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New Solutions for Physician Inventors

By Paul Gianneschi

Once again you find yourself struggling through a challenging case wondering why the device companies don't make a product that meets your needs. While you ponder the reasons why such a device doesn't exist, the perfect product solution suddenly hits you like a bolt of lightning. As you shout "EUREKA" and begin humming a few bars of "I'm in the money," you realize that it actually may take a little work to see your idea materialize into a real product. So what's your next step?

It is important to recognize that you do have options. You could start your own company, but this might prove to require more time and effort than you might choose to devote to your idea. You could share your idea with a familiar device manufacturer/distributor. Many physicians have trusted friends and colleagues throughout the industry. Although this can still be a good option, it has become increasingly difficult for all parties to find success in this type of relationship. The inventor must understand that the lion's share of the work lies not in the invention itself, but in the pragmatic assessment of value, patenting, manufacturing and marketing. This process is complicated, and expensive. Most physicians neither have the time, inclination or expertise to effectively manage such a laborious project.

However, if you are willing to assume a bit more risk and defer your compensation to a later date, there are a handful of new companies and consultants which may help point you in the right direction. Each has a different spin. Some will license your concepts upfront for cash and possibly a small equity position in the new venture. Others will partner with you on the device, assume the development costs and manage the project in return for equity. All offer advantages and disadvantages that should be carefully weighed. A few groups to consider in your search include the Innovation

Mr. Welsh warns, however, that a provisional patent is only temporary and must be followed by a utility patent application. One advantage a provisional patent provides is that it allows you a full year to research your device concept to determine its viability in the marketplace prior to submitting a full-blown utility application. Provisional patents will not require you to list claims, but a utility patent does. The utility patent's claims, however, constitute the basis for legal protection, and as a consequence require greater research at a higher cost.

After protecting your intellectual property, you have to start thinking about engineering and prototyping your product concept. This can be a very expensive proposition, but is a critical step in the process. There are now device companies that focus almost exclusively on product manufacturing. These are the very same companies that anonymously make products for some of the largest and most familiar names in the industry.

According to Rowland Kanner, Vice President of Atrion Medical Products, Inc., a device manufacturer with over \$50 million in annual sales, "It can be an expensive proposition for the average physician to contract for device development services. Depending on the device, it can easily run into the hundreds of thousands of dollars." Mr. Kanner adds, "An option might be to partner with one of the handful of consultants or companies out there working with physicians early on in the development process. These folks help the physician locate sources of funding, or otherwise partner with the physician to help them manage the potential risks and identify the most appropriate development partners for a project. We have teamed up with one of these companies, and it really can make the difference between success and failure for the entrepreneurial physician".

Factory, Seedling Enterprises, San Francisco Science and Hatch Medical. Each company is run by individuals who have spent time developing new products for large device manufacturers or start-ups. These consultant companies exist to hone your concept, protect your intellectual property, package and market your concept to the most appropriate industry group. Their primary interests and accountability are aligned with the inventor.

Regardless of whether you choose to develop your own idea, sell it to industry or use a consulting company, the important steps in developing and safe-guarding your concept are the same. The first step is laying claim to your concept. According to John Welsh, a partner in the Washington, DC intellectual property law firm Aquilino, Welsh and Flaxman, "In addition to doing your homework, it is crucial that you safeguard your idea. Although it's human nature to want to share it with your colleagues, don't. By sharing information you run the risk of inadvertently losing the opportunity to patent your idea (as a result of public disclosure)." Rather, Mr. Welsh suggests, "Executing a simple confidentiality agreement would protect the conversations you have surrounding your device idea, allowing you to share information in a protected manner." Mr. Welsh also suggests filing a provisional patent on the device - a simple and relatively inexpensive measure (around five hundred dollars) to protect your idea.

Finally, someone needs to assess the market value of the concept. This may have as much to do with a company's strengths and strategic plan as it does with the concept itself. According to Mr. Kanner, "Since our company is constantly weighing opportunity against risk, understanding marketplace dynamics can be just as important as the features of a new device. It can also be the factor that drives certain engineering decisions about that device.

Physicians who have successfully navigated the device development process agree that inventors must bring more to a device manufacturer than just an idea. Dick Hawkins, MD, Professor of Radiology and Surgery at the University of Florida, and a well-known inventor and innovator has experienced new product development first hand, "The medical device industry has changed a lot since my sons were making catheters in the basement of our hospital. You now have multi-billion dollar companies focused on the bottom line. As a result, a lot of great product ideas never make it to market."

Dr. Hawkins added, "I have had both successes and failures in my product development efforts. If I could offer any advice to someone just starting to develop new product concepts, I would suggest two things. Get your self a good patent attorney and find a friend or consultant who knows the ins and outs of the industry, and is willing to give you a hand.

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As printed in the July/August issue of SCVIR News



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