

Eureka!

You've got an idea...



*Brian Cox, Sequent Medical Inc. -
Vice President & Chief Technical Officer*

So, you've got an idea for a new medical device or instrument. Your years of training, experience and clinical insight have paid off. But how do you protect your invention and more importantly, how do you realize value from it? Most everyone knows to protect an invention, you patent it. And to do that, you see a patent attorney and he'll take care of it, right? That's true, but it's a bit like saying when you have a health problem, see a doctor. Seeing an attorney is only one of the steps of a process where if you want to optimize the outcome, you need to get involved in some of the details. And in today's competitive world, if you don't optimize your situation, you may end up with little or no value. Let's walk through the basics of securing your invention step by step. Then we can go over some elements of realizing value from your idea.

Before we get into the mechanics, we should review what a patent actually is. A patent is a legal document between the inventor and the government in which the inventor agrees to disclose the invention in exchange for the rights to exclude others from making, using, or selling the invention for a specific period of time. The idea behind having a patent system is actually to encourage creativity. It stimulates the advancement of technological progress by rewarding inventors who disclose their inventions.

The first thing to do after your brainstorm, and yet one of most often overlooked, is to write it down. Resist the temptation to talk to your partner, your golf buddy or even an attorney before you write it down. And by write it down, I don't mean a sentence or two. Sure,

that is a good idea at 2:00 in morning when the light bulb goes on. But, as soon as reasonably possible you need to write something called a patent disclosure. It doesn't need to be a dissertation. But take some time to think through some of the details including methods of delivery. And even if you can't draw more than stick figures, make a few sketches. Ideally, this is done in a bound notebook

*Resist the temptation
to talk to your partner,
your golf buddy or even
an attorney before you
write it down.*

with pre-number pages which are available in any office supply or stationary store. The written description should enable someone with expertise in the field, to make and use your product. Every time you work on your device, note it in your notebook, with dates. Update your notebook with new entries relating to any new developments, analyses, tests, results and descriptions of prototypes. Have at least one independent party witness your notebook entries and sign their name. Act as if you will have to prove it was your invention to a court because you may need to someday.

If your invention is the result of collaboration with other inventors, be careful who is named as an inventor. It is not uncommon for people to be left off and/or added as inventors for dubious reasons. Being the manager, department chairman or other supervisory role does not convey any status as an inventor.

Likewise, anyone contributing to the conceptual creation should not be left off. Doing so could compromise the validity and ultimately the value of your patent.

With your invention documented, you have taken the first step in securing your rights. You may now want to bounce your idea off a few trusted people to determine if it is worthy of filing a patent. Do not discuss your invention with anybody without the protection of a nondisclosure agreement. A nondisclosure agreement is a legal commitment not to disclose your idea to others by those to whom you have told your idea. Generic agreements can often be obtained from corporations or an attorney can prepare a nondisclosure agreement for you.

Picking an attorney is like picking a doctor. If you have a brain aneurysm, you don't go to just any doctor do you? You want someone that has experience with your specific situation. So, look for a patent attorney that has experience with medical devices, drug delivery, or whatever area is best suited to your invention. And don't be overly influenced by his address. While it may seem convenient to pick a patent attorney near your home or office, it's much more important to get experience in your field. With email and express mails services, you'll hardly notice the difference from an attorney that has an office down the street. Try to get a referral or you can try looking in the areas where medical device manufacturers are located.

One thing to consider before starting work on an application is whether to conduct a search of existing patents and applications to determine what other inventions there are that are similar to

continued on page 14

yours. In order for you to obtain a patent, your invention must be novel. Thus, if others have already thought of the essential elements of your idea, it may be a waste of time and money to file an application. Your attorney can conduct a search of relevant "prior art" patents and applications. You should also review the literature of the field of your invention as published texts, journal articles and conference proceedings constitute prior art as well. A search prior to filing is not required but doing so may save you the cost and time of further work if your idea has already been published. Keep in mind that if you have invented a device where there is a lot of prior art, such as stents, searching and reviewing the prior art can get pretty costly due to the sheer volume. In this case, it may be better to just file and let the patent office find the prior art as they will do a search of their own in any event.

You may have heard that you can delay much of the cost by filing a provisional application rather than a full application and that is true. However, I caution you to carefully consider the risks. A provisional application is only as good as your disclosure. If it's sufficiently detailed and appropriately written, provisional applications can be a nice way to cheaply secure your rights while you investigate it further. After filing a provisional application, you have one year to submit a full application. But, if you're not willing to invest the time to learn how to do it properly, it's not a good idea. If after filling a provisional, someone else files a similar idea with a much more detailed application, the value of your invention may prove to be significantly reduced. For those who are motivated and ambitious to learn the details and devote the time, they can even consider filing a complete application themselves. An excellent primer, *Patent it Yourself* by David Pressman is available from most booksellers.

With your patent filed, you can now begin thinking about a strategy to best realize value from your invention. You have a number of options and there is no exact recipe for success. Each invention situation is different and there are many factors to consider. Some of the key factors that will play a role in determining the best plan for your medical invention are:

1. Nature of your invention (improvement, stand-alone product or technology platform)
2. Strength of your patent relative to existing patents
3. Scope of freedom to practice
4. Data needed to validate your concept
5. Applicable markets for your invention
6. Technical feasibility and development challenges
7. Regulatory requirements for sale
8. Competitive landscape

You can consider a spectrum of opportunities from licensing or selling your invention at the outset to starting a company. This is obviously a complex process and it involves expertise in many areas in which most physicians have not had a lot of exposure or education. Talking with industry experts and executives is probably the best way to craft a good strategy. I recommend getting several perspectives as it is more an art than a science. An industry CEO, seasoned marketing executive, successful entrepreneur, venture capitalist, and an experienced R&D engineer are a few examples of valuable but likely different perspectives on your best plan. These discussions may also provide a path to a licensing or sale discussion or the building of a start-up team. Just remember, use a nondisclosure agreement until your patent application has published.

While all of the factors listed above are important, I want to comment specifically on 3) Scope of freedom to practice as I have found it to be ignored or mis-

understood quite often. Many wrongly assume that with a patent in hand, they have been conveyed rights to sell a product. While the patent office looks at novelty in determining the patentability of an invention, they pay no attention to whether a device would infringe an existing patent claim. A freedom to practice assessment involves another detailed search and evaluation of existing patents to determine if the product based on your invention would infringe any claims. This type of analysis should only be done by legal counsel. As a result, this can be an expensive proposition. The decision to conduct such an analysis is not simple but you need to understand that it may be an important factor in the value and best strategy for your invention.

In the later stages of prosecution of your patent application, probably at least two years into the process, you will get an Allowance of Claims notice from the patent office. If you are planning to license or sell your invention, this could be an opportune time to make inquiries with potentially interested parties. With claims allowed, a potential licensor or buyer can better determine the strength of your patent and thus their interest. As a result, your chances of getting into a serious discussion are improved over a recently filed application.

When your patent application is nearing issuance, plan to file a continuation application. A continuation application will allow you or an acquirer to file additional claims. As good as your original claims may be, changes in the marketplace often make new claims important. This will involve additional application fees but keeping the prosecution open with a continuation can make your invention significantly more valuable. Note that a continuation application must be filed before the original application issues. You shouldn't get caught off guard as the patent office will notify you prior to the issuance. But, just to be safe,

A Rose by Any Other Name . . .

Gary Nesbit, MD, President

get your continuation started when you pay the issue fee on your primary application.

Turning your inspiration into a tangible invention requires diligence, time and money. Persistence and attention to the details of the process of patenting can not only protect your invention. It can help insure your invention will become a reality that may have both significant benefit to others and financial return for the inventor. There are a number of steps you can take to improve your odds of realizing value from your ideas. Good documentation of your idea is a critical first step. While your initial spark may be jotted down on a restaurant napkin, putting some time into a detailed disclosure should be top priority. With a patent application filed, the chances of getting value from your invention will be improved by going through a process of weighing various business parameters to develop a strategy appropriate for your device and the market. To help you with that process, get several opinions from those who are doing it everyday.

Brian was a founder of MicroVention (now MicroVention-Terumo). At Micro-Vention, Brian served as Director of R&D and Vice President of Business and Technology Development from inception until December 2004. Prior to Micro-Vention, Brian was Engineering Manager at Medtronic AneuRx, Inc. Prior to AneuRx, he held various managerial and technical positions with Advanced Surgical Intervention, Inc., Allergan Medical Optics, and Pfizer. He earned a B.S. in mechanical engineering and an M.B.A. Brian is an inventor on 28 issued US patents.

As most of our membership knows by now, ASITN's Executive Committee, feels that the time has come to expand our horizons and consider options for a new society name that more accurately captures the essence of our mission and membership.

As we have begun to engage in a Society-wide dialogue about our potential options, we hope and anticipate that you will join us in our enthusiasm to embrace a name that will reflect ASITN's global reach, and will also celebrate the inclusion of multiple specialties in the evolving field of neurointervention.

As our most recent email communication stated, the Executive Committee is committed to making this effort a membership project. As this Society belongs to none other than its members, it is important that this initiative be approached in a spirit of collaboration.

Toward this end, I would like to once again review the upcoming process for this multi-phase campaign. As you note the following timeline, please give special consideration to contributing your thoughts, feelings and suggestions in a timely fashion so that the end result is truly a collective one.

January

A special committee has been created to guide this process, and includes seven (7) members, representative of the three specialties that make up our field, who will steer this initiative under the leadership of former president Jacques Dion, MD, Chair. This committee will communicate each step of the process to the membership through various venues including email blasts, letters and updates in the *Embolus*.

May

Beginning May 1, 2007, all members are invited to submit their ideas for names that would reflect the Society's identity and reach. Members may submit their suggestions by emailing info@asitn.org or calling 703-691-2272.

June

A special session focused on the name change will be held at the Practicum in Chicago on June 15. At this time, members will have the opportunity to voice their opinions, thoughts and concerns as well as ask questions of the Executive Committee and the Name Change Committee Chair, Jacques Dion.

Immediately following the Practicum, members will receive a ballot listing three to five names selected as final options by the committee. Members will have three weeks to submit their vote.

July 30

The new name will be unveiled at the Annual Meeting.

We would like to thank you in advance for your participation in this initiative through your support AND ideas. With the input of many, we look forward to determining a name that will carry us forward and reflect the mission and work of our Society to the greatest extent possible.

Remember that May 1 marks the "open period" for you to submit your suggestions for your favorite names!

Again, thanks to all of you for your many contributions. This initiative, in itself, is a celebration of YOUR hard work and dedication to advance our Society — and our field.

ASITN