Evaluating Freedom to Operate

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

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This article is part three of a series that will present the three big issues in IP: Do you own it? Can you protect it? Do you have freedom to practice it? The first and second parts of the series were published in the March 2014 and April 2014 editions of *Endovascular Today*, respectively.

In this article, we set the context and explore common issues involving that third question. You may have heard terms like freedom to operate (FTO), market clearance, right to practice, or third-party patent evaluation. All refer to the question of whether you have the freedom to practice your invention without infringing upon the patent rights of others. Without freedom to practice your invention, you could be at risk of having to pay monetary damages to a patent owner—or worse, having a court bar you from making, using, or selling your invention (known as an injunction).

HAVING A PATENT DOESN'T PROVIDE A RIGHT TO PRACTICE

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 your patented invention; it does not give you the right to practice your own invention. Whether you can practice the invention yourself depends on the prior patent rights of others.

For example, assume you obtain a patent on a percutaneously deliverable aortic valve with a unique leaflet geometry that leads to a clinical advantage such as superior fatigue life or coaptive characteristics. If you seek to make those valve leaflets out of a proprietary biomaterial, the patent owner of that biomaterial could block you from doing so. If you instruct cardiologists to deploy your valve via a transapical approach, the owner of a patent claiming a method of inserting a valve transapically could block you from doing so, as well. Thus, even if you can patent your technology, whether you have freedom to practice it is a separate question. You will normally need to evaluate and achieve both when bringing your medical device to market.

WHY INVESTIGATE FTO?

There is no requirement that you evaluate FTO, but the expense of product development and the expense and delay of regulatory approvals, among other challenges, are too great to attract a development partner or investment capital unless the investor is comfortable that you have, or are likely to have, freedom to practice your invention. Unless you can attract sufficient capital, you normally have no realistic chance of taking a product to market. It is not uncommon that a problem patent becomes a deal-killer if you are not able to convince a potential investor or acquirer why that patent does not present a right-to-practice problem.

You need to assume that any venture investor or strategic partner (eg, Medtronic, Inc.; Abbott Vascular; Boston Scientific Corporation; Edwards Lifesciences; Covidien; etc.) will conduct some amount of FTO evaluation before closing a deal with you to develop a new technology. Your chances of success are optimized if you can discover any problem patents in advance. That gives you time to develop a strategy on how to proceed. Many times, there are ways to successfully manage risks raised by what at first appears to be a problem patent, but all of them take some time. If an issue that you were not previously aware of arises in real time during diligence, many investors or partners will walk away, even though a solution may have been available. It is almost always prudent to make an appropriate investment in investigating FTO before entering diligence or expending resources on development.

Even if you diligently evaluate FTO, you cannot reach certainty. Many processes in the world of patents can do no more than reduce risk or optimize opportunity. Like

medicine, freedom-to-practice searching is an art as well as a science. It is possible that searches do not turn up the most relevant references. Also, a claim term of a potential problem patent could be ambiguous enough that a judge or jury could disagree with you on what that word or phrase means. Furthermore, an aggressive competitor could file a patent infringement suit against you on a patent that you do not infringe but that is "close enough" to litigate. You may need to spend significant resources just to make the suit go away. Notwithstanding the previous, knowing the patent landscape well can reduce the risk of being blindsided by a patent at an inopportune time, either via lawsuit or if it is brought up by a potential investor or acquirer during diligence.

THE TIMING OF INVESTIGATING FTO

It's usually a good idea to start looking at your freedom to practice your invention early in the process to reduce the risk of finding a problem patent after resources have been expended. Also, analyzing your FTO position at an early stage can allow you to strategically steer product design in a direction that will avoid the potential problem patent. Designing around the problem patent is often possible but can become increasingly financially challenging as the design process progresses.

A freedom-to-practice analysis is more of an iterative process than a single event. A change in product design could warrant an updated freedom-to-practice search or a fresh review of prior search results. For example, you may determine that your self-expanding abdominal aortic aneurysm graft would benefit from an inflatable cuff or other feature to inhibit type I endoleaks. Your first search may have been directed to the wire frame wall pattern. An updated freedom-to-practice search might then additionally look for patents claiming endoleak features that you may not have previously taken into account.

It may also be beneficial to update your freedom-to-practice analysis periodically before any of a variety of valuation or risk events. These include events such as an investment round, exit diligence, or a commercial product launch. New patents are issued in the United States every Tuesday, some of which may have priority filing dates before your technology. Also, claims of pending published patent applications can be changed during the examination process, which is another reason to keep your FTO position updated periodically.

HOW TO EVALUATE FTO

An FTO analysis is best done together with your patent attorney and involves accumulating patents from various sources, then screening the patents for risk. A variety of professional search firms can search for patents with claims that may be relevant. If your device is similar to something on the market, check the packaging or product inserts for patent numbers. You may also want to review patents owned by key competitors in the relevant space. Certain patent families become well known, and you should consider reviewing any that might be relevant. For years, inventors with a new stent wall pattern have wanted to review all of the Palmaz patents and patents assigned to Guidant. If you had a rapid-exchange catheter design, you might review all of the Yock or Bonzel patents in addition to whatever was revealed in the subject matter search. Today, before spending effort on an radiofrequency-based renal denervation catheter, you might want to review the Ardian (now Medtronic) patents and the progress of the associated re-examinations, among others. The list goes on.

Once you identify the patents from the search and other sources, the next step involves comparing features of your device or method against the independent claims of each patent. The claims, which define the scope of the rights under the patent, are the numbered sentences on the last page(s) of the patent. Claim 1 is always an independent claim, and there may be others as well that do not reference other claims. In contrast, dependent claims always reference another claim (eg, "The stent of Claim 1" is a dependent claim). If you do not infringe an independent claim, then by definition, you do not infringe the claims that depend from it.

Understanding a patent claim is not always easy. It may not properly use terms of art, and sometimes, the sheer complexity of describing structures or method steps in a single written sentence produces a linguistic maze. But conceptually, every claim begins with a preamble that sets the context, followed by a series of elements that describe the characteristics of the claimed invention.

Assume that after the rhetoric has been filtered out, a claim reads as follows:

- An abdominal aortic aneurysm graft, comprising:
- A self-expandable tubular wire frame,
- The frame forming an aortic trunk and first and second iliac branches, and
- An ePTFE layer surrounding the outside surface of the frame.

For a device to literally infringe that claim, it must include every element of the claim. So assume, for example, that your proposed graft (1) can only be expanded with a balloon, (2) is a straight segment and not bifurcated, (3) has the ePTFE layer on the inside of the frame, or (4) has a membrane surrounding the outside of the frame made out of something other than ePTFE. In each of those cases, even if your device literally includes every other element of the claim, most lawyers will agree that

there is no literal infringement. You can see that designing around a claim involves determining which claim element, if any, you can literally avoid without sacrificing the clinical objective of your device.

Even if you can avoid literal infringement, however, you may still infringe under a theory known as the Doctrine of Equivalents (DOE). Lawyers spend considerable time analyzing and arguing about the applicability of the DOE, the details of which are beyond the scope of this article. In general, the issue will be whether in the context of a particular patent claim and its history and the prior art, moving the ePTFE from the outside to the inside of the frame (for example) was a significant enough change to place you beyond the somewhat-fuzzy reach of the DOE, or whether that change was really immaterial and should be captured within the spirit of the claim. The assistance of an experienced patent attorney is quite important on an issue such as this.

Complicating matters further, every country has its own patent system. Normally, in the early stage, the focus is on the United States market, but down the road, whoever actually commercializes your idea will probably consider what FTO effort is warranted in each of the relevant foreign markets.

WAYS TO DEAL WITH PROBLEM PATENTS

A problem patent is one that you cannot easily dismiss as irrelevant. There are a variety of potential legal or business options to deal with problem patents. Let's use the example that you are developing a percutaneously deliverable aortic valve with a unique leaflet geometry that is made of a special antithrombogenic biomaterial. You find a patent that claims to use the same special antithrombogenic biomaterial. What do you do next?

One thing to do is to check that the patent has not yet expired. An expired patent no longer presents a problem. United States patents typically expire 20 years after the earliest priority date and can be extended or shortened in various ways. For example, patents can expire prematurely if the owner does not pay maintenance fees, which are due about every 4 years and are required to keep the patent valid. The maintenance fee status of a patent can usually be readily checked at the United States Patent & Trademark Office website (or, for a foreign patent, at that patent office's website) or verified in short order by a patent attorney.

Assuming that the patent has not expired, options include designing around the problem patent, such as by changing your leaflets to pericardium or a nonpatented biomaterial. Another option would be attempting to eliminate the problem patent by attacking its validity; a patent that covers you can only block you if it is also valid. If you find one or more prior art references that describe or suggest that special biomaterial, you may have a good argument that the problem patent is invalid. Various procedural options and strategies are available in this situation.

Business options include negotiating a transaction such as a purchase, license, cross-license, or covenant not to sue under the problem patent. Patents owned by individual inventors or educational institutions (as opposed to a competitive corporate entity) are sometimes available for a business transaction. Approaching the owner of the problem patent directly is an option. However, in some cases, inquiring about the problem patent anonymously through an attorney or agent may be a good strategic option to avoid prematurely revealing your identity in case you were not previously on the problem patent owner's radar screen.

Another option would be to simply delay the commercial launch until the problem patent expires in the relevant patent market. For example, there may be a problem patent in the United States, but the corresponding European patent may have a narrower scope that does not create a freedom-to-practice issue for you. In some cases, the problem patent owner may have given up their rights in other markets altogether. In an age where CE Mark regulatory approval can be quicker to obtain than approval through the US Food and Drug Administration, selling abroad first may be a good business plan; however, important nuances still exist. For example, although sales in Germany may not infringe a United States patent, manufacturing the product in the United States for sales in Germany might. This

TAKE-HOME POINTS

- The three big questions of IP: Do you own it? Can you protect it? Do you have freedom to practice it?
- 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.
- Consider FTO searching early on in the process; update your efforts before key research and development and investment milestones.
- There are a variety of potential strategies to deal with problem patents, including changing your product or method, trying to invalidate the problem patent, negotiating a purchase or license of the problem patent, selling your device in nonpatented markets only, and waiting for the problem patent to expire before launching your device.
- Consult professional counsel with experience in the endovascular field when evaluating your FTO.

and other complexities make it clear that a studied approach to FTO is normally quite important.

Another option is to drop the product and invent something else. There is not always a path to reduce the risk to an acceptable level to justify the time, economic, and emotional costs of pursuing an idea.

CONCLUSION

Whether or not you can obtain a patent on your invention, you (or your new company or strategic partner) cannot commercialize it unless you also have FTO. You can evaluate FTO through a process of accumulating and reviewing patents of potential relevance. Certainty is not normally an achievable result, but an FTO analysis can reveal your approximate level of risk and potentially reveal steps that you can take to optimize your chances of success. You cannot normally obtain funding or license your invention to a strategic partner unless they are comfortable that they will be able to commercialize the product. Remember that there is such thing as too much risk for a given technology, such that moving forward does not make sense. It is better to learn that early, before the expenditure of time, money, and emotional resources on a technology that is not likely to reach the market. But don't give up too easily; many patents that at first appear to be a problem can be designed around or otherwise neutralized after a sufficient critical review.

Remember that the end game for all of the stakeholders in a new medical device effort is to improve patient care. New products will never reach the patient unless you can fund them and get all of the other foundational steps right. If you succeed, you get to enjoy watching the clinical implementation of your vision, and all of the participants in the process may receive an economic return or reward. ■

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