the US. And, as one article described, "Medtronic [which acquired CoreValve in 2009] and Edwards have been battling one another in the courts [ever since], with each side accusing the other of patent infringement related to TAVR."[50] "The litigation between the two companies is . . . notable because of the sheer number of cases filed against one another," stated Nathan Lowenstein, a partner at Goldberg, Lowenstein & Weatherwax LLP, who was quoted in the same article.[51]

Although they perform roughly the same function, the two technologies are different in multiple ways. For example, the Edwards device is slightly larger, made out of stainless steel, and is deployed when a heart specialist inflates a balloon to position it. In contrast, the frame of the CoreValve device is made of nitinol that automatically expands, giving structure to the valve, when the heart surgeon releases it.[52] However, the specifics of the patent lawsuits come down to the details outlined in the patent claims. As Papiernik put it, "You can win or lose on a single word." For example, CoreValve won early suits in the Germany and the UK based largely on the use of the term "cylindrical." According to press coverage on the UK decision, the Edwards patent in question included "a requirement that the stent be 'cylindrical' and it is this integer that was the subject of the dispute. The Court rejected Edwards' submission that confining 'cylindrical' to that which is approximately geometrically cylindrical is to give the claim a purposeless limitation. Although the Court accepted that in some cases a

patentee may use a geometric term without requiring mathematical precision, the result of Edwards' purposive construction was effectively to strike out the requirement for cylindricality altogether, and this, the Court held, was not acceptable. Having considered the relevant passages in the specification, the Court held that the word 'cylindrical', as used in the claims, should be given its ordinary acontextual meaning. Although it is circular in cross section, the CoreValve device varies significantly in diameter across its length. The Court of Appeal agreed with the first instance decision that this device is not cylindrical."[53]

Since then, both Medtronic (CoreValve) and Edwards had experienced wins and losses in the courts. "I have a stack of IP documents that are probably three meters high," Papiernik said. "And we are still not at the end of this story."

When asked for advice about working in a competitive IP space, Papiernik said, "Hire the best IP attorney you can afford as early as possible, and make sure it's someone who will tell you the hard truth. Then work with that person to try to kill the idea. If you can't kill it, then it may have legs to stand on." A strong IP attorney can also help innovators devise ways to strengthen their patent position. For example, he said, "You may be able to modify your design or license key patents" in an effort to mitigate the risk of IP litigation.

Importantly, he emphasized that the idea must be compelling and the market substantial enough to justify a litigious (and costly) situation. In this case, the heart valve market in the US alone is expected to reach $1.5 billion by 2016, with TAVR driving the majority of that growth.[54]

Papiernik further recommended that innovators think globally about their IP position. "Protecting your technology in the US and EU used to be enough, but not anymore. You can't be everywhere as a small company, but reach as far as possible." With TAVR, CoreValve filed patents in the US, EU, and strategic markets in Asia and South America.

More than anything, Papiernik concluded, "You must believe you have a truly defensible position to justify moving forward in a crowded space. But even then, there are no guarantees."

Other important IP concepts

In addition to understanding issues around patents per se, there are a number of basic points about IP that the innovator should understand well.

Documentation

To help to develop a maximally effective patent filing, inventors should begin keeping an **innovation notebook** early in the innovation process (see 1.2 Needs Exploration). Julio Palmaz, inventor of the coronary stent, emphasized that his early documentation proved to be critically important in litigation surrounding the stent, advising innovators to, "Get in the habit of putting down in writing what is in your mind."[55] The contents of an innovation notebook can help innovators tell a holistic story of how their ideas came to fruition, which can be helpful if the invention is ever contested. When performing this documentation, follow these specific guidelines to ensure that the entries are legally defensible:

- **Format** – Choose a *bound* notebook with *numbered* pages. Never tear out or add pages.
- **Process** – Date and sign each page. Never back-date any entry. Even if a problem was observed (but not noted) on the previous day, always date each entry with the actual day it was written. An explanation for the delay in making an entry can be made, but do not falsify any information as this can constitute fraud if an issue ever goes to court.
- **Authentication** – Have a non-innovator act as a witness, signing and dating each page. This can be done every few weeks – it does not need to be done daily.
- **Additions** – Any added material that is pasted in must be "signed over" (this means pasting in the page and

then signing/dating the addition in such a way that the signature is partially on the original page and partially on the addition).

- **Blank space** – Cross out blank spaces to ensure that no retroactive entries can be made.
- **Deletions** – Never white out anything. Use a single line to strike through any errors and initial the corrections.

Inventorship and ownership

Any patent application must include all of the inventors who contributed to the creation of an innovation, as defined by the claims of the patent. To be considered an inventor, an individual must have contributed to the conception of the idea. If someone adds to any part of an invention as it is being claimed, then they are a joint inventor. From the standpoint of patent law regarding inventorship, it is irrelevant whether an inventor was instrumental to conception of a core concept or only conceived of some detail. However, if someone provided only labor, supervision of routine techniques, or other non-substantive contributions, then they are not to be considered an inventor.[56] With medical devices, this issue often surfaces when a prototyping engineer is involved in building the first versions of the device. If the builder of the device is operating entirely under the inventor's instructions, the builder is not an inventor. On the other hand, it is frequently the case that the builder adds a key insight. For example, when one of the editors of this textbook was developing the Smart Needle™ concept (a needle with a Doppler transducer), the engineer who was building the prototype pointed out that moving the transducer to a different position could improve the signal. This was an important addition to the design, and the engineer became an inventor by virtue of this contribution.

It is important to be aware that in the absence of any employment or consulting agreement obligating inventors to assign their inventions to another entity (such as a university or an employer), each inventor has both an ownership interest in the patent and the right to license, commercially develop, or sell the invention *as an individual*, with or without the knowledge or permission of the other inventors. This is true even if the inventor contributed to only a single issued claim. While most inventors prefer to work together to maximize the value of their patent in any licensing deal, the ability of each inventor to act alone is something to consider when involving multiple individuals in the innovation process.

Understanding the implications of ownership for an invention is essential prior to initiating a collaboration. For example, in the case of medical devices, it is common for the inventors of a new technology to seek out a physician expert to validate their early ideas. It can be irresistible for the physician to add some potential improvements to the core idea. These suggestions may be useful and important, but in the process of receiving the feedback the original team may have added a new inventor – at least for some of the claims of the patent. This is particularly problematic if the new inventors have a special relationship with a company that presents a conflict later on, or if they are a faculty member of a university that will automatically assume ownership of the IP (see below).

If it is discovered retroactively that the inventorship on a patent is inaccurate, and the mistake was made in bad faith (for example, if a valid inventor was purposely not included on the patent), the patent can be invalidated.[57] While this happens infrequently, litigators challenging a patent will often start with inventorship as possible grounds for invalidating it.

Student, faculty, and employee inventors

Inventors working in an academic setting must keep in mind that if an invention is conceived and/or developed using significant university resources, the university may assert its rights in taking ownership of the invention. Generally the interpretation of "significant resources" does not include desks, computers, the use of conference rooms, or the use of other commonly available equipment or facilities. University policy regarding IP ownership comes out of the institutions' need to avoid situations in which public resources (such as grants from the NIH) are used to support private enterprise without some oversight regarding the fairness and best deployment of the technology. Among all science and technology areas, the biomedical sciences are, in fact, the area of highest concern for government regulators with respect

to university inventors. Unfortunately, there have been some high-profile and tragic examples of conflicts of interest related to ownership of biomedical innovations (e.g., the 1999 Jesse Gelsinger case).[58] As a result, universities and government agencies have become extremely attentive to issues of IP ownership of medical technologies.

Some universities have language in their policies that states, in effect, that inventions in the faculty member's areas of expertise also belong to the university. For student inventors, policies vary across academic institutions. In some universities, students are treated exactly like faculty; in others, there are no IP regulations. A wide range of policies exists between these two extremes. It is important for any university-based inventor to have a clear understanding of the relevant rules. If the university guidelines are not clear, it can be useful to enlist the assistance of an outside lawyer who has experience with that particular university and its inventorship policies (more information about licensing back one's own invention from a university's office of Technology Licensing can be found in 6.4 Alternate Pathways).

The situation where students are inventing together as a team warrants special mention. If an invention is poised to go forward to commercialization, teams sometimes find that misunderstandings arise regarding the respective contributions of each inventor to the IP. Conflicts can develop when one of the team members feels that s/he has "come up with the idea" in the context of a group ideation process but other team members feel they have made an important contribution in framing the concept. Because of this issue, students in the Stanford Biodesign fellowship and classes create a "memo of understanding" at the beginning of their project about how IP will be divided. The teams typically decide to split the IP evenly, or develop some algorithm for deciding how to value the contribution of a lead inventor. The important thing is that the team has an appreciation of the issues involved upstream of any actual conflict.

Within a corporate context, it is common for an employee to be obligated to assign ownership of inventions to the company, provided that the inventions are within the employer's business or if the inventors used the employer's resources in developing the invention. The company may have an incentive or reward scheme for the inventors, but this varies from organization to organization. For anyone working in more than one company, or for a student or faculty member working for a company part-time as an employee or as a consultant, it is important to understand whose ownership rights apply to any inventions.

Public disclosure

Many inventors underestimate the importance of confidentiality in the patenting process. In the early phases of a new project it is natural to want to share the excitement of the new approach – or present the concept to academic colleagues. As noted earlier, in the US inventors have a grace period of one year to file a patent application from the date that they first publicly disclose the concept, as shown in Figure 4.1.11 (i.e., before the

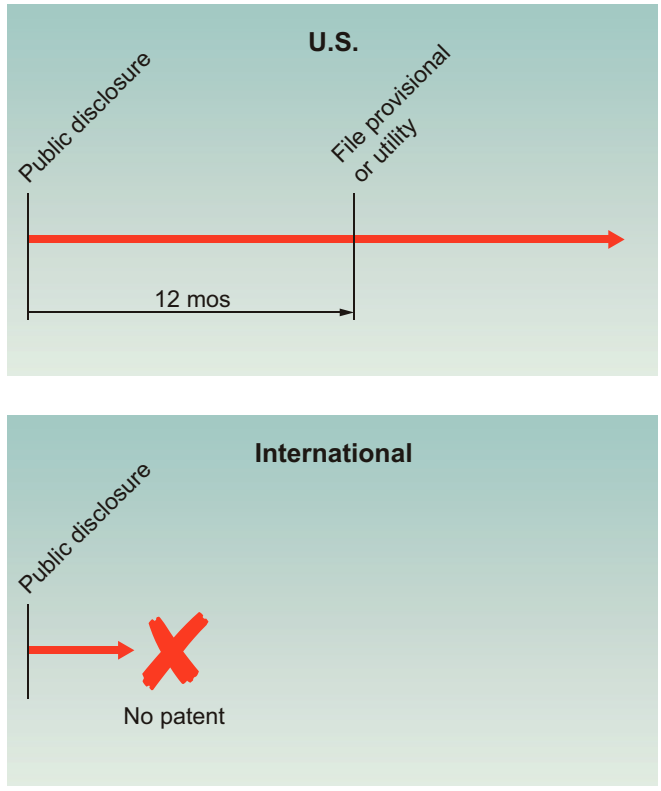

FIGURE 4.1.11
Public disclosure has different implications for patenting in US and international markets.

inventors' own disclosures become prior art that can be used against the patentability of their inventions).

Public disclosure can include publication, presentation, and announcement, as well as commercial use, offerings, or sales. Be aware that casual conversations with colleagues are similarly considered to be a form of disclosure. Medical technology inventors (especially academic engineers or physicians) run a particular risk of submitting an abstract or manuscript that describes their invention assuming that the "confidential" editorial review process protects their patent rights. This situation is at best in the gray zone for public disclosure, and it is wise to file at least a provisional patent application before sending in a manuscript or abstract.

Internationally, there is no grace period. If the innovator publicly discloses the invention prior to filing a patent application, the disclosure is likely to preclude patent protection outside the US, even if the disclosure is within the one-year grace period provided by US law. As a result, experts in the field strongly suggest filing a patent application before making any public disclosures.[59] For medical devices, issues with public disclosure have led many inventions to have coverage in the US only. Depending on the device, this has not necessarily been a significant problem in the past, given the historically large size of the American device market compared to that of other countries. With the expansion of the global markets, however, international coverage is becoming increasingly important, making issues related to public disclosure a serious matter.

Non-disclosure agreements

To keep an idea or invention confidential, inventors are strongly encouraged to use **non-disclosure agreements** (**NDAs**), alternatively known as confidential disclosure agreements. NDAs are legally binding documents that enable an entity to record the terms under which confidential information is exchanged (thus preventing the interaction from qualifying as a public disclosure). Such agreements can be useful anytime an individual or a company must disclose the details of its technical secrets, including (but not limited to) discussions with potential investors, partners, third-party suppliers, employees, contractors, and consultants. For students, the need for confidentiality can extend to faculty members and fellow students, as well as other mentors, family, and friends. In discussions with an IP attorney, confidentiality is legally protected (with or without an NDA) under attorney–client privilege.

The key issue to address in an NDA is *use* (how the party to whom the confidential information is disclosed can use the information that is shared). It is not enough to ask someone to keep quiet about an invention or other confidential information. A strong NDA must explicitly restrict the ways in which the information can be used.

An example of an NDA is provided in online Appendix 4.1.3. In general, an NDA will have several components:

1. It specifies who the legal parties are in the agreement.
2. It defines the content and scope of the confidential information.
3. It provides for some reasonable exclusions from the obligation of confidentiality (for example, when the receiving party can prove they already knew about the information – or when it was public knowledge).
4. It details what the nature of the obligation is for the receiving party – that is, prevent disclosure and specify how the information can and cannot be used (e.g., restrict access of employees to the information; do not publish or otherwise disclose the information).
5. It specifies a time period that confidentiality is in force (typically for three to five years, or in some cases, until the information becomes public).

NDAs are used to protect disclosures made in multiple scenarios – individual to individual; individual to company; company to individual; and company to company. Typically, innovators and companies are discouraged from using NDAs that require the discloser to document in writing what was disclosed orally in the meeting. Although it is always a good idea to summarize what information was shared, the innovator or company should not be required to do so within a specific time frame and should not be constrained by what may or may not have been included within a summary document.

An NDA does not guarantee that a breach of confidence will not occur. However, it does give the company or innovator a stronger legal position if a problem arises. Some entities will not want to sign an NDA and the inventors must decide how much they are willing to disclose without protection. In some situations, disclosure may be still be warranted. For example, venture capital firms routinely abstain from signing NDAs in favor of a generally accepted principle that sensitive information will be kept confidential. In this case, innovators are advised to mark all documents confidential (including each slide of PowerPoint presentations) and disclose only what is absolutely necessary to get the firm interested. In other scenarios, where the level of trust is less certain, it is best not to reveal confidential information without an NDA.

When in doubt, inventors are encouraged to "file first, disclose later," using NDAs to help control the sharing of any confidential information before and after the filing date. Whenever innovators disclose information before filing a provisional or utility patent application, the risk exists that the person(s) they have disclosed to might develop a competing invention based on the revealed information and worse, file a patent application before them, precluding their patent rights. Using a "file first" strategy before disclosing can help minimize this risk.

The following case example on iRhythm Technologies, Inc. demonstrates how the essential information presented in this chapter can be brought together to help innovators and their teams understand the IP landscape for a concept under consideration and begin to establish a strong IP position.

FROM THE FIELD — IRHYTHM TECHNOLOGIES, INC.

Assessing the IP landscape and making preliminary filings

When Uday N. Kumar, John White, Kityee Au-Yeung, and Joseph Knight were fellows in Stanford University's Program in Biodesign, they began working on the need for *a better way to detect potential rhythm disturbances in non-hospitalized patients with suspected arrhythmias*. Arrhythmias are abnormal heart rhythms (atrial fibrillation, described at length in 2.1 Disease State Fundamentals, is one common type). Although some arrhythmias can have few negative health consequences, others can lead to serious heart disease, stroke, or sudden cardiac death.

According to Kumar, a cardiologist specializing in cardiac arrhythmias, "The vast majority of people who have symptoms that could be due to arrhythmia first go to their primary care physician or an emergency room doctor. But physicians in those settings are not enabled to fully diagnose the problem since current cardiac rhythm monitoring technologies are complicated and have many drawbacks that limit their use by these doctors. So, many people never get assessed until they have a very severe presentation, such as passing out or experiencing a cardiac arrest. Unless something relatively serious happens, patients are often told, 'You had palpitations two days ago. But you look fine now. Let's wait and see if it happens again.'" In contrast, if these patients were referred to a cardiologist, advanced monitoring technologies could be used to diagnose the problem and facilitate more proactive treatment, in many cases, before more serious symptoms occurred. "We figured out that enabling better diagnosis through more accessible and simple approaches was the key to getting more people into treatment earlier in the process," said Kumar.

Once the team understood the parameters of the need and the key **need criteria** (as articulated in the **need specification**), its members held a series of **brainstorming** sessions. Together, they generated dozens of potential solutions and screened them against the need. "After we had a solution that we thought would

best meet the need spec," Kumar recalled, "we had to figure out if people had done this before so we conducted IP searches. Our focus was on patents that had already been issued as well as pending patent applications," he added. Importantly, the team did not spend too much time looking at medical journals and other general sources since, as a field, cardiac rhythm monitoring had not experienced a great deal of innovation in recent years. "There just weren't many recent publications out there about talking about cardiac rhythm monitoring," Kumar recalled.

The initial patent searches were meant, in part, to establish the utility, novelty, and non-obviousness of the team's idea. Demonstrating the utility of a device designed to perform outpatient cardiac rhythm monitoring was not a primary concern. However, the team was intent on clearly identifying that its solution was novel and non-obvious. Kumar and his teammates performed many searches using a wide variety of search terms related to the description of the device concept, its functionality, appearance, interaction with the body, and links to the disease. Patents on existing cardiac rhythm monitoring therapies were also searched for relevant information. The team used different combinations of search terms to help ensure that the scope of the research was not too narrow and that nothing was inadvertently overlooked. "You have to be broad in your searches," said Kumar. "The information you uncover really depends on how you search. I used a thesaurus to figure out different ways to describe the same thing. People use different approaches, and you can miss a whole patent if you don't expand your thinking about search terms." The team also realized that being too broad in its search strategy led to many irrelevant results. Understanding the limitations of being too narrow or too broad allowed the team to develop a search strategy that gave them a good sense of what was out there.

As the team reviewed patent documents it became increasingly clear that their solution had several important elements that made it unique. To address the non-obviousness of the device, they spent significant time and energy figuring out where the cardiac rhythm monitoring field was trending. "If you understand where the field is heading, you can determine how you fit in,"

FIGURE 4.1.12
The team with its first provisional patent filing (courtesy of Uday N. Kumar).

Kumar commented. “If we’re going in one direction and everyone else is going another, it shows that we’re on a different path, which makes it difficult for the patent office to say that what we’re doing is really obvious.”

At that point, in parallel with other activities in the biodesign innovation process, the team was eager to seek input and opinions about its solution from other people in the field, “so we filed a provisional patent application,” said Kumar. “It wasn’t just a paper napkin with a sketch. It had a detailed background section and drawings.” It also included a single claim the team believed captured the device’s utility. Filing a provisional application secured a priority date in the patent office and protected the team from third-party disclosure (see Figure 4.1.12).

As biodesign fellows during this preliminary IP assessment, the team did not have the financial means to engage an IP attorney. However, upon completing the program, “I made the decision to start a company,” said Kumar. “That’s when I knew it was time to get a patent attorney involved.” To prepare for his interactions with an IP lawyer, Kumar revisited the team’s early IP assessment and initiated a more detailed review of the prior art. “I spent a lot of time going back to the original patents we had examined. I also did more searching, brushed up on what else was out there, and dived much more deeply into the analysis of specific claims,” he remembered. Kumar and team had started a claims analysis but realized they needed outside expertise to complete it. For this reason, they decided to file the provisional application and come back to claims analysis later, if any of them decided to pursue the project beyond graduation. “At the end of the day, the claims are what matters,” Kumar commented. “In the first instance, it can be discouraging to read descriptions and see figures in another patent that look similar. But ‘similar’ doesn’t mean ‘the same.’ You have to closely examine and interpret the claims, especially the independent claims, to determine whether a potential problem exists.” Kumar looked at both device and method claims, since his product and business model were directed towards a monitoring device and an approach for using the monitoring technology.

Based on his preliminary claims analysis, Kumar narrowed the list of patents to those that were closest and most relevant to its proposed solution. “Then, I went back to look at the text to understand the arguments that were made to support the claim sets. This also helped me think about and refine my own arguments for why the solution was novel and non-obvious compared to what was already out there.”

With his own analysis complete, Kumar was ready to engage an attorney. As a fellow, he had been introduced to Ben Glenn, who regularly volunteered time to be an “IP coach” to teams in the Program in Biodesign. “I recalled meeting Ben and the positive experience our team had in talking with him. He had deep knowledge and experience in medtech, so I sought his help,” said Kumar. He shared his assessment with Glenn as the first step in establishing a close and highly collaborative relationship. Over time, “I spent countless hours with Ben, really explaining exactly what we were doing and bringing him up to speed. This way he could help direct how I could be most helpful as we parsed up the work. Even with a great IP lawyer, the innovator really has to stay involved and understand what’s happening because you know better than anyone else what the technology is intended to do.” In addition to validating the team’s assessment of the IP landscape, Glenn orchestrated a conversion of the provisional application that emphasized the differences and advantages of the device and the method of use. The result was an IP foundation with three utility patent applications (covering the device and associated methods), as well as a PCT application. “In the end, it is hard to overstate the importance of having an experienced IP lawyer such as Ben on my side. He definitely spent a great deal of time really trying to understand the space so that he could thoughtfully put together claims and send them to me. He’d ask, ‘Is this really what you mean?’ and we’d go back and forth, trying to define different elements or combinations of elements to distinguish over the prior art. Being pushed and questioned by Ben was the key to developing claims that really got to the essence of what was patentable about the solution,” Kumar explained.

One important tool that Kumar recommended in developing a preliminary patent position was the USPTO Patent Application Information Retrieval system (or PAIR database) which allows users to access the status of current patent applications. "It gives you all of the history on what's gone on between a patent applicant and the patent examiner," he explained. "By reading these interactions, you can see where applications have been rejected by an examiner, and for what reason. It shows you what claims were rejected, the prior art used in the rejection, and the rationale behind it. With Ben's help, I was also able to appreciate which of the many documents in the file for a given patent application really were significant. This information helped me to think more specifically about where Ben and I might expect push-back in the examination of our own applications, and it allowed us to realistically address these potential issues."

The company that Kumar founded around the IP that he worked on and licensed from Stanford became an important foundational element for iRhythm Technologies, Inc., based in San Francisco, California. In addition to developing the device and establishing the methods to use it, the company has continued to monitor the IP landscape to stay aware of salient new developments in the field. In addition to being granted numerous utility patents stemming from the early IP work done by Kumar and Glenn, the company has also filed additional patent applications.

A final note: using IP to screen and eliminate concepts

There is a practical problem to address head-on in screening concepts from the standpoint of IP. As is clear from the chapter, the amount of work required to perform a thorough patentability and FTO analysis on just one idea is formidable. So, from the standpoint of workflow alone, it is a major challenge for the team to research the IP landscape on multiple concepts. The key, as in many other steps of the biodesign innovation process, is to gather just enough information in a stepwise fashion to make the screening process both effective *and* efficient. Innovators should plan to conduct a series of progressively deeper searches, eliminating concepts with killer risks as they go. At this stage, a "killer risk" is just that – a problem so severe that it makes clear that the project cannot proceed. In the IP space, for example, this could be a major FTO problem where the technology is owned by a company that would have no incentive to license or co-develop a new product.

For concepts not affected by a killer risk, innovators should gather data about IP (along with regulatory, reimbursement, business models – as described in chapters 4.2, 4.3, and 4.4) that enable them to create and use a risk scoring matrix on their way toward a final solution. This exercise is described in more detail in 4.6 Final Concept Selection. But, by carefully understanding the risks related to their concepts on a rolling basis, innovators will position their team to efficiently move from multiple concepts to one final solution.

In the end, the team should only do a detailed patentability and FTO search on, at most, a small set of leading concepts that survive the full screening process described in chapter 4.6. In the interim, the following tips can help make the IP screening process manageable:

1. **Red, green, yellow** – To resist the urge to get too deep into IP too early, set a timeline to do an initial screen of all concepts and, using the best information available in that short time, group the concepts into rough categories based on the initial promise of the IP landscape. Given the time constraint, innovators should start with a patent database like Google (and not try to research the world's literature). Use a simple system for categorizing such as: red (troublesome IP problems), green (looks OK), and yellow (some issues raised).
2. **Accentuate the positive** – For the time being, defer any further work on the concepts that appear to have

major IP problems (remember, if it turns out there are compelling reasons to pursue one of these ideas later on, there may be ways of dealing with the IP issues). Broaden the search on the promising concepts, looking into the biomedical literature. Set a timeline for these searches also – do as much as you can in the defined time period, understanding that there is much more searching ahead. Some of the previously green concepts may move to yellow or red through this activity.

3. **Prioritize based on other screens** – Since the next round of IP searching will be extremely time-consuming, use the screens from the other categories to triage where the team will invest its time going forward. If a concept has serious regulatory, reimbursement, or business model issues, or prototyping is raising questions regarding its technical feasibility, do not waste the team's time with a painstaking IP search.

One last point: remember that at this stage in the biodesign innovation process it is common for innovators to identify problematic patents related to their ideas. In certain cases, these issues constitute killer risks and warrant setting aside a potential solution. However, if the concept looks promising relative to all other screens and is an idea the team is excited about, it may be worth seeking an expert opinion before abandoning the idea. As noted, skilled patent counsels can sometimes identify ways to successfully work within the existing patent landscape that may not be readily obvious to innovators without extensive experience in the field.

Online Resources

Visit www.ebiodesign.org/4.1 for more content, including:

Activities and links for "Getting Started"

- Compile background information
- Search the prior art
- Identify relevant prior art for patentability
- Prepare a patent application
- File a patent application

Videos on intellectual property basics

Appendices that provide examples for:

- A provisional patent application
- A USPTO utility patent
- A standard non-disclosure agreement

CREDITS

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