

The Dilemma for Medical Device Inventors

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The environment for the individual medical device inventor has become extremely challenging in recent years. Those organizations willing to fund further development or license inventions have had to set their acceptance levels ever higher due to forces of a US healthcare ecosystem in great flux. Let's look at how inventors can interact better with potential technology acquirers to increase the chances of progressing further with their ideas.

Who Is the Inventor?

An individual medical device inventor may, for example, be a medical doctor, an engineer, a nurse, or Ph.D. student with a doctoral thesis. In contrast, a corporate inventor is one employed by a medical device company or some other organization. The individual inventor has spent many long and unpaid hours coming up with their invention and building a prototype. He or she is passionate and excited about how their idea has evolved into something that can improve the lives of patients in some fashion. The inventor may even decide to start a company to develop their idea into a marketable and profitable product.

An inventor may start approaching organizations for funding (grants or equity financing) to develop their idea further into a product. Or, he or she may seek out medical device companies with a possible need for the invention because it is in a space the company is in or wants to get in. In any event, the inventor should give serious consideration to forming an entrepreneurial team.

Does the Inventor Need a Team?

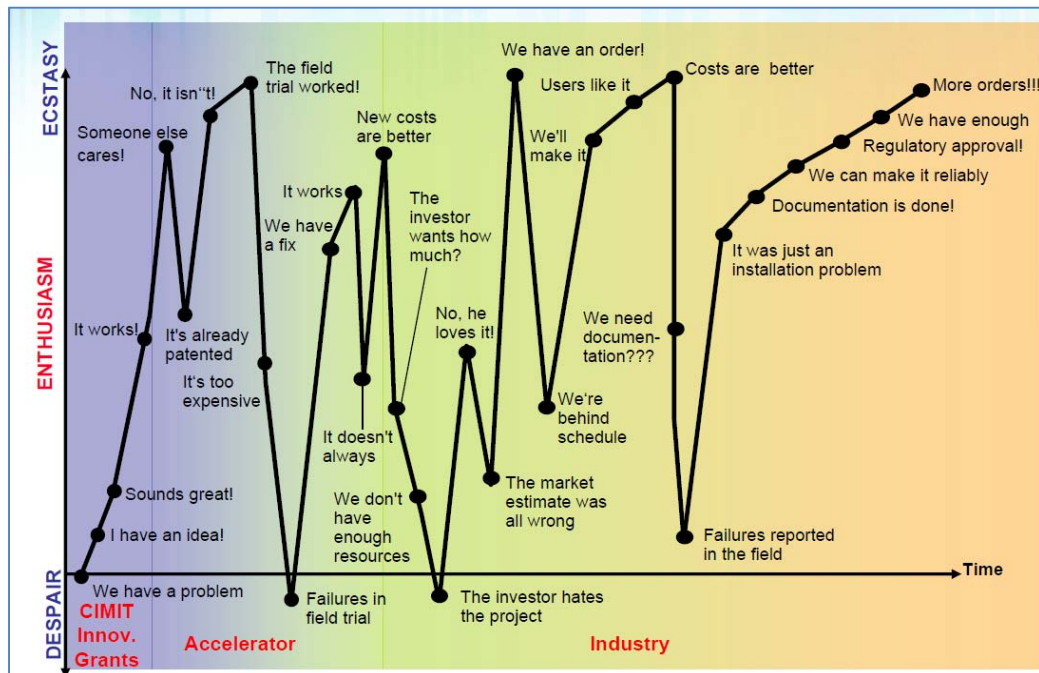
The wise inventor will see the need to form a small, focused team of one or more additional individuals. In addition to a lawyer specializing in intellectual property (IP), someone with an entrepreneurial background in medical device development is crucial. Inventors and entrepreneurs have very different skill sets¹. An entrepreneur is one who organizes, manages, and assumes the risks of a business or enterprise. An inventor is one who produces something for the first time using imagination or ingenious thinking and experiments. Sometimes the inventor will become the entrepreneur; sometimes it will be a different person with entrepreneurial skills. The astute inventor will understand the difference.

The entrepreneur must be a strong and confident leader to bring his or her team through the emotional roller coaster of starting an enterprise to succeed at developing a medical device (see **Figure 1**). The inventor will have the hardest time of this². Inventors are emotionally attached to their inventions; after all, they have invested time, money, and energy into their "baby." Because of this, many inventors only see the opportunity and not the obstacles. Many inventors believe that if they just have the chance to demonstrate their product to a major company audience then the company will immediately appreciate

¹ **Kullman, Patrick.** *The Inventor's Guide for Medical Technology: From Your Napkin to the Market: What Innovators Need to Know.* Minneapolis : Publish Green, 2011. 978-1-937928-22-3.

² *Ibid.*

its value and acquire it. Companies rarely acquire an early technology until "proof of concept" and "proof of principle" are clearly established. Entrepreneurs must get inventors thinking objectively. More importantly, the entrepreneur must ensure that the inventor appreciates the skills, hard work, time, and financial resources that the company will provide to fully commercialize the inventor's idea. If the entrepreneur and the inventor are the same person, problems can arise. Sometimes the inventor must understand that he or she needs to bring someone on who can objectively perform the business functions of a true entrepreneur.



(3)

Figure 1. The Emotional Roller Coaster of Medical Device Development.

Source: www.cimit.org/images/services/Slides_AcceleratorOverview_030811.pdf.

What Is the Viewpoint of a Corporate Strategic Partner?

Medical device companies are shifting their business strategies. While incremental improvements still play a role, they are looking for innovations that can strongly improve outcomes and do it for less money. Regulatory approvals, especially from the FDA, used to be the biggest challenges. Now, companies must also prove to payors (Medicare and insurance reimbursers) that their products save money with cost studies and clinical studies. According to Sami Hamadé³, partner at Aberdare Ventures, companies "have spent decades ... chasing big unmet clinical needs [and] people will pay if you provide value in [that]." Hamadé goes on to say that companies must focus "on technologies that reduce cost or increase efficiencies." Costs and efficiencies must be viewed in terms of total healthcare costs, not just narrow views of the procedure itself.

Large companies find it difficult to be nimble and innovative the way startups can, so they look externally for these types of developments. Because of the rapidly expanding abundance and

³ M. Stuart, Medtech Investing: A Survivor's Game, *START-UP: Emerging Medical Ventures*, December 2012

complexity of knowledge for highly technical products like medical devices, large companies can no longer support large and broad internal R&D efforts as they once did. Open innovation service providers such as NineSigma (www.ninesigma.com) and Innocentive (www.innocentive.com) provide a network of problem-solving initiatives and a “problem-solving marketplace.” For the independent inventor, these open innovation organizations can offer a well-defined problem needing an inventive solution rather than an invention looking for a vague problem to solve.

Established medical device companies will sometimes have a strategic interest in products under development by inventors and fund them⁴. These corporate sponsors are not looking for a financial return but rather have a strategic goal. The target company may be looking at the invention to broaden an existing product portfolio, start a new product offering, find a technology common across several of their medical disciplines, or acquire a disruptive technology. The strategic goal may be for a technology, a product, or a company. The company may also want to block a competitor from getting access to the technology, but usually the company tries to move faster than their competition.

The company may offer the inventor seed money for further development. Terms may include rights of first refusal or geographical distribution rights. The company may acquire licensing rights for the invention. The licensing deal may be for a flat fee over a given time, a royalty for each device sold, or a combination of both.

What Can the Inventor Do to Increase Their Chances?

Companies eliminate a large majority of ideas from further review that inventors actively promote to them. Reasons are varied and may be because there is not a strategic fit or not enough evidence is provided. This does not mean the invention is doomed, as there may be other companies that may have an interest. Additionally, the inventor may approach the company again when there is more evidence.

The inventor is in the weaker position of selling their idea and the target company is in the stronger buying position. The inventor (and team) can do several things that will increase the buying interest of the target company. First, the inventor must fully understand the market, business model, and added value for their product, and do so in the eyes of the target company. The inventor should answer the questions in **Table 1** ahead of time as best as possible. The answers may be different if approaching more than one company. The inventor should try to make a strong network connection and build personal relationships, preferably with a CXO or VP of the target company so they are not cold calling. The inventor should respond favorably to any feedback. If the target company asks for more information or a different approach, the inventor should give the comments serious consideration, re-approach the company, and have patience.

⁴ This section is based on the author’s interview of a person, who prefers to remain anonymous, in strategic investments at a large medical device company.

Table 1. Questions for which Corporations Will Want Answers

Attribute	Questions
Value Proposition	What is the value of the invention for patients, physicians, payers, and other members of the healthcare ecosystem? What is the benefit over existing products/ procedures?
IP / Licensing	What prior art is there around the new idea? Is the new idea protectable by patents? Does the new idea infringe on existing patents?
Market	What is the monetary value of the existing market? What percentage of this market can the device get? What will be the physician acceptance level of the new device, new procedure, or both? What geographical regions will be targeted? What diseases and populations will be targeted?
Competition	What are current or future devices that do the same thing, and why is this one better? Are there indirect competitors such as new drugs or lifestyle changes that could reduce the need for the product?
Economics/ Reimbursement	Does the device reduce procedure time or recovery time? Is the device and procedure reimbursable under existing codes, or do new ones need to be generated?
Regulatory	Does the device require a 510(k) or PMA for US? Are clinical trials required? What are the predicate devices? What are plans for EU approval and rest of world?
Development Status	What state of development is the device in, such as proof of concept, functionally proven in pre-clinical studies, or human clinical trials?
Safety	Has safety testing been done, even at a pre-screening level before formal testing? What are the safety risks and mitigations?
Manufacturability	Can the device be reliably produced in volume on a production line? Can a suitable profit margin be made?

The inventor should not do anything to irritate the company. Even though there may not be a deal today, there may be opportunities for the same or other ideas at a future date. Some of the behaviors that may put the inventor on a bad footing with a potential corporate sponsor include⁵:

- not responding to feedback
- being overly persistent and not taking “no” for an answer
- shopping the idea around to other people within the company division after getting a negative response from one person
- having an attitude of hubris
- not forthcoming with data – gives the impression that data is not convincing or does not exist
- supplying poor data
- running wrong types of experiments for proof of principle and trying to convince the sponsor of their merit

⁵ This section is based on the author’s interview of a person, who prefers to remain anonymous, in strategic investments at a large medical device company.

In Closing

We have seen that eager inventors must form a small team with a balance of objective business thinkers. As an inventor, look at things from the company's point of view and ask yourself the same questions they are likely to ask – it's not about you, it's about them. Your corporate partner should provide you experience and support, not just money. Sometimes your vision for the new device needs to be re-assessed and you should consider pivoting to a different path. View corporate feedback as a learning experience. It is not easy to get big excitement on the first visit. It takes increasingly more and more money to get an invention from one phase to the next and, if it does not get filtered out, more and more funding is needed to get it to a successful product in the healthcare ecosystem (see **Figure 2**). Sometimes you have to accept the fact that your invention does not solve all the relevant issues and move on. If you are diligent, the results can be financially and emotionally rewarding.

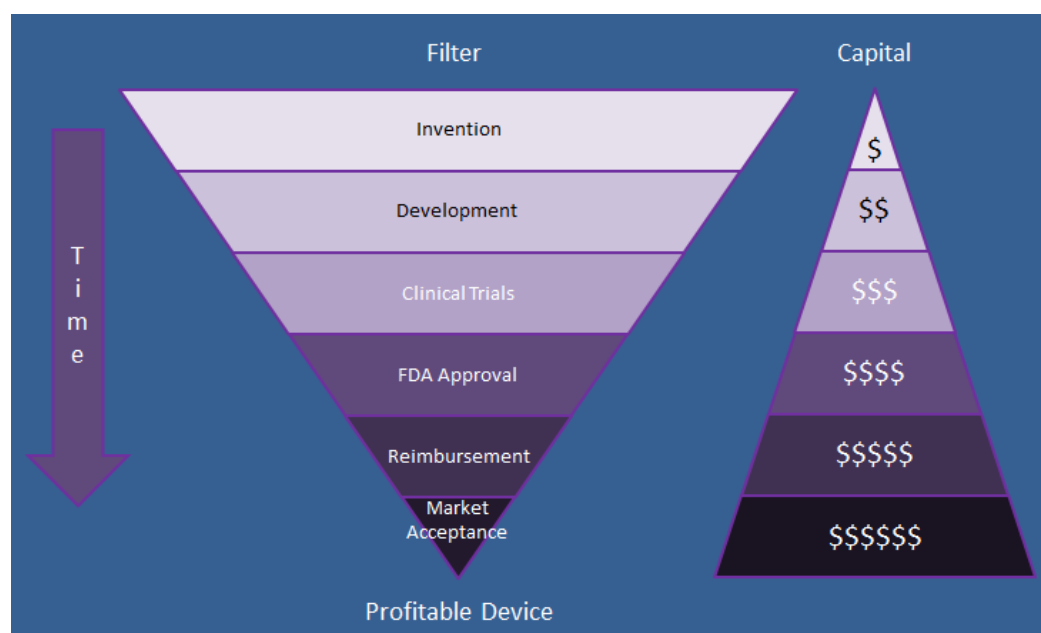


Figure 2. Filters of medical device innovation

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