

Beginning the Patent Process

The second step in bringing your medical device to market is to understand whether you can protect your invention.

BY GERARD VON HOFFMANN, JD, AND BRYAN WAHL, MD, JD

This article is part two of a series that presents the three big issues in intellectual property: Do you own it? Can you protect it? Do you have freedom to practice it? In this article, we explore common issues involving the second question: Can you protect it? The first part of this series appeared in the March 2014 issue of *Endovascular Today*.

DO YOU EVEN NEED A PATENT?

A lot of companies sell unpatented devices and services, relying instead on factors like marketing and price competition to maintain market share. Usually, that will not succeed in the medical device industry. The cost of product development and the cost and delay of regulatory approvals, among other challenges, are too great to attract investment capital unless the investor is confident that you have (or are likely to obtain) adequate patent protection. Unless you can attract sufficient capital, you normally have no realistic chance of taking a product to market. Making a judicious investment in building a patent portfolio is almost always a required first step.

KNOW WHAT RIGHTS A PATENT PROVIDES

A common misconception is that if you are able to patent something, you are free to practice it. This is not necessarily true. A patent gives you the right to exclude others from making, using, selling, or offering to sell a patented invention—it does not give you the right to practice your own invention. Whether or not you can practice the invention yourself depends on the previous patent rights of others. For example, assume you obtain a patent on a stent with a unique wall pattern that leads to a clinical advantage, such as superior flexibility or an improved crossing profile. If you make that stent out of a proprietary nitinol alloy, the patent owner of that alloy could block you. On the flip side, you could block the nitinol alloy patent owner

from selling stents that have your unique wall pattern, regardless of the material.

Possible next steps in this situation are beyond the scope of this article, but these include legal or business options. Legal options include attacking the validity of (in other words, trying to eliminate) the problem patent; a patent that covers you can only block you if it is also valid. Business options include changing your material to a nonpatented alloy or negotiating a transaction, such as a purchase, license, or cross-license of the problem patent. The third part in this series will cover the freedom to practice an invention; for now, be aware that having your own patents is important, but it is also important to consider the patents of others.

TIMING IS IMPORTANT

Last year, the United States became a “first-to-file” patent country. This means that if you and someone else independently came up with the same invention, the first one to file a patent application and comply with all of the other criteria for patentability would get the patent. In other words, even if you were the second to invent, you would win if you beat the other inventor to the United States Patent and Trademark Office (we’ll call it the “Patent Office”) by filing your patent application first. Merely writing your invention down in a lab notebook and having it witnessed doesn’t win in a “first-to-file” system—you need to file patent applications as early as you can.

If you want to preserve the right to patent your invention, never make a nonconfidential disclosure before filing a patent application. For example, you may be motivated to publish positive bench research or clinical data; bounce ideas off colleagues; share new discoveries at grand rounds; or present abstracts, posters, or slide presentations at the next conference. However, if you undertake any of these activities prior to filing a patent application, you may have made a public disclosure—

and irrevocably lost your patent rights throughout at least most of the world. (There are a few limited exceptions, which are beyond the scope of the present article.) Remember to file first before making a nonconfidential disclosure. Also, keep in mind that some journal articles electronically publish either a draft or final form of an article (which, as a result, becomes public) before the date of the actual print publication, and that earlier e-publication is a potential public disclosure. Even the date of submission to an editorial review board can constitute the date of public disclosure, despite the fact that the publication will not occur until months later.

REQUIREMENTS FOR PATENTABILITY

There are many legal criteria that need to be satisfied in order to patent your invention. In the medical device industry, the two requirements most commonly in play are (1) your invention must be novel, roughly meaning it has not been identically known or used in a nonconfidential environment (eg, in public) before, and (2) your invention must also be nonobvious: even if it is novel, your invention must additionally be different enough that a hypothetical person of ordinary skill in the art would not be motivated to modify the prior art to come up with what you have invented. “Novel” is sometimes used interchangeably with “new.”

Despite the conceptual simplicity of the basic “is it new and nonobvious” tests, lawyers spend considerable time in the patent office, the courts, and reviewing the literature debating the many nuances of these tests and how they apply to a given invention. Particularly with respect to the nonobviousness standard, there is a level of uncertainty that cannot be eliminated. Experts in the field can give you an expectation of the likely outcome of an obviousness inquiry based upon their experience in the technology and scholarship in the law, but normally cannot predict an outcome with certainty. The decision to seek patent protection thus nearly always involves a grayscale judgment to put time and money at risk, taking into account upside factors like the size of the market, the extent of the clinical need, and the likelihood that you can navigate the maze of steps it may take to get to commercialization.

But just like an “easy” transcatheter aortic valve replacement procedure, you should not normally perform an obviousness analysis on yourself. We have seen many valuable patents issued on inventions that the inventor dismissed as obvious. Someone else—often, someone with a deeper appreciation for the clinical opportunity than the medical details—caused the effort to proceed. Most of your inventions will probably be obvious to you. That’s why you are the inventor.

Another criteria for patentability is the “enablement” standard: you must describe the invention in your patent application in sufficient detail that someone of ordinary skill in the art would be able to make it and use it without undue experimentation. Most medical devices are, at their core, simple mechanical devices, and enablement is not a problem. If you conclude that it would be advantageous if you could inject contrast at a point 20 cm from the distal end of the catheter, a patent attorney can turn that into a patent application that satisfies the enablement requirement. Even if you are not familiar with the details of catheter design and manufacturing, the hypothetical person of ordinary skill in the art, for this purpose, would be a catheter extruder or designer. They would immediately know several ways to modify the extrusion, proximal manifold, and related assembly steps to accommodate the inventive function. So, don’t hold back just because you may be uncertain of the engineering or manufacturing details, because the law of enablement gives you the benefit of the knowledge of others in the industry.

Yet another requirement is that your invention must fall within certain categories of subject matter in order to be patentable. For example, the abstract discovery that atherosclerotic plaques may lead to a myocardial infarction is not statutory subject matter. However, devices and methods, such as angioplasty catheters or stents, methods of using the stent, methods of making the stent, and a delivery system for deploying the stent, are statutory subject matter. Note that the United States and Australia are essentially the only countries that permit patent protection on diagnostic and therapeutic medical methods. If your invention is a new way of using an existing device—for example, a radiofrequency ablation catheter for a new indication—and international patent protection is important to your business strategy, you may want to spend research and development effort to develop improvements to the device itself.

Additional requirements for patentability exist, such as utility and written description, and many rules related to the form of the submission. These are beyond the scope of this article, but will be well understood by a patent attorney.

PATENT SEARCHING

There is no requirement to conduct a prior art search, but the cost of a search is normally far less than the cost of a patent application. It’s usually a good idea to do a patentability search to reduce the risk of finding a surprise patent later that prevents you from meeting the novelty or nonobviousness standards. Patent searching can also

help you to draft your patent application strategically to more clearly distinguish from the prior art. Like medicine, searching is often an art as well as a science, and no search is guaranteed to find the most relevant references.

As a first step, you may wish to do some preliminary searching yourself using free and readily accessible web tools, such as the United States Patent and Trademark Office website, Google Patents, and PubMed. The next level of searching can be done with the assistance of a patent professional, which may include a search of United States patents and publications, patent and publication searching in key foreign countries, and a search of the medical literature. Remember that brochures, library books, journals, and even product manuals can be prior art. Also, always consider your own previous activities, such as journal articles, conference presentations, posters, abstracts, and other public disclosures (as discussed previously in this article), which could also potentially prevent you from patenting your invention.

WHAT TO PUT IN YOUR PATENT APPLICATION

When drafting and reviewing a patent application before it is filed, there may be a tendency for you to immediately focus in on the claims. While the initial claims are important, the content of the text (specification) and drawings of the patent application at the time the application is filed are even more critical. The reason is that the claims can be amended during the patent examination process months or years after the patent application is filed, in light of prior art that the patent examiner might find, changes to your design, or a competing product that seeks to design around your existing claims. However, the claims can only be changed to recite structural features or method steps that were specifically included in the specification and drawings as originally filed.

This is why it is important to describe, in as much detail as possible, the important features of the invention that appear to add clinical value and are different from the prior art. For key features, you should include alternative structures or dimensions so that you disclose not only your preferred embodiment, but also potential competitive alternatives that you would not want someone else to be able to produce except under an agreement with you. This enables you to preserve the ability to claim those features later.

CONCLUSION

There are many requirements for the issuance of a valid patent. In the medical device field, the biggest challenges are normally overcoming the novelty and nonobviousness criteria. You can conduct some initial

TAKE-HOME POINTS

- A patent gives you the right to exclude others; it does not necessarily provide a right to practice the invention. Whether or not you can practice the invention depends on the prior patent rights of others.
- It is safest to file a patent application before any public disclosures (print or e-publication of a journal article, presenting at a conference or grand rounds, etc).
- Consider patentability searching early on in the process. The results may help you decide whether to go forward and what to focus your patent application on.
- When drafting a patent application, while the claims are important, the primary goal should be to ensure the specification and drawings are as detailed and complete as possible, in order to support future claims strategies.
- Consult professional counsel with experience in the endovascular field when applying for a patent.

searching to reach a preliminary view on patentability. If you are not an inventor with extensive experience, you will probably want to consult with experienced patent counsel to help guide you through the numerous and sometimes complex rules governing the issuance of a valid patent.

New therapies will never reach patients unless they are properly funded. Due to the high cost of research and development and regulatory approvals, among other challenges, investors will generally not fund a new therapy unless they are comfortable that you are likely to obtain sufficient patent protection. As such, making a judicious investment in building a patent portfolio is a very important step in the process. ■

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Gerard von Hoffmann, JD, is a partner in the Silicon Valley and Orange County offices of Knobbe Martens, LLP, an intellectual property law firm with extensive experience in patent strategy and litigation in the medical device industry. Mr. von Hoffmann may be reached at gerard.vonhoffmann@knobbe.com.

Bryan Wahl, MD, JD, is a partner in the Orange County office of Knobbe Martens. Dr. Wahl may be reached at bryan.wahl@knobbe.com.

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