
Key to Med-Tech Success Often Lies in Hidden Details

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Key to med-tech success often lies in hidden details

IN THE BOOK The Tipping Point, author Malcolm Gladwell observes that the success or failure of a social phenomenon, the momentum behind a cause or issue, or the rise and fall of a business venture often resides in a series of small events that come together to create a catalytic “tip.”

Such could be applied to the success and failure of many medical technology, biotech and life sciences companies. It’s often not one major breakthrough that guarantees the success of a new venture, as some may think. Success often lies in the details that in many cases are hidden within lab notes, sketches and e-mails of an entrepreneur thinking through an idea and trying to bring it to life.

Square one

For physicians, surgeons, medical researchers and other health care professionals who dream of owning a medical device company, the thought of becoming CEO can cloud the understanding of what it takes to get there. The key is to start at square one: identifying some of the basic factors of launching a medical technology business, and then, to tip success your way by executing to the nth degree on the details.

Here are tips that may help you turn that idea hastily drawn on a cocktail napkin into a fast-growing medical technology business.

Understand if you have something to protect. One of the most critical tipping points in forming a successful med-

ical device company rests with capturing and documenting a health care professional’s intellectual property—in other words, an inventor’s “marketable” ideas.

Intellectual property is a phrase that is broadly used to describe intangible assets that have an inherent value (in other words, they can be bought or sold like a piece of real estate). Just as a company’s machinery or office furniture have value and can be bought and sold, so too can ideas, methods, names, phrases and logos.

David Kline, author of Rembrandts in the Attic: Unlocking the Hidden Value of Patents (Harvard Business School Press, 2000), says the knowledge economy isn’t rhetoric. “Intellectual assets drive competitive advantage and ultimately shareholder value. Intellectual property can make or break a business. If your competitor owns a patent that precludes you from even being in business in the first place, then you’re in big trouble.”

Document your idea. Properly documenting an idea is a critical factor to starting a new medical technology company. Even if your idea is a twinkle in your mind’s eye, write it down. Get it on paper. Date it. When you do document

your idea, make sure you have a witness, preferably a peer who is knowledgeable in your profession and is willing to sign a confidentiality agreement.

Better yet, begin the daily practice of jotting down notes to yourself each day in a lab book. The discipline of writing down your insights on a daily basis will not only help you document your efforts in a continuous, systematic approach, it will also more than likely inspire further insights.

Don’t ask, don’t tell. Because of the collaborative nature of the health care culture, it’s very difficult for many health care professionals and researchers not to share their ideas with a colleague or to obtain an affirmation from a respected peer that they are truly onto something special. It’s at this point that physician-inventors often create the most problems for themselves—sometimes years down the road.

It’s absolutely critical that if you want to share your idea with someone, even in passing, that they sign a confidentiality

agreement. Likewise, if you have a hint that a peer or colleague is researching or may be inventing a medical product, don’t ask them about it. This is to protect yourself in case you should develop a product or method that may be similar to what your peer or colleague is developing.

Estimate the size of the market. The first place to start is

to identify the number of people who are affected by a particular medical problem. Example: the number of men and women in the United States who suffer from genetic-related heart disease. From there, you need to create a profile of your future customers: who they are, where they live, how and/or why they suffer from a certain medical condition, current treatment options and the success rates of those options, and at what cost to the patient and to the health care

[tips] **1** | Even if your idea is a twinkle in your mind’s eye, write it down. Get it on paper. Date it.

2 | If you want to share your idea with someone, even in passing, make that person sign a confidentiality agreement. That includes assistants, administrators, colleagues, even close friends and family members.

3 | One of the most common mistakes is underestimating the need for a product. Start by identifying the number of people who are affected by a particular medical problem. Shore up your research with professional help.

system do they suffer.

This process involves some digging, into medical journals, medical device trade magazines, the Internet, etc. To develop a very thorough analysis of the marketplace, it may be necessary to enlist the service of an actuarial consulting firm as well as a market research firm.

Determining market size also involves researching similar types of existing products and determining a potential price for your product and what share of the potential overall market that you can realistically capture.

Another aspect of this process is determining how distinct your product is to existing treatment options. When you look at your product, what do you see? Is it a revolutionary or evolutionary advance? Is it therapeutic or diagnostic? Will it cost less and be more effective than the current therapy most often prescribed or recommended? Will it be faster to implant, thereby cutting surgical time? Will it substantially increase a patient's recovery time? Will it substantially improve or enhance how the body performs a function or improve a person's quality of life? The more you can quantify these benefits, the greater the odds that your product will succeed in the marketplace.

File for a patent. Building a patent portfolio is lot like building a fence around a piece of land that you own. The concept behind a patent is to build the highest and largest perimeter fence that will prevent others from taking a portion or laying a claim against your piece of property.

It's crucial to file a patent properly. A poorly submitted patent application can wreak havoc on your intellectual property rights in the future, so hire a reputable intellectual property attorney (registered to practice before the U.S. Patent and Trademark Office) who can examine your ideas, help you obtain a thorough search of existing patents that may be similar to your idea, and help you devise a patent strategy. An experienced attorney will not only understand how high to build the fence around your idea, but how to help you keep that fence up for as long as possible.

To file a patent, in particular for a

device, you will need to have a blueprint (mechanical drawing) developed. Consult with a patent attorney, who can connect you with mechanical and electrical engineering firms that specialize in medical device products. It's at this stage that you will begin to better understand how much it will cost to produce your product, how it will be manufactured, and how it can be sold. Do not be surprised if the design and prototype firm offers suggestions to improve your device and in fact make your original idea obsolete.

Find a mentor. If you've never been through the process of patenting an idea and possibly forming a company, it can be overwhelming. That's why it may be a good idea for you to find a mentor, perhaps another physician who has been

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through the process, to provide thoughtful advice and counsel.

If you don't have any physician colleagues or acquaintances, contact your state's department of economic development to obtain the names of local medical device companies or the names of nearby medical device or medical technology industry associations. Regardless of how well you know potential mentors, make sure that they sign a confidentiality agreement that prevents them from making a claim on your intellectual property.

Determine if it's a product or a company. An idea by itself is not a company. In the initial burst of excitement that comes with developing a new medical device it's easy to let your imagination do the leading. But the fact is, deter-

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mining whether your product has the potential to grow into a company really is dependent on whether that product may lead to other products. In other words, a single product is not a company unless it has a very large market potential in and of itself.

Another thing to ponder is whether the inventor even wants to run a compa-

ny in the first place, which as many entrepreneurs will tell you can be an all-consuming effort and will drastically alter a person's lifestyle. An alternative to consider is licensing the rights or outright selling patents to an established company that may be able to bring the idea to market much more quickly.

The final steps—writing a business plan, attracting the right talent, and raising money—are whole topics in themselves. Get the right people as managers who can execute your business plan.

So, if you want to "tip" your new medical technology venture in the right direction, be sure to focus on the little things that can have a huge impact both short term and long term.